Research Governance and Integrity Team



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Peer Review		
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Version	Date	Reason for Change
Version 1.0	25 Oct 2017	1 st Edition
Version 2.0	21 Nov 2018	Updated Information
Version 3.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. JRCO name change to RGIT
Version 4.0	14 Dec 2023	Scheduled Review

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1. PURPOSE

The Peer Review Office (PRO) assists researchers at Imperial College to obtain regulatory approval of clinical research projects. The scientific merit of a protocol is one of the aspects that ethics committees must consider but can be difficult to assess without specialist knowledge. The PRO facilitates this by arranging for independent peer review, or confirming that it has taken place.

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 a "Favourable Opinion" before the research can be undertaken. For this to happen the REC needs to be satisfied about the scientific validity of the project – hence the need for peer review. Furthermore, projects that are to be adopted by the National Institute for Health and Care Research (NIHR) require fully independent review.

It is difficult for researchers to arrange for independent peer review themselves. The Peer Review Office offers a unique dedicated service for obtaining it speedily. The review is also proportionate, the level being judged according to the degree of risk and burden to participants.

Peer review of clinical research projects is requirement. While the use of the PRO is not obligatory, it does provide a very quick and simple way of obtaining or confirming high quality independent review.

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 RGIT 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 a query, a 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
- Participant Information Sheet

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Questionnaires (if relevant)

3.1.3 Peer Review registration number

Every study which is processed by the Peer Review Office is issued with a peer review number that also appears on the issued peer review certificate. This does not include general queries which do not lead to peer review

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 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 Appendix 1 Peer Review levels grid RGIT_TEMP_048 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 independent reviews at least one of which is by an expert external to Trust/Imperial College London

Level 5 External review-Two independent 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 RGIT_TEMP_048

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 an invitation e-mail that asks them to keep the protocol confidential. Once they accept the invitation, they are sent the conflict of interest form and the peer review form with a timeframe of two weeks to complete the peer review.

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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, depending on the Level. The PRO will assess the quality of the review, (but not the quality of the project itself).

<u>Comprehensive review</u>: is a peer review which addresses the questions on the Peer Review Form. 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

Research Governance and Integrity Team Peer review (Cited 07 Dec 2023)

5. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1 - Peer Review levels grid - RGIT_TEMP_048 Appendix 2 - Reviewer suggestion form - RGIT_TEMP_049

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