

## GUIDES TO UNDERTAKING RESEARCH

### 4.1 Research Integrity

*Integrity : the quality of being honest and having strong moral principles [Oxford English Dictionary]*

There are strong motivations for physician-scientists to publish research papers, including recognition and career advancement, gaining a qualification or consideration for a good post. It is obviously not good to view a piece of work solely as another publication for the CV, nevertheless, such motivations to publish cannot be wished away, and it is important to recognise how it can lead to actions that can violate the integrity of the work.

In most contexts it is useful to think of research integrity as broadly equivalent to ‘honesty’, but in practice research integrity goes well beyond that. Research integrity carries with it an active requirement to ensure there is no deception, intentional or inadvertent, and also that the impulse to publish and advance does not lead to other unethical behaviour such as lack of care for patient personal privacy or agency.

To ensure high integrity it is commonly agreed that it is not enough to rely on a researcher’s intent or goodwill (though that is important), but we need procedures and cultural norms that reliably detect and prevent undesirable behaviour. When we think of deception we should remember the easiest person to deceive is ourselves; scientific methodologies help minimise this and prevent us from credulously passing on falsehoods. Similarly, in human research ethics there are in place processes and procedures that oblige us consider deeply the risks we may inadvertently expose a patient to. We need to use such approaches and if we do not, we are not displaying proper integrity even if we do not mean to be bad.

#### *Integrity and ethics*

Integrity also implies a steadfast attachment to a set of ethical principles. This carries with it in medical research a severely practical consequence, the obligation to apply to an ethics committee for permission to pursue a study if it concerns a human or animal subject. This partly converts an exercise in ethical behaviour into form filling, which is not fun, but has the positive effect of pushing the applicant to scrutinise carefully the important aspects of their work and to use standardised methods regarded as ethically sound. Research ethics processes thus reduce risks that are not at all obvious at the outset of a project, such as risks around insecure storage of personal electronic medical data.

#### *The importance of not making things up*

Presenting or publishing data that has not been honestly generated or that has been made up for clearly fraudulent purposes constitutes serious research misconduct. Science, in theory, should not need policing since a finding that is wrong cannot be replicated so does not find its way into the accepted *corpus*. In practice there are usually severe consequences of fraudulent data, including the waste of time and effort to replicate it and the danger that clinical treatments based on fraudulent data pose to human health. Faked data usually involves the misuse of research funds that supported the researcher, so it is also a civil legal matter and may be a criminal matter. However,

data fraud invokes such visceral dismay amongst scientists and physicians mainly because it betrays the implicit pact to trust each other to be always open, honest and receptive to criticism. Scientific institutions thus have strong ethical rules that render this severe breach of trust an employment-terminating matter at the very least. Such a rupture in this system of trust causes reputational damage to all involved, and betrays the trust that non-scientist taxpayers and charity-funders place in scientific institutions.

#### *The importance of not making things up even a little bit*

While fudging or copying a small inconsequential figure or numerical data may not seem important, it really is. No medical or scientific institution can tolerate even the suspicion of dishonesty, so it is a central part of the culture of science that we learn to police ourselves in minor things, and we cannot function as scientists if we allow ourselves to lapse in this regard. This is not because these minor things are not minor (they may well be), rather it is because it is a failure of self-policing, as well as a failure to adhere to an ethic that so critical to the research endeavour. In clinical research this can even include accepting incomplete datasets as if they were complete, or knowingly analysing datasets that may not have been rigorously or prospectively collected as described

#### *What if it is someone else?*

A really thorny problem arises if we suspect that someone else may be lacking in research integrity. This needs to be tackled with sensitivity as it would be in any other walk of life, as suspicions can be wrong. It may be best to discuss misgivings with the person involved to ensure any problem is fixed and not repeated. Preventing someone from acting improperly in a minor matter is doing them a big favour if it prevents the consequences of a worse infraction (e.g., publishing fraudulent data) later on. It is certainly advisable, and it may be mandated, to

consult with a mentor or an official with responsibility for research integrity. The path taken is very context dependent and depends on the guidelines of the institution (they all have them) so it is best to consult these.

#### *Human research ethics committees*

No committee can oversee clinical activities in detail, so various approaches have been developed to deal with these issues. From a researcher perspective, it broadly means training and ethics application forms. Many issues around research ethics arise from a lack of awareness of the researcher as to what is expected and is permissible. Training, form completion and ethics committee engagement can address these issues effectively, but they also enforce openness about researcher intentions through the requirement to document them beforehand.

#### *Study design*

Less often considered under the heading of research integrity is the requirement for good study design. A poorly designed, underpowered and badly analysed study runs a severe risk of generating misleading data, due to biases and random chance. This must be avoided. There is also an aspect of data analysis formally (and rather curiously) named “Vibration of Effects” which is the ability of a dataset to be analysed by many different statistical tests to give a range of different outcomes, meaning they lack robustness. This needs serious thought.

#### *Conflicts of interest*

This is an important issue defined as researchers having some financial or other strong interest in the outcome of the work. This can at the very least lead to biases in data interpretation. Where these conflicts cannot be avoided the main recourses are to minimise them where possible, and to declare them openly and let others decide if this irredeemably biases the study conclusions.

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**Version** 2.1 (Nov 2020)

**Thanks to** Professor Thomas Hugh and Dr Richard Piper for reviewing and critiquing this article.

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