Peer Review

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1. **PURPOSE**

The Peer Review Office (PRO) was set up to assist clinicians at Imperial College obtain favourable opinion by confirming the scientific validity of research projects. The scientific merit of a protocol is one of the aspects ethics committees must consider, but can be difficult to assess without specialist knowledge.

2. **INTRODUCTION**

The peer review service exists to enable researchers to:

- obtain scientific peer review of their projects
- confirm that satisfactory review has taken place
- provide an advisory service about peer review for researchers

All clinical research must be considered by a research ethics committee (REC) and granted Favourable Opinion before the research can be undertaken. Now that the NIHR uses the system of portfolio adoption, the activities of the Peer Review Office have become even more important for clinicians. Adoption requires independent review which is hard for researchers to obtain themselves.

Where projects need peer review for the Ethics committee or for NIHR portfolio adoption, the Peer Review Office offers a unique dedicated service to obtain appropriate and independent review for clinicians. Appropriate review is judged according to the level of the protocol, that is, the degree of risk and burden to participants.

The requirement for peer review is obligatory, but the use of the PRO is not. The PRO relies on its reputation to obtain expert review with tight time lines (aiming for 3-4 weeks) so that researchers will use and trust the service.

3. **PROCEDURE**

3.1 Application process

The process of obtaining review or certification differs depending on the level of review the project has been judged to require.

3.1.1 How projects for peer review are obtained

Projects for peer review may come from three main routes:

- A JRCO Research Governance Manager or Research Facilitator may forward a project on to the Peer Review administrator for assessment.
- researcher may get in contact directly with queries, protocol, or other research documentation

3.1.2 Documents to be submitted to the Peer Review Administrator

The following documents need to be sent to the peerreviewoffice@imperial.ac.uk.

- Draft IRAS form
- Protocol
3.1.3 Peer Review registration number
Every study which is processed by the Peer Review Office with the exception of general queries which do not lead to peer review are issued with a peer review number that also appears on the issued peer review certificate.

3.2 Peer Review Level Assessment
Projects are assigned to a ‘Level’ by the Peer Review administrator according to the type of interventions proposed and the risks and burdens they impose on participants. The greater the burden, the higher the assigned level, and therefore the increased degree of peer review required.

In order to help researchers identify the level of review needed for individual projects, the Peer Review service has developed a framework. You should be able to determine review level by consulting the Peer Review Levels Grid - Appendix 1 which can also assist with this.

The minimum requirements for peer review at each level are as follows:

**Level 1** No official peer review required but to issue a certificate PRO requires

- 1a Review by project supervisor or departmental colleague
- 1b Existing review by major grant-giving body

**Level 2** Review by project supervisor or departmental colleague

**Level 3** Independent internal review conducted by an expert outside the research team

**Level 4** External review-Two reviews at least one of which is by an expert external to Trust/Imperial College London

**Level 5** External review-Two reviews both of which are by experts external to the host institute

3.3 Reviewer Suggestion form
Once the PRO administrator/team has reviewed the study, an e-mail is sent to the researcher informing them of the Level of their study and a reviewer...
suggestion is sent to be completed. The number of suggested reviewers depends upon the Level of study. Appendix 1.

3.4 Peer Review Process
The peer review process clock starts once the names of the reviewers are received by the peer review administrator. The peer review administrator sends the named reviewer the conflict of interest form and the study protocol with the invite e-mail that asks them to keep the protocol confidential. Once they accept the invite, they are sent the conflict of interest form and the peer review form with a timeframe of two weeks to complete the peer review. The PRO undertakes all administration to obtain appropriate reviews. This allows full review independence where necessary. The process normally takes between 3-4 weeks, depending on the ease of finding reviewers, and how prompt those reviewers are. The Office follows up on all reviews, aiming to ensure requested deadlines are met. If there are delays, the researcher is kept fully informed.

3.5 Adequate Review
For a peer review to be certified by the Peer Review Office it must be comprehensive and may need to be independent.

Comprehensive review: is a peer review which addresses every question or nearly every question on the Peer Review Form-Appendix 3. It may not be possible for reviewers to answer fully Question E Practicalities. This may be a review organised by the Peer Review Office or may be obtained from other sources, for example as part of the funding process.

Independent review: Please see paragraph 3.2 above

3.6 Peer Review process completion
Upon receipt of reviews, they are forwarded on to the researcher together with a certificate all scanned in as one document. Reviews are anonymous unless the reviewer chooses to be identified.

If the researcher already has reviews, the PRO can certify them as sufficiently robust and independent for the purposes of the REC.

3.7 Peer Review database
The Certificate number and study related data is recorded in the Peer Review database for reference purposes.

4. REFERENCES
http://www.imperial.ac.uk/joint-research-compliance-office/peer-review/
5. APPENDICES

5.1 Appendix 1 Peer Review levels grid

<table>
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<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
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<tbody>
<tr>
<td>Short questionnaire studies for use among hospital staff or GPs</td>
<td>Routine history taking</td>
<td>Physical examination</td>
<td>Phase I, II and III drug or device trials.</td>
<td>NIHR portfolio adoption</td>
</tr>
<tr>
<td>Questionnaires asking participants about the quality of hospital services, or requesting other non-personal data, taking up to 10 minutes for a patient, or 20 minutes for a healthy volunteer</td>
<td>Non-intimate physical examination e.g. joint examination, blood pressure measurement</td>
<td>Taking of up to two blood samples of no more than 10mls each for adults, or pro rata for children</td>
<td>Randomized trials of drugs or devices within their licensed use</td>
<td>Use of radiation</td>
</tr>
<tr>
<td>Use of data from medical notes by clinician looking after patient</td>
<td>Histological studies on existing/historical specimens</td>
<td>Taking of extra biopsies during biopsy procedure that is part of normal care</td>
<td>Intimate physical examination, unless it is part of normal patient care</td>
<td></td>
</tr>
<tr>
<td>Studies that have been specifically peer reviewed by either:</td>
<td>Projects using existing stored data</td>
<td>Administration of simple questionnaires that do not involve “sensitive” (e.g. psychiatric, sexual, drug or end of life-related) information, unless that information is part of normal clinical practice for the condition under study</td>
<td>Use of radiation</td>
<td></td>
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<td>i) a major grant-giving body or similar organisation. These include the following: UK Research Councils (including the Medical Research Council), the National Institute for Health Research; and Members of the Association of Medical Charities (including the Wellcome Trust and a large number of specialist or disease-specific charities). This exemption does not include projects that are part of a programme grant but which have not been specifically considered by the grant-giving body.</td>
<td>Administration of simple questionnaires that do not involve “sensitive” (e.g. psychiatric, sexual, drug or end of life-related) information, unless that information is part of normal clinical practice for the condition under study</td>
<td>Venesection involving a single skin puncture: up to 50mls from healthy volunteers, 20mls from patients (or pro rata for children)</td>
<td>Investigation that involves a minimal risk procedure (e.g. arterial blood gas analysis)</td>
<td></td>
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<tr>
<td>Applicants need to be able to demonstrate to the REC and to the IC Joint Research Office that</td>
<td>Taking of blood via existing cannula or at same time as venesection which is part of normal patient care: in single or multiple samples, total volumes as above</td>
<td>New acquisition of personal data that are not part of the normal clinical history</td>
<td>Administration of questionnaires involving “sensitive” information outside of normal clinical practice</td>
<td></td>
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<tr>
<td>the relevant grant-giving body had conducted formal peer review of the particular piece of research proposed. or ii) a pharmaceutical company that has initiated and designed the study.</td>
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| Spirometry  
The obtaining or analysis of non-invasive samples, e.g. urine, saliva, faeces. |
| Single-arm study of a drug or device not affecting patient care decisions  
Clinical intervention study or controlled trial with low risk to participants (e.g. a study of an oral nutritional supplement, low vitamin doses, or dietary intervention) |
5.2 Appendix 2 Reviewer suggestion form

Suggested Peer Reviewer
Please complete one questionnaire for each suggested reviewer
For level 3 reviews, reviewers may be linked to Imperial College and/or its related hospitals but not involved in your research in any way.
For level 4, at least one reviewer must be external to Imperial College and its related hospitals.
For NIHR projects, all reviewers must be external to IC and its related hospitals.

Project title
Chief Investigator
Peer Review number

Suggested Reviewer

Name
Position
Address
Email address
Telephone number
Facsimile number

Have you and the suggested reviewer worked in the same NHS trust or university/college in the last three years? Yes  No
If yes, please specify

Has the suggested reviewer had any involvement with this project? Yes  No
If yes, please specify

Has the suggested reviewer carried out scientific work, clinical research, clinical practice or other work in the field of this proposed project or in a related area in the last five years? Yes  No
If yes, please specify