

ENERI Manual

Research Integrity and Ethics

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Introduction: the manual to the manual

Welcome to the ENERI research ethics and research integrity manual. Before you lies, of perhaps more realistically: is displayed, a resource for both researchers designing or attempting to design research, as well as professionals evaluation that research. True to the ENERI programme, this resource is neither limited to research ethics, nor to research integrity. We do however, recognise that the list of issues, however ordered or prioritised, identified as being part of either, requires some type of label. That label exists to help legitimise them as relevant and significant normative elements of research, as well as allows readers to actually find what they are looking for.

This does not mean that the boundary between research integrity and research ethics is not fuzzy at best, and that ongoing debate on how to organise both normative frameworks collaboratively is best targeted to help actual practices. Recognising that such debates require flexibility and resources that can grow and shape themselves (obviously with all the help it, and we, can get) to be of the greatest value for that debate, we chose to design this *living* manual.

It's alive

This e-manual is a living resource, inviting engagement rather than consumption. It contains no technical or technocratic instruction, but rather seeks to instill deliberation around issues of research ethics (RE) and research integrity (RI). While we have included scores of links to a diverse array of RE and RI prescriptions, we do not seek to harmonize them. Rather, we intend to allow the reader to access, assess, weigh and judge them for themselves, seeking merit where she deems fit.

A living manual requires curation, care and contribution. These three actions initiated with the authors but cannot be limited to them, to facilitate it from reaching the largest possible relevance. This means that cases may be added in section 3, and changes, expansions, additions and more more can be suggested and ultimately made, to sections 1 (RI) and 2 (RE).

We hope this resource provides what you seek,

DT, DS, PL, BP,
LA and OZ.

1. Research Integrity

1.1. Conceptual issues

1.1.1. *The Researcher in Society - towards the “virtuous researcher”*

How does something acquire our trust? Why do we trust science? And importantly, for contemporary discussion on the role of science in society, of course, do we trust it less?

Virtue and moral character

The history of the modern science we know starts in the early seventeenth century England – the time of the scientific revolution. We call it a revolution is because from that time onward, the experiment made its entry into science (Shapin and Schaffer, 1985). So how did the young and new experimentalists of that day create credibility for their claims? To find out, we first have to understand who they were. There really weren't that many scientists in the seventeenth century. There were no big national or European funding agencies supporting science, so those pursuing science had to fund themselves. More difficult still, being a scientist wasn't an actual career, it was more like a hobby – all scientists were in some way, amateurs. Being employed at a university at that time did not make you a scientist. It made you a teacher. So, who, in seventeenth century England had a lot of money and not much to do all day, leaving their days and cash-purses free to fiddle around with science? Amongst a few others, nobility. Sir Robert Boyle, Lord Kelvin, etcetera. They were also all white and all male. Quite importantly, coming from a very small and very elite circle, they knew each other, or knew of each other or their reputation. They were noblemen, gentlemen, and with that label came attributed qualities such as modesty, honesty and above all else, moral character (Shapin, 1991, Shapin and Schaffer, 1985).

Harvard historian of science Steven Shapin has described this process as the social history of truth, in which he points at social structures and relationships allowing truth claims and their credibility to emerge (Shapin, 1994). If all scientists know one another, they can go visit each other for tea and biscuits and physically witness one another's experiments. Actual peers, actually reviewing each other's work. When unable to attend, a testimony from another trustworthy-by-default gentleman would do.

As the amount of people practicing science slowly rose, they no longer fitted in a single salon requiring the need for innovative structures of knowledge distribution. The written account of the experiment was born – a predecessor of the scientific paper and a literary technology or innovation (Shapin and Schaffer, 1985). That account could be trusted because of its origin, because of the impeccable moral character of the gentlemen that drafted it. Accordingly, the credibility of science

finds its origin in elite structures of people who drew credibility from their social standing, from class. Bluntly put, they considered themselves better than others and considered themselves trustworthy because of it. This is of course an exaggeration, the one-page compression of bookshelves full of scholarly work. The core message here is the realisation that characteristic of those who make knowledge matter: their social circles, their moral character, their virtues, their titles and the systems and networks that host them. They did in the seventeenth century, and they still do now.

We scientists are no longer noblemen. Science has grown big and we no longer all know one another personally. Familiarity and class no longer suffice as strategies to assess and weigh moral character. Our credibility is drawn from other characteristics: affiliation with peerage has given way to affiliations with respectable institutions of science. Displays of moral character and virtues have given way to detailed methodology sections and increasing movements towards open science, in an attempt to make the nobleman's salon encapsulate the entire globe. Upper class social circles have given way to other social circles and familiarity has given way to a complex social, political, technical and epistemic organisation of science and scientific work (Hackett et al., 2017, Shapin, 1995). Science became institutionalised, apparently relying on methods, procedures and standards, but in the end, the characteristics of those who make knowledge still matter; albeit less on the level of the individual and more on the collective level of how we organise science (Shapin, 2008).

Naïve conceptions of ideal science held by many scientists and the public alike are based on those seventeenth century practices – if they ever existed in such a form: disinterested science, independent and free of values, ideologies and politics, knowledge for knowledge's sake.

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Apples and barrels

They introduce a relevant issue of scale for discussion of research integrity, namely the location of moral character, of virtue. Are these individual characteristics, to be attributed to each and every scientist personally, or are these attributes of the way we organise science, making virtue the product of the system, rather than its content.

In 'The Academic Citizen. The virtue of service in university life', Macfarlane (2006) discusses the role of the academic (as an individual) in the context of university life, as well as in the context of the responsibilities of citizenship inside and beyond the walls of academia. Service and virtue are, however, not context-independent. Desirable behaviour in the context of research integrity (and research ethics) intersects with a series of virtues as well as practicalities, a series of norms and values, and well as structures and materials.

Norms and value systems shaping institutional and individual behaviour are often unobserved inside any given disciplinary culture because of their implicit and shared character. Only when different norms and value systems encounter one another, do (small and subtle) differences between them become visible. Such encounters are interdisciplinary collaborations in science. While individual cases of scientific misconduct generally receive a lot of attention (consider affairs surrounding Schön, Stapel, Hwang, and others), threats to scientific integrity emerging from the interdisciplinary collaborative dimension are under studied. Disciplinary cultures have their own value systems and practical arrangements prescribing what counts as ‘research integrity’ and ‘proper science’ and what disqualifies. Different epistemic cultures draw from different traditions, prefer different methods, study different objects and have their own social and practical standards - because they have a history of getting the job done in that discipline (Knorr-Cetina, 1999). To engage in an interdisciplinary collaboration, means to expose oneself and one's work to other experts, evaluations of research integrity from within their own, different, value systems and inviting their critique in the hope to find something new and innovative (and vice versa). For a more in depth discussion and inclusion of literature on issues of (inter)disciplinarity in plagiarism, also see section 1.2.1.

As a consequence, individual dimensions of virtue or moral character, intersect with collective, structural evaluations of good science, allowing problems such as institutional corruption to interfere with virtuous individuals. Consider Lessig's definition of institutional corruption:

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“Institutional corruption is manifest when there is a systemic and strategic influence which is legal, or even currently ethical, that undermines the institution's effectiveness by diverting it from its purpose or weakening its ability to achieve its purpose, including, to the extent relevant to its purpose, weakening either the public's trust in that institution or the institution's inherent trustworthiness.” (Lessig, 2013)

In reference to science, such systemic and strategic influences can be external – the flow of research funds from for-profit actors into academia, or ideological pressures shifting the research agenda, labelling problems as taboos, or entire disciplines as superfluous. They can also be internal, in the ways in which science organises its own reward infrastructures and performative metrics (De Rijcke et al., 2016), designs perverse incentives (Edwards and Roy, 2017) prioritises methodologies over others and conceptualises its hierarchies of evidence (Murad et al., 2016).

Institutional corruption is not about corrupt people. It is about good people operating in a system that drives out the good, a structure that dictates specific behaviours – all within the law. Individual moral character is thus far from sufficient to build morally responsible research practices. Research integrity – as a descriptive field, as well as a normative practice, cannot limit itself to apples alone. As a

consequence, strategies that are universally promoted and called for in the context of fostering responsible research, education, outreach and mentoring, are despite all of their worth, unable to address the issue in full.

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1.1.2 Research, Evidence and Truth?

Introduction

Research integrity, in as far as it describes and prescribes a *modus operandi* for conducting and organising good scientific work, is dependent on a specific understanding of the relationship between scientific work and its product. However, the products of scientific labour are multiple, and debating and discussing their epistemic and ontological status has been the core of the philosophy of science.

In research practice, as it appears before researchers, research integrity takes two forms: first as a series of guidelines or policies externally imposed upon researchers, and second, as a series of internalised norms or understandings of desirable practices. The latter may stem from educational measures, but we may hypothesize that they flow mostly from researchers being actively socialised into practices in which such norms and understandings dominate, though high proximity and active mentoring, for instance. As such the latter operationalisation of research integrity is interwoven with practice much more tightly than the former. The first operationalisation is less tied to practice, and much more to a systems-level understanding of what ideal science looks like. These operationalisations may not overlap all the way, but what they share is that they depend on what researchers or high level guideline-writing committees understand science to be.

Different philosophical traditions exist to describe science's relationship with the world it aims to access and describe. Some of those traditions grant science unimpeded access to reality, whereas other argue that science and scientists can only access reality through senses, through computations of impressions or even not at all. This manual does not provide an overview of these traditions – even a summary would be well beyond the limitations posed by this text. Here, we will introduce a few relevant variations across such philosophical traditions and make explicit what type of consequences for research integrity they may have.

Three positions

Logical Positivism

Positivism states that all our knowledge is based upon sensory experience, our observation of the world, which is subsequently interpreted. Only when observations are verified can they achieve status as evidence, supporting facts and ultimately truth. Knowing starts with observing. Theory follows. The more observations support the theory, the more likely it is, that it is true.

Critical rationalism

Critical rationalism states that we cannot observe without pre-existing theoretical understandings of the world. Knowing starts with theory. Observations are required to test the theory. Critical

rationalism states that through critique we can get closer to the truth. Confirmation or verification cannot do that – only the active attempt to disprove a theory. Observations are required in the context of disproving. The more attempts to disprove a theory fail, more likely it is, that the theory is true.

(Social) constructivism

Social constructivism states that our understanding of the world is actively constructed and that facts or truth are not discovered, but made. Scientists are the key, but not the only, actors engaged in constructing facts and consensus about them is what establishes them as true. Social constructivism, puts credibility and consensus ahead of truth: only with enough credibility and a consensus that is shared widely enough and by the right actors, will a theory or claim acquire the status of truth or fact. In the sociological study of how consensus arises and how credibility is gathered, a lot of ingredients begin to matter that did not matter beforehand: who came up with a claim or theory? What is this person's status? That status can be about the employing institution, or an individual's track record. It can be about the rhetorical strategies employed, social ties between institutions and individuals that existed before the claim was ever coined. The study of consensus-building is about power distributions: one who has little power cannot build international consensus by herself – powerful and strong allies with international reputation and prestige are required to lift the status or credibility of a claim. Consensus is social and political and as a consequence, so is science and its claims. Knowing requires alliances and the stronger the alliance, the more true a facts or theory becomes.

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Consequences for research integrity

What do these different philosophical traditions bring to the debate on research integrity? First, we have to acknowledge that they are not equally distributed among research professionals. While social constructivism is a domain mostly occupied by sociologists of science, logical positivism has been abandoned by most philosophers of science since the 1970s. Despite this, logical positivism or closely related positions are still very dominant in the images of science that scientists have themselves as well as being a large and significant part of the public credibility that underpins science. Other positions exist (including relativism, scientific realism, actor-network theory, empiricism, etc.) all with their own interpretations of how the sciences are able to produce knowledge.

Research integrity is meant to safeguard the capacity, the ability to make knowledge, that we attribute to the sciences. However, a different epistemic position translates into a different process to safeguard. In positivism, the key element granting science access to knowledge is its ability to observe untainted. In rationalism, science's capacity to create knowledge is mainly understood as its ability to critique. In constructivism, science's ability to create knowledge is shaped by its ability to persuade, convince and to find allies. Not only require all three different safeguards, more strikingly,

the safeguards requires from one epistemic position may negatively influence practitioners' adhering to a different philosophy's ability to produce knowledge.

To safeguard science's ability to observe freely and to prevent those observations to be coloured, influenced or downright corrupted by ideologies, hope or potential financial reward, would require the design of a practice, as well as the education of practitioners, targeted at keeping those influences away. In practice, this can take many shapes, but it refers back to one of the Mertonian norms – disinterestedness (see chapter on conflicts of interests for more details), striving to keep science pure. Social constructivism, however, relies on such connections – to other peers, but also to outside actors including companies, NGO, public associations, political organisations and so much more.

Research integrity in practice is thus dependent on the philosophical tradition that describes the relationship between data, evidence, results and ultimately truth (with varying definitions of all of them). No one considers thought experiments to be examples of data fabrication because we recognise that thought experiments stem from a specific epistemic tradition allowing these routes towards knowledge. In most other cases, recognising relevant epistemic differences will be more difficult. However, such matters are rarely discussed at large, often because practitioners are unaware of their own conceptualisations – they just represent the norm in the practice they are engaged at. This means that such conversations require negotiations and explications, and existing guidelines need to be read, understood and applied within the limits of the epistemic framework they originate from. Guidelines, such as the European Code of Conduct or the Singapore Statement are products of the scientific community itself, although heavily supported in their writing, by professional research integrity experts, and largely conceptualize science in a positivist sense.

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Further reading

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Penders, B. 2017. *Beyond Trust: Plagiarism and Truth*. *Journal of Bioethical Inquiry*, March 2018, Volume 15, [Issue 1](#), pp 29–32 [\[Click here\]](#)

1.1.3 Detrimental Research Practices and Research Misconduct

A distinction has generally been made in guidelines on research integrity between the “big three” of plagiarism, fabrication and falsification on one hand, and other questionable research practices (QRPs) such as misattribution of authorship and failure to declare conflicts of interest. One implication of this purported distinction has been that only the former have tended to be categorised as serious misconduct, while QRPs are merely seen as minor breaches of integrity, and possibly not as misconduct at all. To illustrate this trend, one need only look at the definitions used widely for decades in the United States: “Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” In contrast, QRPs were defined as “actions that violate traditional values of the research enterprise and that may be detrimental to the research process.” (1992 Academies report, Responsible Science) (Though this definition was widely adopted, some US institutions had more specific policies defining research misconduct less narrowly.)

In 2017 these definitions were revisited and partially renamed, but not actually revised. The definition of research misconduct remains identical, meaning that plagiarism, fabrication and falsification are still the focus. Furthermore, the same questionable distinction remains: the big three are still categorised as misconduct, and other misbehaviours are regarded as lesser offences. However, in recognition of the growing importance attributed to QRPs, these have now been renamed as detrimental research practices (DRPs)(though some experts in Europe instead call them “unacceptable research practices”). This change seems to be mainly cosmetic. While on the surface this might seem like a more concrete term as it sounds more definite to say detrimental, the actual definition of the term retains the somewhat hypothetical aspect. DRPs “may” have detrimental effects, which means that the term is essentially unchanged in its basic meaning. The new National Academies report provides several examples of such practices:

- Detrimental authorship practices that may not be considered misconduct, such as honorary authorship, demanding authorship in return for access to previously collected data or materials, or denying authorship to those who deserve to be designated as authors.
- Not retaining or making data, code, or other information/materials underlying research results available as specified in institutional or sponsor policies, or standard practices in the field.
- Neglectful or exploitative supervision in research.
- Misleading statistical analysis that falls short of falsification.
- Inadequate institutional policies, procedures, or capacity to foster research integrity and address research misconduct allegations, and deficient implementation of policies and

procedures.

- Abusive or irresponsible publication practices by journal editors and peer reviewers.
 - National Academies. Fostering Integrity in Research. 2017

Notably, this list does not mention failure to disclose conflicts of interest. More importantly, some DRPs may be more detrimental than some “serious misconduct”, calling the distinction into question. For example, plagiarism is theft and fraud, but it does not (normally) harm science itself. In contrast, failure to disclose conflicts of interest can bias interpretation of results in ways that can affect science. Guest authorship and ghost authorship (see linked section) also involve theft in ways that can be much more serious for researchers’ careers than being plagiarised. And failure to raise concerns about misconduct itself may be a much more serious problem than minor cases of plagiarism. These are just a few examples but they clearly call into question the validity of the distinction made between serious misconduct and DRPs. Generally, it may be more helpful to discard this distinction and focus on breaches of research integrity. All DRPs and ‘serious’ misconduct’ are breaches of integrity, and most will be misconduct unless honest error is involved.

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1.1.4 Social Responsibility

Upholding integrity

All researchers have a responsibility not only to science but also to society. This responsibility manifests itself in several ways. First, at a basic level, researchers must maintain scientific integrity, to ensure that the results they produce are reliable and can be used with confidence by the society that ultimately funds them. Fabrication and falsification of results are not only dishonest behaviours, they also compromise the integrity of science itself, potentially contaminating future research endeavours, wasting resources and public trust. That public trust is not only an output of responsible research, it can also act as an input to societal relevance as it can be a requirement for influence and social value as wielded by researchers.

In this section, we will first discuss the relevance of relevance as an input in research – articulating relevance as a required characteristic of research. Second, we will discuss the relevance of relevance as a social characteristic of practitioners and institutes.

Doing relevant research

Next to doing research responsibly in the sense that the researcher adheres to normative procedures and protocols, a second aspect of social responsibility is doing research that is relevant. Even if a research project is perfectly designed, has excellent methodology, and is conducted with great rigour resulting in superb analysis and reporting, it might be useless if the research question itself is irrelevant or the problem it addressed has no social or scientific relevance. Research integrity consists not only in designing and conducting research to certain standards, but also in identifying relevant research questions.

What does relevant mean in this context? This question can be answered in different ways, but essentially it means that the research must have some potential impact on society - even if by reinforcing or improving the body of scientific knowledge which will ultimately benefit society rather than by directly affecting society.¹ For example, a study that aims to reproduce the results of a previous study may not yield novel results, but will reinforce the findings of the earlier study, improving the evidence base for society. The relevance requirement has gained greater prominence in recent years, being mentioned in more guidelines and even featuring in some national legislation (the Swiss Human Research Act states that “research on human beings can take place only if the scientific

¹ The principle of relevance refers also to the basic principle of Research Ethics, i.e. the principle requiring that any research project must have potential to produce social, applied or scientific merit. For example, recently updated CIOMS guidelines refer to the principle of social value in its Guideline 1.

question concerned is relevant for one of the following domains: understanding of human diseases; the structure and functioning of the human body; and public health”. (Swiss Federal Government. Human Research Act). Although not specifically written in this context, research and writing on the ‘new production of knowledge’ can be read this way too (see [NPoK](#) and [RTS](#)).

Relevance is not only relevant in terms of yielding beneficial results. Irrelevant research also wastes the resources invested in it. It has been argued, for example, that it is wasteful to conduct further research on homeopathy because the evidence that it is ineffective beyond a placebo effect is overwhelming. Research without relevance is also detrimental to any human or animal participants; at best, their time is wasted, and at worst, their lives may be lost, depending on the nature of the research. Harming humans and animals in the course of relevant research is already unfortunate, but loss of life in pursuit of irrelevant aims is deeply unethical (the flip side of this is another type of relevance: in some research (notably clinical trials), participants can benefit directly from the research so it is relevant in that sense). Note that a study can also be rendered irrelevant by bad methodology even if the research question is relevant. If a study has too few participants for statistical power, its results will not be valid, and will thus be irrelevant. But reports of such studies are sometimes published, meaning that papers that are fundamentally flawed and whose results are thus irrelevant contaminate the scientific record, skewing the knowledge base and allowing methodology experts such as John Ioannidis to argue that [most published research findings are false](#).

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Relevance as a social attribute

Next to relevance being a characteristic of research processes and research outputs, relevance is also a perceived quality, attributed to institutes and individuals by various publics. To be perceived as relevant in a debate, to be perceived as a legitimate voice, a legitimate expert or a legitimate proxy to speak on behalf of others, conveys power.

Acting responsibly, adhering to research integrity, or at least the perception of it, translates indirectly into credibility. In the words of Onora O’Neill, trustworthiness requires reliability, honesty and competence. In the context of research and scientific situations, the honesty and reliability requirements are best caught by the research integrity label (although competence is of interest too, see below), whereas research ethics is spread across all three. To earn credibility, or to become trustworthy, means to build one’s relevance. Note that this process can take place on multiple levels. Individual researchers build their credibility, trustworthiness and relevance as much as institutions do – ranging from local colleges to global organisations such as the WHO. Perceived deviant behaviour, meaning breaks the norms and values as recognised elements of research integrity, individual or institutional, translates into a loss of relevance.

Relevance as a social attribute is, albeit different from the ones mentioned above, a resource that can be wasted. Committing fraud, overstepping one's epistemic domain, or, for institutions, appearing either institutionally corrupt, or hosting a researcher who has committed fraud, will diminish one's capacity to yield desirable change – relevance wasted.

Dual use of research

More concretely, another issue arises with respect to relevance. It is dual use of research results, an issue often associated with research ethics, but also with clear research integrity connotations. Research must be relevant, but researchers must also ensure that they have considered its potential relevance in terms of misuse of their findings. Dual use was originally defined as any technology that can be used for both peaceful and military means, but in the context of research integrity it refers primarily to any misuse of knowledge, data or scientific discoveries (including technology). In the United States Dual Use Research of Concern is defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”

For example, one of the main worries in dual use is that terrorists could use new tools to engineer bioweapons. However, dual use issues are not limited to life science research. Interview data about smoking habits could be obtained with the intention of developing new strategies to help people stop smoking, but the same results could be used by tobacco companies to target advertising designed to increase smoking rates. Dual use concerns also highlight a tension between two different themes in research integrity. Open data is regarded as an important aspect of integrity because of the need for transparency and reproducibility. But making all raw data available increases the risk of unethical dual use occurring. All researchers have a responsibility to anticipate and take measures to prevent any dual use of their findings.

Limits of competence

Revisiting O'Neill's requirement for trustworthiness (reliability, competence, honesty) also presents us with another questionable behaviour researchers may engage in, perhaps unknowingly. Whereas transgressions on the honesty requirement very obviously translates into a loss of trustworthiness or credibility, transgressions of the other requirements can also do so in perhaps unexpected ways. To do unreliable incompetent science renders, as argued above, even the most relevant science irrelevant.

However, limits of competence are not in themselves limited to data collection or experimental work. Limits of competence are also at play when researchers take public stage in the context of research communication or as expert witnesses or expert commentators. Consider, for instance, the status of the

so-called prominent rock-star scientists, including people such as Brian Cox or Neill deGrasse Tyson. They are highly sought after as public figures speaking with authority on scientific issues as they present themselves as current events. They are, by training a particle physicist and an astrophysicist. Yet routinely they are asked to provide (very public and very powerful) comments on issues varying from vaccination to climate change and from nutrition to science policy. They are overstepping the epistemic culture they are part of, reaching beyond the limits of their competence, and jeopardizing their trustworthiness.

Of course, trustworthiness and the public relevance that flows from this, is a perceived quality. The consequence of this is that to many, Cox and deGrasse Tyson are (a) doing nothing wrong and (b) their relevance as public intellectuals remain unscathed. Similarly, the opposite positions exist. From a research integrity standpoint, limits to one's competence impose limits on how one ought to present our expertise – individuals and institutes alike.

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1.2. Practical Issues

1.2.1. Plagiarism

Introduction

Plagiarism is listed among the three deadly sins in research, along with fabrication and falsification, in almost all international literature on research integrity. The moral status of plagiarism is not, however, on par with the two other cardinal sins. The dominant view is that that plagiarism does not corrupt the content of science, only the distribution of credit in it, whereas fabrication and falsification do both. Plagiarism, in other words, it is not harming science in its endless search for truth, while fabrication and falsification do. For instance, [Bouter et al.](#) worked towards quantifying the effect of plagiarism on truth (relatively small) and trust (bigger).

Plagiarism is intricately tied into cultural positions on ownership of ideas and of text. Ownership of ideas and text are not the same, nor are conceptualisations of ownership of both. Most of the discourse on plagiarism is Western-centric and refers heavily to individualistic norms for originality. Practically, many of the guidelines and codes-of-conduct available refer to both ideas and text. In practice, however, enforcement is often centralised on text, for practical purposes.

Ownership and Language

[Pennycook](#), for instance, shows that our culturally, and temporally divergent ideas about ownership shift how we think about plagiarism (and how we act accordingly). As a result, the way professionals and students think about plagiarism and originality cannot be separated from the teaching or research system they are embedded in. The research and teaching culture performed through infrastructures co-determine what counts as cheating, fraud, or decent academic behaviour, see [Ashworth et al.](#)

On top of this, plagiarism is intertwined with language. Many researchers publish in languages different from their own (English in the case of most scientific and scholarly work). This creates practical problems because, however good researchers get at English, they never become native speakers, forever limiting their ability to express themselves in myriad ways. Originality on the level of sentences becomes harder with every paper a researcher publishes who is not so proficient at English. [Currie](#) has studied a case of plagiarism in detail, in which this and a number of other issues feature prominently. The choice to reuse sentences used before, motivated by various reasons, does not restrict itself to the writing of others, but may mean that researchers re-use descriptions they have used before. This practice has been named self-plagiarism, which features increasingly prominently in research integrity discussion. It is discussed below in a separate section.

Guidelines

A variety of definitions for plagiarism circulate. We will not reproduce all of them. However, to understand conceptualisations and existing suggestions, codes and guidelines to prevent and deal with plagiarism, a few help to sketch the landscape. For instance, the World Association of Medical Editors (WAME) defines plagiarism as:

[T]he use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source. [[WAME Website](#)]

The Committee on Publication Ethics (COPE) offers, as a strategy to avoid plagiarism, to diligently include sources and ask for permission when including larger amounts of someone else's work. In contrast, the Office of Research Integrity offers a more complex list of [28 guidelines](#) to avoid plagiarism. However, despite the explicit inclusion of intellectual property – or ideas – in the definitions of plagiarism, operationalisations strikingly target text. For instance, in the [2011 COPE discussion paper](#), plagiarism is operationalised as a problem of 'text similarity' (p.8), explicitly discussed in the context of the tools available to detect such similarities (ranging from old-fashion peer reading, to complex algorithms). It makes similarities concrete by suggesting that duplications of >100 words are to be labelled as 'major plagiarism', while duplications <100 words are only 'minor', with different sanctions attached. To be fair, unauthorised attribution of hypotheses, data, finding and arguments are mentioned too.

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Quite a few open norms exist in the various guidelines available, for instance excusing the verbatim inclusion of descriptions of common, or standard techniques. Which techniques are considered standard or common by whom, is still up for debate. Similarly, authors may disagree whether a description is similar, or not, knowledge is common, or not, and whether or not ideas are original, or not – all, of course, on a gradient ranging from very to slightly.

Understanding practices

As a consequence, when it comes to plagiarism – the international rules are often expected to provide clarity, yet usually require deliberation and negotiation. That does not mean that plagiarism is to be excused or approved. It just means that if you want to have a decent conversation about plagiarism – or work towards minimising it – you need to take local research infrastructures and local research cultures into account. Avoiding plagiarism is not as simple as it may seem, as [Fisher and Patin](#) demonstrate in their study. Fisher and Patin join the chorus in research integrity discourse, calling for additional education on proper conduct – an important way to socialise new researchers into complex social and political practices. However, additional teaching or telling people how to behave is not

effective if that particular behaviour is either not perceived as deviant or wrong, or if no stimulus exists to change it. [*Read more in our sections on metrics and rewards*]

Self-plagiarism

Strictly speaking, self-plagiarism is an oxymoron, for it would imply stealing from oneself. It is also not labelled as misconduct by the Office of Research Integrity [[read more](#)] and regularly referred to as text recycling or duplication. [Horbach and Halfman](#) have, as a pilot study, scanned nearly a thousand publications of prominent Dutch researchers in a variety of disciplines and learned that the practice is rather common, but also very unevenly distributed among those disciplines. While estimates of the incidence of self-plagiarism vary, Horbach and Halfman, through a conservative methodology, diagnose 6%.

Deviating from plagiarism proper, self-plagiarism's moral status is unclear. While many find the practice unacceptable, others argue that it is unavoidable or does not exist. Horbach and Halfman cite [Callahan](#) as taking a position in favour of self-plagiarism, as helping and assisting the development and maturation of ideas through multiple written iterations. Even if, in a legal sense, self-plagiarism is problematic, copyright infringement is less so. The re-use of text touches upon [both](#).

Further Reading

[Avoiding Plagiarism, Self-plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing](#), the Office of Research Integrity.

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1.2.2. Reviewing Peer Review: Problems and Potential

Introduction

Peer review occurs in a wide range of activities—from assessments of professional performance to decisions about tenure (Lee et al. 2013). The peer review of scholarly texts emerged during the 17th century with the establishment of national royal academies in Europe (Biagioli 2002; Lee et al. 2013; McCarty, Borgert, and Mihaich 2012; Resnik and Elmore 2016). Originally it was not designed to assess academic rigor. Rather, in the hands of carefully screened and court-appointed ministers, it existed as a form of state censorship and the control of publication licensing (Biagioli 2002). This is in stark contrast with its present function as a means to establish research integrity, credibility and value in journal publications—albeit inconclusively, as we shall see. The expansion and diversification of science after World War II saw the creation of many new scientific journals and, with these, the intensification of peer review mechanisms for journal publication (McCarty, Borgert, and Mihaich 2012). However, these procedures varied widely and lacked formal consensus about how they should be practiced. It was not until the 1980s that peer review itself emerged as a field of scientific inquiry in its own right (ibid). While dominant models of peer review exist today, these are joined by multiple calls for its revision and improvement. This section reviews the current debate on peer review for scientific journal publication and points out the key interrelated problems and potentials.

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Problems

At its best, peer review should uphold the ethos of the academe in a fair and impartial manner. So, when critical issues surface revealing peer review as problematic, they tend to cut to the social and epistemological bone of its justification. There are several key and interrelated problems linked with the ethics and integrity of peer reviewing, which critics have brought to light. A comprehensive sweep of this literature is beyond the section's scope, but it points out three salient and interrelated themes.

Ineffective per review

Many critics claim that peer review is an inadequate system for catching methodological flaws, fabrications, falsifications, plagiarism, and other forms of research misconduct and deception (Resnik and Elmore 2016; Teixeira and Fontes Da Costa 2010; Ware 2011). Article retraction is one effect and indicator of peer review's inability to catch misconduct, at least in the pre-publication phase (see Fresco-Santalla and Hernández-Pérez 2014). Another related critique is that it is slow and needlessly delays publication (Ware 2011). A more general critique is that its procedures are inconsistent, with

diverse and even contradictory practices in play from journal to journal, which requires authors to expend resources on the strategic positioning of their submissions.

Misconduct in peer review

The critique of peer review often equates to concerns about the misconduct of editors and reviewers. For instance, Shaw (2015) suggests that reviewer anonymity, offered by some models of peer review, allows amply opportunity for poor behaviour including biased evaluations and recommendations. Teixeira da Silva and Al-Khatib (2016) reports a case where a publisher was forced to retract 32 articles after discovering that editors had fabricated reviewer evaluations to manipulate publication. In another example, Resnik and Elmore (2016) report an online study where author responses confirm instances of unfair reviewer behavior including personal attacks, confidentiality breaches, and demands to unnecessarily cite reviewer's own work (i.e. reviewer ego-bias).

Biased peer review

Bias in peer review is another key area of critical debate. Lee et al. reflect that: "It is the impartial interpretation and application of shared norms and standards that make for a fair process, which—psychologically and epistemologically—legitimizes peer review outcomes, content, and institutions. This is why critics' charge of bias in peer review is so troubling: Threats to the impartiality of review appear to threaten peer review's psychological and epistemic legitimacy" (Lee et al. 2013, 3). In their article, Lee et al. survey a remarkable range of bias "genres" at play in the peer review process, which helps ground the description below (see also Resnik and Elmore 2016; Schwartzman 1997; Shaw 2015; Teixeira da Silva and Dobránszki 2015; Ware 2011).

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Quality-related. This bias concerns the reviewer ability to objectively assess the true quality of submissions. Subgenres include: a) "deviation from proxy measures for true quality" where an article is submitted and rejected by one (top) journal but subsequently submitted and accepted by a different (top) journal; and b) "low inter-rater reliability" where evaluation discrepancies exist between two or more reviewers of the same article. (For further discussion of this issue, see Resnik and Elmore's (2016) section: Inconsistent Review.)

Content-related. Disciplinary preferences or theoretical / methodological orientations towards certain content or approach can also bias the evaluation of submission. Subgenres include: a) confirmation (or rejection) based on the aforementioned preferences or orientations (e.g. schools of thought); b) conservatism, which rejects ground-breaking / paradigm-shifting (innovative) approaches that challenge the status quo; c) interdisciplinary research, which may challenge disciplinary (mainstream)

boundaries; and d) publishability, where research demonstrating positive rather than negative results is deemed more publishable.

Author-related. This genre includes bias linked with author identity or status, which negatively or positively play on the review of his or her article, including: a) prestige and class; b) institutional affiliation; c) national origin; d) language; or e) gender.

Reviewer-related. Here bias concerns how reviewer identity (prestige, class, institutional affiliation, national origin, language, gender, etc) affects his or her review style or tendency to evaluate certain submission types more strictly or leniently than others. Similarly, reviewer ego bias may occur when submissions receive lower evaluations that fail to reference the reviewer's own work (see content-related bias above). Conflicts of interest may also bias reviewer evaluation especially if gone undetected (see also Conflicts of Interest section).

Editor-related. From one perspective, peer review exists to offset or augment editorial power, but from another the editor retains complete control over the entire process, including the selection of reviewers (Guédon and Siemens 2002, in Fitzpatrick 2010). In both perspectives the editor role is key. Yet, distinguishing possible editor-bias in peer review depends on the degree to which editors employ a hands-off or hands-on approach. Editor bias can parallel reviewer bias, but it can also stem from the economics and politics (i.e. systemic) concerns of journal publication.

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Potential

An increasing number of scholars have proposed ways to address the problems of peer review and its potential reform. For instance, Resnik and Elmore (2016) survey several recommendations found in the literature. These include increasing the number of referees (more than two per submission), the addition of referee training programmes, and improved referee instructions. Other recommendations focus more specifically on revising editor behavior to promote integrity and fairness in the peer review process. Editors can enhance referee selection and practice with more stringent referee recruitment and guidance, and by carefully checking reviewer assessments for unbiased, professional content. Editors can also remain transparent about decisions to accept or reject submissions for publication and offer clear rationale for both. Proposals for peer review reform also include alternatives to more traditional models.

Models of peer review

As noted above, multiple models of peer review exist. These differ widely between publisher and journal as well as the degree of transparency and the stage at which evaluations are made (Fresco-

Santalla and Hernández-Pérez 2014). Peer review has typically involved pre-publication assessment by small group of appointed reviewer(s) and editor(s). There are currently two dominant models:

Single-blind peer review. In this model, reviewer identities are kept from the authors but reviewers know author identities.

Double-blind peer review. Here both authors and reviewers remain ignorant of one another's identities.

The rationale with both the single-blind and double-blind models is to encourage reviewers to make honest assessments without concern for author redress. As Lee et al. (2013) explain, single-blind model is used most frequently because it is less burdensome and expensive to operate than the double-blind model, which requires more effort to mask all signs of author identity from the submission. On the other hand, the double-blind model is regarded by some scholars as the fairest because reviewers cannot make biased assessments against authors (Shaw 2015). However, Shaw warns that blinding the identity of reviewers renders them unaccountable—for instance, authors are unable to point out conflicts of interest.

Triple-blind peer review. In this case the identities of authors are blinded for both reviewers as well as editors. However, editors still know reviewer identity.

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Non-blind or open peer review. This model of peer review is where both identities of authors and reviewers are known to each party. Several different versions exist, with which journals are currently experimenting, including online community pre and post-publication stages (Fresco-Santalla and Hernández-Pérez 2014).

Shaw (2015) points out, however, that many open forms of peer review retain the problems of bias against authors. To counter this, he suggests a modified double-blind model where editors and reviewers are both blinded to author identity. He concludes that, “the peer review system should be based upon the principle that blinding should be used only to prevent bias in decision-making” (ibid: 4). We agree. Nevertheless, we encourage continued experimentation with open-access peer review, possibly hinged with non-binding pre- and/or post-publication online community consensus, performed in ways that protect author identity.

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1.2.3. Bibliometrics Approach (*The Matrix of Metrics*)

Introduction

Bibliometric methods concern the systematic, quantitative measurement and analysis of publications, authors and their citations. This activity has existed for over a century (Hood and Wilson 2001). This field contains several related and overlapping traditions including Bibliometrics, Scientometrics, Informetrics, Cybermetrics, and Webometrics. The Science Citation Index (SCI) is one of the earliest databases created and used for citation analysis. Today web-based indexes like the Web of Science (Clarivate Analytics) make this index available online. Other important bibliometric data sources include Scopus (Elsevier), Google Scholar (Google), PubMed/MEDLINE (US National Library of Medicine), and SciFinder/CAS (American Chemical Society).

Types and Definitions

While methods of citation analysis have been around for some time, the Journal Impact Factor (JIF), has driven bibliometric's growing influence in academic work. Created by Irving Sher and Eugene Garfield in 1955 (Garfield 2006), JIF figures the annual average of article citations for a given journal. For better or worse, JIF establishes a comparative benchmark of journal quality. Its influence remains today, but the search for additional measures of quality and impact, along with the advent of new forms of publication and distribution, have spurred the creation of other metrics to benchmark not only journals but the academic performance of institutions and individuals. The chart below overviews the other main bibliometrics currently in use.

Metric	Description
5-year impact factor	Average citations of papers in a year to papers published in the previous five years. From the Web of Science. Published annually in the Journal Citation Reports (JCR).
Age weighted citation rate (AWCR)	Measures the average number of citations to an entire body of work, adjusted for the age of each individual paper.

Altmetrics	Tracks online attention received by individual papers including Tweets, blog posts, citations, Wikipedia mentions, Mendeley and other reference listings, Facebook and Google+ posts.
Article Influence! score	Calculated by dividing the Eigenfactor! score by the percentage of all articles recorded in the JCR that were published in the same journal. Article Influence! is similar to the impact factor and SCImago journal rank.
Aggregate impact factor	Calculated in the same way as the impact factor but takes into account the number of citations to all journals in the category and the number of articles from all journals in the category. An aggregate impact factor of 1.0 means that, on average, the articles in the subject category published in the previous one or two years have been cited once.
Cited half-life	This is a measure of the age of articles being cited. It calculates the halfway point (half of the citations to articles published before a date and half after that date) to give a measure of the longevity of what the journal publishes. For example, if in 2015 the cited half-life of a journal was 5.0, then this means that half of all citations to it were to articles published before 2010 and half to articles published after 2010.
Eigenfactor! score	Citations are weighted according to the prestige of the citing journal so citations from top journals mean more than citations from lesser journals. Uses a five-year citation window. Published annually in the JCR. All journal self-citations are excluded.
Egghe's g-index	Aims to improve on the h-index by giving more weight to highly cited articles. The g-index is the highest number of papers of a researcher that, on average, have received g or more citations.
Google Scholar TM metrics	Lists the top journals by disciplines and subdisciplines using the journals' 5-year h-index and h-median.
Hirsch's h-index	The h-index is an article level measure designed to evaluate individual authors. The h-index indicates the number of papers (h) that have been cited at least h times.

Immediacy index	<p>This is calculated in the same way as the impact factor but looks at only one year</p> <p>(ie number of citations to articles published in a year divided by the number of articles published in the same year). It measures how rapidly the journal is cited and therefore</p> <p>whether it is publishing in a rapidly developing area. Published annually in the JCR.</p>
Impact factor	<p>Average citations in one year to articles published in the previous two years. Published annually in the JCR.</p>
Impact per publication (IPP)	<p>Measures the ratio of citations in a year to scholarly papers published in the three previous years divided by the number of scholarly papers published in those same years. Calculated by Scopus.</p>
PageRank™ algorithm	<p>Google-based evaluation: The ‘top’ articles tend to be those that have been cited/linked to</p> <p>more than others. The calculation used is a commercial secret and so cannot be fully evaluated.</p>
SCImago journal rank (SJR)	<p>Based on weighted citations in a year to papers published in the previous three years. From Scopus! and published in the SCImago journal and country rank reports. Citations</p> <p>are weighted by the prestige of the citing journal, much like the Eigenfactor! score. Journal self-citations are limited to 33%.</p>
Source normalised impact per paper (SNIP)	<p>Measures average citations in a year to papers published in the previous three years. From Scopus! and published twice a year. Citations are weighted by the citation</p> <p>potential of the journal’s subject category, making this metric more comparable across specialties.</p>
Y-factor	<p>Uses Google PageRank with the impact factor to measure and distinguish the quality of citations. Aims to improve the impact factor.</p>

Citation Rate Differences

The increase of bibliometric information has become an integral part of academic writing, referencing, publication, and research practice more generally. A guiding assumption behind the creation and use of bibliometric data is that cited works have greater impact and quality than non-cited ones (\wedge citation rate = \wedge citation quality/impact). However, as one bibliometric analyst argues, there are several reasons why an author might decide to cite or not, which may have little to do with the impact or quality of the citation (Neophytou 2014). These reasons include: discipline (science, social science and humanities have different citation traditions and schedules); type (for example, literature reviews typically receive more citations than cases studies or editorials); date (older publications can accumulate more citations over time than newer ones); and source (large databases like Google Scholar likely generate higher citation scores) (ibid). Other factors include: language (English versus other languages); reputation (popularity of a specific journal or author); disproofs (articles that contribute new ideas or theories receive more citations than ones that refute or falsify); subjective bias (self-citation or work of colleagues/friends). Thus, creating metrics to figure academic quality is all well and good but it remains important to account for the limitations of each metric as well as the context of use. The next section reviews critical literature tackling important issues of bibliometric creation and usage in practice.

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Critical Studies

Empirical examples. The critical study of bibliometrics in practice is a new area of inquiry. Examples of recent case studies include the interplay between bibliometric data and: the norms and values of research practices in biomedicine (Rushforth and de Rijcke 2015) and the life sciences (Fochler et al. 2016, Müller and de Rijcke 2017); variations in authorship contribution and career implications (Jabbehdari and Walsh 2017); global university rankings (Hammarfelt et al. 2017); and scholars' self-citation and quantification practices (Hammarfelt et al. 2016).

Uses and misuses. Close empirical attention to how bibliometrics are used has produced a number of key insights concerning the ethics and integrity of research practice. Examples reflect concerns about validity and limitations (de Rijcke and Rushforth 2015), ratings manipulation (Oravec 2017), trust and accountability (Oravec 2017, de Rijcke et al 2016, Hammarfelt et al. 2017), strategic gaming (Oravec 2017, Hammarfelt et al. 2016, de Rijcke et al 2016), displacement of research goals (Müller and de Rijcke 2017, de Rijcke et al 2016), narrowed forms of scientific quality (Fochler et al 2016, de Rijcke and Rushforth 2015, Rushforth and de Rijcke 2015) and reduced interdisciplinarity (de Rijcke et al 2016).

Theorizing bibliometrics in practice. Critical studies suggest have employed different theoretical approaches to understand bibliometric practices. Some literature employs game theory to study how actors (scholars, institutions, and publishers) strategically manipulate quantitative bibliometric measures to improve their rankings (Oravec 2017, Hammarfelt et al 2016). Other studies take a different tact, drawing on valuation theory to explore more closely how actors negotiate and attribute different forms of worth and scientific quality in practice (Fochler et al 2016, Müller and de Rijcke 2017, Hammarfelt et al. 2017). Furthermore, valuation has been approached with the notion of “folk theory” or “folk knowledge” to explore how academics employ subjective or untested assumptions to make sense of bibliometric ratings and position new scientific knowledge (Rushforth and de Rijcke 2015, Oravec 2017).

Implications and Guidelines

De Rijcke et al. suggest that bibliometric tools are attractive to policy makers because they promise the reduction of complexity (2016:166). Yet, herein also lies the peril. Before the use bibliometric data becomes part of research policy and decision-making one should start by first considering the issues outlined above concerning validity, manipulation, trust, strategic gaming, research goals, interdisciplinarity, as well as the figuring of scientific quality and impact more broadly. Hicks et al. (2015) have provided a useful “Manifesto” to help guide the use bibliometrics data. Their ten recommendations are: 1) Quantitative evaluation should support qualitative, expert assessment; 2) Measure performance against the research missions of the institution, group or researcher; 3) Protect excellence in locally relevant research; 4) Keep data collection and analytical processes open, transparent and simple; 5) Allow those evaluated to verify data and analysis; 6) Account for variation by field in publication and citation practices; 7) Base assessment of individual researchers on a qualitative judgement of their portfolio; 8) Avoid misplaced concreteness and false precision; 9) Recognize the systemic effects of assessment and indicators; and 10) Scrutinize indicators regularly and update them.

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1.2.4. Authorship

Introduction

One of the perennial challenges in research integrity is accurate authorship attribution. Authorship of publications is, alongside obtaining grants, the key element of career progression in research due to the way the current system is designed. This means that authorship is very important. It is so important to some researchers that they are happy to be named as authors when they did not contribute anything substantial - or anything at all - to a particular paper. These are 'guest' authors or honorary authors (an ironic name as there is nothing honourable about it). It is also so important that junior researchers are sometimes left off author lists when they did contribute substantially, because they aren't deemed to have 'earned' authorship yet or their inclusion could dilute the credit given to the other authors. These are 'ghost' authors. Finally, ghostwriters are often paid by researchers to write articles in the expectation that they will not be credited.

It should be noted that authorship paradigms differ between disciplines and what counts as a substantial contribution in one discipline may not count as one in another. For example, most papers in medical journals have several authors. In contrast, philosophy papers often have only one author (Cutas & Shaw 2014) and sometimes pages of acknowledgments. Often the people mentioned in these footnotes have actually contributed more than many of the authors of clinical research papers. The following sections focus more on the disciplines of science and medicine, because it is here that the problem is probably worst. Authorship issues exist in all fields, however.

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Guest authorship

Authorship is ambiguous and its accurate attribution is heavily dependent on hierarchy. Junior researchers who are new to writing papers for journals are to a large extent at the mercy of senior researchers, who pass on dominant authorship practices to their new disciples. If a lab leader or department head expects to be named as an author on every paper written by any of his staff, he will probably get what he wants. If a junior researcher is brave enough to question why the senior should be credited when he hasn't even read the paper, a mid-level researcher might attempt to justify the authorship by arguing that none of them would have a job if the professor wasn't providing the grant and the lab facilities. This might seem reasonable to a junior researcher, but it is not (see Guidelines section below). Authors have to contribute to the writing of a paper. The hint is in the word itself.

The phenomenon of guest authorship raises great difficulties for researchers. Not only can they come under pressure to acquiesce in adding people who are not authors to papers, it is often junior authors

who actually submit papers to journals. Most journals now ask for a statement that all authors contributed substantially. If the submitting researcher ticks the box next to this statement (or inserts such a statement in the paper) he or she is violating research integrity (and many would say is also guilty of misconduct). But for many researchers, the alternative could be losing their job and career. Guest authorship in itself might seem like a relatively unimportant transgression, but it implicates all other authors in deception (and possibly fraud) and allows senior researchers to unjustly pad their CVs, sometimes widening the gulf in power between them and junior researchers. For any given paper, adding ghost authors will dilute the perceived contribution of the actual authors. And of course, if junior researchers come to believe that guest authorship is ok, this might be the first step on a slippery slope to other research misbehaviours.

Ghost authorship

The flip side of guest authorship is ghost authorship, where researchers who deserve to be named as authors are not given this recognition. It is even possible that a junior researcher could end up doing most of the research on a given project, writing most of the paper and submitting it, but still not end up as an author (an indignity rendered even worse if the paper also features guest authors). While guest authorship is freeriding, and dilutes the visible contribution of the other authors, ghost authorship amounts to theft of intellectual property. If someone has contributed, he or she deserves credit. Furthermore, the person who did most of the research is normally the guarantor of that research. If that person is not even credited as an author,

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In the case of paid ghost authors, the problem is rather different. Often, such authors are happy not being named on papers as they are paid for their services. But equally, if they do all or most of the work on a paper, it can often mean that the other authors are all rendered as guest authors (One study found that no named authors would admit they were the authors of one particular paper on cancer.) The main issue with guest authors is not lack of recognition, but that the named authors may not have conducted the research, much less read the paper in question. This is a magnified version of the last issue mentioned in relation to junior researcher ghost authorship.

Authorship order

In addition to establishing who should and shouldn't be an author, there is the secondary problem of what order the authors should be listed in. Generally, the first author is assumed to have done most work, while in many disciplines the place of last author is regarded as indicating seniority. Again generally, most researchers would prefer not to be the middle author. But different disciplines and journals have different conventions. Some use alphabetical order, some use descending contribution

order, and some use the first/senior author paradigm. Even when researchers agree amongst themselves that they should all be named as authors, the specific order can result in disagreement. It is now possible for people to be named as “co first authors” or even “co senior authors” so that a paper could actually have four (or more) authors in the two ‘best’ positions. Generally, discussion about who should be included as an author, and potentially the order of authors, should be discussed in advance (though subject to modification) in order to avoid disappointment and conflict later.

Contributorship and the future of authorship

Because of the ambiguity surrounding the concept of “substantial contribution”, some journals are moving towards contributorship statements that are published alongside traditional author lists. These statements make it clear(er) who did what on a given research project; e.g., DS did that, DT did that, BP did this. As well as providing clarity for readers, requiring authors to provide these details also encourages reflection about who deserves actual authorship, and acts as a disincentive to include guest authors and exclude ghost authors. An honest contributorship statement on a paper with guest and ghost authors would have to include a sentence like this: “X and Y did nothing. Z did everything else but isn’t on the author list because we paid him.” Contributorship statements also allow for recognition of effort that does not qualify researchers for authorship, such as providing biosamples or machinery.

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However, while journals are moving towards contributorship, they are not yet moving away from authorship. Contributorship lists are often buried at the end of articles behind a paywall, while authorship lists are highly visible. It has been suggested that *replacing* authorship lists with contributorship statements would be the best solution, as it would replace a flawed and ambiguous system of attributing credit with a less vague and more specific one. But paradigms are resistant to change, and “author of 20 papers” will sound better than “contributor to 20 papers” for the foreseeable future. All researchers should treat authorship seriously and sensitively.

Guidelines

Because of all of these issues, various organisations including the International Committee of Medical Journal Editors (ICMJE), Committee on Publication Ethics (COPE) and World Association of Medical Editors (WAME) have developed guidelines that set out what criteria must be met for someone to qualify as an author (at least for those publishing in biomedical journals).

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

[<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>]

The creation of these guidelines is good in the sense that they provide a benchmark that can be used to guide whether someone should be named as an author. But they are not unproblematic. First, what constitutes a substantial contribution? Substantivity is subjective. I might get upset if I think I have made a substantial contribution and you think I haven't. (Indeed, if I'm right and I'm not credited I will become a ghost author). While rigorous application of the ICMJE guidelines should prevent 'total' guest authorship where the named person made zero contribution, it will not weed out authors who merely read papers and gave a few comments.

It has also been pointed out that these authorship criteria might be *too* rigorous. Imagine that someone has a great idea for a study, someone else conducts the research, and someone else again writes and submits the results. None of these people would qualify as an author. The contributorship statement (see below) for this paper would say something like "X had the idea, Y did the research and Z wrote this paper. But none of us are authors" (Shaw 2011).

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1.2.5. Conflicts of interest

Introduction

One of the core issues in research integrity is conflicts of interest. Indeed, it would not be an exaggeration to say that there would be very few issues in research integrity if there were no conflicts of interest. Why are CoI so integral to integrity? Because integrity is about doing what is right despite any temptation to do what is personally advantageous. Cicero was perhaps the first to identify this key conflict between what he called “the honourable and the useful” (Cicero). If you are a junior researcher and your group leader wants his name to be included on anything you write even if she did not contribute, this might seem like an authorship rather than a CoI issue. But if it was not a CoI issue all junior researchers would simply say “no way” in response. In fact, they do not (tend to do so), because they realise that their jobs and careers depend to a large extent on keeping their bosses happy. Thus the researcher’s interest in respecting the rules of authorship (the honourable) is in conflict with his interest in remaining employed (the useful). Similar conflicts come into play throughout the research environment.

In a conflict of interest, a person has two competing interests that could bias their judgment or behaviour. In this section we explore three major and one minor type of conflicts of interest (financial, personal, intellectual and medical), and clarify what is meant by perceived and potential conflicts of interest. (It is actually quite difficult to classify the above example as it involves personal conflict, but is really in essence a financial conflict of interest - though the researcher might really love his job and want to keep doing science, the real concern in most cases will be ensuring income for oneself and one’s family. As such, capitalism is perhaps the root cause of most conflicts of interest and thus of most research misconduct.)

Financial conflicts of interest

In medical research, as in many other disciplines, the focus until very recently has been on financial conflicts of interest (Wienfurt et al 2006). Here, the concern is not so much loss of financing as in the example above, but the lucrative incentives that doctors can attract for involvement in research, and which can influence their decisions and judgment. For example, a doctor might be paid by a pharmaceutical company to do some research and write a paper for a journal. He might think that he remains entirely objective, but the evidence shows that authors paid by industry are more likely to give positive evaluations of drugs being tested. Because of this, all financial conflicts of interest of all authors must normally be disclosed when a paper is submitted to a journal. This applies not only to *current* COI, but also to any over the last few years (specific duration is journal-dependent).

Having a COI is not necessarily a breach of research integrity, as long as that COI is declared. Disclosing it allows readers to consider whether the payment or other financial interest might have biased the reporting of the study (or its design or analysis, or even the decision to conduct the study). But failure to disclose a COI is a serious breach of research integrity because it represents deception that threatens transparency and robs readers of important information about how to interpret research results. Notably, failure to disclose COI is not classified as misconduct by the definitions in use in the United States, which define the ‘big three’ of plagiarism, falsification and fabrication as misconduct and failure to disclose COI as a “detrimental research practice” (see linked section for critique of this term).

Personal conflicts of interest

Personal conflicts of interest are much less heavily regulated than financial CoI, yet they are perhaps even more important. Here, the concern is not being biased by financial interests, but the possibility that personal connections (whether positive or negative) could threaten the objectivity of research decisions. For instance, many journals state that authors should not nominate reviewers with whom they have recently collaborated or who work in the same department. This is because collaborators are more likely to give favourable reviews to their colleagues. Even if journals operate a blind review system (see linked section), collaborators are likely to know or guess the authors of a given paper - and unscrupulous authors can even tip off colleagues that they will be nominated as reviewers. There have been several cases of so-called ‘review rings’ where researchers agree to review for each other and give positive evaluations. In addition, journals allow authors to indicate non-preferred reviewers, in order to avoid referees known to have particular COIs against particular authors. While the checks implemented by journals are good in principle, journals lack the resources to police reviewer nominations with any rigour so the system relies on author honesty.

But personal COI extends beyond potentially biased reviewer nominations, as personal connections operate on a variety of levels. Even if they have never worked together, researchers can meet and socialise, generating biases. Opponents can clash at conferences, generating animosity that last for years. Personal COIs do not need to be declared, but both positive and negative ones should be actively avoided when nominating reviewers or referees anywhere in the research process and when making hiring decisions.

Intellectual conflicts of interest

Intellectual conflicts of interest are even more ephemeral than personal ones, but they do exist. Researchers who have worked for several years on one topic are likely to believe in a particular truth or paradigm, and become biased against any alternative explanation (Harbour 2014). For example, take the topic of breast cancer screening. Some research groups only ever publish papers in favour of such screening; others publish only papers that are against screening. It is important to note the connection between intellectual and personal conflicts of interest. If someone has a different intellectual view, one can become personally biased against that researcher in ways that bias decisions and interactions. Another type of intellectual COI concerns affiliation. If a researcher is writing about breast cancer screening and is a member of a Breast Cancer Screening Charity, this affiliation might be seen as intellectually biasing and should be declared. There can also be political aspects to intellectual conflicts of interest.

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Non-affiliation-related Intellectual conflicts of interest are insidious and hard to detect or declare. One way to both try to avoid them and to warn readers about them is to practice self-reflection. For example, in writing a new paper about a familiar topic, I might strive to maintain an open mind and not take any conclusions for granted. When submitting the new paper, I should declare that “I have written papers critical of X in the past” to inform readers about my past views on the subject. But even if researchers are proactive and engage in reflection and declaration of intellectual COIs, journals often remove all conflicts that are not connected with financing and affiliation.

Medical conflicts of interest

There are also medical conflicts of interest (Shaw 2014). These are a subset of intellectual (and sometimes personal) conflicts of interest and concern how one’s own medical experience (including those involving family members) can affect one’s research in medicine or other health-related topics. In one case, a principal investigator’s running of a cancer trial was called into question when his child developed the same condition. This personal factor coloured his views on the disease and his

treatment of participants. In this case, he should have stepped aside and asked someone else to run the trial - but he did not and this led to difficulties.

In other cases one's own intellectual views on a particular medical practice can be affected by one's personal experience. For example, if someone conducts research on the social implications of deafness, it might be prudent to disclose whether he or she is actually deaf. If someone is writing about obesity and smoking, one's views could be dependent on whether one is an obese smoker. These factors should generally be declared, but journals are likely to remove them.

Perceived and potential conflicts of interest

Finally, much of the literature about conflicts of interest involves discussion of “perceived” and/or “potential” COI. What is the difference between a perceived COI, a potential COI, and even a perceived potential COI? A perceived COI is in the eye of the beholder and might not be a real COI. For example, if a researcher based in a city that happens to host several pharmaceutical companies writes an article critical of alternative medicine, some supporters of alternative medicine might perceive a conflicts of interest where none exists. All perceived COIs are perceived as potential COIs, but many will not be potential COIs. A potential COI is one that should be declared even if it does not bias the researcher. For example, there might be some very objective researcher somewhere who reports results accurately even if paid handsomely by a Pharma company. Potential COIs do not really need to be distinguished from COIs because both need to be declared.

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2. Research Ethics

There are many handbooks and manuals on research ethics available. This contribution is designed to help members of Research Ethics Committees or Independent Review Boards (herein, RECs) from many different disciplines to question different aspects of their work. It does not pretend to be a comprehensive guide to law and ethics in the area; it is designed to provoke discussion. This is a substantial reworking, revisions and additional sections, of the work undertaken for EURECNET.

2.1 Conceptual Issues

2.1.1. *What are the “ethics” in Research Ethics, and how should they be handled by RECs?*

Should Ethics Committees be ‘ethical’?

This is, of course, a very peculiar question to start with, because on one level the answer is, ‘yes, of course!’ At another level, however, this is a non-obvious question, because the meanings of ‘ethics’² are not clear. At one level, it is about ‘professional’ behaviour - RECs should behave professionally (i.e. with a bureaucratic and procedural integrity and consistency). At another it is about ‘doing the right thing’; it is about ensuring that proposed research will (and to a lesser extent does) conform to agreed standards (although what those standards are and by whom they are agreed is also not obvious). But, there is a more fundamental question underpinning the meaning ‘ethics’ of the ethics committee: ‘what is the authority for the committee’s pre- and proscription of researchers’ behaviour?’ - or put simply, what is ‘ethics’? This section aims to open this discussion.

The Helsinki Declaration captures exactly the problem: Article 1 of the Declaration states,

“The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.”³

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The Declaration then contains a number of principles - principles that accord to those, for example, of Beauchamp and Childress, of autonomy, non-maleficence, beneficence, and justice. So, informed consent is the gold standard, precaution should be operated in relation to risk, and human welfare is paramount.

Article 23 of the Declaration introduces the REC/IRB:

“The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research

² ‘Ethical’, being an adjective, is difficult - an ‘ethical review’ is more a review that would be conducted in an ethical manner, rather than a review relating to ethics (although it tends to be used to mean the latter). So, here ‘ethical’ is avoided.

³ WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964, and subsequently amended, most recently in 2013) <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

“The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study’s findings and conclusions.”

Two elements are interesting at this point “must be duly qualified” and “must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration”. How does the Declaration, and the requirements for ethics committees, fit into the broader framework of ethics?

What are ‘Ethics’?

The Declaration is very practical. It produces a number of key areas and presumptions about what is acceptable behaviour. These approach prescription in a number of key areas, but still require a degree of negotiation or interpretation. And yet, ‘ethics’ are contested.

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The contest appears first at an almost functional social level. There is a distinction to be drawn between colloquial and formal ethics. *Colloquial uses of the term* are an appeal in popular use to mean that something is ‘right’ or ‘acceptable’, very much in line with the predominant cultural standards in a particular community. It is more a linguistic way of labelling behaviour as acceptable or unacceptable without any appeal to a formal, systematic basis for the claim. Another version of ‘colloquial ethics’ might be termed ‘practical ethics’ - i.e. a more systematic focus on what is right and wrong, but based in the beliefs of the individual decision-makers, without a formal analysis of the basis of those beliefs. *Formal uses of the term* are an appeal to ethics as formulated in the branch of philosophy that is moral philosophy or ‘applied ethics’. What is the significance of the distinction? Perhaps only the degree of systematic formulation of the idea of what is appropriate: formal ethics is concerned with the derivation of the claim to an action being ‘right’ much more than colloquial ethics; colloquial ethics has a more overtly subjective operation. In terms of authority to prescribe or proscribe the behaviour of a researcher (in the application or interpretation of broad rules), it would seem that Formal ethics’ systematic approach and appeal to a philosophical red-tread may have a greater authority than Colloquial ethics’ appeal to a perception of the popular culture. But, in the absence of a framework to adjudicate between competing understandings and interpretations of ethics,

it is difficult to resolve the dispute. This places a great emphasis on the constitutional authority of the REC/IRB, which in turn goes to the transparency of its operation.

Formal ethics has a greater systematisation of its basis - it is grounded in principles of philosophy - but does this help a REC/IRB? Again, the issue is about the competition between different types of ethics. The obvious distinction is between 'teleological or consequentialist' theories, and 'deontological or duty-based' theories. These form the basis of every basic ethics course, and most ethics review committee members will be able to articulate the distinction.

Teleological, or consequentialist, theories of ethics look only to the consequences of an action as the determinant of the correctness of an action. Perhaps the best known of these theories is the Utilitarianism of Jeremy Bentham and John Stuart Mill. Their work is captured in the idea that an action is correct if it produces the greatest utility for the greatest number (although there are different ways of expressing that central idea). There are many bioethicists who operate with this consequentialist perspective today, notably John Harris and Peter Singer. In a rights-based world, it is very difficult to accept the theory completely - that there are no 'trump' positions.⁴ One cannot say, for example, that to kill someone is wrong if that action brings the greatest utility; the 'greater good' really does allow for this most radical expression. This rather exposes the problem of Utilitarianism, one that is found in Mill: Utility is not obvious; happiness is somewhat subjective, or at least dependent on perspective. So reading Mill, it is clear that there are certain values in play that are brought to the balancing and that it is not a *de novo* calculus on every occasion. And that is perhaps in part because Bentham and Mill were seeking to answer a different question from 'what is right?' They asked, 'how should governments govern?' Their question is a question of political ethics, political theory, at its heart, that perhaps already acknowledges that government, and to a large extent 'ethics', is conducted in the environment of a competition for limited resources. 'How should a government make decisions over limited resources?' 'By seeking to maximise utility/ happiness.' This places the decision-making within its culture, but that does not detract, as Mill recognises, from the danger of the 'tyranny of the majority' - that the answer does not necessarily produce a completely right decision. 'Utility' and 'happiness' are not self-evident.

Deontological, or duty-based, theories seek to address this problem of subjectivity in ethics by making an appeal to external validity for the theory. Immanuel Kant is probably at the forefront of this, with other theorists such as Alan Gewirth. They ground ethics in reason. They seek to show that as humans are rational, that rationality, that reason, requires particular understandings of the relationship between

⁴ to use the term that Ronald Dworkin brings to his modification of Utilitarianism in his book *Taking Rights Seriously*.

rational actors upon which the rational being must act. Kant expresses this through the “Categorical Imperative”, and Gewirth through the “Principle of Generic Consistency”. Kant’s Categorical Imperative has a number of expressions in his work, but its central core is that a right action is one that can be universalised (i.e., there can be no special pleading, every rational being must be able to make the same claim), and that individuals must be “treated as ends in themselves, not merely as means to an end”. Thus, the rational being, on pain of self-contradiction, cannot instrumentalise others. Internally, this is again a matter of interpretation; it is not self-evident from the theory what a ‘right’ action or duty might be in any given situation. And there is considerable debate (and rejection) of the duty-imposing rationality of Kant’s philosophical under-pinnings.

Within deontological approaches, John Rawls and Norman Daniels have developed justice approaches. Rawls’ Justice Theory addresses some of the concerns levels at Kant, and gives the practical method of reaching ethical decision, the Veil of Ignorance. Rawls suggests that the ethical decision is the one that the reasonable person would have to concede, even against his or her own interests and desires, and that this would be achieved by placing the reasonable person outside society, behind a veil, not knowing the place that s/he will have in the society on returning after making the decision (the ‘veil of ignorance’). In that situation, the reasonable person, stripped of interests but having to entertain the possibility of being the least protected person in society, will act to protect the interest of that least protected person, and thereby produce the ‘just’ decision. How far, however, this produces an objective justice is questionable: the neoliberal reasonable person produces a very different ‘just’ decision from the socialist, and yet each will claim reasonableness, fairness and justice. And this is the heart of the problem: humans are not purely rational or reasonable, they are formed in society and that is a melting pot of culture, politics, religion, emotion and interest. Humans are not purely rational, but rather tend towards self-protection, and ethics seeks to require a curbing of that self-interest without either knock-down arguments (they hang on belief in the type of ethics that resonate with the individual’s interests) or sanction (the stick to ensure compliance).

The problem for RECs (and others trying to consider what constitutes a ‘correct’ action is that, the theories above can produce diametrically opposed answers to the question, ‘what is the right thing to do?’ A consequentialist could well conclude that the right answer is the opposite of the conclusion a deontologist would make, and yet both within their own terms claims that their outcome is ‘moral’ or ‘ethical’. And this is the problem, when a claim is made that some behaviour is ‘unethical’ or ‘immoral’, one must ask, according to what criteria - because there is a good chance that the behaviour to some will be arguable as correct. To avoid this seeming contradictions this causes in the heart of the ‘ethics’ of the Research Ethics Committee is difficult - it is almost as though the inclusion of ‘ethics’ in the review is a political rather than philosophical appeal (that the research will be validated within the acceptable norms of a particular community - a question of power).

Virtue ethics, and Discourse ethics may bring some assistance to this difficulty. Virtue ethics, with its origins in, for example, Socrates, Plato, and Aristotle, was popular in pre-enlightenment thinking, up to its adoption by Aquinas. It sought to answer the question of how one should live the ‘good life’ (εὐδαιμονία - eudaemonia). This is attractive as it is a more holistic approach to ethics - that whilst the individual must make episodic decisions, it acknowledges that the decision-making is not isolated, and one will make mistakes from which one must learn; critical self-reflection will gradually ensure one becomes virtuous, ‘flourishes’. However, the virtues themselves are contested. Over time, the values that constitute formal virtues have changed; the virtues are culturally specific. Virtue ethics lost its dominance with the enlightenment, but found a resurgence in the second half of the 20th century, notably through the work of Elisabeth Anscombe. Again, however, the virtues are contested.

It is then, perhaps, in the discourse ethics of Habermas that a (partial) solution might be found. Habermas addresses the imperfection of human reason by indicating that a constructively critical dialogue between stakeholders is essential to establish ethics, and that is discussed and changeable over time. This is not, perhaps, new. The ‘Politeness’ of Ashley Cooper, Third Earl of Shaftesbury in 1711 has a similar pre-enlightenment grounding in conversation as a social duty, whereby individuals can be ‘polished’ and polite society negotiated. Another iteration of this approach is ‘experimental ethics’ where participants are invited to develop their understanding of particular issues to develop their critical ethics response to an issue.⁵ However, how this is undertaken is a matter for practice (see particularly section 2.2).

How then should RECs relate to ethics?

This is a more interesting question than at first it appears, because the question ‘why should I follow ethics?’ is itself a difficult question. The compulsion to conform to ethics is not necessarily because of a knock-down appeal from a particular theory, or, indeed, from a fear of sanction (although there may be a contractual obligation to follow to particular codes of conduct, but even they are open to interpretation). Ethics might simply be an invitation to a systematic discourse about what could be considered as right or wrong, that finds its authority from the investment of the stakeholders in the process. At least, it would seem incumbent on RECs to consider the range of ethics questions, and to articulate the ‘ethics’ perspectives of the individuals and the committee itself; RECs, in order to claim

⁵ This differs from ‘empirical bioethics’, as merely taking public opinion unchallenged, does not recognise the social duty to interaction and reflection. Indeed, this could be one of the characteristics of ethics: ethics are positions that have to be devised, teased out, challenged - it is a work that the individual citizen has to undertake as part of the social contract, part of the contract to live in community. It is not enough to believe that ‘what i reckon’ is a sufficient basis upon which to claim an authoritative position to pre- or proscribe the actions of others.

authority in the community, might need to show critical self-reflection on the range of questions that attend ‘what is ethics?’

Questions for Discussions

How far should RECs and IRBs be concerned with Formal rather than Colloquial ethics?

How do I make ‘ethics’ decisions?

What is the basis of my ‘ethics’?

How do I adjudicate between ‘ethics’ positions?

How should this be drawn into the work of the REC/IRB?

How far should REC/IRB ethics be about observing practical protocols more than debating defensible ethics positions? (Is a REC in place to have debates about ethics, or to apply practical standards understood by different communities)?

How far should I expect researchers to conform to my idea of what is right?

What opportunities should I give to the researchers to explain their ethics perspective?

How do I approach interpretations of codes of conduct?

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2.1.2. Autonomy and Solidarity - the struggle of the public interest

Arguably, the dominant post-enlightenment value is ‘autonomy’, grounded in a particular construction of liberalism. However, a relatively short time before this, after World War II, solidarity and welfarism held the same dominant political and philosophical sway. Bioethics research (research in medicine, life sciences, and biotechnology) is an area where the movement between the two positions remains extremely difficult to negotiate. This is essentially because individuals wish to hold two, contradictory positions: many wish to hold the two positions - I want to be able to receive life-saving treatment for whatever disease or illness I might present to healthcare, but simultaneously I do not want to participate in the research that will ensure the therapies I crave.

Barbara Prainsack and Alena Buyx have done much to develop a new theory of solidarity, and this is gaining traction in bioethics discussions. However, the grip of autonomy is very strong. Thomas Beauchamp and James Childress famously developed a theory of bioethics focusing on “autonomy”, “non-maleficence”, “beneficence” and “justice”. Devised in the 1970s and 1980s, and responding to predominantly interventionist medical research, autonomy is rated highly - as it is in the Nuremberg Code, and in the Helsinki Declaration. Considered against the secondary processing of already gathered data for related research purposes, the dominance of solidarity might be challenged, but in the bioethics paradigm it is almost intractable. One wonders, however, how the collectivist, welfarist citizens of the late 1940s or early 1950s might have seen this modern dominant individualism, and the seeming contradiction of the expressed desires.

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1. When did liberalism lose its moorings in morality?

One approach to this conundrum and paradigm shift might be found in the definition of liberalism. If one looks back to the pre-enlightenment and early enlightenment expressions of liberalism of, for example, John Locke, Ashley Cooper, Third Earl of Shaftesbury, Adam Smith, Immanuel Kant, there is an undergirding commonality of solidarity. Locke’s theory of private property allows an individual to own property on the basis of his or her added value through labour, but only to the extent that there is sufficient resources left available for others. Shaftesbury’s ‘politeness’ is predicated on the interdependency of individuals and their duty to consider the needs of others in forging a polite society (one that could replace the social order removed by civil war and the overthrow of divine right monarchs). Smith, before writing *An Inquiry into the Nature and Causes of the Wealth of Nations* wrote *The Theory of Moral Sentiments* which focuses on the necessary shared moral platform created through empathy between individuals. Kant, in the Categorical imperative, whilst fully embracing the enlightenment primacy of the individual, identifies through reason the necessity to hold others as ends in themselves not merely as ends to one’s desires.

One can perhaps go further. Nikolai Kropotkin, the central figure of anarchism, writes his central work *Mutual Aid* around the imperative of empathy across species; to Kropotkin, anarchism is about individuals taking control of decision-making not only about their own lives, but about their life in community with others. Anarchism has duties to others, and a mutual responsibility of care. Even in his late work on ethics, Jean-Paul Sartre seems to move from the individual as the sole focus of existentialism, to the struggle for the individual to make sense of his or her life in relation to duties to others.

This balanced liberalism - this autonomy in balance with solidarity towards others - can be seen until the 1980s. The political shift to neoliberalism, found in the Monetarism of Margaret Thatcher in the UK and Ronald Reagan in the US, saw a social shift to a liberalism that rejects, rhetorically if not fully in all social policy, the welfarist solidarity of the post-war years. Solidarity is seen as nurturing dependence and a lack of the duty to provide for oneself. One wonders to what extent the excess of the market (culminating in the financial crisis of the early 2000s) was part of the Thatcherism or Reaganomics, but the policies of individualism facilitated a social shift that allowed individuals to reject notions of the collective. This, as in all society, is seen in bioethics. The question is how should RECs respond to this shift, and to the seeming contradictions in reasoning that it produces in relation to health research and healthcare. Is it the role of RECs simply to reflect the dominant culture of the day, or, as a matter of ethics, to challenge it? One of the key areas for this is the appeal to the ‘public interest’ as a justification for overruling the individual interests of an individual.

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2. *Considering the Public Interest*

The public interest is a useful legal tool. It enables judicial or bureaucratic discretion to resolve fact situations that were unforeseen at the time of the drafting of the particular rule. The problem is that because it has an element of pragmatism about it, its operation is not clearly defined. It often operates through a rather Utilitarian calculus of weighing the harm to the individual who will be deprived of a particular right ‘in the public interest’ with a notional sense that the public at large will benefit from the deprivation of that right and that is a desirable situation; the deprivation of rights of one individual or a few individuals is worth sacrificing in the interests of the many.

If one is a Utilitarian, this is perhaps acceptable, although the calculus is often, in the case law, applied in a rather vague way; it is almost as if the public benefit part is rather self-evident in the operation of a public interest argument (see for example, the appeal often made to ‘the public interest’ by newspapers or other news media in pursuing a story that intrudes on the privacy of an individual). In a rights based ethical environment this is much more problematic.

Townend has made a three-stage argument to attempt to operate an appeal to the public interest in a rights-based ethical environment.⁶

Stage One. This is essentially a refinement of the Utilitarian calculation. The problem of the Utilitarian calculation is that it poses one individual's loss against the potential gain of many; one individual could lose, for example, 100 units of happiness, whereas the 'public' made up of 101 individuals might only gain 1 unit of happiness each, but the effect is to tip the balance in favour of the mass. A more balanced approach would be first to weigh the potential loss of the individual against the potential loss to a notional individual member of the public: one balancing with one. If one took the foreseeably worst affected member of the public this might produce the fairest consideration of the public interest argument.

Stage Two. This moves the argument from Utilitarianism to a rights-based consideration. Taking Kant's Categorical Imperative, an individual must, in making choices, treat others as ends in themselves not merely as means to one's ends; one should not instrumentalise others. Having made the Stage One calculation, the individual is presented must respond to the question, will you insist on your rights? That rights-claiming is, of itself, an action that is subject to the Categorical Imperative. Confronted with the information that another individual will suffer more as a result of my defending my privacy than I would lose by not defending it, I would have to ask myself if I was merely using the other person as a means to my ends, rather than treating him or her as an end?

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Stage Three. Of course, Stage Two produces an individual's moral response to the dilemma of the appeal to the public interest. Stage Three attempts to universalise that response as a Law. Law making is itself a human action that is subject, in Kant, to the Categorical Imperative. When considering whether to make a Law, the Law-maker can only place a burden upon an individual that s/he would be bound to accept under the Categorical Imperative. Therefore, if the Law-maker sees the need to make a Law in a particular area, then s/he can only require of the individual that which morality would also require - as under Stage Two. And the appeal to the public interest is the example of such a requirement; the individual's rights must be challenged because of the supervening needs of another.

Mark Taylor takes a Rawlsian approach to the construction of the public interest. Rawls relies on the reasonableness of rational actors. Thus, the public interest is constructed by an appeal to what the

⁶ Townend, D. *The Politeness of Data Protection: Exploring a Legal Instrument to Regulate Medical Research Using Genetic Information and Biobanking*. Maastricht: Universitaire Pers Maastricht (2012) chapter 4, especially pp. 114–116.

reasonable person cannot disagree with, even when it is against his or her particular interest. The reasonable person, when confronted with a request in the public interest, might not like the request, as it may conflict with his or her personal desires, but he or she cannot deny that the request is reasonable and should be followed.

Questions for Discussions

How far is it the duty of the REC to consider the balance between autonomy and solidarity?

How far should the REC consider questions of collective needs when considering the application of, for example, the Helsinki Declaration?

Does the analysis of liberalism, and the necessity for a moral, solidarity to underpin claims to individualism, resonate, or is this a denial of a moral shift in economics and society?

Does your REC ever consider ‘appeals to the public interest’?

This might be overt or rather implied.

If so, how is the balance struck?

Do you make an express calculation, or is it a vague appeal?

Does the ‘rights based’ nature of some ethics present a problem for such an appeal?

If so, does Townend’s three-stage approach help?

Are alternative methods or ethical considerations available that produce a better outcome?

Further Reading

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2.1.3. The Gold Standard of Participant Protection - Anonymisation and Informed Consent

Introduction

(Research participant) autonomy is seen as a central premise of bioethics and of human dignity. One's right to choose to participate in medical research in an informed way, and to be protected from identification within research as far as is possible, is almost unquestioned. It is at the heart of the Belmont Report⁷ and the work of Beauchamp and Childress;⁸ it is one of immediate concerns for RECs in their assessments of research protocols.

Arguably, anonymisation and informed consent are seen as default safeguards of participant autonomy. However, neither anonymisation nor informed consent are without their conceptual and practical problems.

A. Anonymisation

There are a number of problems, at different conceptual levels.

1. Meaning

"Anonymisation" is used to mean different things in different jurisdictions and disciplines. In certain settings, it is taken to mean that the participant will no longer be identifiable in the research - i.e. in the raw data and in the processed data and products of the research, the participant will not be identifiable. In other settings, anonymous data might relate to a downstream use of the data - the data, in the hands of the individual in question (perhaps a second researcher using the data gathered by another) holds it without identifiers, but the participant could be re-identified by linking the data to the key held by another. To some, this would describe a form of "pseudonymisation" of data; data held in a form that prevents immediate identification of participants without access to a key held separately. These terms are to a very large extent context specific, and the context will define the meaning of the terms. However, this uncertainty of language itself produces confusion.

2. Availability

⁷ Belmont Report (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. [hhs.gov/ohrp/humansubjects/guidance/belmont.html](https://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) (Last visited 1st September 2014).

⁸ Beauchamp, T. and Childress, J. *Principles of Biomedical Ethics*. (7th edition). Oxford University Press, New York.

When data was processed without electronic means, or at least before the linking power of the internet, the concept of removing parts of the data such that the remaining data no longer identified an individual (or perhaps a group to whom the individual belonged) might have been more possible. Of course, it was never completely possible. Data that relate to an individual are dynamic composites of snips that link together in different ways making individuals more or less identifiable at any given time, depending on who is looking at the data. And equally, it is extremely rare that a single snip alone identifies a particular individual (perhaps in any meaningful sense); personal data are composite and context specific (as Taylor has shown).

First, even one's name, alone, means relatively nothing. The name "David Townend" printed on an otherwise blank piece of paper means nothing on its own. It only resonates and finds identifying meaning when it is linked to other information. Thus, if someone 'Googles' his or her own name, in the vast majority of cases, one finds a number of entries for that name. First, that person will know that (almost invariably) not all the references relate to him or her; most often, the name relates to a number of individuals. However, in that realisation, there is a second element: each reference gives a context within which the name becomes identifying. So, an individual labelled "David Townend" might be a Professor in Maastricht (and because of the long memory of the internet, a Senior Lecturer in Sheffield), a person giving a number of conference papers in relation to Law, a singer in a jazz band, or a bass soloist in a number of choral concerts. Only some people will know that these elements different contexts relate to a particular holder of the name "David Townend", and that they should be distinguished from a host of other "David Townend"s for whom there are results.

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The second major observation is that the same information has different value in different contexts. Add the name "David Townend" to a list of students and identify him as the tutor of the group, and the value is increased, but perhaps of little worth; add the tutorial times and the addresses of the people on the paper, and in the hands of a door-to-door sales person, it has a particular value (at those times, no-one is in) whereas in the hands of a house-breaker, the list has another value (at those times, no-one is in!). And arguably, there is no intrinsic value in any particular type of data (e.g. medical or genetic data); even 'sensitive personal data' has different values in different combinations and in different contexts.

This means that in some situations, we over-compensate for the presumed value of data; in other situations we might under-estimate the value of data.

In terms of the possibility of anonymisation of data, the composite, dynamic, context specific nature of data, and the vast amount of data available on-line and on demand, anonymisation is perhaps a promise that can no longer be made. It is based on an idea that data sets are fully independent - fully

free of external connections. If that were possible, a data-bubble might have sufficient 'snips' removed to render the remaining data without identifiers. However, such bubbles burst. Data sets are not held in perfect isolation of other data, and snips can be linked to identify individuals from other means.

3. *Desirability*

Anonymisation has been (some would argue still is) a great safeguard for identity. However, is it a great safeguard for dignity?

Imagine that one finds that one's tissue and medical data, given for research on the strict understanding that it would be anonymised, has been used for chemical weapons research. To many, such a finding would offend his or her dignity.

Likewise, imagine that one finds that the tumour that has just been found by one's doctors and is inoperable at its stage of growth was seen (as an incidental finding) in a scan that one had as part of a research project one year earlier in a much smaller and operable state. But for the safeguard of anonymity, the researchers would have sent such data to one's Personal physician. Again, a safeguard of one's dignity?

Of course, these two examples are not uncontested in themselves, but they are contested, and make the claim to the supervening value of anonymisation as a natural safeguard to (medical) research participants itself debatable.

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Questions for Discussions

How far does a lack of clarity in the meaning of "anonymisation" (and related concepts) cause difficulty, especially in multi-centre or multi-disciplinary research?

How far do we treat different types of data as necessarily requiring and deserving of higher safeguards, without seeing the context within which is processed?

On the other hand, how far is it possible to offer "anonymity" to research participants in the 'information age'?

What response can be offered if that is the case?

How far is "anonymity" desirable?

Does this answer differ at different stages of the research?

Is (the concept of) "confidentiality" a better safeguard for the participant than privacy?

i.e. a binding duty on those who receive the data not to identify the participant (similar to a duty owed, for example, by a medical doctor to his or her patient).

B. *Informed Consent*

Informed consent is difficult. It is at the heart of the modern consumer (transactional) society. Individuals have freedoms of choice, and are accountable for the actions; they have the duty to inform themselves to their own satisfaction before entering a transaction as there will be no appeal to 'I didn't know' in the 'caveat emptor' market. However, there are exceptions to this hard world. Sellers have legal duties, to greater or lesser degrees depending on the jurisdiction, to tell the truth or not to conceal or cloak relevant information. More than that, although increasingly lost as the commercial model roles out under the guise of individual freedom and self-determination, 'professionalism' demands a different relationship between people.

Caveat-emptor-contracting thrives where there is, or is presumed to be, 'equality of bargaining power'. Where there is inequality of bargaining power, some duty of protection is often required of the stronger party at Law - a 'fiduciary duty'. In situations where the bargain is forged with, or perhaps because of, an imbalance of power (for example, between doctor and patient, lawyer and client, banker and client, teacher and pupil, guardian and minor or incompetent adult), the stronger party is (most often) required to act in (or to protect) the interests of the weaker party.

Research with human participants arguably (strongly arguably) falls into this fiduciary duty. Researchers have in the vast majority of cases much greater knowledge of the area, its risks and potential benefits, than the participants in their research. That imbalance, that vulnerability, must be protected. And one major element of this safeguard is to require the researchers to inform the participants about what they are proposing to do and what they expect the outcomes to be - arguably, to give some background about the choices they have made in developing the methodology. They must inform the potential participants to redress the knowledge imbalance and to equip the potential participant to make a real choice about whether or not to participate.

Does this mean "full information". This is difficult. One must redress the knowledge imbalance, but there are arguably some caveats. First, by definition, in research there can be no "full knowledge"; research is testing a hypothesis about what *might be* the case. Therefore, there is a gap in the knowledge that is available that is shared by the researcher and the potential participants. So the informed consent is already not about full information. Second, there are limits on how much information is relevant. As in clinical medicine, choices have to be made in informing potential

participants about which information is relevant. Remoteness of risk and proportionality must be in play, with a strong measure of 'reasonableness' to stop the drive to information becoming a requirement to inter-connect all knowledge to the particular research. Again, the standard is not binary - information / not information - it is a spectrum.

This second problem can be seen in the area of biobanking. Biobanks operate on the basis of developing a repository of information for the purpose of 'research' (perhaps with some limits, for example, relating to disease type and the like). Access to the data set to create cohorts for particular research projects then, depending on the model, is made on the basis of the initial, broad consent of the participants to participate in the Biobank for research purposes. This causes problems to some people: informed consent requires detailed information about every research project and broad consent, by definition cannot be informed consent; to others, without broad consent biobanks become impossible to operate. Now, of course, the second argument - the practical argument - whilst important, is not of the same nature as the first. However, 'broad consent' and 'informed consent' are not *opposite* arguments, as the first argument implies.

When one takes the words, the opposite of 'informed' is not broad but 'uninformed'; the opposite of 'broad' is 'narrow' or 'specific'. Whilst it is conceptually difficult to imagine how one could give 'uninformed consent' as the concept of 'consent' itself seems to require a degree of information - at least to know that consent is required in a particular situation -, it is, arguably, possible to give 'informed broad consent' as well as 'informed narrow consent'. This is because, as we have already admitted, information in consent is not a binary informed / uninformed, but rather a question of being *sufficiently* informed to make a fair and binding decision. The question then is, 'who judges sufficiency?'

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Presently, the sufficiency of information is governed in the most part by the REC. Researchers produce information sheets and these are scrutinised and accepted by RECs as part of their validation of research. Whereas participants have the opportunity to ask questions of the researcher, and, arguably, to shape the interaction about becoming informed to make the decision to participate, in practice one wonders how far this is a real or free dialogue. Is this problematic? Yes, if it does not fit the needs of the participants.

The information sheets reflect the perceptions of those who write them (and RECs are co-authors of the sheets given their role). However, when one looks at studies of expressed sensitivities of citizens, some people will share those perceptions and concerns, whereas others will not, judging less information to be 'sufficient', and others again will require more or different information. One size

does not fit all. And some will make a judgement that informed broad consent is sufficient, others will require informed specific consent.

Why is this a problem? Because increasingly, the size that is adopted does not allow for individual participants to make their choice, and that super-sizing of informed narrow consent makes many new research methodologies impossible when they would be acceptable to some participants - which is, perhaps, ironic, when the purpose of informed consent is to protect participant self-determination.

How might this be solved?

Dynamic consent. Many have written on dynamic consent, and some projects are developing models of dynamic, participant-centred consent. The idea is to develop consent interactions between (potential) participants and researchers that allow the participant to determine the level (and, perhaps, nature) of his or her participation. Such mechanisms could be on-going, perhaps making use of secure internet portals such that individual participants could develop increasingly sophisticated consent profiles as their understanding and relationship with the research (or, for example, Biobank) develops. Likewise, the portal could be used by the researchers or Biobank as an educational or information tool to share findings and discuss methods, even difficulties, with the public.

Questions for Discussions

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How far does this analysis of informed consent as problematic ring true?

Is 'informed narrow/specific consent *necessarily* required to meet the safeguard of informed consent, or can broad consent be sufficient?

Is participant-determination of sufficiency of information acceptable?

How far is dynamic consent a desirable and practical development in informed consent?

Are data science - online - portals the only realistic mechanism for delivering truly dynamic consent?

Further Reading

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2.2. Procedural Issues

2.2.1. *Representing Local Sensitivities in RECs*

As indicated a 2.2.1, above, there is quite an argument for harmonisation of ethics review in the increasingly international arena of medical research. A major objection to this is that the review must reflect local concerns - i.e. local sensitivities and local (cultural) differences. However, this claim must be defended. Very often it seems that the only qualification of a connection to 'local sensitivities' that a REC can make is that the members are themselves from the local community. That said, as professionals, often from a rather uniform strata within the local society, their exposure cannot be said to be representative, and without systematic connection to the whole society can few committees fulfil their stated mission to represent local sensitivities?

1. Is 'local' review required?

The most international requirement for ethics review of research protocols (with human participants) is the Helsinki Declaration. In its current iteration, there is no requirement that the review be 'local'. Article 23 of the 2013 revision states:

"The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

"The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions."

Indeed, whereas the detail of this provision has grown over the various revisions of the Declaration from its first version in 1964 (and its predecessor in the Nuremberg Code, 1949), the references to the ethics review have not specified a 'local' review. The review must be independent of the researchers

(which a local review might not provide), and a knowledge of the laws in the particular jurisdiction is required. In the light of this, how should the appeal to a local review be considered?⁹

2. *Is there any evidence of local sensitivity?*

When one looks at the relevant Eurobarometers, it can be seen that there are different opinions expressed within the public about a range of issues related to biotechnology. Perhaps it is because of the nature of the Eurobarometers - i.e. they are quantitative assessments of opinion, based on ranking given ranges of answers for set questions; they are not open-textured questions - they tend to show that in all countries the range of sensitivities is expressed, but to greater or lesser extents. However, as the range is expressed in particular areas, and a REC must accommodate the range of sensitivities, not simply the dominant sensitivity, when looking at the range of potential participants, the particular weight of one sensitivity as against another could be questioned. However, there are differences, so perhaps there is space to accommodate those differences. How then could a local committee act to accommodate those local sensitivities?

3. *Should RECs have lay members?*

This is a difficult question, because it is not obvious what a ‘lay member’ is. At one level, it could be a person who is not skilled in medical research and not a professional engaged in a discipline that would be seen as an expert contributor to a discussion of the applied ethics. Thus, a school teacher specialising in music, for a clinical trial that does not relate to a music therapy, assuming no special disciplinary knowledge, although a professional person, would be a lay person in relation to the research in question. S/he would not bring disciplinary expertise to the decision-making. However, after reading a number of protocols, it could be argued that such a person would begin to develop an understanding perhaps not of the science (because the number of similar protocols brought before the committee might not give that learning opportunity), but certainly an expertise in the ethics, and the approach of ethicists and lawyers. At that point, the ‘lay’ nature of the involvement might be challenged; the lay person, with exposure to the process of the committee’s work becomes expert in the language and process of the committee. So, to avoid this, perhaps, the lay person needs to be drawn from the local community for a short exposure to the committee only, perhaps from a random selection from the electoral roll. However, this raises another difficult question: is there a level of basic ‘committee literacy’ that is required to be able to give the application a fair reading, and to support the lay person; is there a basic education and experience requirement needed to enable an effective (rather than token) participation? If this is the case, is the representative a truly ‘lay’ person?

⁹ It should be noted that the local review is not required in all jurisdictions. In the UK, for example, multi-centre research is reviewed by specialised multi-centre committees.

A second consideration is, what is the function of the lay person's participation. The lay person is on the committee to bring a non-expert voice to the discussion, but does that person have to be able to represent the range of opinions expressed in the society? Is the person at the table to bring their own views (which could be in tune with a tiny number of members of the community), or to represent all the voices and opinions in that community? If it is the former, and indeed, to some extent the latter, how is that person chosen to represent the community? What is the legitimacy of the appointment to the committee? In a democracy, should this person be elected to the office? If not, should the person be chosen through a job advert and interview, and if so, what qualities should an appointment panel look for in the person?

4. How can RECs connect to local sensitivities?

It is questionable that even one local 'lay' person will connect a REC to the sensitivities of the local communities. It might, if the person is from a different part of society from the members of the committee, extend the representation by that one step. Arguably, unless membership of the committee is extended to include many more lay representatives, systematically drawn from across the society so as to represent the range of sensitivities expressed locally, membership of the committee is not the vehicle to ensure the representation of local sensitivities. There are, however, other ways.

Drawing on qualitative research methodologies, the views of the communities that the REC serves can be gathered and used to inform the REC members and their decisions. For example, RECs could develop 'citizen juries' or 'focus groups' whereby individuals from the local community, drawn from different districts, could be invited to discuss issues raised by cases in the previous year or six months, or particularly difficult issues faced by the REC (not, perhaps, actual cases, but themes and issues drawn from cases). This would not be to second-guess the committee decisions; this would be a way to connect the committee to its community.

Practical experiments like this would be particularly useful at two levels. First, it would give substance to the claim that a REC was connected to its community, that it responded to local sensitivities. However, second, the systematic recording of local sensitivities would provide body of qualitative evidence as to the extent that there is significant local variation between communities to justify the extra resources required, in multi-centre research review, to run numerous full reviews of the same protocols, with little or no communication between RECs to produce workable solutions for researchers.

Questions for Discussions

How far is the claim that RECs use ‘local sensitivity’ as a justification for not seeking a harmonised system for multi-centre reviews sustainable?

When my REC looks at a multi-centre protocol do I contact the other RECs involved?

Why don’t I do that?

How does my committee connect with ‘local sensitivity’?

Do we have ‘lay’ members?

Are there better ways of finding out what local people think about the issues we face than those we currently use?

Would qualitative methodologies be appropriate?

Further Reading

Medicine and Law (2017) 36:1 Theme Issue on Ethics Review Equivalence.

Edward S. Dove, David Townend , Eric M. Meslin, Martin Bobrow, Katherine Littler, Dianne Nicol, Jantina de Vries, Anne Junker, Chiara Garattini, Jasper Bovenberg, Mahsa Shabani, Emmanuelle Lévesque, Bartha M. Knoppers (2016) “Ethics Review for International Data-Intensive Research” *Science* 25-03-2016 Vol. 351 Issue 6280 Pages 1399–1400

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2.3. Practical Issues

2.3.1. *Capacity and Vulnerability in research*

At the heart of autonomy is the right to choose. This is part of one's decisional privacy - the right to make decisions about oneself. It is not, as a privacy right in line with Article 8 of the European Convention on Human Rights, an absolute right - it is a right tempered by the legitimate needs of the State to act (perhaps in rare occasions only) for the supervening rights of others. Autonomy is tempered by the public interest, and at the outset this is worth remembering. However, informed consent is a presumed starting point in safeguarding the interests of participants in research. This requires competence on the part of the participant.

Competence is, to a very large extent, the province of the individual sovereign state. There is a presumption that on attaining majority, the individual will not only have a right to decide for herself, but will have a duty to do so. There is a presumption in majority of capacity. The duty of the REC is twofold: to ensure that the researcher has a willingness and ability to provide intelligible and sufficient information to the participant to meet the participant's curiosity in respect of that participation; and, to ensure that the vulnerable - those who do not have the competence to decide for themselves - are identified and protected.

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Again, in respect of the vulnerable, the definitions of vulnerability are largely determined by the sovereign state. Therefore, majority is set as an age by the State, although some States recognise the growing capacity of individual minors before that formal age of majority, and allow them to participate in decision-making about particular issues where they show competence. Indeed, some jurisdictions make a presumption that from a particular age the minor has a degree of decision-making competence. This is a matter for familiarisation with individual jurisdictions. Likewise, jurisdictions will have specific rules about when a person of the age of majority will either lose that capacity or will not have attained that capacity. There is such difference here, it is not appropriate to comment in a general manual. However, there is one observation that is crucial.

How far should RECs be mindful that the participant in research may be placed into a form of vulnerability by a lack of understanding of the particular scientific context of that research. This might make particular inducements to participate improper, it could create a problem of therapeutic misconception. However, this must be balanced by a duty to respect the autonomy of the individual participant; one must avoid paternalism. However, this does not mean that researchers, like any other

professionals, do not owe duties of care - potentially fiduciary duties - to place the welfare of the participants before their own interests. This is arguably the tone of the Helsinki Declaration.

Questions for Discussions

How can a REC strike an appropriate balance between respecting the autonomy of the individual participant, and ensuring an appropriate duty of care (perhaps a fiduciary duty) towards that participant?

How can the special responsibilities towards vulnerable groups be ensured?

Do, for example, the different specific legal rules for protection vulnerable participants, provide sufficient protection?

Is the duty to ensure that there is sufficient information available, to be sent to every participant in, for example, an information sheet or pack, or is it more important to ensure that the researcher is willing and able to engage with individual participants about his or her concerns?

2.3.2. Participant Benefit, Paternalism, and Therapeutic Misconception

Introduction

In the course of the decades following the introduction of the Belmont Report, the distinction between clinical research and treatment has profoundly influenced theoretical developments in the field of research ethics as well as related policy work. At the same time this distinction, despite its importance for the identification of activities subject to ethical review, has ignited a prolonged controversy in academic and policy circles about how different research and treatment essentially are. The notion of the therapeutic misconception (TM) referring to the possibility of mistaking research for therapy is conceptually rooted in this distinction. TM has similarly attracted disagreements over its precise contours and normative importance.

In the context of recent global expansion of clinical research the difference between clinical research and treatment as well as the meaning and applicability of the TM concept become ever more complex and uncertain. In the sections that follow we summarize the relevant developments in the field of research ethics and consider how the globalization of clinical research poses challenges for the design and application of ethical frameworks. We conclude by cautioning against the direct export of ideas about what research and treatment mean to the culturally diverse locations where clinical research is now being conducted; we then suggest steps to move discussion of the research/treatment boundary forward. We do not intend to offer any ready-made solutions; rather we hope to make a contribution by setting an agenda for future conceptual and practical work on the topic.

Ethical Issues at the Interface with Treatment

The Distinction between Research and Treatment

The importance of distinguishing between research and treatment has long been a fundamental precept of research ethics.^[1,2] Introduced in the Belmont Report (1978),^[3] by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research this distinction has had a significant impact on contemporary research ethics and the regulations governing research with human subjects. Many bioethicists have warned against the dangers of conflating research with treatment, stressing that while patients receive individualized treatments intended for their medical benefit, clinical research participants are exposed to uncertain risks for the purpose of creating generalizable scientific knowledge for future generations of patients. On the extreme end, some commentators have insisted that research and treatment are such fundamentally different activities that they should be governed by a different set of ethical rules.^[4]

A common concern is that conflating research with treatment threatens the validity of informed consent, considered the cornerstone of ethical research conduct. In order to be able to make a meaningful decision to enroll in a clinical trial, research participants must appreciate the risks posed by experimental drugs, devices, and treatment regimens,^[5,6] and understand how research practices can interfere with their medical care to be able to make a meaningful decision to enroll in a clinical trial. Individuals who do not understand the difference between research and treatment, thinking that their enrollment in a clinical trial will provide individualized therapy, are assumed to be laboring under the therapeutic misconception.

Evolution of Therapeutic Misconception

While this appears to be rather straightforward, the concept of therapeutic misconception remains unsettled, which demonstrates the continuous unrest about the foundational ethical issue of the boundary between research and treatment. Appelbaum et al. first coined the term therapeutic misconception in 1982. Introducing the concept to the wider bioethical community, he wrote, “To maintain a therapeutic misconception is to deny the possibility that there may be major disadvantages to participating in clinical research that stem from the nature of the research process itself”.^[7] Originally the concept of therapeutic misconception was narrow and specific, and referred to the failure to understand the restrictions placed upon medical treatment by the research protocol.^[8] It occurs, for example, when a research participant is unaware of random assignment to a control group, thinking that she was assigned a medication best suited for her medical condition.

Since the appearance of that article, the meaning and influence of the TM has expanded. As Kimmelman^[2] perceptively points out, in literature the concept of the therapeutic misconception has broadened from confusion about procedures within a particular protocol to a presumed confusion about clinical research in general. For example, a workshop devoted to the TM and the controversies surrounding the concept, held at the University of North Carolina at Chapel Hill in 2005, defined the therapeutic misconception as existing when ‘individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge’ [⁹, p.17³⁶]. In some interpretations the therapeutic misconception came to include almost any kind of benefit expectation. Further variations on the theme include: therapeutic misestimation (underestimating the risk, overestimating of the benefit or both) and therapeutic optimism (hope for the best personal outcome).^[10] More recently, a sub-category of therapeutic optimism, “unrealistic optimism,” was proposed.^[11, 12]

Proliferation of TM-related concepts and the expansion of the meaning of the TM itself have allowed to attach the label of “misconceived” to almost any perspective on, and expectation from, clinical research departing from conventional Belmont Report-based definition. At the same time in the midst of the discussions about the boundary between research and treatment some have suggested that clinical research and practice are not sharply distinct but rather intimately intertwined, inviting more controversy around the notion of TM.^[13] Thus, the contours of therapeutic misconception as well as ethical importance of various interpretations of it continue to be debated.

Globalisation of Clinical Research and Corresponding

Travels of Clinical Experiments and Research Ethics

The globalization of clinical research involving the shift of clinical trials from North America and Europe to lower-income settings is ongoing. This expansion of clinical research has been accompanied by a parallel move of frameworks for ethical research conduct, consisting of regulatory guidelines, practices and ideas (14,15). However, there is no certainty about how these frameworks operate in settings that are culturally and economically different from those of Europe and North America.

Qualitative studies have exposed the novel tensions that occur when clinical trials are carried out in these diverse contexts.^[16-20] Empirical work in the field suggests that when ethical frameworks accompanying clinical trials arrive in different localities, they are construed and reinterpreted in light of existing social, cultural and political circumstances. In this way, transferred systems of human subject protection are operationalized and localized through becoming embedded in existing knowledge and practices. It is becoming clear that one of the greatest challenges in research ethics in

its quest to conduct research ethically everywhere around the globe is to ensure that its provisions are adequate and meaningful in the multiple and diverse settings where clinical trials are being carried out.

Therapeutic Misconception in Diverse Settings

The concept of therapeutic misconception originated in the West, has been developed and debated mainly by academics from economically rich countries of the West and, as with other ethical concepts associated with clinical trials, is being transferred to different non-Western contexts. Bioethicists worry that in lower- income settings individuals with low education levels, with limited or no access to adequate medical services, and who are unacquainted with clinical research may be particularly vulnerable to TM. At the same time, empirical studies on the topic, most of which were conducted in the USA and Europe, suggest that the boundary between clinical care and research is often ambiguous in practice settings even in these high income locations.^[21] These empirical findings indicate that the relationship between research and treatment is not fixed, but constructed and potentially contested by individuals involved in medical experimentation.^[22] Existing evidence invites a more nuanced approach to the research/treatment interface that allows for a multiplicity of perspectives to be considered.

In developing world settings it is especially difficult to determine if individuals exhibit the therapeutic misconception. Cultural contexts and social conditions may affect individuals' perspectives, including the way they conceptualize research and treatment, and we have scant evidence about how this occurs. Our own research showed the presence of features related to the interface between research and treatment in South African and Ghanaian landscapes that cannot be fully accounted for by the concepts in the field of research ethics discussed above in this article. At least some individuals in South Africa and Ghana conceptualize clinical research as an activity to find ways to improve local health. They expect that the results of clinical trials will be translated into advances in healthcare available in their communities and consent to participate in research with this expectation.^[23,24] However, in general, we lack conclusive data on how research and treatment are understood in diverse non-western settings and the implications of these for defining concepts in research ethics.

Against this background we must be cautious in using the contested concept of therapeutic misconception. While it is undoubtedly important to dispel extreme misunderstandings, for example the unawareness of placebo use in a placebo-controlled trial, outright application of the therapeutic misconception label runs the risk of rejecting legitimate, alternative perspectives on what research and treatment means as being misconceived.

Conclusion

The key ethical issue of the boundary between research and treatment and the related concept of the therapeutic misconception continue to heated debates. Globalization of clinical research and the need to ensure ethical research conduct in all diverse settings where experimentation is being transported intensify the need to move this discussion forward. In doing so one important step is systematic investigation of how the notions of research and treatment are received, interpreted and acted upon in diverse locations where clinical research is now being conducted and comprehensive analysis of the implications these hold for defining the concept of therapeutic misconception.

However, for this suggested step to be productive, a conceptual leap is required in attitudes and approaches to managing divergent perspectives on concepts in research ethics. Meanings of 'research'

and ‘treatment’ are culturally situated and it is important to prevent antagonizing alternative views. While we do not doubt the necessity of ensuring an understanding of procedures involved in clinical research, we argue that there is a need for respectful engagement and dialogue with various perspectives on the meaning of research and treatment. This approach allows for different views to feed back on frameworks for ethical research conduct, ensuring their applicability and acceptability in various settings. This is necessary not just to ensure the ethical treatment of research participants, but also to support continuous operation of international clinical research: for establishing community relations and legitimacy of research in various settings.

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Questions for Discussion

Is the concept of therapeutic misconception (TM) indicative of a failure of adequate information in consent processes?

Does TM show a paternalism towards participants?

Is it an appropriate response to individuals' hope that research will lead to benefit, even when there is clearly no benefit (and this is expressed to participants)?

What are legitimate questions for participants to take into account when considering the risks and benefits that they are willing to accept in choosing whether or not to participate in research?

How far can these be judged by people other than the participant?

How can the participant be given a voice in choosing how to participate?

2.3.3. *RECs and the Human Rights Agenda*

Under the Human Rights instruments, rights relevant to REC work include:

- ☐ The right against torture
- ☐ The right to privacy / private and family life
- ☐ The right to freedom of expression
- ☐ The right to participate in the scientific and cultural advances of one's society
- ☐ The right to own property (including intellectual property)
- ☐ The right to the highest attainable standard of healthcare (1966 Covenant)

At this point, there is no need to discuss each of these in great detail. The right not to be tortured is one that RECs, by discussing the pain and harm to research participants that is likely in a protocol, are mindful of this right; privacy is worked out through, for example, data protection (although the extent of privacy is discussed elsewhere in these pages); freedom of expression operates to some extent to protect the researcher's right to independence (of thought) in framing and executing research questions.

There are overarching principles to see in these rights. First, they are a product of their framers. They are the expression of what it is to be 'human' from a western, democratic perspective, largely grounded in the aftermath of WWII. The agenda is one that is an expression of late-Enlightenment thinking, strongly flavoured with belief in market economics (perhaps at that time, in a Keynesian form, but certainly accommodating of Neo-Liberal economics that followed in the late 1970s and early 1980s in, for example, US and UK).

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Questions for Discussions

What is the definition of 'dignity' that underpins the agenda, and how can it be worked out in practice?

Are there particular requirements that go with the agenda, or is the definition a little like an ethics debate (i.e. dependent upon the interpretation and belief of the particular interpreter)?

How can the right to participation in culture and scientific advance and the right to healthcare, etc., be reconciled with the right to private property (including intellectual property)?

What is the relationship between human rights and duties?

Who owes the duties that flow from the statement of human rights?

The starting point is signatory States, then citizens calling signatory States to account, and then citizens calling each other to account. If there are rights to, for example, healthcare, who owes that duty? Is it just the State, or can citizens call directly upon each other for that duty, and what might that require?¹⁰

What is the role of the REC in ensuring human rights?

What does this mean in practice – particularly in looking at issues of resource allocation that follow from the research sanctioned by RECs?

Is the proposed and foreseen future use/exploitation part of the ethical assessment?

To answer these questions, the following opinions might be a useful starting point.

1. The jurisprudential significance of the Human Rights agenda

The Nuremberg Trials in the aftermath of the Second World War posed a difficult question to law and legal authority. Atrocities were committed, and the evidence of mass murder and torture (not least under a claim of medical research) showed moral offences of the worst kinds undertaken systematically and as part of the Nazi philosophy and regime. And that was part of the Law's problem. The regime, with its attention to detail, not only recorded its actions in detail, but it ensured that constitutionally and legally, the actions were part of the law of the regime. The individuals charged and appearing before the courts at Nuremberg could advance a defence that what was done was legal - that it was within the law as it applied at that time.

To Legal Positivists, this posed a very significant problem. How could an individual be held accountable in a court of law for actions that were legal? One response was, of course, to ask whether the actions were within the letter of the law - and many of the atrocities were outside the ambit of the law. But others were within the scope of the law. Legal Positivists separate the moral and the legal - a law is valid if it is created in the appropriate way in a particular State (follows the constitutional procedure for making law in the particular jurisdiction), without any further evaluation about the normative substance of the law in asking if the law is valid. For the Legal Positivist, to dismiss the defence that the act was sanctioned by law because the action was immoral was not an available

¹⁰ See on this idea of duty relationships, Ignatieff, M. *The Needs of Strangers*. (1984) Chatto and Windus Ltd, London.

response - that would be a response for a Natural Law Theorist (who would see both the constitutional procedure and substantive morality as necessary conditions for the creation of a valid law).

Part of the international response to the problem was found in the Universal Declaration of Human Rights. The Declaration produced a set of rights that all individuals could claim as the basis of their citizenship. The authority - the element that made them binding on States - was that each State that signed the Declaration accepted that they should be bound in them in their domestic law. So, from that point on, there could no longer be a defence that the immoral act was legal, as States and individuals were to be held to a higher set of constitutional, legal principles that override particular laws that can be argued to be out of line with the basic principle.

Human Rights are therefore not moral rights, and they do not require law to be moral. They are a set of specific legal rights that operate within the legal realm. This, of course, poses a question that has two aspects: how strong are these rights (for individual people)? With the two elements of: how are the rights enforced and how are the rights interpreted?

2. Criticisms of the Human Rights agenda

Human Rights can, perhaps, be described as the last ‘grand narrative’. They are the dominant dialogue within which both international and domestic law is maintained - they are the dominant paradigm of late twentieth and early twenty-first century jurisprudence. However, they are not without criticism. The Universal Declaration has no teeth. Unlike, for example, the European Convention on Human Rights or individual State constitutions, the Universal Declaration is not enforceable, of itself, in a court. It is enforced within the crucible of international politics, particularly in the United Nations. However, that enforcement is limited as is seen regularly. To the REC, that is to a very large extent irrelevant - the REC (in Europe) should seek to abide by the Declaration (and Convention and Charter) as not only a matter of law, but also of ethics and morality. But it does have a relevance in the broader effectiveness of the concept and enterprise.

There are, however, other criticisms that can be made about Human Rights, issues about their scope and operation. Professor Baroness O’Neill in her 2002 BBC Reith Lectures “A Question of Trust” speaks about the Human Rights agenda.¹¹ She asks if the rights included are the appropriate ones for the Declaration; whether they reflect the particular concerns of the moment when they were negotiated. Whilst there are additions to the agenda - notably in the 1966 Covenant on social rights -

¹¹ O’Neill, O. *A Question of Trust: The BBC Reith Lectures 2002* (2002) Cambridge University Press, Cambridge.

not all States have accepted the broader range of rights. She poses a second criticism: why is the agenda framed as 'human rights' rather than the more practically important 'human duties'? This is a particularly sharp criticism of the narrative. Rights imply duties, but without detailed clarification of the duties of delivery and protection. When this is linked to the criticism that the agenda is a matter for political negotiation at the international level, the criticism is well made.

A final criticism relates to this. It is worth asking how the rights are interpreted where they are enforced. The jurisprudence of the European Court of Human Rights, not least with its acceptance of the margin of appreciation (the lee-way that individual States can have in applying their own cultural interpretation of the rights), could be said to leave a little to be desired in the protection of fundamental rights and freedoms. It is open to debate, but a strong argument can be made that the human rights agenda is undermined by the failure to accept 'economic discrimination' as relevant to the interpretation of the rights. When one considers, for example, the right to healthcare or housing, the general interpretation means that where an individual is excluded from healthcare or housing by virtue of gender, sex, race, and even to some extent age, then these are accepted to be breaches of human rights. Where one is excluded from participation in the healthcare or housing market by virtue of the fact that one cannot afford - economic discrimination - this is not seen as a breach of the human right. In terms of global poverty, this is, to many, disappointing and indicative that the human rights agenda is part of a broader economic agenda.

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Further Reading

Universal Declaration of Human Rights

European Convention on Human Rights

African Charter on Human and People's Rights

International Covenant on Economic, Social and Cultural Rights

European Convention on Human Rights

EU Charter of Fundamental Rights and Freedoms

Universal Declaration on Bioethics and Human Rights

Universal Declaration on Human Genome and Human Rights

International Declaration on Human Genetic Data

Oviedo Convention - Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

Risse, T., Ropp, S. C., Sikkink, K. (eds.) *The Power of Human Rights: International Norms and Domestic Change* (1999) Cambridge University Press, Cambridge.

Joseph, S., McBeth, A. *Research handbook on International Human Rights Law* (2010) Edward Elgar Publishing Ltd, Cheltenham.

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Ignatieff, M. *The Needs of Strangers*. (1984) Chatto and Windus Ltd, London.

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2.3.4. Privacy

The right to privacy or to a private life is enshrined in the human rights canon, and is a fundamental principle of autonomy in bioethics. Its definition, however, is not immediately clear. This is in part because the right itself is not an absolute right; privacy is a right held in balance with the interests of the public. Article 8 of the European Convention on Human Rights, for example, sets up in Article 8(1), the right to private and family life, but in Article 8(2) creates the right of the State to derogate from that right in what might be described as a narrow public interest.

At Law, the starting point of privacy is, arguably, Warren and Brandeis and “The Right to Privacy”.¹² They frame privacy as the ‘right to be left alone’ - a starting premise that the individual is sovereign in his or her own life, and that the State and others have to justify any claim upon him or her. And this, perhaps culturally of its time and place, is the typical statement of privacy as an outward looking boundary.

When one looks at the literature from other disciplines, it is clear that there are a variety of different interpretations of what constitutes ‘privacy’. DeCew gives a comprehensive account of the different approaches to privacy, capturing this disciplinary diversity.¹³ For bioethics, Allen has produced a valuable typology of privacy.¹⁴ She identifies four different aspects of privacy:

- “Informational Privacy” - medical information is central to much of the research that is seen by RECs, and is regulated largely under data protection legislation. However, how far de-identification of data protects one’s dignity sufficiently leaves a question of privacy for RECs beyond data protection.
- “Decisional Privacy” - concerns the question of who makes decisions concerning the individual; who determines an individual’s choices and the scope of those choices. This links back to the question of autonomy raised, for example, in the discourse model (discussed above).
- “Physical Privacy” - again, common in REC consideration, but probably not considered as a ‘privacy’ issue, interference with one’s person, or personal ‘space’ requires REC consideration.
- “Proprietary Privacy” - we have things that have different sorts of value to us individually, things that can be replaced easily, other things that have only sentimental value. These things go towards constituting individuals’ privacy.

¹² Warren, S. D. and Brandeis, L. D. (1890) “The Right to Privacy.” *Harvard Law Review* 4: 193–220.

¹³ DeCew, J. (2008) “Privacy.” *The Stanford Encyclopedia of Philosophy*. Edited: Zalta, E. N.
<http://plato.stanford.edu/archives/fall2008/entries/privacy/> (last visited 1st September 2014)

¹⁴ Allen, A. L. (1997) ‘Genetic Privacy: Emerging Concepts and Values.’ In: Rothstein, M. A. (ed.) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* Yale: Yale University Press, pp. 31–60.

These elements of privacy are usefully identified and discussed by Allen. However, the question remains, how far does this get to the heart of the function of privacy?

When one considers a classic 'privacy' issue, for example the use of one's genetic information in biobanks and research using genetic information, a number of studies of citizens' sensitivities have been conducted, for example, the three Eurobarometer studies relating to biotechnology. The studies show a range of sensitivities, for example, in relation to the need for informed consent, the need to be re-contacted for subsequent research, the availability of the data for commercial companies or uses. Each shows that some will be in favour, others against each proposition. Townend has argued that this indicates that privacy has a subjective rather than objective quality. Whilst there might be a desire to create a normative standard through a statement of the right to privacy, in practice, privacy has a more 'barometer' like quality, measuring the relationship or disquiet that the individual feels in relation to his or her society - a measure of social contentment. This becomes very important in considering the adequacy of privacy protection in a medical research protocol, as there the crucial question is not whether the privacy safeguards fit an objective standard, but whether they are sufficient for the individual participants who are involved.

The question of whether the privacy is successfully argued should be approached not from the perspective of the limit of the individual's reasonable claim to privacy, as this will not produce a convincing argument to many. Rather, Townend argues, a better starting point is to argue the opposite - why, in the public interest, a request (or in some circumstances, perhaps even a demand) can be made upon the individual to participate. This, at least, has the possibility of making an appeal through a more objective claim: whilst I appreciate that you feel that you have a privacy claim in this situation, consider this broader public interest appeal to your participation

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Questions for Discussions

How far do you, in your REC, discuss the meanings of 'privacy'?

Do you feel that there are definable, objective privacy norms?

If there are, how are these created?

How far is it important to take individual participants' sensitivities into account when considering privacy issues in medical research?

Further Reading:

Warren, S. D. and Brandeis, L. D. "The Right to Privacy." *Harvard Law Review* 4: 193–220 (1890).

DeCew, J. "Privacy." *The Stanford Encyclopedia of Philosophy*. Edited: Zalta, E. N. (2008)
<http://plato.stanford.edu/archives/fall2008/entries/privacy/> (last visited 1st September 2014)

Allen, A. L. 'Genetic Privacy: Emerging Concepts and Values.' In: Rothstein, M. A. (ed.) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* Yale: Yale University Press, pp. 31–60 (1997).

Townend, D. *The Politeness of Data Protection: Exploring a Legal Instrument to Regulate Medical Research Using Genetic Information and Biobanking*. Maastricht: Universitaire Pers Maastricht (2012).

2.3.5. Data Protection

1. Introduction - the journey to the General Data Protection Regulation 2016/679

In the late 1970s, there was an international realisation that computers had, and would continue to develop, extraordinary power to store and process large amounts of data, and that this revolution had the potential to produce the potential for harm as well as benefit to people to whom the data related. Therefore, under the auspices of OECD an international agreement was reached about privacy in processing personal data in 1980.¹⁵ In Europe, the Council of Europe agreed a translation of that international expectation for its Member States in 1981.¹⁶ These two developments introduced into many national jurisdictions a detailed (and to some extent harmonised) expression of privacy in relation to the electronic processing of personal data held about their citizens.

By the 1990s it was clear in the European Union (as it is now), that the processing of personal data was at the heart of a lot of modern commerce, and that if citizens were to have confidence to participate in a single European market they had to have confidence that their data would be processed in at least as good a way as it would be processed within their home jurisdictions. It was also realised that the protection envisaged in the early 1980s, relating to only electronic processing of personal data, was inadequate, and that the regulation of the processing of personal data had to start from a presumption that data protection covered all forms of processing of personal data. This could be relaxed in certain areas (for example, purely domestic processing of personal data for private use by citizens), but it was necessary to widen the scope of the concept of "processing" of personal data so that the protections were more widely available than simply relating to the rather arbitrary 'electronic processing' coverage of the first iteration of data protection. The response was Directive 95/46/EC on the processing of personal data. Today, nearly 20 years on from that Directive, the EU has completed a further reform of the data protection regime, again, taking into consideration further developments in technology - particularly the processing of personal data via the internet and world-wide web. The opportunity was taken to seek a further and more effective harmonisation of data protection law, with a move from a Directive¹⁷ to a Regulation¹⁸. The process of reform, publicly, started on 25th January 2012 with the publication by the European Commission of its draft Regulation on processing personal data. The legislative process to agree the Regulation was extremely difficult. Whereas the initial

¹⁵ OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data <http://www.oecd.org/internet/ieconomy/oecdguidelinesontheprivacyandtransborderflowsofpersonaldata.htm> (Last visited 1st September 2014). These guidelines have been updated to their current version last updated in 2013.

¹⁶ Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data <http://conventions.coe.int/Treaty/en/Treaties/html/108.htm> (Last visited 1st September 2014).

¹⁷ with indirect effect, requiring implementation (transposition) into Member States' law.

¹⁸ with direct effect in Member States' law.

response of the Council was favourable, it was not expressed in a ‘first reading’ of the Bill in Council. The Parliament, with the work of the LIBE select committee, tabled a record number of amendments to the Bill. A first reading in both institutions took years to achieve. Thereafter, faced with an almost intractable impasse, the Bill moved into Trilogue - a process whereby representatives from the Council, the Parliament, and the Commission directly negotiate to (seek to) achieve a workable compromise that is then presented for approval in the Council and in the Parliament. The General Data Protection Regulation 2016/679 (GDPR) was adopted on 27th April 2016 into EU law on 27th April 2016. It comes into force in the Member States on 25th May 2018.

2. The shape of European Union data protection

The GDPR is very familiar to those who know both Directive 95/46/EC and the earlier Council of Europe Convention. The same basic structure is in place. A small table of the mapping between the Directive and the Regulation is given after the ‘Reading’ at the end of this part.

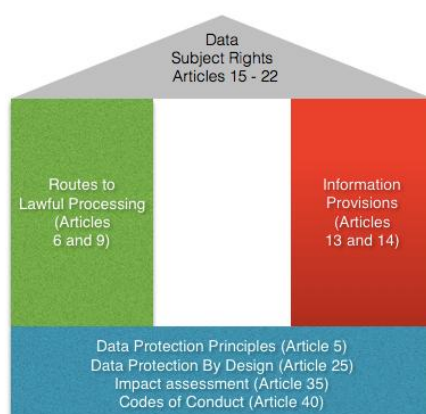
- Data protection concerns the processing of (sensitive) personal data, relating to data subjects by data controllers (perhaps through data processors), still under a high degree of control from the national control of Supervisory Authorities. The addition to the dramatic personae in the GDPR is the inclusion of Data Protection Officers who will be appointed at an institutional level and play an important role in relation particularly to high impact processing.
- Data controllers owe duties to data subjects, particularly to process the data fairly and lawfully (Articles 5, 6, and 9), and to inform the data subject about the processing (Articles 13 and 14).
- Data subjects have rights, essentially to ensure their own protection, particularly to gain access to the data that is processed about them, to have that data corrected where it is incorrect, to block its processing, and to have the data erased (Article 15–22). In relation to research, the much discussed “right to be forgotten” does not apply.
- Member States each have the duty to create a Supervisory Authority that must operate the registration of data processing, engage where appropriate in responding to ‘high impact’ processing, investigate and prosecute complaints of breaches in data protection law, ensure the operation of the Regulation in their jurisdiction, with some discretionary powers within the Regulation still falling to them (as in the Directive).
- Member States must also ensure that there is a compensation and punishment regime in place in its jurisdiction in line with the requirements of the Regulation. The sanctions available under the Regulation are much higher than those under the Directive.
- The EU supervisory authorities are strengthened under the Regulation. There is a EU Data Protection Supervisor, and the Article 29 Working Group becomes the EU Data Protection Board.

“‘Personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person” (Article 4.1, GDPR)

Article 4 provides the definitions that operate in the interpretation of the GDPR. Whilst it might be too obvious to mention this, it must be done: definitions and understandings of terms in other disciplines or contexts have no bearing on the interpretation of words that are defined in the GDPR. In particular, the concepts of 'anonymisation' and 'pseudonymisation' that operate in many of our disciplines have to be put aside when thinking about the GDPR. In the GDPR the concept in operation is **identifiability** (although the GDPR does define pseudonymisation); can the (potential) data subject be identified either from the data in the possession of an individual or that data in combination with other data that are reasonably foreseeable to come into the possession of that individual (not just the data controller). If the answer yes, then the person to whom that data relates is a data subject and GDPR applies to them (through the domestic law of the jurisdiction in which s/he is situated). If the answer is no, then the GDPR does not apply. If the answer is that the data subject is no longer identifiable, following a process of removing sufficient identifiers from the data to make re-identification impossible, then the GDPR does not apply to future processing, but it is perhaps arguable that there are some continuing duties towards the data subject that arose when the data subject identifiable in the data (or in the data and reasonably foreseeable connections with other data). Thus, rendering data 'anonymous' or 'pseudonymising' data and the rules relating to that in particular disciplines is not relevant to the GDPR: ***the question is only about whether the data subject can be identified, within the definitions contained in the GDPR.***

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We should now turn to the basic structure of the GDPR. There are essentially four key elements: the data protection principles, the routes to lawful processing, the information provisions and the rights of data subjects. Those familiar with the Directive will see the similarities immediately.



A. The Data Protection Principles

Whilst not formally titled as such, there are a number of principles that underpin the GDPR. These are contained in Article 5. Data should be processed fairly, lawfully and transparently (Art. 5.1.a). Transparently is a new addition and must refer to the processing techniques rather than the content - as confidentiality and privacy of information must be maintained.¹⁹ (Routes to) Lawful processing are found in Article 6 (for general personal data) and 9 (for sensitive personal data). The processing must be limited (Art. 5.1.b) to those necessary and compatible with the declared purpose(s). Further processing must not be incompatible. The data collected must be only that which is necessary for the purpose of the processing (Art. 5.1.c), and must be accurate as far as possible and “where necessary” (Art. 5.1.d). There is a presumption that data should be de-identified as soon as possible (relating to the purposes of the processing)(Art. 5.1.e), and data must be stored securely (Art. 5.1.f).

In addition to these principles, there is now a presumption in Article 25 of “data protection by design” - that where data will be processed, the controller must build into the enterprise systems that ensure data protection. This is a new concept that will have an impact in research - a protocol must show that data protection has been designed into the research as a ‘bottom-up’ principle.

Most importantly, whereas under the Directive a Data Controller was under an obligation to notify the Supervisory Authority of any processing of personal data, and the Supervisory Authority was under a duty to undertake, where necessary prior checking to ensure compliance, there are major changes. Prior checking, given the amount of work involved compared to the general funding of Supervisory Authorities was not particularly successful under the Directive. The GDPR requires all Controllers undertaking processing that is likely to be of high risk to the data subject’s (data protection) interests must make an ‘impact assessment’ (Article 35) before any processing is undertaken. The Supervisory Authority must make a list of processing that is to be considered as high risk. Article 35 outlines an extensive, systematic evaluation that must be undertaken where an impact assessment is required. Prior consultation with the Supervisory Authority must be undertaken where the controller is not able to provide mitigation for high risk processing. There is a potential weakness here as Article 36.1 does not require an external evaluation of whether mitigation is achieved. Of course, the prudent Controller will ensure that there is either mitigation of risk, or consultation - and the evaluation of a Data Protection Officer may assist in this where such a person is appointed. However, the imprudent Controller may only be found out in the event of a breach, and whether a high sanction will be sufficient to compensate the loss is not always clear.

¹⁹ See, GDPR Article 12.

It will be noted that there are considerable opportunities for Supervisory Authorities to produce local interpretations of the requirements of the GDPR. There are some measures that suggest that the Board will have a role in attempting to achieve the harmonisation desired for the GDPR, but the fact that the Regulation still contains many of the Directive's discretions rather indicates that there is not harmony between Member States in this area, and differences will persist. Likewise, the GDPR is a 'general' Regulation, attempting to cover all processing of personal data. This is, of course, a Herculean, almost fantastical task, because there is such variation between processing sectors as to what constitutes acceptable limits and interpretations of the Regulation. Therefore, it is to be hoped that the opportunity offered for European Commission and EU Data Protection Board approval (under Art. 40), will be taken to create sectoral Codes of Conduct - sectoral interpretations of how to interpret the GDPR in particular circumstances, for example, in life science and genomic research. RECs should be aware that there may well be sectoral Codes that apply to research presented to them.

B. Fair and Lawful Processing.

Under Article 5.1.a, data controllers are given the duty to process data fairly, lawfully and transparently. Lawful processing is to some extent dealt with under Articles 6 and 9 (to some extent, in that if there are other legal conditions acting in relation to the data, then they must also be followed to achieve lawful processing).

Article 6 sets out the conditions for lawful processing of personal data. The first conditions relate to informed consent, either directly given or given through a contract. The second condition is where the processing is in the vital interests of the data subject. The third conditions relate to duties imposed by Law. The fourth route to lawful processing is where the processing is in the interests of data controller and would not be in contrast with the fundamental rights and freedoms of the data subject. The final route is through an appeal to the public interest.

Article 9 prohibits the processing of sensitive personal data (i.e. "racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation" - Article 9.1). Thus, medical research often concerns sensitive personal data under this definition. The prohibition can be lifted in certain conditions, found in Article 9. First, where the data subject has consented to the processing ("except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject" – Article 9.2 – which might be considered a highly paternalistic approach to the data subject when compared to other uses of consent in, for example, medical research). Second, the data controller is acting under a legal obligation or right under national employment Law. Third, the vital interests of the data subject require the processing. Fourth, and with "appropriate

guarantees”, the processing is necessary for activities of bodies such as political parties or trades unions, etc. Fifth, that the data are already published by the data subject, or are necessary in legal proceedings. Sixth, that the processing is necessary for preventive medicine or occupational medicine. Seventh, the prohibition can be lifted for various medical purposes – diagnosis, treatment, prevention, and the management of health care. Most interestingly is the inclusion of the eighth condition, Article 9.1.j:

“processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.”

Equally, Member States may create new legislation to allow processing of sensitive personal data in the “substantial public interest”.

Article 9.1.j is a substantial change from the position of research under the Directive. Article 89 reuses that essentially research is undertaken on data that has been pseudonymised, unless that compromises the purpose of the processing. However, this is not *the* lawful processing for research, as satisfying Article 9 is not sufficient; there must also be a route to lawful processing available under Article 6, and Article 9.1.j is not mirrored in Article 6. In one of the earlier draft Bills, there was, under a then Proposed Article 6.2 a route to lawful processing for general processing simply for research. However, this was removed in the negotiations. Thus, whilst the prohibition on processing sensitive personal data may be lifted for scientific research with an appeal to Article 9.1.j, there must still be a route to lawful processing under Article 6. What a REC must bear in mind is that there are a number of routes to lawful processing and not only informed consent. For example, an appeal could be made to processing the data in the public interest, or for the legitimate interests of the controller without damaging the interests of the data subject. This would require a case to be made, but in principle it must be an available route. We will return to informed consent after the basic shape of the GDPR is outlined.

C. Information Provisions.

In order for the Data Subject to act on his or her rights under the GDOR, he or she must know about the processing. Whereas there is a limited amount of protection afforded to the data subject through the Supervisory Authority, and perhaps through other bodies such as RECs in relation to medical research, in the vast majority of cases, the regime is arguably a 'self-help' regime. Data controllers must observe their duties towards data subjects, but the rights of the data subject (perhaps particularly those relating to his or her specific sensitivities) are very largely left to be enforced by the data subject. Therefore, the data subject must be informed about processing that is to be undertaken on

their data, and who is responsible for that processing. This is addressed in Articles 13 and 14 of the GDPR.

There are, essentially, two scenarios addressed in relation to informing the data subject about processing: either the data controller is collecting the data directly from the data subject for foreseeable processing (**direct gathering**), or the data controller receives the data from a third party (most probably another data controller)(**indirect gathering**).

There is, of course, a further scenario: a data controller, having gathered or received data for a particular purpose (or set of foreseeable purposes), then sees another unforeseen purpose for which the data could be processed. 'Processing for further purposes' is, unfortunately, not dealt with simply under the Directive, so we will leave it to one side for the time being and return to it for separate consideration (in Discussion Point 2).

The information that must be given to a data subject before his or her data are processed are the contact details of the data controller and a description of the purpose of the processing to be undertaken. When the data are gathered directly from the data subject, the information must be given to the data subject. Where the data are to be processed by a third party, then again, the presumption is that the information must be given to the data subject unless s/he is already in possession of that information, or that it is impossible or would require a disproportionate effort (Article 14.5.b). In cases of impossibility or disproportionate effort the Member State must provide alternative safeguards.

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What is clear is that the data protection regime requires those who gather data directly from data subjects to provide information so that the data subject can protect their own rights. There is no Article 14.5.b equivalent in Article 13 – no ‘impossible or disproportionate effort’ – and this is understandable. If the data subject is there for a direct gathering of data, then the information can be given.

D. Data Subject Rights

The rights of a data subject are largely the same, in respect of research, as those available under the Directive 95/46/EC. As indicated above, the ‘right to be forgotten’, which is largely driven by concerns about the internet, is not available to data subjects where the processing is for research (Article 17.3.d). It is worth noting that research, under the GDPR includes applied research (Recital 159). One question that remains is how the right to withdraw operates in relation to research. It has long been a standard of research that a participant is included in a voluntary way and can withdraw from the research at will. However, there could be another argument, given the potential impact of

withdrawal from a study on the scientific impact of the study, and given the difficulty of withdrawing from processing once results of a study have been published.

The GDPR addresses this to some extent. Article 21 - the “right to object” - under the general provision indicates that data subjects have a right to object to processing “unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject” (Article 21.1) However, under Article 21.6 the provision for research is slightly different:

“Where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89(1), the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, unless the processing is necessary for the performance of a task carried out for reasons of public interest.”

It remains to be seen how “on grounds relating to his or her particular situation” will be interpreted and whether there will be a harmonised interpretation in the Member States to this.

A right that may produce difficulties for researchers is Article 20 - “the right to at a portability”. Under this Article,

“The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided.”

Two conditions attach - that the route to lawful processing is informed consent, and that the processing of the data is automated. This does not have the administrative cost clause of the Article 15 “right of access”, and much will hang, for research, on the interpretation of “which he or she has provided to a controller”. There is an on-going question relating to data ownership about how far personal data simply relate to the data subject, being generated through the labour of the data controller. But if one, for example, took the example of genetic information derived from a blood sample, how far does that constitute data ‘provided to a controller’, or is it only the blood sample that is provided? At the other end of the spectrum, when a data subject participates in the highly structured information gathering of, say, a biobank, how far must the biobank provide all that data “in a structured, commonly used and machine-readable format”. At that point, the interests of third parties (protected under Article 20.4) may restrict the amount of data that is available to the data subject through the participation in a biobank. The reasoning for this is considered in the first question below.

3. Questions still unresolved by the GDPR

A. Who is the Data Subject? Dealing with genetic relatives.

There is often a problem in medical research, particularly research using genetic data or biobanks, about individuals who are the genetic relatives of the participant. There has, arguably, been something of a difficulty in knowing how to deal with this 'penumbra' of relatives. The temptation is to think that only the direct research participant is a data subject. And, indeed, it is convenient to think in that way. At first thought, if we were to treat all the genetic relatives of the potential participant as data subjects, then research would immediately collapse under the weight of informed consent negotiations. However, this pragmatic solution does leave an uncomfortable feeling. Let us consider, for example, the situation of a genetic relatives in a single purpose research project. Arthur presents himself for enrolment having being identified as a potential participant for the study. He gives blood, urine and saliva samples, and a medical history as requested. Arthur has three brothers, his parents are still alive, as is one of his father's brothers who has two daughters. He indicates that his mother had a great-aunt who they know to have emigrated many years ago to Australia, who they know had a son through an affair, but because that branch of the family was quite religious, contact was lost with the great-aunt, and Arthur believes that given her age she must have died some years ago.

Making Arthur's extended family - the ones that he has named so far - all data subjects has the feel of a crazy, unreasonable suggestion. And yet, each of them has grey similar things to lose - harms to suffer - from a participation in research that Arthur has. Arthur is not a special case because he has been invited to participate in the research; the rights to privacy and data protection that Arthur must be able to enjoy must, arguably, must also be enjoyed by those who are identifiable in the data disclosed by Arthur. We know a great deal about the relatives that Arthur's samples (and history) disclose to the research data controller.

This is, however, not catastrophic when we allow the structure of the GDPR to dictate the answer. Arthur is the data subject from whom an Article 13, Direct gathering operates. All Arthur's relatives are data subjects from whom the data are gathered *indirectly*. Therefore, those genetic relatives are within the conditions of Article 14, and must be informed of the data controller's contact details and the purpose of the processing where informing them is reasonable - where it is not impossible or requiring a disproportionate effort. The question becomes one of fact and balance - what are the potential risks to one's fundamental rights and freedoms arising through participation in balance with how much effort would it take to notify the data subject? 'But s/he might not want to participate'

cannot be a reason not to notify him or her (but remember that notification is not to gain informed consent under the GDPR.²⁰

B. Informed Consent

There was considerable concern in the research community during the passage of the Bill. After an initial draft from the Commission that indicated that there would not be a need for researchers to rely on a narrow, highly specified consent for, for example, biobanking or data intensive research, the provision that allowed research as a route to lawful processing in Article 6 was lost. The approved GDPR text has a compromise, but it is not one that is without difficulties.

As in the Directive 95/46/EC, informed consent is the first of the routes to lawful processing for general personal data (Article 6.1.a) and for lifting the restriction on processing sensitive personal data (Article 9.2.a). These are not, of themselves problematic texts:

“the data subject has given consent to the processing of his or her personal data for one or more specific purposes.” (Art. 6.1.a)

“the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject.” (Art. 9.2.a)

Further, the GDPR includes two specific Articles on consent: Article 7 on general issues about consent, and Article 8 on gaining consent from minors. These are more concerned with the procedures for gaining and evidencing consent. The problem arises in the definition of consent contained in Article 4.11 - the definitions Article - where:

“‘consent’ of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;”

This appears to create a requirement that informed consent is “specific”. It may well amount to an attempt at clever legal footwork to suggest that “freely given, specific, informed and unambiguous” are qualifiers to “indication”, and not the substance of the consent itself - that the data subject must be specific in the indication, not specific in the consent itself. These could well be taken to amount to the same thing: to indicate specifically is to specify the parameters of the consent envisaged. Likewise, it may well be insufficient to argue that specifying “research” in a broad consent way

²⁰ And one might argue, if the route to lawful processing is a research in the public interest route, where the data subject's rights are highly restricted, and their interests are protected by alternative safeguards, then this might go to the proportionality of the effort.

would satisfy the requirements of Article 4.11 on its own. However, a last minute inclusion in the GDPR was Recital 33, which it is worth reproducing in full:

“It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.”

This, it is widely accepted is designed to allow research the opportunity for ‘broad’ informed consent. However, as a Recital, it does not have the same immediate weight as an Article, and must therefore be accepted into the common interpretation of the GDPR, perhaps ideally through a Code of Conduct. What would be disappointing is if this was left to individual Member State Supervisory Authorities to take a view on the relationship between Article 4.11 and Recital 33. Further, RECs must be aware of the interplay between the two elements of the GDPR.

C. Processing for further purposes.

The Data Controller must inform the data subject of all the purposes for which s/he wishes to process the data if he or she collects the data directly from the data subject or, where he or she indirectly collects the data, where it is possible and not requiring a disproportionate effort. Imagine the situation of Anna, professor of oncology at a large university hospital. She gathered data from 150 data subjects about a particular cancer she was studying. The research was completed, and she published papers on her findings. Some time later, two developments happened: Anna herself made a new, and rather surprising connection to a different cancer, and realised that a further processing of her original data set could lead to interesting results; Anna’s funding body require her, as a condition of the grant, to make her data available to other researchers (unidentified) through a ‘data hub’ - which requires a standardisation of the metadata and the linkage of data with other data sets, and therefore (pseudonymised) identifiability of data subjects (to prevent duplication of subjects in the dataset).

There are a number of routes to explore here. The first is, of course, are the two developments covered by the original route to lawful processing and information provisions? There is a chance that the informed consent has been broad enough to cover both developments, and the information about the processing was similarly broad to cover the possibility. However, this may well not be the case. Let us consider the two elements of routes to lawful processing and information provisions separately.

Under the Directive, the route to lawful processing element was very difficult for this sort of secondary processing. The Directive, under its Article 6.1.b was very ambiguous about secondary processing for a compatible purpose, because the drafting could be interpreted as either meaning that

compatible processing for the same purpose was acceptable, or processing for compatible purposes was acceptable. The first draft of the GDPR from the Commission sought to clarify this immediately. Under the Proposed Article 5, it provided that data should be gathered for a specific purpose and not further processing in an incompatible way - the first element; and then under the Proposed Article 6 it made it clear that processing for further purposes was acceptable where the purposes were compatible with the original purpose for the processing, and special provision was made for presuming that research was a compatible purpose. The political negotiations have slightly muddled that initial clarity. The ambiguous wording of the Directive is imported into the GDPR in Article 5.1.b:

“personal data shall be (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (‘purpose limitation’);”

However, Article 6.4 is retained concerning processing for a compatible purpose:

“Where the processing for a purpose other than that for which the personal data have been collected is not based on the data subject's consent or on a Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1), the controller shall, in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected, take into account” a number of conditions.

This is perhaps not elegant, but it does spell out that the possibility for processing for a purpose compatible with the original purpose is envisaged under the GDPR. It is further underlined in the first paragraph of Recital 50:

“The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required. If the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Union or Member State law may determine and specify the tasks and purposes for which the further processing should be regarded as compatible and lawful. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing. In order to ascertain whether a purpose of further processing is compatible with the purpose for which the personal data are initially collected, the controller, after having met all the requirements for the

lawfulness of the original processing, should take into account, inter alia: any link between those purposes and the purposes of the intended further processing; the context in which the personal data have been collected, in particular the reasonable expectations of data subjects based on their relationship with the controller as to their further use; the nature of the personal data; the consequences of the intended further processing for data subjects; and the existence of appropriate safeguards in both the original and intended further processing operations.”

D. Identification, De-identification, and Re-identification There is a significant problem in the personal data sharing and data-intensive health, medicine and life science research community. Large data sets, in order to be useful, need to be up-dated regularly, so that the life-experience of the individual data subject can be followed; medical histories and genomic data as a snap-shot are useful, but as an on-going narrative they are so much richer. Therefore, it is necessary to keep the dataset (be it centrally located, or federated²¹) in an identifiable form. This will be in a pseudonymised (coded) form for security, but it will be possible to identify individuals within the set.

The first problem therefore arises when data is passed from the dataset to researchers. It is highly likely that this will be passed in a de-identified way; the identifiers in the dataset that is passed to the researchers will have been stripped from the data, and individuals will not be identifiable from the aggregated data or the data that is passed. However, because there is a technical possibility that the data could be re-identified by connecting the data back to the original, identifiable dataset, many jurisdictions take this to mean that the data remains personal data (identifiable) throughout its life, and that the researcher with the de-identified set is bound by the conditions of the GDPR. The GDPR is concerned with the reasonableness of the potential for identification. There is a first set of questions to be asked here: [is this possibility of re-identification one that should be reasonably considered as a threat to the interests of the data subject such that the GDPR should bind the researcher in this scenario, and what conditions might be sufficient - for example, in the data sharing agreement - that might mitigate that threat \(are there, for example, technical safeguards to prevent re-identification that would be sufficient; is an undertaking, with sanctions, against re-identification sufficient\)?](#)

The second problem moves from the internal difficulty of imagining the dataset and its key, and the likelihood of re-connecting the key and the de-identified data to the external question of the likelihood of connecting the de-identified data in the hands of the researcher (either deliberately or accidentally) to an external dataset (perhaps already held by the researcher, or falling into her hands from a third party) that then re-identifies the data subject. Indeed, this possibility begins to question whether, in an

²¹ i.e. maintained at different locations but linked, for example, in a way that allows remote interrogation.

internet culture with so many different datasets being connected internationally with increased computing power, it is still possible to speak of unbreakable de-identification; is it impossible to be truly ‘anonymous’ in any circumstances anymore (remembering that identification is not a matter of names and addresses, but any data that, when connected together, identify an individual). So, the second question is, regardless of the possibility of connecting the de-identified dataset to the original identifiable source, what is the likelihood that the de-identified dataset will be connected to sufficient other data to re-identify the data subject? How remote does this possibility have to be to disengage the GDPR?

Of course, at another level both of these questions presume that disengaging the GDPR is a good and desirable thing. In most cases this is not necessarily the case, but there is a case to suggest that there is a difficulty in maintaining the GDPR for data sharing and data-intensive research. If the GDPR is engaged in anonymous data sets, only the information provisions have a ‘disproportionate effort’ or ‘impossibility’ limitation. There must be a route to lawful processing, and the reluctance to ‘change horses’ between routes to lawful processing for processing for secondary purposes is already noted. So, if the original route to lawful processing was informed consent, and the informed consent was not broad enough to capture the secondary processing, and the wording of that original consent precluded an appeal to compatible processing (which is not uncommon), then is re-consenting the data subject to be able to connect the privacy-protected data the only way forward? This would seem to be at odds with the spirit of Article 89, and Recitals 33 and 50, for example, which seek to enable data sharing and data-intensive research for health, medicine and life science research.

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REC members may well take a view that this is not a matter for RECs and that they should depend on the EU Data Protection Supervisor and Board for guidance. To some extent, of course, this is correct; those bodies, and the Court of Justice of the European Union, have the authority to pronounce definitively on the interpretation of the GDPR. However, RECs see the practical setting of these dilemmas for research, and so they can voice an opinion to contribute to the empowered authorities’ deliberations. Further, and most importantly, personal data privacy and confidentiality are not only legal matters, they pose ‘ethics’ questions also, and there the REC has responsibilities. Does, for example, ethics demand specific informed consent where the GDPR might countenance the public interest? We would suggest that answer is ‘no’, indeed, ethics may take a more solidarity-based view - that the desire for medical research and therapies in an increasingly individual-focused society requires that research be allowed to take place in the public interest. It could be that the ethics debate forces the legal, data protection debate to reconsider some of its more extreme autonomy-based (and solidarity-rejecting) interpretations of confidentiality and privacy. But that is for debate.

Questions for Discussions

Is this a reasonable approach to the problem of genetic relatives?

How far will informed consent present a problem to new data intensive research methodologies and data sharing?

How does your REC deal with requests for processing for further purposes that were not foreseen at the initial gathering of the data?

How far, and in what circumstances would your REC allow processing of data where informed consent was not gained, but where, for example, an appeal to the substantial public interest was made?

Further Reading:

General Data Protection Regulation 2016/679

<http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32016R0679>

Data Protection Directive 95/46/EC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>

OECD *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (1980)

<http://www.oecd.org/internet/ieconomy/oecdguidelinesontheprivacyandtransborderflowsofpersonaldata.htm>

OECD *The OECD Privacy Framework* (2013) h

https://www.oecd.org/sti/ieconomy/oecd_privacy_framework.pdf

Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1981)

<http://conventions.coe.int/Treaty/en/Treaties/html/108.htm>

Townend, D. *The Politeness of Data Protection: Exploring a Legal Instrument to Regulate Medical Research Using Genetic Information and Biobanking*. Maastricht: Universitaire Pers Maastricht (2012) chapter 4, especially pp. 114–116.

European Commission *Data Protection Special Eurobarometer 431*, (2015),

OECD *Recommendation of the OECD Health Council on Data Governance* (2017)

Mapping the key provisions of the Data Protection Directive 95/46/EC onto the GDPR 2016/679

Concept	95/46/EC	2016/679
General Purpose of the Legislation	Art. 1 (& Art. 3)	Art. 1 (& Art. 2)
Restrictions on scope	Art. 13(1)	Art. 23
Definitions (used within the legislation)	Art. 2	Art. 4
Data Protection Principles	Art. 6	Art. 5
Routes to Lawful Processing of General Data	Art. 7	Art. 6
Routes to Lawful Processing of Sensitive Data	Art. 8	Art. 9
Informed consent	Art. 2(h)	Art. 7 & Art. 8 - and Art. 4(11)
Information Principles	Art. 10 & Art. 11	Art. 12 (transparency and modalities)(new) Art. 13 & Art. 14
Rights of Data Subject	Art. 12 to Art. 4	Art. 15 to Art. 22
“Data Protection by Design and Default”	-	Art. 25
Supervisory Authority	Art. 28	Art. 51
Working Group	Art. 29	-
European Data Protection Board	-	Art. 68
Impact Assessment	-	Art. 35
Prior Checking	Art. 20	Art. 36
Data Protection Officer	-	Art. 37
Registration with Supervisory Authority	Art. 18	
Code of Conduct	Art. 27	Art. 40
Research Processing	[Art. 13(2), Art. 6(1)(b), Art. 11(2)]	Art. 89 (see also Recital 50)
Transfer of Data to Third Countries	Art. 25 & Art. 26	Art. 44
Remedies, liabilities and penalties	Art. 22 to Art. 24	Art. 77

2.3.6. The Regulation of Clinical Trials in Europe

The problem

Drug development is potentially dangerous. The vast majority of citizens hope that, should they become ill, medical science and care will have solutions to restore their health. Those solutions are, very often, toxic to the human; the solutions involve the controlled use of compounds that uncontrolled would be extremely harmful to the individual. Equally, the effectiveness of particular compounds as responses to particular diseases (increasingly it is understood in particular individuals) is not self-evident, and the process of identifying, refining and producing the drug is extremely challenging on a number of levels.

Further, historically, medical research has not necessarily been undertaken for the benefit of humans or conducted in a way that has respected the fundamental rights and freedoms of the participants. International agreements have been made in response to particular atrocities, and local laws and practice have been developed to govern this commercial enterprise. And that is the balance that has to be struck in governance: within a free market, how can the interests of innovation, science, commerce, society, and individuals be balanced appropriately?

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An interpretation of the response

Pharmaceutical developments are international business. Drugs are developed with a view to local and international markets. These developments occur both in a fierce business context and in a fierce safety context; free markets govern the business choices, but the safeguarding of the rights of patients and of those who participate in the three stages of clinical trials has been a matter for domestic law, balancing local sensitivities and ethical concerns with creating an environment in which pharmaceutical industry is attracted, encouraged and retained.

Rightly, much is made of evidence of historic and historical medical research malpractice. As discussed in earlier pages, it is clear that industry in this area will not regulate itself, or at least it is clear that historically researchers have not always acted in ways that respect the fundamental rights and freedoms of participants in research. In this area, the most prominent international response has been the Nuremberg Code, followed by the Helsinki Declaration of the World Medical Association. This, along with the more general expressions of human rights found in the Universal Declaration, European Convention, and national human rights law, binds medical research (and health care) to a common agenda to safeguard human dignity and the specific rights of individuals. These requirements need specific translation into law at binds natural and legal individuals.

Increasingly, pharmaceutical enterprise has become a European activity rather than simply a Member State concern. Whilst stand-alone clinical trials are still conducted at the local, individual site level, they are often now conducted as multi-centre trials, and increasingly in multiple jurisdictions. Clinical trials are therefore an area that have been regulated at the European level since the Directives 2001/20/EC on clinical trials and 2005/28/EC on good clinical practice. Whereas at first sight, given the ethical and scientific focus of the regulatory regime, it might appear that this area is not one over which the European Union has competence, the legal justification for this harmonisation is for the creation of the single economic market (also taking into account duties towards public health)²²; harmonisation of approvals for clinical trials enhances efficiency in the European market, and avoids unfair advantages for individual Member States that might operate a system below standards at other states felt bound to employ to safeguard the fundamental rights and freedoms of human participants in the trials and ultimately the consumers of the drug.

Specific requirements:

The EU has sought to harmonise the regulation of clinical trials since 2001. The Clinical Trials Directive (2001/20/EC), in terms of its commitment to ethical review, enshrined the Helsinki Declaration in European clinical trials governance. Of itself, the Helsinki Declaration, as an agreement of the World Medical Association does not have binding legal effect. However, as in the case of the Clinical Trials Directive, it can be given legal impetus through contract law (e.g. as an employment condition) or through national, EU or international law. . Under the Directive, Clinical Trials governance follows the principles and expectations of the Helsinki Declaration.²³

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Following concern that the Directive did not sufficiently effect harmonisation of trials, the Directive has been replaced by the Clinical Trials Regulation (536/2014). There are a number of issues that cause problems under the Regulation in relation to ethical review and the place of RECs. It should be remembered that the first proposal for reform of the Directive removed ethics review from the ambit of the European regime, leaving it with the Member States. Under the final, accepted Regulation, ethics review by RECs remains a part of European clinical trials governance. There are three major questions for the RECs posed by the Regulation: the place of ethics in the process, the timing of ethics review, and the potential for operating a more centralized ethics review. The first two are, arguably interlinked. First, however, a general note about the Regulation.

²² For the current iteration of the competence to legislate, see Articles 114 and 168 of the Treaty on the Functioning of the European Union.

²³ The Directive remains in force until the full operation of the Regulation (particularly the full operation of its on-line Portal); sponsors of research can in this present time opt either to use the Directive or the Regulation.

Multi-centre clinical trials cause some difficulties for effective governance. A system where scientific and ethics review have to be carried out under procedurally (although not necessarily substantively) different rules causes inefficiency and delays that make Europe less attractive to potential clinical trial sponsors and researchers. The Regulation seeks to address this by aiming for a centralised system for the administration of the scientific review process: the “Reporting Member State” will manage the scientific review process. It must be noted, at the outset, that the ethics review does not share the same case-management structure. The process itself is essentially divided into two parts: Part I concerns primarily scientific substance; Part II concerns primarily ethical issues. The Reporting Member State receives the application and, under Part I, makes a preliminary assessment of the proposal. This is then opened to general review by the other Member States involved in the proposal, before the Reporting Member State gathers the Member States’ reviews in a final report. Under Part II, each Member State makes its own, independent review, communicated to the Sponsor of the trial. The communication, and the sharing of information, will be achieved across the processes (for Parts I and II), through a single European portal.

1. What is the place of ethics in the review process?

Part I primarily relates to scientific substance; Part II to ethical issues. However, this is not as neat in practice: the Regulation allows for ethics review under both Parts I and II. Is this sensible?

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What are the ethics questions that have to be asked about a clinical trial proposal?

- i. Is this the sort of activity that we (as a society) wish to pursue? (This is the sort of question that we are used to hearing in relation to, for example, human embryonic stem cell research. Some jurisdictions accept hESC research, others do not, as ethical decisions.)
- ii. Is the science sound? (To be an ethical trial, the science must be sound – it being unethical knowingly to conduct ‘bad’ science.)
- iii. Are the human participants in the clinical trial adequately protected? (And here there are established responses to the harm/benefit analysis of participation – for example, the primacy of informed consent and autonomy.)

Whereas the third of these questions can be answered in Part II considerations (and the Regulation outlines many of the typical safeguard issues that need to be taken into account), the first two questions are much more linked to Part I. Or rather, the Regulation’s acceptance that ethical questions can be asked in Part I cause something of a problem. And this is a problem about timing. We must street the “primarily” science and “primarily” ethics. It is problematic, to suggest that Part I is only concerned with scientific issues.

2. Can the timing operate effectively given the current nature of RECs in Europe?

Much of the criticism of the new Regulation from RECs has been about the timetables. This is in part understandable, but the problem goes beyond the simple timetable problems. On its face, the arrangement of Part I and Part II looks as if they should follow chronologically. Having assessed the science, the three ethical questions can be asked. Of course, this is inefficient – would it be sensible to continue with a scientific review of something that fails the first question? Equally, is it sensible to continue a review where the science is not good? This also indicates that there is a question as to which personnel in review should answer the different questions.

The concern of the RECs seems, from an outsider's perspective, to be, 'how can we as an underfunded, part-time, voluntary committee fit into the tight timeframes imposed by the Regulation?' Clearly, if the REC considers that all three questions have to be answered within Part I, the traditional ethics review cannot be achieved. However, if the three questions are separated, there might be a chance to ensure that the review is possible, essentially within the Part II timeframe. Whereas Part I starts with the Reporting Member State's initial view, and then moves to a short period for Member State assessment before the final report writing by the Reporting Member State, Part II has a longer potential period for the REC reviews.

RECs will have access to the documents of the application through the portal. They can immediately start to answer the three questions described above. They can feed their answers to the first two questions into the Part I process (asking about the general acceptability of the research first, and then responding to the scientific review to assess whether the science is sufficiently robust), and answer the third question explicitly within the Part II timetable.

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3. Is ethics review given to harmonisation?

The presumption behind the structure certainly of Part I of the Regulation, if not of Part II, is that harmonisation of review is possible. Science has an international language and an international set of standards. There are arguments that science has local meaning and constructions, but there is a much greater harmonisation than is to be found in normative review and standards. It is possible, as, for example, in the way that the European Court of Justice operates, with a starting point of a preliminary opinion being written by an Advocate General, before it is given over to wider discussion by the judges and other interested parties in the dispute. There, there is a common language of the Law – perhaps with local accents – but not local dialects, going to different vocabularies and grammar. Ethics, and especially the ethics of the REC, is a matter of dialect.

One of the purposes of an REC is to bring local sensitivities to the evaluation of a protocol. This mitigates against harmonisation. A harmonising, preliminary opinion model presumes that there is a

common ground – that one reviewer can make a first assessment of the materials that others can then review as a starting point for their own work. For the Law or for science, this is possible to a very large extent. The first reviewer presents their opinion, certainly, but from a common disciplinary language. Subsequent reviewers can take that starting point and review the reasoning within the preliminary draft. In REC, local sensitivity-based-review there is not a common starting point. REC ethics might have similarities, but the subsequent reviewer cannot assume that the first reviewer is asking the same questions that s/he is required to ask, or chooses to ask on behalf of his or her local community. There is not a harmonised substantive ethics so each REC cannot assume that the first reviewer has approached the materials in a way that covers the same grounds or reflects the same ethical views. (We will leave aside just how each REC gathers that local sense and assume that it is present.) It is not that the secondary reviewers do not trust the first reviewer to have done a good job – the question in the ECJ or scientific review – or whether they agree with the conclusions drawn; RECs simply do not know, without a full assessment of all the materials, whether they would place weight on the particular parts relevant to the first committee.

Thus, if the Regulation timeframes are going to be rigorously enforced, and RECs are going to be able to contribute without either a radical revision of their funding structures and operating practice (i.e. to become professional, full-time RECs) or a move to developing harmonised substantive ethics (i.e. moving away from local sensitivities), perhaps one solution is to ensure that the questions to be asked and answered by RECs in clinical trial situations are allocated most effectively within the Part I/II division.

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4. Further questions

Whereas the three preceding questions are of fundamental importance to the operation of ethics review within the Regulation, there are some further issues that require consideration. For example, how will commercial and patient interests be balanced in relation to the presumption of transparency of information in the Regulation? How will the portal operate – particularly, to whom (and at what points) will the Member States give access rights? Much of the implementation process is still under negotiation at the European Medicines Agency.

Questions for Discussions

Is this an accurate assessment of the function and practice of RECs in relation to clinical trials?

Particularly, does this make sense of the time frames?

How far is the Part II timescale workable for RECs as they are currently operating?

Does separating the sorts of questions that a REC asks help in trying to see a manageable timeframe for RECs?

What sort of recommendations can we make about ensuring that the process is manageable and workable under the Regulation?

Access to the documents?; working practice?; administrative support?

Are the exemptions to transparency sufficient (i.e. that the information is commercial sensitive or is personal data)?

How will your committees interpret those exemptions?

Are there further, bigger questions about the Regulation that need to be addressed by EUREC at this stage?

Further Reading

Clinical Trials Regulation (536/2014)

Decristoforo, C., Penuelas, I., Elsinga, P., Ballinger, J., Winhorst, A., Verbruggen, A., Verzijlbergen, F., Chiti, A. “Radiopharmaceuticals are special, but is this recognized? The possible impact of the new Clinical Trials Regulation on the preparation of radiopharmaceuticals.” *Eur J Nucl Med Mol Imaging* 41:2005–2007 (2014).

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Gefenas, E., Cekanauskaite, A., Lekstutiene, J. Lukaseviciene, V. “Application challenges of the new EU Clinical Trials Regulation”, *Eur J Clin Pharmacol* (2017) 73: 795. <https://doi.org/10.1007/s00228-017-2267-6>

Petrini C (2016) “What is the role of ethics committees after Regulation (EU) 536/2014?” *J Med Ethics*. doi:10.1136/medethics-2015-103028

Shaw, D., Townend, D. “Division and discord in the Clinical Trial Regulation” *J Med Ethics* 2016;0:1–4. doi:10.1136/medethics-2016-103422

2.3.7. *Intellectual Property and the concept of property*

Whereas intellectual property issues are not primarily the concern of RECs, there is a combination of rights that might require consideration by an REC if they arise in relation to a protocol.

First we must assume that the jurisdiction in question is party to the Universal Declaration on Human Rights and the 1966 International Covenant on Economic, Social and Cultural Rights Protocol on Economic, Cultural, and to the TRIPS agreement, implementing the option under Article 27(2) concerning the morality clause. These duties set up the following ethical question that could fall into the remit of the REC at least to consider.

Under Human Rights there is a right for each citizen to participate in the cultural and scientific life of his or her community. There is equally a right to private property, including intellectual property. Under the 1966 covenant citizens have the right to the highest attainable standard of health care. Under the TRIPS agreement, a country can block the patenting of an invention “the commercial exploitation of which would be contrary to morality or *ordre public*”.

Increasingly, applications for research funding require the applicant to provide details of their IP strategy within an environment of “Responsible Research and Innovation”. What is very interesting, given the push for value for money from public funded research, and the requirements for open access to data in such research, there is rarely a question that there should be a return of the investment of public funds to the funder if the research has produced a lucrative product. This could be done in a subtle way, rather than requiring a repayment of the whole amount advanced at the outset. For example, a small percentage of net profits (set at a low rate of exchange (even at a very low percentage) could tie the funder into the property of the initial investment.

The Concept of Property

Intellectual property rests, conceptually, very heavily on the property theory of John Locke. Locke based his right to private property on the idea of ‘labour’. Individuals can claim property in a thing because of the added value they bring to the creation of the thing through their labour. Nozick asks why by adding labour the individual takes the whole thing, and does not merely lose the addition. However, Locke’s idea (or, this part of Locke’s idea - because we conveniently forget Locke’s caveat that private property only attaches when sufficient is left for everyone else) had enormous purchase for the shift from feudal property to industrial revolution property.

The industrial revolution, as Proudhon points out in the aphorism ‘property is theft’ commodified labour in a wage-labour economy. Individual workers’ effort could be exchanged, not for a proportion

of the product the labour produced, but for an exchange value detached from the property (dependant upon the availability of that labour), and the organiser of production was able to command the 'property' in the produced goods and services. This is very familiar. As is the colloquial use of the term 'property'. Most will think of 'things' when asked to describe 'my property' - one's house, car, laptop, perhaps stocks and shares, bank account, and the like - but 'property' is 'things'. This seems to be the world order - the ownership of things within private, industrial revolution property.

There are a number of questions to ask here, however. First, and this was hinted already: the concept of property is a changing paradigm. Property has not always been private, industrial revolution property. As C B Macpherson reminds us, before the industrial revolution, property was based on social obligations (in the feudal society). He suggests that the paradigm can change again (for him, to property based in social rights and then political rights). Charles Reich made similar observations. Today, in a neoliberal socio-economic culture, it is difficult to remember that 'property' is only a conceptual paradigm, and that it can be challenged. Or do we sit with Francis Fukuyama, that this socio-economic paradigm is as good as it gets?

Perhaps the second observation about property is the one that makes questioning the paradigm most relevant to RECs. RECs, in modern biotechnological research, are faced with uses of data, time, resources, and the like, that are very different from those of even the end of the twentieth century. Individuals are increasingly the commodity of the industry that is behind health, medicine and the life sciences. And that may be a good thing, but equally, RECs are asked to ask that question for society: is this progress and unrelenting good thing in our society? Are the relationships that the paradigms we see appeal to necessarily good? What is the ethics of these relationships? ***And that is the key: property is not about things, it is not even about the relationship between people and things, it is the relationship between people about things, and that makes property a moral question.*** This is not completely off the current agenda - this is the, often unspoken, theoretical underpinning of 'benefit sharing'. Grounding 'benefit sharing' in an understanding that an appeal to that something is 'my property' is not an absolute appeal allows the questioner to ask, 'but morally, what is the extent of your claim, given these competing claims to those resources?' and 'what is the relationship between you, creating the product, and these individuals and society?' If we are truly 'ethics' committees, do these not seem to be legitimate questions to ask on behalf of not only or local society, but, in the light of human rights to healthcare, shared participation in the benefits of science, and simple human dignity, our neighbours everywhere?

Questions for Discussion:

- how far is the ethics of the IP strategy a matter for REC consideration?
- is this simply a matter for the relevant IP granting authorities?

- how far is the IP strategy, given the obligations outlined above, ethical?
- is it sufficient that the IP strategy simply conforms to the free market opportunities in the jurisdictions in question?
- how might an REC voice any concerns it might have about the IP strategy?
- do any of these answers change in relation to access to the results of medical research in developing economy countries?

Further Reading:

TRIPS Agreement, particularly Article 27.

European Patent Convention, particularly Articles 52 and 53.

Patentnemnd uten portefølje? En analyse av etiske utfordringer ved patentering. Publikasjon nr. 7 Forskningsetiske Komiteer, Oslo (2008).

Dreyfuss, R. “TRIPS - Round II: Should Users Strike Back.” *U. Chi. L. Rev.* 71:21 (2004)

Bently, L., Sherman, B. *Intellectual Property Law*. (4th edition). Oxford University Press, Oxford (2014)

2.4 Appendices

2.4.1 Basics of EU law in relation to RECs

The European Union is a Supranational State - in as much as the Member States each surrender part of their sovereignty to the European in relation to specific issues, whilst retaining their sovereignty in relation to the remaining areas (which are the vast majority of their activities). The Union has taken a relatively short time to evolve - from a treaty concerning coal and steel between six neighbouring Member States at the end of the 1940s, through a European Economic Community, to the single market of the European Union which currently has 28 Member States.

At Law, this has been achieved through two treaties - the Treaty of European Union (TEU), and the Treaty on the Functioning of the European Union (TFEU), as they have become - which have seen a number of iterations through various amending Treaties (notably the Treaty of Maastricht in 1992 and the Treaty of Lisbon in 2009). These are analogous to the 'operating software' in a computer system. They give the legal 'code' within which 'apps' (European legislation on specific issues) can work. This is a useful analogy - as the operating software of, for example, Microsoft or Apple have gone through a number of versions, some minor changes, some major, providing an environment in which specific tasks can be addressed.

Each 'app' (separate piece of legislation addressing a particular practical question, for example, the harmonisation of data protection, or clinical trials practice) is created in line with the Treaties' requirements, and needs to be based in the ceded authority given to the Union by the Member State. The major authority to legislate is to create measures to harmonise domestic legislation to create a single market across Europe.

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Creating the Single Market: Article 114

Whilst Human Rights are important to the European Union, they are not the central motivation for legislation. Member States have handed their sovereignty to the Union primarily in relation to creating the single market – the Union remains primarily a commercial Union, with some social aspects (for those States that have agreed to this aspect). The Single Market is seen emerging strongly through the Maastricht Treaty (1992/3) and then further in the Treaty of Lisbon (2009).

In practice, then, the authority upon which Law is made in the EU is Article 114 (TFEU) – a motivation to harmonise Member States' Laws in matters that relate to the creation of the single market. This has quite a broad ambit, based on the need to harmonise the environment within which Member States operate commerce. This has two aspects: the positive impetus to create a single trading environment, to avoid trade barriers; and to avoid unfair competition. In relation to the second principle, this can extend quite a long way into working practice – for example in the Working Time Directive. Where a State seeks to operate in a way that respects the human dignity of workers, it would be unfair to allow another State that does not respect that dignity to profit from the behaviour; the economic harmonisation can take on a strong social, or human rights flavour.

In relation to medical research, the processing of personal data, the conduct of clinical research, the use of animals is regulated, amongst other things, at the European Union level; legislation seeks to harmonise research practice in particular areas to ensure the effective operation of a “single European

research area”, and to further the common purpose (under Horizon 2020) of “Responsible Research and Innovation”, and to avoid unfair competition between Member States.

Equally, the European Union has a strong commitment to Human Rights, both in the Charter of Fundamental Rights and Freedoms (2000), and in the commitment in the Treaty of Lisbon for the Union itself to become a signatory to the European Convention on Human Rights. These commitments become binding upon in Union Law, as each piece of legislation must attend to these fundamental principles (although the rather open nature of these principles is discussed elsewhere in the pages). So, whilst the guiding authority to legislate is to produce economic harmonisation, this has to be achieved with due regard to human rights principles.

Article 168 (TFEU) requires that the EU, in legislating, must consider public health issues. This, to some extent, is obvious; public health has no geographical boundaries, and in a Union that has as its central principles the freedom of movement of its citizens, there are immediate practical public health issues to consider. Member States share their sovereignty about public health duties with the EU (whilst retaining sovereignty over private health matters, for example, the organisation of their domestic health systems). However, the question remains, what is public health? And to some extent, as medical research is a large part of the collective research agenda of the EU framework programmes and Horizon 2020, the question becomes a peripheral question for RECs.

General points about European Union Law

1. "Directive"

There are three types of primary legislation that the EU institutions can produce: "Regulation", "Directive", and "Guideline".

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Regulations have "direct effect" in Member States' law, and in the law of countries in the European Economic Area - from the day that they come into effect as described in the Regulation, a Regulation is, as it stands, part of the law of the MS or EEA jurisdiction without further implementation. They used to reflect specific areas with a high level of political and practical agreement, and high harmonisation goals.

Directives have "indirect effect". MS and EEA are bound to implement the Directive, but they must translate it into their own law (by primary or secondary legislation, etc.) to give effect to the Directive. The European Commission is charged with ensuring that the Directive is implemented (which it largely does by responding to complaints first at a political level - letters to the national government - or through a case at the European Court of Justice. Directives traditionally cover a wider area than Regulations, and tend to have more areas of discretion for the MS; there will be issues, perhaps reflecting political disagreement in the legislative process, where there is no general agreement about, for example, how far a measure should go in relation to particular aspects of the issue, and in that case the MS is given space to accommodate its own view. However, this is only discretion within the strict limits set by the Directive. The Directive should not be considered 'optional'; a Directive is binding on the MS and EEA.

Guidelines are optional, reflecting a political wish in the Union, but insufficient consensus to produce harmonising, binding legislation.

2. "Recitals" and "Articles"

Directives and Regulations have a standard form - first a series of propositions "recitals", starting "whereas" and individually numbered from 1-n, and then a set of rules "Articles", separately numbered from 1-n.

Recitals start with the legal authority and something of the legal context of the Directive or Regulation, they then relate to the Articles, giving an indication of the reasoning for each Article. They are not specifically tied to the relevant Article - certainly not on a 'Recital 1 relates to Article 1' basis; there could be two or three Recitals per Article - Articles tend to follow a pattern - authority and context, broad purpose, definitions of terms as they are used in the particular Directive or Regulation, major law, other aspects included in the legislative opportunity, implementation, and knock-on effects for other legislation.

Whilst Articles are clearly binding, there is an interesting debate about the effect of the Recitals in Law. They clearly have a different purpose in the creation of the legislation and cannot be used directly in the same way as Articles, and they do not receive the same level of detailed attention in the process, they cannot be dismissed as legislative 'junk'. They have an interpretative purpose and give insight about the intention behind Articles.

3. From the proposal of the European Commission and the 'ordinary legislative process'

Under the Treaties, particularly as they are strengthened by the Treaty of Lisbon amendments, legislation is now mainly conducted through 'Ordinary Legislative Process' or the 'co-decision' process. The European Commission is the institution that has the right to propose (draft) legislation for the Union (this can be of its own volition or at the suggestion of the European Parliament or European Council or Council of Ministers). Once presented, both Parliament and Council have to agree the legislation - through a process of, normally, two 'readings' in each place, but essentially through a process of lobbying and political negotiation (that may be more or less to do with the specific issues in the proposed legislation). It differs from legislation that is created by Council with only the opinion of Parliament - which was the norm at the beginning of the European project, but with increased arguments for democracy through the Parliament, has diminished largely to matters that require new money from MS or where the competence (the ceded authority) of the Union is in question or where the Union does not have competence. The further part of the process is taking the opinion of two committees - the European Economic and Social Committee and the Committee of the Regions.

Questions for Discussions

How far is an understanding of the process of the creation of EU Law, and the operation of EU Law important to RECs operating in or with the Member States of the EU?

How far should the work of RECs seek to harmonise to follow the EU agenda?

What are the areas where greater harmonisation could be achieved?

What might the role of RECs be in the legislation process?

How far should RECs lobby at the national and European level on issues in which they operate?

How far should RECs seek to draw attention to perceived gaps in the legislation relation to the harmonisation of the governance of medical research in the European Commission?

What is the relationship between European governance of medical research and international governance of the same?

Further Reading:

Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:C:2010:083:TOC>

Hervey, T. and McHale, J (2015) *European Union Health Law: Themes and Implications* Cambridge University Press, Cambridge

Mossialos, E., Permanand, G., Baeten, R., Hervey, T. *Health Systems Governance in Europe: the Role of EU Law and Policy*. (2010) Cambridge University Press, Cambridge.

Pinder, J., Usherwood, S. *The European Union: A Very Short Introduction*. (3rd edition). (2013) Oxford University Press, Oxford.

2.4.2 Relevant international and European law

Each link will open in a new window.

Universal Declaration of Human Rights

<http://www.un.org/en/documents/udhr/>

International Covenant on Economic, Social and Cultural Rights

<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>

European Convention on Human Rights

http://www.echr.coe.int/Documents/Convention_ENG.pdf

EU Charter of Fundamental Rights and Freedoms

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF>

African Charter on Human and People's Rights

<http://www.achpr.org/instruments/achpr/>

Helsinki Declaration

<http://www.wma.net/en/30publications/10policies/b3/>

Universal Declaration on Bioethics and Human Rights

http://portal.unesco.org/en/ev.phpURL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

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Universal Declaration on Human Genome and Human Rights

http://portal.unesco.org/en/ev.phpURL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

International Declaration on Human Genetic Data

http://portal.unesco.org/en/ev.phpURL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

Oviedo Convention - Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

<http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>

Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research <https://rm.coe.int/168008371a>

Data Protection Directive 95/46/EC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>

General Data Protection Regulation 2016/679

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679>

OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data
<http://www.oecd.org/internet/ieconomy/oecdguidelinesontheprivacyandtransborderflowssofpersonaldata.htm>

Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data
<http://conventions.coe.int/Treaty/en/Treaties/html/108.htm>

Clinical Trials Regulation 536/2014
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.158.01.0001.01.ENG

Clinical Trials Directive 2001/20/EC
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF>

Good Clinical Practice Directive 2005/28/EC
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF>

Protection of Animals Used for Scientific Purposes Directive 2010/63/EU
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>

Agreement on Trade-Related Issues of Intellectual Property (TRIPS)
http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

European Patent Convention
<http://www.epo.org/law-practice/legal-texts/epc.html>

Directive on the Legal Protection of Biotechnological Inventions 98/44/EC
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>

Treaty on European Union and the Treaty on the Functioning of the European Union
<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:C:2010:083:TOC>