Feasibilities (Commercial and Non-commercial studies)

Document Control Sheet

Title:	Feasibilities (Commercial and Non-commercial studies)
Document Status:	Final
Document Type:	Standard Operating Procedure
Version Number:	V01.1
Document location:	W:\Governance\SOP Library\Current SOPs & policies\Governance SOPs
Author:	Libby Mullings, Senior Research Advisor
Owner:	Libby Mullings, Senior Research Advisor
Approved By:	Dr Karen Bell, Head of Research, Development and Innovation
Date Effective From:	31st August 2022
Review Frequency:	2 yearly
Next Review Date:	31st August 2024

Revision History:

Version:	Date:	Summary of Changes:	Responsible Officer:
V01.0	01/02/2019	New Document	Libby Mullings
V01.1	31/08/2022	Updated to reflect move to RDI and include WI for feasibilities	Natalie McLuckie

Approvals: this document was formally approved by:

Name & Title / Group:	Date:	Version:
Karen Bell Head of Research, Development and Innovation	31/08/2022	V01.1
Natalie McLuckie, Lead R&D Facilitator	31/08/2022	V01.1
Marie Frew, R&D Assistant	31/08/2022	V01.1

Dissemination Arrangements:

Intended audience:	Method:	Date:	Version:
Head of RDI	Access on shared drive	See spreadsheet	V01.1
Senior Research Advisor	Access on shared drive	See spreadsheet	V01.1
Lead Research Nurse	Access on shared drive	See spreadsheet	V01.1
Lead R&D Facilitator	Access on shared drive	See spreadsheet	V01.1
R&D Assistant	Access on shared drive	See spreadsheet	V01.1

Linked Documentation:

Document Title:	Document File Path:
Feasibility tracker	W:\Project Team\Projects\FEASIBILITIES 2020\ Feasibility Tracker
Agreements sent for signature	W:\Project Team/Projects/2022 Projects\Agreements sent for signature

BACKGROUND

NHS Ayrshire & Arran (NHS A&A) in line with the Chief Scientist Office (CSO) five-year strategy 'Delivering Innovation through Research' undertake feasibility processes to promote potential research opportunities. Feasibilities for studies may present from different routes. These may include the NRS (NHS Research Scotland) feasibility team (NRSF), directly from the study centres, Clinical Research Organisations, Pharma Companies or NHS A&A staff. Feasibilities also include Expression of Interests and Site List requests.

PURPOSE

To provide accurate detailed information between NHS A&A and study centres to determine the capability and capacity of undertaking a potential research study.

SCOPE

This process involves all staff directly involved with the feasibility process in the RDI team.

RESPONSIBLE PERSONNEL

Head of RDI
Senior Research Advisor
Lead Research Nurse
Lead R&D Facilitator
R&D Assistant
RDI Support Officer

ABBREVIATIONS

CDA - Confidentiality Agreement
CLO - Central Legal Office
CSO - Chief Scientist Office
NHS A&A - NHS Ayrshire & Arran
NRS - NHS Research Scotland
NRSF - NHS Research Scotland Feasibility Team
RDI – Research, Development and Innovation
SRA - Senior Research Advisor
SOP - Standard Operating Procedure
WI - Work Instruction

PROCEDURE

WHO?

Medical Director
Head of RDI
Senior Research Advisor
Lead Research Nurse
Lead R&D Facilitator
Research Nurses
RDI Support Officer
Senior Pharmacist Clinical Trials

WHEN?
When study feasibility is received by the RDI office.

HOW?

1. The Lead R&D Facilitator or Head of RDI in absence of the Lead R&D Facilitator) will process feasibilities. The RDI Support Officer will be copied into all email correspondence in order that they can save the correspondence and documentation in the appropriate folders and update the feasibility tracker in accordance with the WI for feasibilities (see appendix 1).

2. The Lead R&D Facilitator will triage the feasibilities:
    i. No information provided – decline
    ii. Oncology – Phase 2 haematology decline
    iii. Decline all feasibilities where the clinical speciality has already indicated do not wish to participate in research
    iv. Vaccine studies – decline due to insufficient Pharmacovigilance set-up
    v. Phase 1 studies – decline

3. The Lead R&D Facilitator will process the feasibility according to the instructions from the study centre. If the feasibility presents from NRS Feasibility Team follow instructions on NRS SOP on SReDA.

4. If a feasibility agreement is required the Lead R&D Facilitator will send to the Central Legal Office (CLO) to be checked. On completion the CDA/ agreements will then be passed to the Medical Director for signature in accordance with the WI for processing feasibility agreements (see appendix 2) and returned to trial centre following their instructions.

5. Feasibility documentation will be sent to NHS A&A staff for review using ‘Consultants interested in research’ spreadsheet on shared drive.

6. If there is interest in the feasibility, the Lead R&D Facilitator will assess if a meeting is required including the staff member, and the Lead Research Nurse/Research Nurse.

7. Completion of the feasibility document will take place in the format requested by the trial centre.

8. If the feasibility progresses to become a study then the feasibility folder will be re-named to the allocated RDI number with an F at the end e.g. *2022AA123F* and moved to the RDI Project folder on the RDI shared server.

OTHER RELATED PROCEDURES
RDI SOPs
RDI Naming Convention process

REFERENCES
Delivering Innovation through Research 2015 (www.nhsresearchscotland.org.uk)

APPENDICES:
Appendix 1 - Work Instruction for Feasibilities
Appendix 2 – Processing of Feasibility agreements

APPENDIX 1

WI for feasibilities

WI NUMBER	RDI 07
VERSION	V01.0
AUTHOR (S)	Jordane Duncan and Marie Frew
APPROVED BY	Dr Karen Bell, Head of Research, Development and Innovation
DATE APPROVED	26th August 2022
EFFECTIVE DATE	10th September 2022
REVIEW DATE	10th September 2024

Version History Log

Version	Effective Date	Details of significant changes
V01.0	10th September 2022	New document.

1. **INTRODUCTION**
   This Work Instruction describes the process for saving emails, populating, organising and moving feasibilities in the tracker. The tracker is found in the shared Research and Development drive under 'Project Team-Projects-Feasibilities 2020-Feasibility tracker.

2. **PROCEDURE**
   2.1 **When a new feasibility comes in:** Feasibilities are received via email in the shared RDI Project Team mailbox, and are issued by the Lead R&D Facilitator for review to relevant clinicians. The RDI Support Officer will be copied into these emails. When a new feasibility is received the RDI Support Officer creates a folder in the shared Research and Development Project Team drive under Projects\FEASIBILITIES 2020 and then the relevant year, using the correct Feasibility number, project name/title. In this folder create 2 new sub-folders named "Documents" & "Correspondence". The

Feasibility Number should be hyperlinked to the File. The correspondence folder is where all relevant correspondence will be saved for this project. Any attachments are saved into the documents folder (when further emails are sent make sure the most up to date version of a document is saved).
All emails should be saved as: “YYYY-MM-DD TIME (from) - info” for example:

- 2022-06-01 09.00 NRSF - Potential new study
- 2022-06-01 12.00 RDI - Issued for consideration

Once saved, the feasibility details need added to the feasibility tracker (see 2.5) and the email should be deleted from the shared RDI Project Team mailbox.

2.2 **When a feasibility is rejected.** The RDI Support Officer will be copied into an email letting them know the study will not be taken forward. The email needs to be saved into the correspondence folder created in 2.1 and named appropriately (eg) “2022-06-01 15.00 RDI - not taking this study forward”. Once saved the tracker needs updated to show study is rejected. Column N – *Local Response*, type “Not taking this study forward” and colour the cell green, Column O – *Decline Category*, insert code, Column P – *Reply sent to NRSF and Company*, type the date the email was sent and Column R – *Site confirmed/on hold/rejected*, type “Rejected” and colour the cell grey.

2.3 **When a feasibility is accepted.** Once an email has been received to say a feasibility has been accepted, this needs to be saved in the relevant folder and the feasibility tracker updated. Under Column N – Local Response, type “Taking forward”, and Column R – *Site confirmed/on hold/rejected*, type “Confirmed” and colour the cell grey. There will also be a new RDI project number created for this and this should be added to Column S – *RDI Project Number*, update the feasibility folder name to this new RDI number and include F at the end eg. 2022AA045F then cut and paste the folder into the relevant year in the shared Research and Development Team folder - W:\Project Team\Projects.

2.4 **When further emails come in or a feasibility is revisited.** Ensure all that emails are saved into the previously created folder, and add in any relevant details in the ‘notes’ tab on the feasibility tracker.

2.5 **How to complete the feasibility tracker (in horizontal tab order)**
Text should be added in either blue or black dependant on which Lead RDI Facilitator issues the email – following the Key on the tracker

- **Feasibility Rcvd Date**: Date the Study Centre (SC) or NHS Research Scotland Feasibility Team (NRSF) sent the first email to NHS Ayrshire and Arran RDI Team

- **Study Type**: Commercial or non-commercial usually found in NRSF or SC email title

- **Feasibility number**: under NRS Number in NRSF email. (hyperlink this to the relevant folder)

- **Company/Sponsor**: under Sponsor in NRSF email or name of SC

- **Title**: A paragraph explaining the study – under Title in NRSF email

- **Company Contact**: this can sometimes be found at the bottom of the email but it is generally Feasibility@nrs.org.uk

- **Lead Nurse**: This is populated if the feasibility is accepted the Lead Research Nurse will be able to advise who this has been allocated to

- **PI**: this is only populated if Feasibility is accepted

- **Specialty**: details under 'Therapeutic area' in NRSF email

- **Sent to**: copy & paste who the email has been sent to for consideration

- **Date sent for review**: Date email sent to staff for consideration

- **Deadline for review**: The date NRSF or SC needs response by – details under deadline in NRSF email.

- **Notes**: For adding in any important information

- **Local response:** If the study gets rejected enter 'Not taking this study forward' if the study is accepted enter "Taking forward" – and colour the cell green

- **Decline category:** This info is on the email template that goes back to NRSF

- **Reply sent to NRSF and Company:** add the date the study was rejected or a response issued

- **Date EOI submitted:** add the date Expression of Interest (EOI) is sent to the SC or NRSF

- **Site confirmed/on hold/rejected:** add in Confirmed, On Hold or Rejected when known – and colour the cell grey

- **RDI Project number:** once a study is confirmed an RDI number will be allocated and the study will be known by this instead of the feasibility number

For reference: see below: an example of an email template you will receive from NRSF (This will be forwarded onto you and with any other relevant correspondence from the Lead RDI Facilitator for saving)

DEADLINE:	Deadline Tab
TITLE:	Title Tab
THERAPEUTIC AREA:	Specialty Tab
SERVICE:	Ignore
NRS NUMBER:	Feasibility Number tab
NIHR STUDY (if applicable):	Ignore
SPONSOR (if known):	Company/Sponsor Tab
CRO (if applicable):	Ignore
ATTACHMENTS:	Ignore

2.6 On a weekly basis check the feasibility tracker Column L '*Deadline for review*' and if the deadline date has passed and Column P '*Reply has been sent to NRSF and Company'* is not completed then check the project file and the shared RDI Project Team Mailbox in case a response has been sent and not recorded. If no response has been sent and the project was notified to us from NRSF then you need to complete the document "SOP026 - Annex 5 - Standard NHS Health Board Response" this will be in the documents section of the project file. Open the original email sent from NRSF click reply, copy and paste the SOP026 - Annex 5 - Standard NHS Health Board Response” into the email – tick ‘No response from Local Investigator’ add your name and NHS Ayrshire and Arran at the bottom of the email, and send to NRSF. If we were notified of the feasibility from the SC then reply to the original email advising we are unable to take this forward. Then follow instructions as per 2.2.

3. ABBREVIATIONS

EOI – Expression of Interest
NRS – NHS Research Scotland
NRSF - NHS Research Scotland Feasibility Team
RDI – Research, Development and Innovation
SC – Study Centre

4. ASSOCIATED DOCUMENTS

N/A

APPENDIX 2

Processing of Feasibility agreements

1. Once completed and agreed the document(s) will be sent to the Medical Director for signature (clarify if wet signature is required)
2. Update spreadsheet on RDI c-shared (Agreements sent for signature)
3. Update feasibility tracker on RDI c-shared
4. Documents will be returned to the trial centre in accordance with instructions verified in email