CHAPTER 9

A FRAMEWORK FOR REVIEWING DUAL USE RESEARCH

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ABSTRACT

'Dual use research' is research with results that can potentially cause harm as well as benefits. Harm can be to people, animals or the environment. For most research, harms can be difficult to predict and quantify, so in this sense almost all research could be seen as having dual use potential. This chapter will present a framework for reviewing dual use research by justifying why the responsibility for approving and conducting research does not sit with Research Ethics Committees (RECs) alone. By mapping out the wider research landscape, it will be argued that both responsibility and accountability for dual use research sits on the shoulders of broader governance structures that reflect the philosophical and political aspirations of society as a whole. RECs are certainly still important for identifying potential 'dual use research of concern', and perhaps teasing out some of the details that may be hidden within research plans or projects, but in a well-functioning system should never be the sole gate keepers that determine which research should, and should not, be allowed to proceed.

Keywords: Dual use; dual use research of concern; Research Ethics Committee; Institutional Review Board; research governance; research integrity

'Our need will be the real creator'. Plato

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INTRODUCTION

The general response that humans have to hardship is to be innovative. Nature, in the sense of environment and disease, has been a strong driver of innovation, but so too has human conflict. As research is often the foundation for innovation, it is no surprise to find that research agendas are often based upon addressing threats, be they viral pandemics or conflict between nations. While it is no bad thing that the narrative of scientific humanism (either secular or religious) is broadly optimistic, it is naïve to think that research agendas can be separated from the context of conflict. Understanding and making sense of this context is an important role for research ethics.

Perhaps the most obvious, or at least well known, manifestation of research ethics comes from the activities of Research Ethics Committees (RECs), also known as Institutional Review Boards (IRBs) in US-influenced countries. These committees are made up of scientists, lawyers, philosophers and lay-members, whose role is to analyse research plans and come to judgements on ethical issues. Historically, the need for these committees (henceforth referred to as RECs) has been driven by the need to protect participants, especially following atrocities committed during the Second World War. Their establishment in the medical sciences is most famously described in the Declaration of Helsinki (WMA, 2013), but over the last 50 years or so RECs have also become well established in most other research areas. This has brought about challenges especially in fields where methodologies, culture and sometimes philosophy differ from the 'medical model' of research. However, although still viewed as a problem by some in the humanities (Lincoln & Tierney, 2004), the issues highlighted by the expansion of RECs have been broadly positive as it has helped to move the philosophy of research ethics beyond just considering the physical protection of research participants, to also encompass the support of researchers and good research practice (Trace & Kolstoe, 2018).

While this has been a broadly positive development, it has created overlap, and sometimes conflict, between the role and contribution of RECs and other structures within the research community (such as professional bodies, peer review, grant committees, etc.) (Kolstoe & Carpenter, 2019). For instance, in recent years concerns relating to 'research culture' (Wellcome Trust, 2020) and 'research integrity' (Vitae, 2020) have become important. Likewise concerns relating to results reproducibility, publication practices and quality control (through peer review or otherwise) have increasingly been raised (Munafò et al., 2017). Is it feasible or desirable for RECs to play a role in governing such things? If not who should be responsible?

These issues have provided a strong catalyst for attempts to plot out the social and institutional structures that underpin research so as to better understand where accountability and responsibility lie, or should be made to lie (Science and Technology Committee – House of Commons, 2018). This process has also forced greater clarity in understanding who within society is responsible for different aspects of research agendas, and likewise defines the limits of all groups, structures and organisations that are engaged with research – including RECs (Moore & Donnelly, 2018).

A case in point is the development of offensive Chemical, Biological, Radiological and Nuclear (CBRN) weapons (sometimes euphemistically referred to as 'deterrents' or 'capabilities'). The indiscriminate destruction caused by such offensive technologies created the need for internationally enforced treaties and agreement prohibiting many aspects of research that might lead to the refinement of such weapons. These agreements are codified in law, and thus become a formal, legally enforced, charter adhered to by most institutions and others involved in research activities (NTI, n.d.). While the socially or scientifically aware REC member may remain alert to the possibilities of research in these areas, it is seldom the formal role of RECs to identify and form judgements on such research, simply because such research is limited by treaty, law or policy well before it gets anywhere close to a REC review.

However, CBRN research focussed on offensive weapon capabilities, and subject to international agreement, presents an overly simplistic case. There are plenty of other research projects that are not directly focussed on creating new weapons, but which may develop technologies or knowledge that could be applied in multiple ways – both helpful and harmful. Such technology may be psychological, biological, cyber or other types of research with the so-called 'dual use' capacity (Kavouras & Charitidis, 2019). Who, or what structure, within the research landscape should be responsible for reviewing the underlying research activities and determining whether they should or shouldn't be allowed to proceed? Is this a role for RECs?

In the following, I will argue that making judgements on so-called 'dual use' is not a role for RECs. While I will concede that REC members should remain alert for *any* potential ethical issues that may arise from a specific research protocol, I will present a framework that places accountability for 'dual use' applications well upstream of the REC review. In order to justify this framework, the chapter will first define research ethics, and then map out how RECs fit into the broader research approvals landscape. This is important because researchers (and often even REC members) find the research approvals landscape confusing and often repetitive, especially when it comes to identifying who has responsibility and accountability for different aspects of research. This is particularly pertinent for considering dual use issues that could be argued as representing some of the most harmful results of research. Following this mapping exercise, the chapter will provide some practical advice for RECs who may be concerned about potential applications of the research they review by briefly considering (using examples) how RECs can better expand the idea of 'dual use research of concern' (DURC) (EPA, 2016).

A FRAMEWORK FOR DEFINING ACCOUNTABILITY AND RESPONSIBILITY IN RESEARCH

The term 'research ethics' is generally used quite broadly to encompass all ethical considerations pertaining to research, but the remit of RECs is often significantly

narrower. According to the Declaration of Helsinki, the role of a REC is to specifically consider research protocols:

> The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. (WMA, 2013)

And according to the World Health Organisation (2009):

> The main responsibility of a research ethics committee is to protect potential participants in the research, but it must also take into account potential risks and benefits for the community in which the research will be carried out.

These declarations make it clear that REC review is situated at a particular point of time within the research process: RECs consider research plans once detailed protocols have been developed, but prior to the start of data collection. This is the reason why RECs are referred to as IRBs in many countries, perhaps trying to distinguish between committees that are established specifically to review research protocols in this defined way, and those that are set up to discuss wider ethical issues that may impinge upon multiple research protocols. This distinction is important because the review of detailed protocols is a complex task requiring specific technical or methodological expertise (or at least insight), while the review of wider ethical issues is often more abstract and less immediate. For this reason, it is important to distinguish clearly between the role of RECs reviewing protocols and the role of other groups within the research landscape that have been established to consider wider ethical issues framed in terms of which types of research 'should', or 'should not', be allowed to occur.

Asking this latter question of what research 'should' or 'should not' occur is a complicated matter that touches on other areas including politics, philosophy and law. As research is essentially a community effort to discover more about the world, or address specific problems, it should be no surprise that communities of experts play an important role in establishing the priorities within their areas of interest. This may happen in a number of different ways, but primarily occurs through the distribution of research funds in the form of research grants. The effect of this is to essentially remove the ultimate accountability for the topic of research from the researchers themselves, in favour of placing it upon the community that commissions the research through deciding the funding allocation. This works in different ways in different contexts (both national and scientific), but does mean that the decision of what should or shouldn't be the subject of research becomes heavily influenced by the wider value-forming processes that specific nations or cultures choose to employ when making funding allocations. However, it is important to note that while this ultimate accountability rests with society, from a pragmatic perspective the responsibility for making decisions about specific research projects as they are subsequently (often following funding decisions) developed and implemented lie with others in the system.

To better understand how these more detailed responsibilities are distributed it is helpful to consider three related, but distinct, concepts that are common to many research systems: (1) research integrity, (2) research governance and (3) the role of the REC. Understanding these three roles is key to understanding how dual use research should ideally be handled.

Research Integrity

Should an individual researcher ever create something, or do something, that may harm others or the environment? It is helpful to consider the issues surrounding this question under the heading of research integrity, or more specifically the moral integrity of the researchers themselves.

However, in doing so, it needs to be acknowledged that the word integrity is often used in two senses in relation to research. Integrity of *research* refers to issues of trustworthy methods and reproducibility of results, while integrity of *researchers* refers to the character traits of the individual(s) conducting research. But, on reflection, these two uses can be collapsed into a single practical definition wherein a researcher, who shows the character traits of integrity, will produce research that also has both methodological and structural integrity. Thus, the best way to understand research integrity is to simply consider the attitudes and values of researchers themselves because if they are appropriate, the outcome of the research can also be considered to have integrity. This is clearly important when considering dual use research because it suggests that researchers themselves, if showing integrity, may draw lines as to what they will, or will not, be prepared to do.

Surveys of researchers and research stakeholders have listed the key traits of a researcher as being rigorous, accurate, original, honest and transparent (Joynson & Leyser, 2015). Ongoing empirical work has sought to further define, refine or even weigh these desirable traits (Wellcome Trust, 2020), but for the purposes of this chapter, research integrity will be taken to mean the *character traits of researchers that allow the production of reliable and trustworthy research results*. Given this definition, it becomes clear that research integrity is developed through research training and experience. Such training commences in school science lessons, continues through undergraduate study, and then perhaps most critically, is informed by the mentorship that is provided while studying for higher research degrees and subsequently working within professional research teams, often subject to the principles and values of membership in professional research associations.

While such specialist experience is probably the main driver for developing the traits required for research integrity, wider personal experience based upon upbringing and other psychological factors also need to be considered as influential to the attitudes and traits shown by researchers. As a consequence, and as with any other population of humans, while there may well be some traits that are common to all or most researchers (perhaps rigorous, accurate, original, etc.), there are also likely to be legitimate differences of opinion between researchers who may equally be considered to be acting with integrity so far as their actual research conduct is concerned.

One area of difference concerns the reasons or motivations behind why an individual may be conducting research in the first place. Here, some people may be driven by a strong desire to create research that helps others, others may be driven by curiosity, others by competition or the search for novelty (Joynson & Leyser, 2015) and still others perhaps by a feeling of loyalty towards their society

or way of life. Such differences are to be expected, but do mean that they may manifest as different opinions as to what research is, and is not, acceptable. In this sense, for any given researcher to act with integrity, they must also act in line with their wider values, thus creating a legitimate difference between researchers.

Given this definition of research integrity, it is entirely reasonable for researchers to disagree with each other as to the appropriateness of different research projects. But, the important thing to note, is that it is not 'research integrity' itself that prohibits certain types of research, but rather how research integrity is manifest in different individuals due to the complex interaction between specific research values and then wider personal or cultural values.

These differences are broadly positive because healthy debate protects against extremism. In general, researchers and scientific communities are particularly strong at convening conferences, forums and other fora to discuss (often heatedly) differences of opinion. This is the reason why professional societies exist. Their influence is particularly important because they lead to the development of codes, declarations and even the laws through which research is governed.

However, one critical observation is that while such discussions are often referred to as 'research ethics', they often occur within the context of broad professional and even political debate. Committees may well be set up to examine specific issues and create specific 'ethical' guidance, but these are not RECs in the sense described above. While it is entirely reasonable that REC members may want to get involved with such broader ideological discussions, especially if establishing precedence based on research protocols that have been reviewed, the main role of RECs is to keep their focus quite narrow, focussing specifically on the specific project protocols they are given to review. Confusing this specific role with wider issues regarding research or researcher integrity detracts from the value that RECs add to the research ecosystem.

Research Governance

Distinct from research integrity that, as argued in the previous section, focusses on the moral values of researchers themselves, research governance is the name given to the processes, policies and laws that govern research programmes and projects (Kolstoe & Carpenter, 2019). In this broad sense, review by a REC is a necessary part of the research governance process, but RECs are not the whole research governance process, and nor do they give final 'approval' for research to occur. Although research can often not occur unless a REC favourable opinion has been granted, it is in actual fact the employer/research sponsoring organisation that gives the final go ahead or approval for activities conducted by their researchers. This is not well understood and causes confusion for many researchers who think (mistakenly) that the role of a REC is to provide overall approval for research. Viewing RECs in this way is inaccurate because it obscures the important point that in order to provide a balanced ethical opinion, RECs should have a degree of independence from both the researcher and the establishment that is funding/conducting the research. While of course bias will always creep in to any decision making process, one of the aims for a REC is to try to acknowledge, and therefore

address, as many biases as possible. A helpful analogy may be that RECs should be to institutions as peer reviewers are to journal editors. Similarly while editors, not peer reviewers make the final decision as to whether a manuscript can be published, it is research governance systems, not RECs, that make the final decision as to whether a research project can go ahead. This is true even if in practice an unfavourable opinion from a REC will often stop most research projects from proceeding.

Maintaining this independence does not mean that institutions should not play a role in establishing and supporting RECs, but rather that this support should be mainly procedural and administrative. Institutions must support the *REC process* without interfering with the REC's *freedom* to review and come to opinions on research protocols. Quite often this can be achieved by ensuring a certain proportion of members are 'independent', meaning not otherwise employed, or subject to direct line management, from authority structures within the institution or organisation seeking to conduct the research. How independent 'independent enough' is, and how many of such members there are on a committee, is a matter of opinion and perhaps policy. While it would clearly be a problem if independent members were directly antagonistic towards researchers or the research organisation, at the same time it would defeat the object of independent review if REC members always approved every idea that came before them because of close ties with the sponsoring institution, company or organisation.

The next section will discuss the role of RECs in detail, but for the purpose of understanding research governance, the key point is that REC review may be mandated by governance policy, and RECs may well be supported or directed within governance structures specifically through guidance created for them, but RECs should always be one step removed from these governance structures so as to allow freedom in ethical decision making (Iphofen, 2017). This independence is critical particularly if the subject or topic of the research is contentious.

But why have this independence? Surely it will speed up research preparation if RECs are forced to follow the lead from the institution that they support? While this is undoubtedly the case, the main argument for REC independence comes from a 'due diligence' perspective. Insurers, trustees, donors and independent funders are keen to ensure that institutions, be they universities, government departments or private companies, are trustworthy and adhere as close as possible to their established mission, business task or objective. Where this involves research, given the high propensity for waste (Chalmers et al., 2014), it is very much within the interests of the organisation to build in as many independent checks as possible, one of these being independent REC review. A good research governance policy will therefore provide clear guidance as to how a sufficiently independent REC can be established, alongside perhaps the framework within which it is expected to function.

Establishing a governance framework coupled with guidance for REC review is absolutely critical especially when considering potential dual use research. For instance, if the REC is established within an organisation – such as the military – where the overall aims and objectives are defence related, this framework and guidance should make it absolutely clear to the REC that they should expect

to review military related research. Likewise, RECs in organisations that have a stated non-military aim should not expect to receive research that has direct military application. While projects may, from time to time, slip through, it is actually a governance responsibility upstream of the REC review to decide what projects are broadly within the remit of the specific organisation. RECs can then be free to focus on the details of the research protocol itself, rather than worry about whether or not the organisation should be carrying out this type of research in the first place.

Role of RECs/IRBs

So far in this chapter, I have argued that the ethical and moral debates surrounding dual use research belong upstream of the REC review – primarily as part of the discussions surrounding funding allocation, broader subject level research integrity considerations (often at a funding or professional society level), but then supported by governance processes and guidance that should be screening out, or making decisions about, which potential research projects should not proceed well prior to review by RECs. But even with these processes in place, how should RECs consider or at least approach potential dual use research?

The first thing that RECs need to do is have a clear idea of the policies and guidance produced by their hosting organisation, along with the governance structures within which they are expected to operate. If, for instance, the organisation hosting the REC has a remit for defence research – such as in a defence establishment – it would be inappropriate for the REC to object to such research on principle. This does not mean that the REC shouldn't feel free to raise concerns, but rather that such concerns should be pursued at a relatively high level perhaps as a parallel process to the review of specific research protocols, with the aim of creating or modifying guidance so as to deal with future occurrences of the situation at hand (more details of how this might work are provided in the final section). While policy level decisions are under consideration, RECs need to ensure they comply with extant policy and guidance as a matter of due process. If individual members of RECs find this difficult from an integrity perspective they should discuss this with the committee, and potentially abstain from decisions or even resign their positions if they feel morally unable to agree with the overall governance structure and guidance within which the REC is expected to operate. To summarise, it is not the RECs role to determine the governance structures within which they operate, although they can feedback their views on whether current policy is effective and thus hopefully engage constructively to review and improve policy over time.

Secondly, the REC role is not to judge the personal integrity of the researchers. Whereas the competency of researchers to conduct the proposed study is clearly an issue for the REC, wider judgements on the integrity of the researchers themselves are not a matter for the REC. This is because, and as mentioned above, research integrity is a complex mix of personal, professional, societal and even political values. RECs need to understand that researchers may hold a wide range of views as to the types of research that should (or should not) be

conducted. If the REC is concerned by these broader opinions or attitudes (in contrast to specific concerns regarding the protocol under review) these should again be raised parallel to the reviewing of research protocols with professional bodies, or by pursuing dialogue with specific research communities or governance structures.

This distinction between making a decision on a protocol using extant governance policy and guidance, and raising broader integrity or governance concerns at a higher level can feel like a very limiting compromise imposed upon REC members especially if they have specific concerns about the application of research programmes or ideas. However, it must be acknowledged that predicting the ultimate use of research findings, and also making character/integrity judgements about specific researchers, is a very difficult task. If RECs were expected to do this for every project that they reviewed it is unlikely that they would come to any decision or have time to consider other important aspects within their remit (such as the protection of research participants). As a consequence, the REC must make the pragmatic decision to focus on the concerns raised by the specific project at hand so as to come to an expedient decision and then, if REC members still feel strongly inclined, pursue any wider concerns about issues of dual use or similar with those who can influence or change both governance policy and/or professional guidelines.

In this respect the membership, and attitude of the members of RECs is critically important. Alongside having the requisite (as defined by the relevant governance policy) mix of expert and lay members, the members also need to understand that their role is not to create new policy directly, or influence the values of research communities on the fly as they review specific projects. While of course REC members will pick up key experience that will be valuable in the subsequent creation or modification of policies, guidelines and in some cases even laws, this input should be saved for the correct time, which is seldom during the REC review of a specific project protocol.

The only exception may be when REC members, due to their experience, note a legal issue. While the responsibility for ensuring legality and obtaining legal opinions is a research governance issue (as this is where the accountability ultimately sits), it can be helpful for a REC to flag to the research team that they may need to look into the legality of some aspects of the proposed work. A good example of this comes from data protection legislation (and particularly confusions cause by the EU's General Data Protection Regulation) wherein RECs may be more familiar than the researchers as to the best ways for the required information to be presented.

DUAL USE RESEARCH OF CONCERN

The complexities of trying to determine the potential for research specifically within the biological sciences in relation to the creation of potentially weaponisable biological organisms has recently led to the term Dual Use Research of Concern or `DURC' being used (EPA, 2016). Although the term has primarily come from the life sciences, it is useful more broadly as it distinguishes between a

set of research that may potentially have more than one use which, as mentioned in the introduction, could include almost any research, and the set of research that causes specific concerns *due to* this dual use. Since some research may move in and out of the category of DURC depending on the way that it is governed, or alternatively it may not be clear until after the protocol has been developed exactly what the concerns might be, it is not unreasonable for RECs to play a legitimate role in highlighting DURC to both the governing institution and more widely if necessary. However, while playing an important role in initiating such conversations (with individuals from RECs perhaps legitimately becoming involved in subsequent debates) it must be reiterated that the REC role is very much to initiate these discussions, not develop ad hoc policy or guidance. The REC will therefore often need to accept that there is no policy reason why a specific project under consideration should not go ahead at that time, even if the REC has broader concerns that the extant policy environment is not suitably dealing with the specific DURC. The REC does, however, have an important subsequent duty to flag the issue so as to initiate policy change.

One, perhaps fairly straightforward, example where a REC might play an important role in identifying DURC would be the situation where, when reviewing a protocol, the REC considers that some of the information being gathered by the researchers (if put in the public domain) might be useful for planning or implementing a terrorist attack. In this situation, the REC would be acting well within its remit to ask the research team whether they had considered this possibility, and perhaps ask for a written response detailing how the research team will mitigate against this risk in much the same way as the REC would ask for details of the mitigation of any other risk. If the REC is not satisfied with the subsequent response it could provide an unfavourable opinion (again in the same way as when unsatisfied by responses on any other topic) and then feed its reasoning back to the organisation responsible for the research. While not directly proposing solutions, by serving as a blocker to the research the REC would be flagging the issue as a serious, research stopping, concern that requires further thought by others within the research system and perhaps the development of new guidance/policy.

A second, more complex, example of DURC might be in the development and testing of a novel technology (such as a radar system) that alongside civilian applications may also be used to increase the lethality of a weapons system. Here, the REC would initially need to consider whether the support for such research was allowed under the governance framework within which both the REC and the research team operated. If, for instance, the REC was situated within a university that had a clear commitment not to engage with research that has a clear lethal potential, the REC would be acting well within its remit to provide an unfavourable opinion for such a project on the grounds of governance policy. In this case, the REC would also need to flag to its appointing authority that this research should not have been allowed to reach the REC in the first place. Conversely, if the REC was instead situated within a governance structure and organisation/institution with a clear military or defence remit, it would be unreasonable for the REC to provide an unfavourable decision on the same grounds. This is not to say that REC members should not express specific concerns about

how the research may be conducted and/or applied, but rather that such concerns should be based upon the premise that there was no reason, per se, that lethal research should not be conducted due to it being acceptable under current policy/governance arrangements. The REC may well still decide to provide an unfavourable opinion on other grounds such as risk to participants, or even concerns that the resulting technology may cause unacceptable injuries to enemy combatants, but the justification for this unfavourable opinion would need to be specific to the protocol/application rather than based upon a blanket disapproval for research of this kind.

In these examples, presuming unfavourable opinions from the REC, what happens next would be down to the actions of the research or governance team. While these teams may well be frustrated by the REC decision, they are in a much better position to initiate further discussions within the research integrity and governance realms, simply because as researchers in the field they are both members of the relevant communities and also (hopefully) experts in the scientific/methodological area. As a consequence, they are far better positioned to raise the issue, participate in discussions, and hopefully come up with an acceptable solution that could subsequently be supplied to the REC in the form of guidance should another, similar, protocol be presented for review. The solution could, for instance, take the form of a new policy, process or procedure endorsed by the field (or at least sponsoring institution), demonstrating how they acknowledge the original issue flagged by the REC, and detailing an agreed course of action. While individual members of the REC may still feel uneasy, and of course the REC would still be able to ask further questions if needed, demonstrating that the research fits within formal guidance endorsed by the sponsoring organisations, and even potentially the field of research, should go at least some way to allaying the RECs concerns.

If, however, a REC continued to feel strongly about certain types of research (either methodologies or programmes), and the solution did not seem to evolve through the process outlined above, the onus would then be on the chair of the REC to raise the issue with the authority appointing the REC, perhaps directly asking for guidance for how to deal with the issue should/when it occurs in future protocols. As a consequence, the solution for both the REC and the researchers would be improved guidance ideally agreed by both researchers and the authority governing the REC.

CONCLUSION

Almost all research has the possibility for dual use, some of which may also cause legitimate concern. Considering this potential is primarily a role for research communities, or at least the communities that are responsible for commissioning, funding and governing the research in the first place. Arrangements can then be made through the use of guidance in the form of professional (integrity) standards, and more explicit governance policies or arrangements. Ideally any potential for DURC would be identified and dealt with long before a research

protocol was presented to a REC. However, should a REC have concerns regarding DURC in a protocol under review, they should first look to see whether this DURC was considered acceptable under the committee's terms of reference. If not, the REC should seek clarification with the researchers as they would any other concern before providing an unfavourable opinion. As with any other unfavourable ethics opinion this should give the researcher cause to discuss the concern within their research field and governance contacts. If the research field or governing institution/sponsor disagreed with the REC, such discussions should lead to new or better guidance that could be presented to the REC alongside any future applications of a similar nature. Although the REC should not formally take part in these discussions (as such discussions are not within the remit of the REC reviewing specific protocols) it would be well within the responsibility of the REC chair and other members to take part in subsequent debates in a personal capacity, so as to help provide new guidance on the DURC in question that could be then be applied during future REC reviews.

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