

UNIVERSITY OF YORK

Federal Wide Assurance Institutional Review Board Procedures

To avoid subsequent delays, PIs requiring Federal Wide Assurance compliance are encouraged to contact the Research Integrity Officer in the Research Strategy and Policy Office as soon as possible, for informal guidance and support prior to submitting their application for ethical review

1. *Committee responsible for undertaking ethical review under the University's FWA*
 - (a) The Institutional Review Board registered under the University's Federal Wide Assurance is the [Health Sciences Research Governance Committee](#). This Committee is responsible for:
 - Carrying out ethical review and approval of projects which require FWA compliance;
 - Continuing review of the ethical conduct of projects which require FWA compliance; in accordance with:
 - the University's Code of practice and principles for good ethical governance and its stated principles protecting the rights and welfare of human subjects;
 - the requirements set out in the US Department of Health and Human Services (HHS) Protection of Human Subjects regulations at 45 CFR part 46 (the 'Common Rule').

The Institution number is: IORG0008279
The FWA Assurance number is: FWA00022439
The IRB identification is: IRB00009924 University of York IRB #1
 - (b) Secretarial support for the business of the Institutional Review Board will be provided by the Research Integrity Officer, liaising with the Senior Research Secretary for Health Sciences.
 - (c) Details of meetings and deadlines for submission can be found via the above link. Submissions should be emailed to the Senior Research Secretary for Health Sciences, copied to the Research Integrity Officer.
2. *Ethical review and approval*
 - (a) If the PI is based in a department other than Health Sciences, he/she must initiate in good time a conversation between the Chair of the department's usual ethics subcommittee and the Chair of the IRB in order to agree the process. This may include:
 - Deciding on the appropriate form to use for the submission;
 - Deciding whether full or expedited review procedures are to be followed according to the degree of risk (see below);
 - Where full review is required, deciding whether a member/members of the department's usual ethics subcommittee should attend the IRB meeting for the item in question to provide specialist advice.

The Research Integrity Officer will support co-ordination of the appropriate arrangements.
 - (b) The PI must provide sufficient information within the submission to address FWA requirements explicitly (see sections 46.111, 46.116 and 46.117 of the Common Rule: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), and enable the IRB to assure

compliance easily. A supporting checklist is available from the RSPO to assist with this and may be enclosed as part of the submission. Please note that if the research involves any of the following:

- pregnant women, human foetuses, neonates
- biomedical and behavioural research involving prisoners
- children

the PI must inform the Research Integrity Officer and Research Grants and Contracts as soon as possible so that they can check whether the funder also requires compliance with subparts B-D of the Common Rule (as applicable) – see above link - as part of the conditions for approval under FWA. If so, this must also be demonstrated as part of the application. In the event that a proposed project involves prisoners, the Research Integrity Officer, working with the Chair of IRB, will ensure that the additional requirements regarding representation are met.¹

- (c) Except when expedited review procedures are followed, the IRB must meet in person to review projects which require FWA compliance. The majority of registered members must be present, including at least one of those registered as ‘Non-scientists’ according to the HHS definition (list held by the RSPO). Approval must be subject to a formal vote, carried by the majority of those present.
- (d) Expedited review procedures may be used at the discretion of the Chair in relation to the following categories of research: www.hhs.gov/ohrp/policy/expedited98.html where minimal risk is involved², and/or to consider minor changes in previously approved research during the period (of one year or less) for which approval is authorized. However, research activity may only be turned down following review by full committee. Any research approved under expedited review must be reported to the full IRB.
- (e) At the point of approval, the IRB will also determine an appropriate schedule for continuing review of the project (see below).
- (f) The IRB will review each project and either approve the project as submitted, approve the project subject to meeting specified conditions, or reject the project. The Chair/Secretary of the IRB will notify the PI of outcome in writing. If the IRB has decided not to approve the activity, the reasons for the decision will be stated and the PI given the opportunity to respond, and where appropriate, to resubmit an amended application. Where approval has been granted, the PI will be notified of:
- the need to seek additional ethical review/approval if there are significant amendments to the approved protocol for the project, prior to implementation (except when necessary to eliminate apparent immediate hazards to subjects). This will include revised consent

¹ (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board, only one Board need satisfy this requirement.

² Minimal risk is understood as follows: ‘the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests’ Common Rule 46.102(i)

documents where appropriate (eg statements of significant new findings which may affect consent);

- the need to report any unanticipated problems involving risks to subjects or others as soon as possible to the PVCR and the Chair of the IRB;
- the schedule for continuing review of the project.

- (g) The IRB's decisions will be reported to the University Ethics Committee as part of the Health Sciences Research Governance Committee's annual return.

3. *Continuing review*

- (a) The IRB will carry out continuing review of the ethical conduct of projects which require FWA compliance at least once a year, or at more frequent intervals as appropriate to the degree of risk. The schedule for review will be established at the point of ethical approval (see above), and the process will be managed by the IRB Secretary, working with the Chair.
- (b) The review process will follow the University's *Procedure for monitoring the ethical conduct of projects requiring FWA compliance*. Where the project qualifies for expedited procedures (see paragraph 2d above), the process may be conducted via Chair's action, as set out in the above document.
- (c) Under the Common Rule:
- the IRB shall determine if projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. If so, this should be identified by the reviewers at stage 1 of the review process and the relevant information requested via the PI as part of the stage 2 response.
 - the IRB also has the authority to observe or have a third party observe the consent process and the research, should it decide that this is necessary.

4. *Record keeping*

Full records relating to projects considered by the IRB will be maintained centrally by the RSPO, in line with 46.115 of the Common Rule. IRB records must be retained for at least 3 years and must be accessible for inspection and copying by authorized representatives of the funder at reasonable times and in a reasonable manner.

5. *Procedures for handling problems or noncompliance*

- (a) In the event of unanticipated problems involving risks to subjects or others and/or adverse events, these must be reported as soon as possible by the PI to the PVCR and the Chair of the IRB. The Research Strategy and Policy Office and the Research Grants and Contracts Office will provide assistance in notifying the funder and the OHRP where appropriate as promptly as possible of the problems and action taken, including suspension or termination of IRB approval where this has been deemed necessary. Further guidance from the OHRP can be found here www.hhs.gov/ohrp/policy/advevntguid.html.
- (b) Allegations of serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB will be handled under the University's Policy and Procedure for the Investigation of an Allegation of Research

Misconduct, with particular reference to procedures for breaches of the University's ethical framework. The Chair of the IRB must be notified and where appropriate, suspension or termination of IRB approval should be considered. In the event that:

- i. IRB approval is suspended or terminated
and/or
 - ii. the allegations are upheld
the Research Strategy and Policy Office and the Research Grants and Contracts Office will provide assistance in notifying the funder and the OHRP as promptly as possible, advising the PVCR as appropriate.
- (c) Details of the OHRP's notification procedures can be found here:
www.hhs.gov/ohrp/compliance/reports/index.html.
6. *Maintaining Committee registration*
- (a) Membership of the above Committee was registered with the HHS Office for Human Research Protections on 17 September 2014. Any subsequent changes to Committee membership as constituted for FWA purposes must be reported to the University's Research Strategy and Policy Office as soon as possible, so that changes can be registered via the OHRP website and continued compliance with FWA IRB membership requirements can be checked. Changes to Chair or the contact person for IRB registration (currently the Research Integrity Officer) must be reported to the OHRP within 90 days and will result in new effective registration period.
 - (b) The IORG-IRB registration must be renewed at least every 3 years; the current registration expires at 3pm on 17 September 2017.

Dr Alice Wakely
Research Integrity Officer
23 October 2014
Updated 22 December 2015