Standard Operating Procedure

Proposed Studies Process

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BACKGROUND

The Research & Development team is responsible for assessing and managing the processing of all potential new studies in line with the UK Policy Framework for Health and Social Care Research (2020) which defines research as ‘’the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods’’.

The processing of proposed studies is dependent on an initial assessment to determine if a study is deemed as research; service evaluation or audit.

PURPOSE

To ensure that all proposed studies are managed correctly.

SCOPE

All new proposed studies presented to the R&D Team.

RESPONSIBLE PERSONNEL

Head of Research, Development & Innovation
Senior Research Advisor
Lead R&D Facilitator
R&D Assistant

ABBREVIATIONS

HRA – Health Research Authority
NHS A&A – NHS Ayrshire & Arran
RDI – Research, Development & Innovation
R&D MA – Research & Development Management Approval

PROCEDURE
WHO?

Lead R&D Facilitator
R&D Assistant

WHEN?

This process applies to studies before the R&D Management Approval review process begins.

HOW?

1. A proposed study can present to the R&D team by a phone call, email, confirmed feasibility or communication in the R&D Team.

2. The Lead R&D Facilitator/R&D Assistant will add details of the proposed study to the to the Proposed study spreadsheet in the shared drive in the 'Proposed No Study Number Given' tab and set up a folder in the relevant years Proposed Projects file in the shared drive.

3. The R&D Assistant will update the proposed study spreadsheet with details of all correspondence and documents sent/received and save all emails in the proposed file.

4. The Lead R&D Facilitator/R&D Assistant will contact the researcher to obtain all information about the proposed study and find out what stage the study is at in order to progress.

5. If there is any question on whether or not the study is a research project the Lead R&D Facilitator/R&D Assistant will send out links to the HRA decisions toolkits and the HRA definitions of the different types of studies, using the 'first contact documents required' email template (Appendix A). The researcher will be asked to complete and return a copy of the HRA decision tools results pages.

6. On a weekly basis the Lead R&D Facilitator/R&D Assistant will meet to go through all projects on the 'Proposed No Study Number Given' tab in the Proposed study spreadsheet. Setting timelines for follow-up and emailing those due for follow-up. This should routinely be followed up every month unless specifically informed by the researcher that they will not be submitting until a later date. Saving all emails sent/received in the proposed study file and updating the spreadsheet.

7. The Lead R&D Facilitator/R&D Assistant will monitor and discuss the studies that breach the allotted timeline or don't respond to emails after several attempts. A template email will be sent to researchers that do not respond (Appendix B)

8. If the HRA decision tools inform that the proposed study is research the Lead R&D Facilitator/R&D Assistant will:

    - Review the documentation available to confirm if research.
    - Issue the R&D MA Process (Appendix C) to the researcher and advise on the required steps to submit the study for R&D Management approval and any Regulatory approval that is required for the type of study.

- Follow the R&D Management Approval process SOP5.
- When the project has been allocated an R&D number the R&D Assistant will move the study from the 'Proposed No Study Number Given' to the 'Archive Proposed No Study Number Given' tab on the Proposed Studies Spreadsheet and move the project file to the relevant R&D project number file, correspondence folder and re-name it as pre-submission.

9. If the HRA decision tools inform that the study is not research, the Lead R&D Facilitator/R&D Coordinator will review the documentation available to confirm the outcome.

10. If the study is deemed to be a Service Evaluation by the Lead R&D Facilitator the R&D Assistant will:

    - Ensure the completed HRA decision tools are on file
    - Check we have protocol/proposal including supporting documents (if available)
    - Read through documents to confirm agreement of Service Evaluation decision with Lead R&D Facilitator
    - Check if study is for an academic qualification and if so request copy of University approval
    - Await ethics approval/letter if applicable (check decision tools)
    - Issue the email template 'Evaluation Acknowledgement' (Appendix D) cc Lead R&D Facilitator and Head of RDI and save this in the study folder
    - Move the study from the 'Proposed No Study Number Given' to the 'Archive Proposed No Study Number Given' tab on the Proposed Studies Spreadsheet and update the comments section to confirm deemed Evaluation.
    - Add the study details to the relevant year tab in the Evaluation Table in the shared drive and move the study file to the relevant years Evaluation Project folder.

11. If the study is deemed to be an audit by the Lead R&D Facilitator the R&D Assistant will:

    - Issue the email template 'Audit projects email template' (Appendix E) cc Lead R&D Facilitator, Head of RDI and Information Governance and save this in the study folder
    - Move the study folder to the "Audits" folder within the relevant year of "Projects" folder
    - Move the study from the 'Proposed No Study Number Given' to the 'Archive Proposed No Study Number Given' tab in the

Proposed Studies Spreadsheet and update the comments section to confirm deemed Audit

12. If the proposed study does not go forward the R&D Assistant will move the file folder to the 'Not taken forward or completed folder' in the relevant years Proposed Study folder in the shared drive and move it from 'Proposed No Study Number Given' to the 'Archive Proposed No Study Number Given' tab on the Proposed Studies Spreadsheet.

OTHER RELATED PROCEDURES

SOP5 R&D Management Approval Process

REFERENCES

UK Policy Framework for Health and Social Care Research - UK Policy Framework for Health and Social Care Research - Health Research Authority (hra.nhs.uk)
HRA Decisions Toolkit Research - http://www.hra-decisiontools.org.uk/research/
HRA Decisions Toolkit Ethics - http://www.hra-decisiontools.org.uk/ethics/
HRA defining research table DefiningResearchTable_OCT2022.docx (hra-decisiontools.org.uk)

APPENDICES:

Appendix A – Email template first contact documents required
Appendix B – Email template informing proposed study is being withdrawn
Appendix C – R&D MA Process
Appendix D – Email template for Evaluation
Appendix E – Email template for Audit

Appendix A

Email template – first contact documents required

Dear XXXX

For us to progress can you please complete the HRA decision tools (links below) for this project inserting your project title into each one, then saving the results and return them to us:

Research Toolkit Link
http://www.hra-decisiontools.org.uk/research/

REC Toolkit Link
http://hra-decisiontools.org.uk/ethics/

Please also see points below that will help with the last question in the research decision tool above.

Is Your Information Generaliseable?
• Is the focus on the broader health system in Scotland/UK, rather than specifically on identifying the service a Health Board provide (or fail to provide) to meet the express needs of the cohort
• Findings which are potentially of value to those facing similar problems elsewhere, i.e., generalisable
• Findings are able to be made more widely or generally applicable.
• The larger the sample population, the more one can generalise the results.

Please also find attached link for information to the HRA defining research table http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf

We will also need a copy of your project proposal/protocol. We have a protocol template for use if required. ***(Include the following if for an academic qualification)** (if the university has not already provided one). As this project is for an academic qualification the University should be taking on the role of Sponsor for your project can you confirm this with them and let us know.

For Ethics and R&D Management application you will need to submit your project to IRAS - the national application system. (www.myresearchproject.org.uk) This would need to be done depending on the outcome of the decision tools above. Once you have completed the decision tools and returned them to us – we can discuss the way forward.

Many thanks

XXXX

Appendix B

Template for informing that proposed study is being withdrawn

Dear XXXX

We have not received an update on your proposed study entitled “XXXX” since **enter date**. We assume that you no longer wish to take this study forward and will remove this study from our pending list. Please do get back in touch with the R&D team if this is incorrect or if you want to go ahead with the study at a later date.

We look forward to working with you again in the future.

Kind regards

Appendix C

R&D Management Approval Process

Research cannot be undertaken within NHS Ayrshire and Arran without formal written R&D Management Approval.

In order to obtain this you must register online with IRAS at the following site *https://www.myresearchproject.org.uk* and then contact the RDI team, who will assist you with your application.

Prior to your project being considered for R&D Management Approval you must submit the completed IRAS form and all supporting documents electronically through the IRAS system by uploading the documents and phoning the Central Booking system.

What do applicants have to do?

1. Complete the IRAS Form
2. Upload all supporting documents to the checklist tab for the IRAS form and enter details for the documents in the rows (including subtitles, version numbers and dates, as appropriate)
3. Make sure the application is ready to submit and passes the verification step. The IRAS Form e-submission tab gives guidance on this
4. Book in the application for review using the Central Booking Service. If the study requires Research Ethics Committee (REC) review, the service will book the REC meeting slot at the same time as enabling e-submission. For non-REC studies the service will enable e-submission. Applicants will receive a confirmation email from the Central Booking Service
5. Add the booking information to the first page of the IRAS Form
6. Click the “E-submit application” button to submit the application.

NB. The Central Booking Service asks questions relating to the application in order to assign the application to the correct reviewers. Please make sure that the person making the call to the Central Booking Service understands the study.

Please follow the Step-by-Step Guide on IRAS

Supporting documents:
You should enter the details for all of the supporting documents that you are submitting in the ‘Checklist’ tab for the application form in IRAS.

***** The Organisation Information Document (OID) *****

This replaced the SSI form as of 5th June 2019. Guidance is available on IRAS https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack

It is the Sponsors responsibility to localise the OID and email it along with the relevant delegation log for the site (if applicable) to NRS Permissions CC (NRSPCC) who will then make the Local Information Pack available to participating NHS sites in Scotland (there is no need to supply documents already electronically submitted as part of the IRAS Form application as they will be made available to participating NHS sites in Scotland via NRSPCC).

The Sponsor should email the localised OID(s) after the IRAS Form submission is validated. If there is more than one localised OID, then they should be sent via a single email to NRSPCC.

IMPORTANT: The Sponsor is expected to use a template email when sending the localised OID to NRSPCC. This can be accessed via https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack under *Participating NHS Organisation in Scotland*, the email template is at the bottom of the paragraph.

Documents to be submitted:

IRAS Submission:

IRAS form
Protocol / Proposal (must include version numbers and dates)
Final versions of supporting documentation (must include version numbers and dates):
- questionnaires
- participant information sheet
- letter of invitation
- consent form
- GP letter

All ethics correspondence including final ethics favourable opinion letter
Abbreviated CV of Chief Investigator, Principal Investigator and all named local co-investigators (should be signed and dated)
Copy of grant application and final award letter (**if applicable**)
Clinical Trials Authorisation (MHRA Letter) (**Clinical trials only**)
Costing Template (**Commercial Projects only**)
Evidence of Insurance/Indemnity (**Non-NHS Sponsors only**)
Clinical Trials Agreement (CTA) or site agreement (**if applicable**)

UK Local Information Pack:
Covering email using standard template format (mentioned above)
Localised OID (Organisation Information Document)
Delegation Log (**Clinical trials only**)
Schedule of Events / Schedule of Events Cost Attribution Tool (SoECAT) (**Non-commercial studies only**)

Please note that for commercial trials there is a £700 +VAT charge for processing R&D Management Approval and a 25% levy on all other income.

If you require further information and guidance please contact the research and development team – RandDProjectTeam@aapct.scot.nhs.uk

To ensure your study meets the requirements of the Data Protection Act 2018, GDPR, Caldicott Principles and the Common Law of Confidentiality please refer to the *Guidance on Data Protection, Caldicott and Confidentiality for Researchers* *http://athena/kmeh/kmeh/igs/Pages/DataProtectionandResearch.aspx*

The UK policy framework for health and social care sets out the principles of good practice in the management and conduct of health and social care research in the UK https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Appendix D

Email template - Evaluation

Dear

Title

Many thanks for submitting the paperwork for your study. We have reviewed your proposal and have determined that it is not appropriate to classify it as Research according the guidance issued by the NHS National Research Ethics Service (NRES).

The NRES guidance is outlined in a summary leaflet which can be accessed via the following link DefiningResearchTable_OCT2022.docx (hra-decisiontools.org.uk)

As the project is not research, it does not require to be reviewed by an NHS Ethics Committee, and does not require formal R&D Management Approval to be undertaken within NHS Ayrshire & Arran.

We would, however, like to highlight a number of issues that you should consider when carrying out your project:

- As your project has not been defined as Research, it will not be managed as such, nor will it be subject to regular review or monitoring by the R&D Department. Furthermore, you should avoid referring to it as research in any paper or presentation.

- You should ensure that you have agreement of appropriate senior staff to carry out your project in their area.

- You should be aware of any potential ethical issues, discuss these with colleagues and advisors, if necessary, and ensure patient safety as your first priority.

- You should comply with all relevant Health and Safety and Data Protection legislation and guidance, and avoid using patient identifiable information unless it is essential – seek guidance from the Information Governance department if required (informationgovernance@aapct.scot.nhs.uk).

- You should ensure that all confidential information is maintained in secure storage.

- You should maintain a well organised project file at all times, including copies of any agreements, protocols questionnaires etc.

- You should seek to publish the results of your work as widely as possible.

If you make changes to the protocol in the future, please resubmit the paperwork to Research and Development for review, as this might change the status of the project.

Good luck with your project and if you require any assistance in the future please don't hesitate to contact us.

Kind Regards
XXXXX
(on behalf of Karen Bell, Head of Research, Development and Innovation)

Appendix E

Email template - Audit

Dear XXXX

(Insert Title)

We have now looked over the paperwork supplied for your study above.

As R&D does not need to review/approve Audit work it is the Clinical Service that will agree participation and you should link in with information governance, email: InformationGovernance@aapct.scot.nhs.uk and any other appropriate services to ensure that the work is compliant with the necessary regulations/guidance.

Good luck with your Audit.

Kind regards
XXXXX
(on behalf of Karen Bell, Head of Research, Development and Innovation)