SOP-QA-10 V6

Title: Applying for Research Ethics Committee opinion

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Document History

Version	Description of update	Date Effective
5	Updated to reflect new procedure and IRAS process at 3.2 to 3.17 Clarification on the submission process of REC and R&D forms at 3.20	5-6-23
6	New owner/author assigned. Clarification on PRS and referral to full committee for review at 3.9 Removal of reference to Annual Progress Report at 3.16	19-12-24

1. Scope

1.1 This SOP applies to Chief Investigators (CI) planning studies sponsored or co-sponsored by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG) which require NHS Research Ethics Committee (REC) approval.

1.2 NHS REC approval is required when NHS patients, tissue or data are used in a research project.

2. Responsibilities

Chief Investigator	Ensure sponsorship arrangements have been approved by Sponsor/co-Sponsor prior to submitting a study for ethical review. Ensure favourable ethical opinion, MHRA approval (if required), local NHS R&D permission (also known as Confirmation of Capacity and Capability in England and Wales) any other relevant approvals are in place, before recruitment begins.
Principal Investigator	Ensure local NHS R&D permission is in place before recruitment begins.

3. Procedure

Agreeing Sponsorship:

3.1 ⚠ Before applying for NHS REC ethical opinion, the sponsorship arrangements for the study shall be confirmed. This shall be done in accordance with SOP-QA-4 - Applying for sponsorship.

Complete the Online IRAS Application System:

3.2 Applications for the following categories are made using the Integrated Research Application System (IRAS) portal which can be accessed at https://www.myresearchproject.org.uk. Full instructions on how to complete the form are available through the 'Help' pages and via the online IRAS e-learning module.

- Clinical investigation or other study of a medical device.
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

- Basic science study involving procedures with human participants.
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology.
- Study involving qualitative methods only.
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
- Study limited to working with data (specific project only).
- Research tissue bank.
- Research database.

Applications for the following categories are made using the combined review process which utilises an alternative version of the IRAS form. Access to the platform and a full user guide and instructions can be accessed on the HRA website IRAS combined review

- CTIMP.
- Combined CTIMP and MDCI.

Applications for the following categories are made using both the combined review process and standard IRAS. Detailed instructions are available in IRAS help and on the HRA website IRAS combined review.

- CTIMP that involves ionising radiation.
- Combined CTIMP and MDCI that involves ionising radiation.

If the project does not meet any of the above criteria (eg 'other' category), Research Governance shall be contacted for further assistance: researchgovernance@abdn.ac.uk

3.3 When the application form is complete this must be electronically signed by the CI (and any other relevant signatories) before it is released to Sponsor for electronic authorisation.

3.4 If the application form is acceptable, Sponsor shall assign an electronic signature to the form.

3.5 ⚠ Any changes made to the REC form after electronic signatures have been assigned invalidates **all** signatures on the form. If changes are made, they shall be approved by Sponsor **prior** to implementation; the form must be re-signed by all parties prior to submission.

Submitting the application to the NHS REC for an Ethical Opinion:

3.6 Once all required signatures have been obtained, the REC application shall be submitted to the REC electronically through IRAS (see 'E-submission' tab on IRAS). Each step of this process must be followed or the application will not be valid. This includes the following steps:

- Ensure that all required questions are marked as 'complete' within the IRAS form. This is enabled by checking the grey tick box at the right hand side of each question until it displays as green.
- Undertake the 'check the form' feature to ensure that all areas are complete.
- Upload the supporting documents to the IRAS checklist. These should all be version one and dated accordingly.
- Ensure that all electronic signatures are in place.
- Verify the application is ready to submit
- Book the application via the online booking system on IRAS to arrange which committee shall review the application and the date of the meeting.
- Electronically submit the application.

3.7 Any incomplete applications will not be validated and shall be returned to the CI.

3.8 A validation letter, which acknowledges the submission and confirms that it is valid, shall normally be issued by the NHS REC after submission. The letter shall also invite the CI to attend, if they wish, the NHS REC meeting at a specific time.

NHS Ethics Approval Process

3.9 The NHS REC must notify its decision within 60 days of receiving the valid application submitted for full REC review, and within 21 days for applications submitted using the Proportionate Review Service (PRS). Research projects which raise no material ethical issues may apply for NHS REC approval using the PRS. These applications are reviewed by a sub-committee rather than at a full REC meeting with an aim to notify the final decision to the applicant within 21 calendar days of receipt of a valid application. Researchers should consult the PRS toolkit and verify eligibility for PRS with Sponsor before the application is submitted. Applications for PRS must still be submitted using the IRAS system. If the NHS REC deems the application unsuitable for PRS, REC will notify the applicant and explain the reasons. The application will then be booked to a full REC meeting, in discussion with the applicant.

The PRS toolkit and further information on PRS is available on the HRA website.

The NHS REC can reach the following decisions:

- Final decision – which could be favourable or unfavourable.
- Provisional decision with conditions, with a request for further written information.
- No opinion – the application shall be referred to a full committee for review.

3.10 The NHS REC may make a provisional decision about the research and ask for further information on specific aspects of the project. Such a request can only be made once. The 21/60 day clock stops whilst the NHS REC await the response. Sponsor must be kept updated and copied in on any correspondence with the REC during the review period.

3.11 If the response is not deemed satisfactory, the NHS REC may request a second response to the same questions (no new issues can be raised) or can reject the application. The clock only re-starts when a complete response is received. A final decision should then be issued.

3.12 Once NHS REC approval is granted, research must not start at a site until all other relevant approvals have been granted (eg MHRA) and NHS R&D have given local R&D Management Permission, or Confirmation of Capacity and Capability in England and Wales, for the site.

3.13 A copy of the NHS REC favourable opinion letter must be filed in the Trial Master File (TMF) alongside copies of the signed IRAS form, the supporting documents submitted for review and any correspondence relating to the review process. If the project involves multiple sites, a copy of the favourable opinion letter shall be sent to each PI for inclusion in each site file.

3.14 Once all required approvals have been obtained, the final approved versions of the study documents shall be sent to Sponsor (researchgovernance@abdn.ac.uk) for the Sponsor file.

3.15 The research should start within 12 months of the date on which a favourable opinion from the NHS REC was given. A study is generally considered to have commenced when the first participant gives written informed consent to participate or, where this does not apply, when any procedures in the protocol are initiated.

3.16 ⚠ Where research does not commence within 12 months, the CI should inform the NHS REC directly in writing. If the research does not start within 24 months, the CI should inform the REC who may review the ethical opinion and decide that a new application is required, or they may grant a further 12 months of approval.

3.17 ⚠ After approval, the NHS REC must be informed and an application submitted for approval of any substantial amendments to the protocol. All amendments must be approved by Sponsor in the first instance. This process is detailed in SOP-QA-19 - Amendments.

3.18 The CI also has the following responsibilities to the NHS REC:

- Development Safety Update Report (DSUR) as detailed in SOP-QA-21 – APRs and DSURs.
- Notification of Suspected Unexpected Serious Adverse Reactions (SUSARs), as detailed in SOP-QA-22 - Adverse Events in CTIMPs, and relevant Serious Adverse Events (SAEs) for non-CTIMP studies.
- Inform the NHS REC who provided the favourable opinion when the project finishes, or terminates early, using the end of study declaration (see SOP-QA-31 Research project closure).

Regulatory and R&D Approvals

3.19 If MHRA Regulatory Authority approval is required (CTIMPs and MDCI only), this must be in place before NHS R&D Management Permission is granted. It is the CI's responsibility to apply for these approvals when they are required.

NHS R&D Permission(s):

3.20 ! Local NHS R&D Management Permission/Confirmation of Capacity and Capability is required at each recruiting site if involving:

- NHS Staff
- NHS Patients
- Tissues
- Organs
- Data
- NHS Facilities
- NHS Equipment

The application process for this is also completed using the IRAS system through the combined REC and R&D form, meaning only one electronic authorisation request is required by the CI and Sponsor for both REC and R&D approval, if applicable. Detailed guidance and instructions on completing and submitting the combined REC and R&D form can be found on the IRAS website. Once the IRAS application is complete it will be automatically submitted to the lead R&D office through the IRAS system at the same time as REC submission.

If the project includes multiple sites in Scotland and/or sites in England, Wales or Northern Ireland, the application will be automatically submitted to the NRSPCC (NHS Research Scotland Permissions Coordinating Centre) team who will liaise with the coordinating centres for each nation and share relevant documents to facilitate study setup.

⚠ A copy of the REC favourable opinion letter must be provided to the R&D office(s) by the CI once issued. This will not be provided by the REC or made available via IRAS. Evidence of a

favourable ethical approval is a requirement for R&D permission/Confirmation of Capacity and Capability and approval(s) will not be issued until this has been received.

If your project falls out with the remit of the NHS REC, but still requires local R&D approval, please contact the Research Governance Team via researchgovernance@abdn.ac.uk for further guidance and assistance.

4. Abbreviations and definitions

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
DSUR	Development Safety Update Report
HRA	Health Research Authority
IRAS	Integrated Research Application System
MDCI	Medical Device Clinical Investigation
MHRA	Medicines and Healthcare products Regulatory Agency
NRSPCC	NHS Research Scotland Permissions Coordinating Centre
PRS	Proportionate Review Service
REC	Research Ethics Committee
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

5. Related documentation and references

SOP-QA-4	Applying for sponsorship
SOP-QA-19	Amendments
SOP-QA-21	APRs and DSURs
SOP-QA-22	Adverse Events in CTIMPs
SOP-QA-31	Research project closure
TMP-QA-38	Patient Information Sheet guide