UNIVERSITY OF YORK
University Ethics Committee

FWA Institutional Review Board

Continuing review procedure for monitoring the ethical conduct of projects requiring FWA compliance

To comply with Federal Wide Assurance requirements, a research project must undergo a review of its ethical conduct at least once a year, or at more frequent intervals as appropriate to the degree of risk. The schedule for continuing review will be established at the point of ethical approval by the University's registered Institutional Review Board (IRB), which will also conduct the review.

Full continuing review procedure

1 At the University of York, a full continuing review takes the form of a paper-based exercise. The IRB Chair should appoint two reviewers from the IRB membership in line with the committee's protocol for allocating work and avoiding conflicts of interest. Where possible, these should be members who were involved in the original approval for the project. The IRB should decide whether or not the review should be conducted anonymously, in the light of its usual practice.

2 The review should be conducted using the report form attached as Appendix 1, as follows:

(a) The IRB Chair should contact the lead PI for the project based at York to inform him/her that the review is to take place, and enclosing a copy of the report form (for information only at this stage).

(b) The IRB Chair should arrange for a copy of the project details as originally signed off by the committee plus a copy of the report form to be sent to the designated reviewers.

(c) The review should then be conducted as detailed on the report form, co-ordinated through the IRB Chair.

3 The completed report form should be considered formally by the IRB, and the reviewee notified of the outcome. Any matters for concern should be referred by the IRB Chair to the PVC for Research to pursue further as appropriate, supported by the Research Strategy and Policy Office and Research Grants and Contracts, with reference to the requirements of FWA and of the funder.

4 A summary of the process and its outcomes should be reported to the University Ethics Committee and the University Research Committee for information.

5 A full record of the process, including the completed report form, any supporting documents and the relevant IRB minutes, will be maintained by the Research Strategy and Policy Office. Records of any action beyond this level will be maintained by Registry (Research Strategy and Policy Office/Research Grants and Contracts/Secretariat to University Ethics Committee/HR as appropriate).

Approved April 2014 (generic process)
Expedited review option approved by PVCR December 2015

Expedited review procedure

1 Where a project is low risk and qualifies for expedited IRB review at the initial approval stage[1], it may undergo continuing review via Chair's action rather than the full continuing review procedure.

2 Under a continuing review via Chair's action, the Chair of the IRB (or his/her appointee) will review the details of the project as signed off by the IRB, and discuss with the PI, either face to face or via a phonecall, how the project is being/has been conducted, with particular reference to areas which have ethical implications.

3 Where there have been no significant changes to the project and no other issues have arisen in the course of the discussion, the Chair will report formally to the IRB that the review has taken place and that there are no outstanding issues to report. The PI will receive a copy of this report, and the outcome will also be reported to University Research Committee and University Ethics Committee for information.

4 If, in the course of the discussion between the Chair and the PI, it emerges that there have been significant changes to the project, including those which mean the project no longer qualifies for expedited procedures, and/or if other issues arise, the full continuing review procedure will then be followed.

[1] See University of York *Institutional Review Board Procedures*, paragraph 2d.

APPENDIX 1

UNIVERSITY OF YORK
University Ethics Committee

Review of the ethical conduct of projects requiring FWA compliance

To comply with Federal Wide Assurance requirements, a research project must undergo a review of its ethical conduct 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 by the University's registered Institutional Review Board (IRB), which will also conduct the review. At the University of York, an ethical conduct review takes the form of a paper-based exercise overseen by the University Ethics Committee.

The reviewers appointed by the IRB and the reviewee - ie the lead PI for the project based at York - are asked to complete the form in sequence as indicated, attaching any supporting documents. *Please expand the text boxes as needed. The report will be considered formally by the IRB, and the reviewee will be notified of the outcome. If, in exceptional circumstances, there are any matters of serious concern, these will be referred to the PVC for Research and pursued with the funder and the US Office for Human Research Protections as necessary.*

A summary of the process and its outcomes will be reported to the University Ethics Committee and the University Research Committee for information.

Project title:
Principal Investigator (name and department):
Date of review:

1. **For the reviewers:** please look over the project details as signed off by your committee (enclosed with this form). Then agree a list of areas which have ethical implications, for the PI to report against on how the project is being/has been conducted. *(eg ensuring informed consent, securing special permissions, storage of research data, data access arrangements, etc).* Please list these areas below, then forward the form to the Chair of your committee, who will arrange for it to be sent to the reviewee.

2. **For the PI:** please provide <u>concise</u> details of how the project has been/is being conducted under the headings listed above, focusing on ethical considerations. Please highlight any changes which have been made and/or any subsequent issues which have arisen, with details of how these have been handled. If you feel it would be helpful, please attach supporting documents *eg a copy of the informed consent form, any protocols, any special permissions.* Please then return the form and any attachments to the reviewers via the committee Chair.

3. **For the reviewers:** please consider the PI's response against the project details signed off by the committee and provide brief comments below, flagging up any recommendations or concerns. If there are points of information which could be resolved by a phonecall or email to the PI, please do so (assuming the review is not being conducted anonymously). Please return to the PI via the committee Chair, including details of any additional information subsequently provided by the PI in response to your queries (if applicable).

4. **For the PI:** to complete the process, if you would like to respond to the reviewers' comments, please do so below, then return the completed form plus any attachments to the committee Chair.

Thank you for your time and co-operation. If you have any queries or comments about this process, please contact Alice Wakely in the Research Strategy and Policy Office: alice.wakely@york.ac.uk