STANDARD OPERATING PROCEDURE

Receipt of online ethical self-assessment forms (SAFs) and applications for ethical review (AERs)

The definitive versions of all University of Birmingham Research Support Group Research Ethics Standard Operating Procedures appear online, not in printed form, to ensure that up-to-date versions are used. If you are reading this in printed form, check the version number and date is the most recent one as shown on the ethics website.

THIS DOCUMENT IS ONLY VALID ON THE DAY OF PRINTING

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Author: Mrs Susan Cottam
Signature: 
Date: 1/9/2016
Approved by: David Law
Signature: 
Date: 1/9/2016
1 VERSION HISTORY LOG

<table>
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<tr>
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<th>Effective Date</th>
<th>Details of Significant Changes</th>
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<td>1</td>
<td>01/06/2012</td>
<td>This SOP replaces the previous Research &amp; Commercial Services SOP “Ethical Review Committees - Standard Operating Procedures” (last updated August 2007)</td>
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<tr>
<td>1.1</td>
<td>01/09/2016</td>
<td>Update of SOP version 1.0</td>
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Current version to be reviewed by: 01/09/2019

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3 IMPLEMENTATION PLAN

This Standard Operating Procedure (SOP) will become effective on the Effective Date above and shall be adopted by all members of the Research Ethics Team and University Ethical Review Committees.

Approved Research Ethics SOPs will be posted in the relevant area of the University Website.

4 PURPOSE

This SOP has been written to describe the procedures to be followed when receiving completed ethics self-assessment forms (SAFs) and applications for ethical review (AERs).

5 SCOPE

5.1 This SOP applies to all online self-assessment forms (SAFs) and applications for ethical review (AERs) received following the Effective Date.

5.2 It covers the central university processes for the ethical review of research projects undertaken by members of staff (including honorary staff) or postgraduate research (PGR) students.

5.3 It does not cover the review of research projects undertaken by taught postgraduate or undergraduate students, or research undertaken by anyone else not included in 5.2 above.

6 BACKGROUND

The University of Birmingham implemented a centralised process for the ethical review of all staff research projects in 2007, and postgraduate research (PGR) student projects came within the remit of the process in 2010. This centralised process replaced any previous arrangements for ethical review at School/College level for staff and PGR student projects.

Undergraduates and taught postgraduate students are not subject to the University’s ethical review process, but should seek advice from their respective School or Department. Applications for undergraduate student or taught postgraduate student studies may be reviewed on request.

For both staff-led and PGR student projects, the initial stage of the ethical review process is to complete and submit the online University Ethical Review of Research Self Assessment Form (SAF), which indicates whether further ethical review is required. Depending upon the nature of the project, further review may be sought via the NHS, BERSA (for research
involving animals) or via the University Ethical Review Process. If ethical review is required via the University Ethical Review Process, an Application for Ethical Review Form (AER) should then be submitted. An overview of the University Ethical Review Process, including the submission of the SAF and the AER is given in appendix 11.2.

All SAFs and AERs are received and acknowledged by the Research Ethics Assistant (see overview of the processes in appendices 11.2 and 11.3). Once an AER has been received and acknowledged it will be submitted for review via the University’s Ethical Review Process.

7 RESPONSIBLE PERSONNEL

Research Ethics Team, Research Support Group
Research Support Group Management Team
University of Birmingham Humanities and Social Sciences (HASS) Ethical Review Committee
University of Birmingham Science, Technology, Engineering and Mathematics (STEM) Ethical Review Committee
University of Birmingham Research Governance, Ethics and Integrity Committee (RGEIC)
Principal Investigators

8 PROCEDURES

8.1 Receipt of a Self-Assessment Form (SAF)

8.1.1 On receipt of an SAF the Research Ethics Assistant (REA) will enter the details of the project on the Research Ethics Database, will assign the project a unique ‘ERN’ reference number, and will set up a file and the necessary electronic folders, in accordance with the relevant RSG Research Ethics Guidance Note.

8.1.2 The REA will check the SAF for validity and/or omissions, and will request any further information or clarifications from the Principal Investigator (or the supervisor, in the case of PGR student projects).

8.1.3 The REA will send a regular (usually daily) update to colleagues in Research Accounting, detailing all staff-led projects for which an SAF has been submitted. Notification of the submission of an SAF is required by Research Accounting before any funds can be released.

8.1.4 The REA will send an acknowledgement email to the PI, which will include the ERN reference number and will advise what, if any, further ethical review is required for
the project.

8.2 Receipt of an Application for Ethical Review (AER)

8.2.1 On receipt of an AER the Research Ethics Assistant (REA) will check the Research Ethics Database to confirm that an SAF has already been received for the project. If an SAF has not yet been received, the REA will contact the PI to request an SAF.

8.2.2 Once an SAF has been completed, the REA will match the AER to the relevant ERN reference number in the Ethics database, and will add the details of the AER to the record in accordance with the relevant RSG Research Ethics Guidance Note.

8.2.3 The REA will check the AER for completeness, and will also check the relevance of the information and accompanying documentation provided. The REA will request any further information or documentation required at this stage from the PI.

8.2.4 The REA will set up the necessary electronic and/or paper files for the application and will pass these to the Research Ethics Officer (REO) or the Deputy Research Ethics Officer (DREO) for initial risk assessment.

8.2.5 The REA will send an acknowledgement to the PI, advising them of their ERN number and of the likely time required to review their AER.

9 SUPPORTING DOCUMENTS

The current version of all RSG Research Ethics Guidelines may be found on the Research Support Group web pages.

RSG_RE_SOP - 001 Submitting the online self-assessment form and applying for University ethical approval
RSG_RE_SOP - 003 Review of applications for ethical review (AERs)
Research Ethics Guidance Note “Receipt of online ethics self-assessment form (SAF)”
Research Ethics Guidance Note “Receipt of application for ethical review (AER)”
Research Ethics Guidance Note “Review of application for ethical review (AER)”
Research Ethics Guidance Note “Revising system for allocating and tracking HASS medium risk reviews”

10 REFERENCES

General Information on University Research Ethics processes, including advice on submitting the online SAF and completing and submitting the AER, may be found on the ethics web pages.
## APPENDICES

### 11.1 Glossary of Terms

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<th>Abbreviation</th>
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<tr>
<td>AER</td>
<td>Application for Ethical Review</td>
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<tr>
<td>DREO</td>
<td>Deputy Research Ethics Officer</td>
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<tr>
<td>PGR</td>
<td>Post Graduate Research</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>REA</td>
<td>Research Ethics Assistant</td>
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<td>REO</td>
<td>Research Ethics Officer</td>
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<tr>
<td>SAF</td>
<td>Self Assessment Form</td>
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11.2 Process for receiving, logging and acknowledging SAFs

- SAF submitted
- Enter SAF details into database
- Send daily update to Research Accounting of new SAFs received
- Send acknowledgement to PI using mail merge
- SAF logged and acknowledged
11.3 Process for receiving, logging and acknowledging AERs

- AER submitted
  - Match AER to SAF. If necessary ask PI to complete SAF
  - Enter AER details into database
  - Send acknowledgement to PI
  - Check AER for completeness - if necessary liaise with PI to clarify or obtain additional information
  - Set up paper and electronic files
  - Assign risk level
  - Pass to REO/ DREO to commence review process