United Lincolnshire Hospitals NHS
NHS Trust

Research Study Planning and Feasibility

SOP Title	Research Study Planning and Feasibility
SOP No.	SOP 14
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1. Purpose:

The purpose of this SOP is to detail the responsibilities of Chief Investigators, Principal Investigators, Research Nurses, R&D and LCRF staff in the planning and feasibility process for all research studies to be undertaken within ULHT.

This SOP covers local procedures for the following:

- Submitting an Expression of Interest (EoI) for both NIHR Portfolio adopted studies and Non-Portfolio studies
- Planning and arranging a feasibility meeting for both NIHR Portfolio adopted studies and Non-Portfolio studies to ensure the research project/clinical trial is feasible in ULHT.
- Completing a Site Specific Information (SSI) form and obtaining necessary authorisations
- Guidance on completing an IRMER Procedure 8 for trials involving radiation.
- Guidance on completing R & D Pathology form

2. Applies to:

All Principal Investigators, research nurses, R&D, LCRF, Trent CLRN and support department staff who are involved in the planning and feasibility process for all research studies to be undertaken within ULHT.

3. Relevant SOP documentation:

SOP 13 – Authorised Signatory
SOP – Draft Sponsorship
IRMER 8 Procedure

4. Definitions:

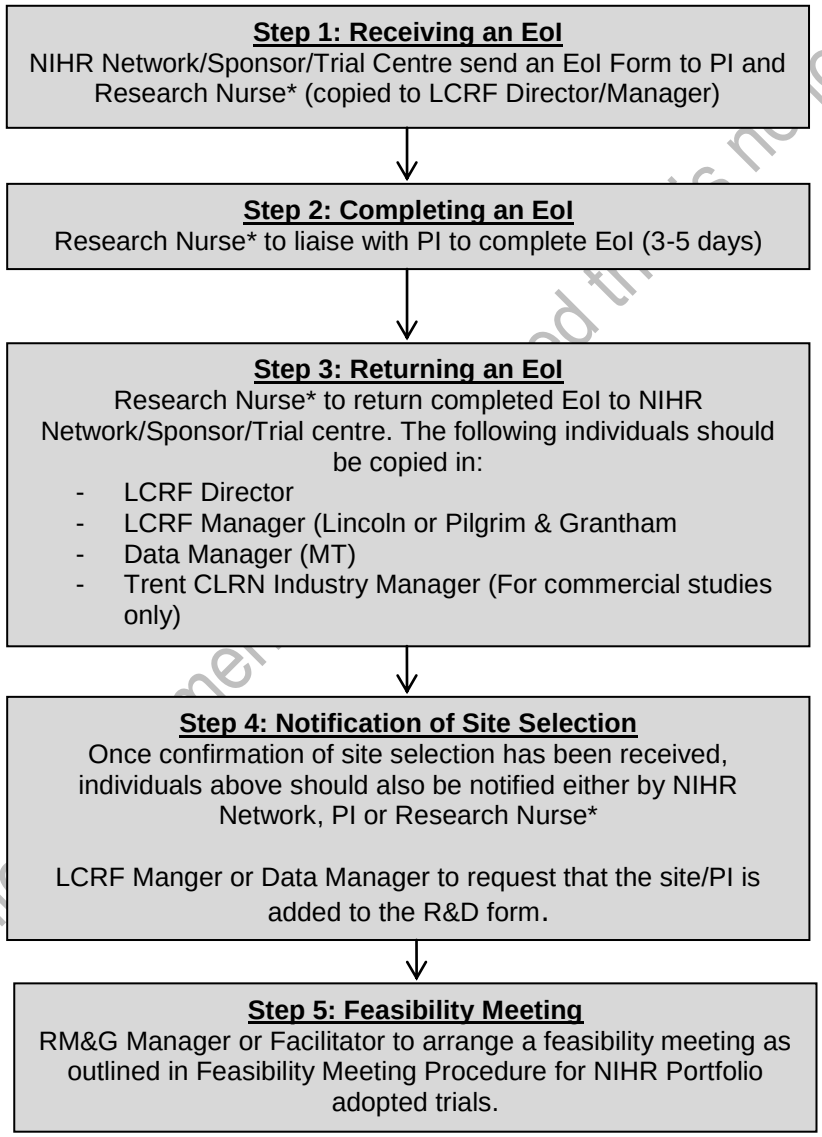
ULHT – United Lincolnshire Hospitals NHS Trust
LCRF – Lincolnshire Clinical Research Facility
PI – Principal Investigator
SSI Form – Site Specific Information form (IRAS form)
IRAS – Integrated Research Applications Service
IR(ME)R – Ionising Radiation (Medical Exposure) Regulations (2000)
MPE - Medical Physics Expert
RPA- Radiation Protection Advisor

6. Procedure:

Step 1: Expression of Interest (EoI)

Expression of Interest forms are sent to potential investigators to invite interest in running both Commercial and Non-Commercial trials at ULHT. If the investigator is interested in the trial, the EoI is completed and returned back. A completed EoI does not commit the investigator to the trial.

a) Procedure for submission of an EoI for NIHR Portfolio adopted trials:



*Where a Research Nurse has not yet been identified, the LCRF manager will undertake these duties instead.

b) Procedure for submission of Expression of Interest (EoI) for Non-Portfolio Trials:

Step 1: Receiving an EoI
Sponsor/Trial Centre send an EoI Form to PI (copied to LCRF Director/Research Governance Manager)

↓

Step 2: Completing an EoI
PI to complete EoI (3 to 5 days)

↓

Step 3: Returning an EoI
PI to return EoI to the Sponsor/Trial centre. The following individuals should be copied in:

- Research Governance Manager
- LCRF Director

↓

Step 4: Notification of Site Selection
Once confirmation of site selection has been received, individuals above should be notified by the PI.

↓

Step 5: Feasibility Meeting
The Research Governance Manager is to inform the PI of the level of support available for the proposed study
The PI is to arrange a feasibility meeting as outlined in Feasibility Meeting Procedure for Non-Portfolio trials.

Step 2: Planning and Feasibility

- In general, once confirmation of site selection and that the site/ PI has been added to the R&D form has been received, a feasibility meeting should be arranged between all relevant individuals. The purpose of a feasibility meeting is to assess the ULHT and the CI/PI readiness to deliver study successfully including patient recruitment targets. The chair of the meeting will make sure that the study is assessed against Research Support Services (RSS) study planning tool. RSS study planning tools help to manage operational risks and to record the proportionate management actions needed to complete the NHS Permission process and deliver the study. The planning tool also assesses the likelihood of the organisation being able to successfully complete the NHS Permission process within a reasonable timescale, and can then complete its contribution to the study effectively and safely. It is a tool to ensure operational risks are identified early and addressed proportionately.

- The feasibility process is a 3 stage process:

  1. Feasibility is arranged and the relevant documents are circulated.
  2. After the feasibility is completed another email is circulated with the feasibility notes and action points to be completed.
  3. Email circulated stating if the study is feasible and a date by which the study should receive NHS permission from the Trust.

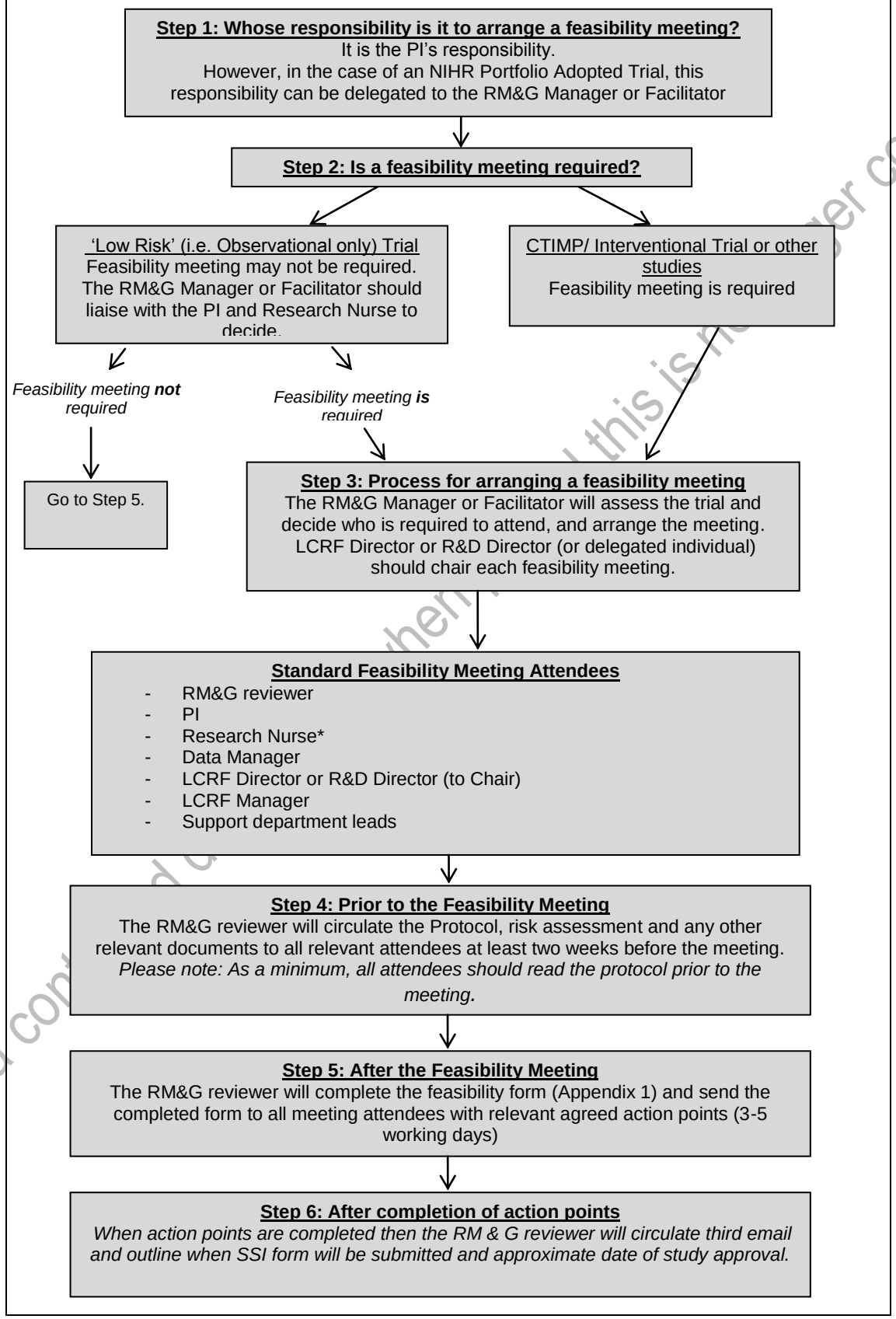
- A representative from each support department is required at all feasibility meetings, as appropriate.

Additional Feasibility Meeting Attendees (as required)

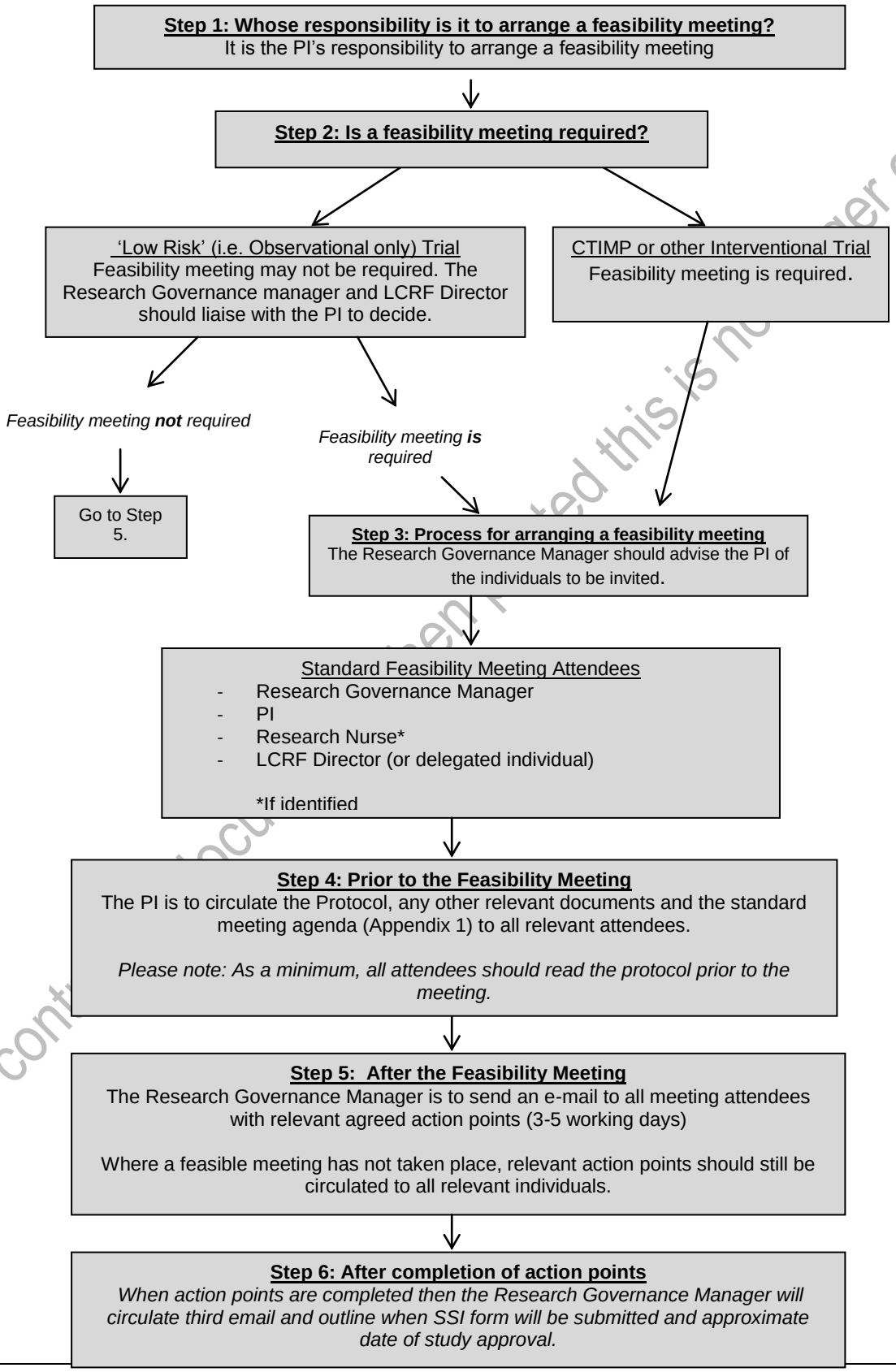
- Pharmacy*
- Radiology*
- Pathlinks-Blood sciences, cellular pathology, Microbiology, immunology.
- Medical Physics*
- Industry Manager (for commercial studies)
- Sponsor/Trial Unit Representative (where appropriate)

*Where support departments cannot attend, the RM&G reviewer is to liaise with the department to establish whether the trial is feasible.

a) Feasibility Meeting Procedure for NIHR Portfolio adopted trials



b) Feasibility Meeting Procedure for Non-Portfolio Trials



Step 3: IRMER 8 Procedure and Radiology Sign Off

a) The completion of an IRMER 8 Procedure is required to control the exposure of volunteers to ionising radiation for research purposes. It also identifies responsibilities and the necessary consideration when carrying out a research exposure, ensuring local compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER).

If the research protocol includes medical exposures that involve ionising radiation, even if it is part of normal patient care, an IRMER 8 must be completed. Completion is not approval for the trial to run.

Please refer to the IRMER 8 Procedure and complete appendix 2. Please note this should be completed at the feasibility meeting.

Where a study involves scans (e.g. PET scans, CT scans) at NUH an MPE form (Appendix 7) needs to be completed and submitted to the NUH MPE inbox (mpe@nuh.nhs.uk) as soon as possible.

Where an ARSAC is required please consult the ARSAC flowchart in Appendix 6.

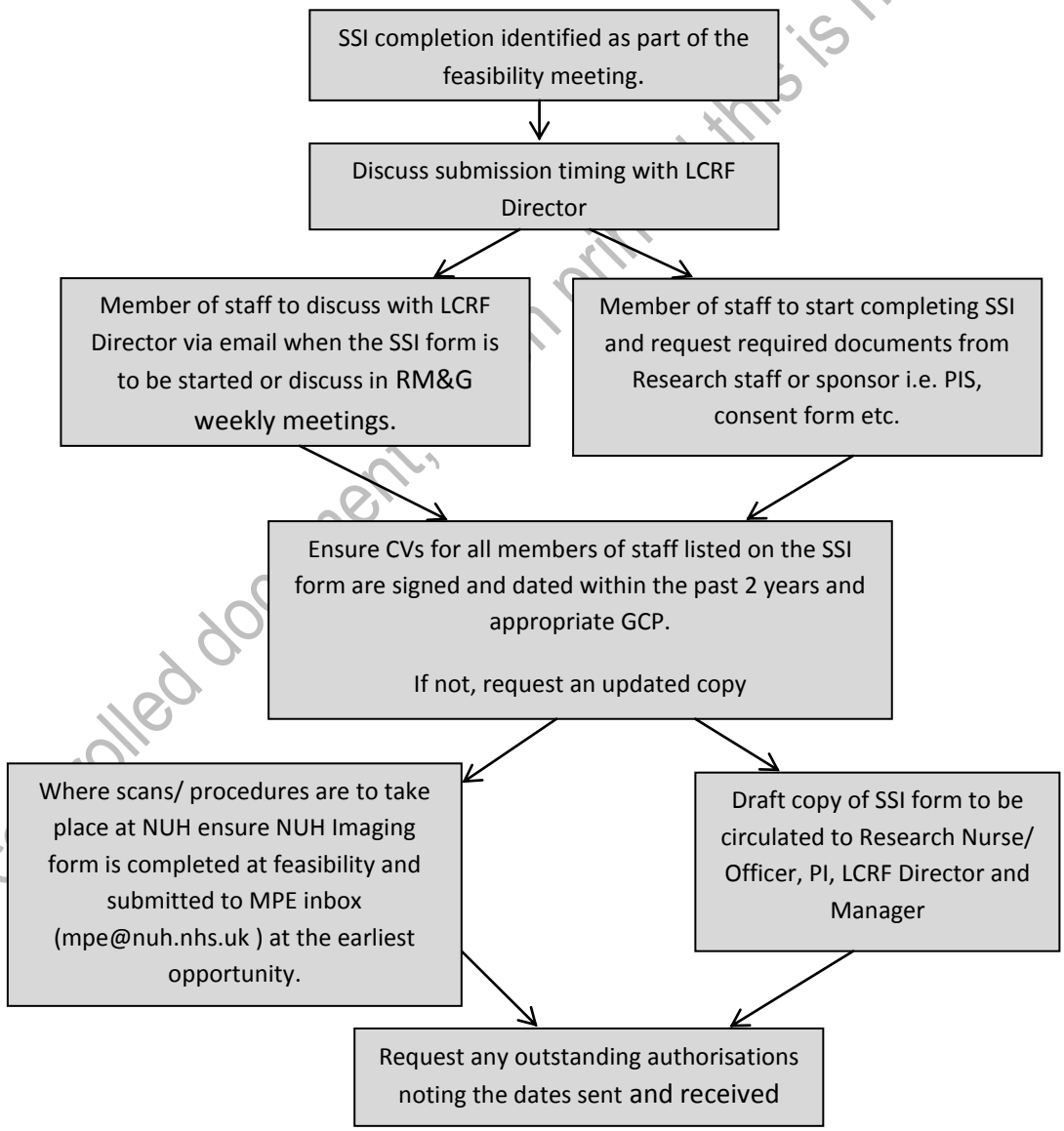
Step 4: SSI Sign off and Submission

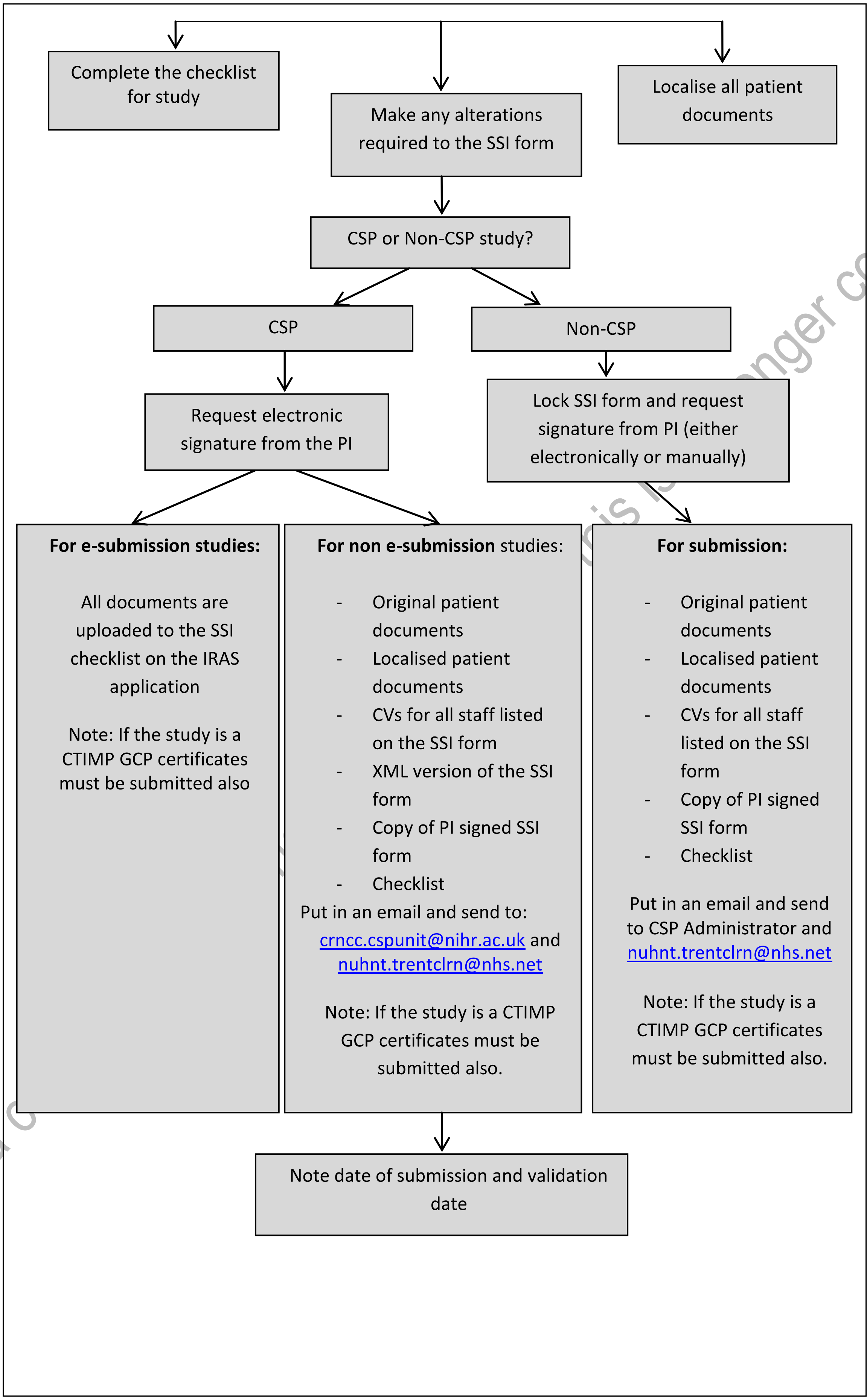
An SSI must be completed for all multi-site trials to be undertaken within ULHT (with the exception of studies where ULHT acts only as a PIC site). It is the PI's responsibility to complete an SSI form. In the case of NIHR Portfolio adopted trials, this responsibility may be delegated to or support may be sort from a research nurse or Data Manager.

SSI forms are completed via the IRAS website – www.myresearchproject.org.uk and are generated from the NHS R&D form for the study.

All PI's must have an IRAS account.

a Procedure for SSI Sign off and Submission for NIHR Portfolio adopted trials:




Complete the checklist for study
Make any alterations required to the SSI form
Localise all patient documents
CSP or Non-CSP study?
CSP
Non-CSP
Request electronic signature from the PI
Lock SSI form and request signature from PI (either electronically or manually)
For e-submission studies:
All documents are uploaded to the SSI checklist on the IRAS application
Note: If the study is a CTIMP GCP certificates must be submitted also
For non e-submission studies:
- Original patient documents
- Localised patient documents
- CVs for all staff listed on the SSI form
- XML version of the SSI form
- Copy of PI signed SSI form
- Checklist
Put in an email and send to:
crncc.cspunit@nihr.ac.uk and nuhnt.trentclrn@nhs.net
Note: If the study is a CTIMP GCP certificates must be submitted also.
For submission:
- Original patient documents
- Localised patient documents
- CVs for all staff listed on the SSI form
- Copy of PI signed SSI form
- Checklist
Put in an email and send to CSP Administrator and nuhnt.trentclrn@nhs.net
Note: If the study is a CTIMP GCP certificates must be submitted also.
Note date of submission and validation date

7. Responsibilities

- Overall it is the PI's responsibility to complete an EoI, arrange a feasibility meeting, complete an SSI form and obtain relevant approvals before a trial can be granted local NHS permission and therefore be conducted at ULHT.
- In the case of NIHR portfolio adopted trials/studies, these responsibilities may be delegated to an appropriate individual as depicted within the procedures in this SOP.
- In the case of Non-Portfolio trials/studies, advice and guidance may be sought from R&D staff; however it remains the responsibility of the PI, or in the case of single-site trials, the CI, to ensure that the appropriate planning and feasibility procedures have been followed.

8. References

The Ionising Radiation (Medical Exposure) Regulations (IRMER) (2000) Department of Health

Site identification and feasibility. Available: http://www.crncc.nihr.ac.uk/Life+sciences+industry/tools/medtech_route_map/site_identification_feasibility (Accessed on 14/02/2013) National Institute of Health Research

Research governance framework for health and social care: Second edition (2005) Department of Health

Research Support Services framework - Streamlining the management and governance of R&D studies in the NHS (2011) National Institute of Health Research

This SOP will be reviewed every two years, a more updated revision of the SOP will be implemented if new local, national or international regulations change. This would therefore replace the existing document. All SOPs can be located on the Research and Development's shared file and a hard copy of all SOPs are kept in the SOP Trial Master File

Appendix 1

Feasibility Assessment

Study Title:
Study ID:
Principal Investigator:
Contact information:
Sponsor:
Adopted/non-adopted:
Date of feasibility:
RM&G Reviewer:

Risk Assessment

☐ Low ☐ Medium ☐ High

(Please see sponsorship SOP 15)

1. Protocol
a) Version number at time of feasibility:
b) Overview of the study
c) What is standard of care and what is extra?
d) What is the standard patient pathway for this patient group?

2. Resource
a) Who will be working on the study?

b) Is there a co-investigator?
(Recommended for CTIMP studies)

c) Emergency arrangements/ out of hours

d) What studies are currently being run by the Principal Investigator?

Study Name	*Recruitment*	*Recruiting to time and target?*

e) Are there any competing studies?

3. Recruitment

a) What will the primary recruitment methods be?

- ☐ Nurse/Doctor approaching patient
- ☐ Database
- ☐ Posters
- ☐ Radio/newspaper adverts

e) Who will be responsible for identifying patients & driving recruitment?
If a research nurse/ officer, check they are part of the clinical care team- if they are not, they cannot search patient database/notes until consent is signed by the patient

f) Who will be taking consent?

g) Patient visits:
Who will do what?

h) How many potentially eligible patients are currently seen?

I. Per month	
II. Per year	

i) What is the anticipated screen failure rate and how has this figure been achieved?

j) Proposed recruitment target

k) Is there anything in the protocol design or inclusion/exclusion criteria which may impact recruitment?

l) Study Period

a) End of recruitment date	
b) End of follow up	
c) Expected closure date	

m) Forecasting patient recruitment
Discuss with the research team when they anticipate recruiting patients in to the trial. This information will allow R&D Finance to forecast commercial income

N.B Discuss with the site the importance of being recruitment ready. Provided staff are involved in the clinical care of the patient the nurse/doctor can take some time prior to R&D approval to identify a list of potential patients, check inclusion/exclusion criteria. As soon as R&D approval has been granted, the patients can then be approached.
The study team need to aim for the first patient to be recruited within 30 days of NHS permission.
Please note that site initiation must not be before R&D approval.

Financial Year	**Recruitment Target**
Year 1	
Year 2	
Year 3	
Year 4	

4. Facilities

a) Does the site have adequate facilities & equipment to accommodate the study?
(Please tick all that are applicable)

- ☐ Patient/ research area/ clinic area
- ☐ Blood Pressure Machine
- ☐ ECG
- ☐ Freezer
- ☐ Fridge
- ☐ Centrifuge
- ☐ Water Bath

☐ Other

Comments:
(If not, how will the site access facilities/equipment?)

5.Other support departments:

a) Which support departments will be required to conduct the study?

☐ IRMER (Please see appendix 3)

☐ ARSAC

☐ Cellular Pathology (Please see appendix 4)

☐ Microbiology (Please see appendix 5)

☐ Immunology (Please see appendix 5)

☐ Blood Sciences (Please see appendix 5)

☐ Cardiology

☐ Medical Photography

☐ Surgery

☐ Radiotherapy

☐ Radiotherapy QA

☐ Chemotherapy Suite

☐ Ultrasound

Pharmacy: *please ensure that pharmacy is visited at the Site Selection Visit by the Sponsor so that any concerns can be raised early.*

b) Which Pharmacy will be used?

☐ Trust pharmacy

☐ Lloyds pharmacy

c) Does Pharmacy have adequate storage facilities for the IMP?

☐ Yes ☐ No

Comments:

d) Do they have the capacity?

☐ Yes ☐ No

Comments:
e) Is there anything unusual about this drug/drug regime?
☐ Yes ☐ No Comments:
f) Will Pharmacy have to source drugs or are these provided by Sponsor?
☐ Yes ☐ No Comments:
g) Will these drugs be paid for by the Sponsor?
☐ Yes ☐ No Comments:
h) Chemo drugs- infusion devices- PVC infusion bags- which make? (Macopharma model not approved by some Trusts)

6. Governance	
a) Have the team relevant experience to conduct the study; has everyone got up to date CV and GCP training?	
☐ Yes ☐ No Comments:	
b) Is additional authorisation for access required or are staff employed by the Trust?	
☐ Yes ☐ No Comments:	
c) Completion of SSI form:	
Who will be completing the SSI form:	
Do they have an IRAS account?	☐ Yes ☐ No

Does the PI have an IRAS account for electronic sign off?	☐ Yes ☐ No ☐ N/A

d) Who will be responsible for submitting information to the support departments identified above? Are they aware of the new process (e-mail authorisations)?

e) Who will submit all the documents to R&D? Are they aware of the process and requirements?

☐ Yes ☐ No

f) What contracts / agreements are required?

☐ CTA
☐ MTA
☐ NUH MPE

7. Funding

a) For non portfolio studies have the costs been reviewed prior to feasibility?

☐ Yes ☐ No

Comments:

b) For portfolio studies, are there any extra costs that will need to be identified post feasibility? (Service support costs, excess treatment costs/ research costs)

☐ Yes ☐ No

Comments:

8. General

Site file:

1) Who will be responsible for ensuring the site file is kept inspection-ready?

2) Where are the files and study related documents stored?

3) Are there any issues with the space identified?
☐ Yes ☐ No Comments:

9. Anticipated or known timelines	
a) Ethics approval	
b) MHRA approval	
c) Estimated SSI submission date	
d) Trust Approval	
e) Initiation (After Trust approval)	

10. Action Points				
	Action Point	To be completed by (insert name)	Date by which completion is required	Completed
1				
2				
3				
4				
5				

To be completed by RM & G Manager or Facilitator or Research Governance Manager in case of non-portfolio.

Name _____ Date _____

Please scan the signed attendance register from the feasibility meeting and insert into this document below.

Where appendices have been completed please scan and insert below.

Appendix 2-

Appendix 3-

Appendix 4-

Appendix 5-

Appendix 7-

Appendix 2 - IRMER Consideration

To be completed, at feasibility, by Principal Investigator, or delegated individual, in consultation with local MPE / RPA

1) Who are the Practitioners who will justify the medical exposures for the study? *The named practitioners will be contacted post feasibility (via email) to confirm that the protocol has been reviewed and medical exposure justified.*
2) Who will be referring participants for medical exposures for the study? *(Identified by staff group)*
3) Who is the local RPA/MPE for the study?

4) Does approved PIS accurately reflect additional radiation and risk to which local participants will be exposed?
Yes ☐ **No** ☐ **If No, please provide additional comments:**
5) Can the protocol be performed at the site within the estimated range of dose made by the lead MPE?
Yes ☐ **No** ☐ **If No, please provide additional comments:**
6) Any additional comments

Details of proposed radiation exposures:					
Please name the procedure below (e.g. CT, x-ray, etc.)	**Frequency and proposed total number of exams**	**How many of these are routine?**	**How many are additional to routine care?**	**What is the Dose Constraint or the individual Target Dose?**	**Is an ARSAC certificate required?**
1)					
2)					
3)					
4)					
5)					
6)					
7)					

Appendix 3

Northern Lincolnshire and Goole Hospitals NHS
NHS Foundation Trust

PATH LINKS NHS PATHOLOGY

Cellular Pathology Directorate

Research Trial/Investigation Proposal Form

Trial Details *To be completed by Principal Investigator/Trial Coordinator*

Name of Project ……

Principal Investigator ……

Proposed start date …… Proposed end date ……

Number of patients expected to recruit …… Non / Commercial Trial (delete as appropriate)

Protocol attached?
YES / NO (Delete as appropriate)

CPA Certificate Required?
YES / NO (Delete as appropriate)

Trial requirements ***Details / Comments***

Withdrawal of paraffin blocks or slides ……
YES / NO (Delete as appropriate)

Postage and packaging by laboratory ……
YES / NO (Delete as appropriate)

Technical laboratory requirements
……
YES / NO (Delete as appropriate)

Consultant Pathologist input
e.g. Tumour block selection
……
YES / NO (Delete as appropriate)

Trial Funding *To be completed by Principal Investigator/Trial Coordinator*

Covered under **CLRN** funding **YES / NO** (Delete as appropriate) **Trent / N&EY&NL** (Delete as appropriate)
Separate trial funding **YES / NO** (Delete as appropriate)

If Yes, fee claimable and address for invoice to be sent:

……
……..

Proposal form submitted by:

Name: …… Date: ……

Contact details:
……

Directorate Authorisation *To be completed by Cellular pathology*

Name …… **Cellular Pathology Directorate Operational Manager**

Signed …… Date ……

Name …… **Cellular Pathology Lead Histopathologist for trial**

Signed …… Date ……

Completion of the Research Trial/Investigation proposal form

The first 2 sections of the proposal are completed by the Research & Development trial coordinator

The Research & Development trial coordinator should:

- Summarise the Cellular Pathology requirements for the trial from details within the protocol to be submitted with the proposal.

  Note: The attaching of the trial protocol alone is not acceptable.

- Indicate if the trial is covered under CLRN funding and the appropriate CLRN. The department will recover costs through the respective CLRN funding framework.

- If a trial is not covered by CLRN funding, the fees claimable and where invoices are to be sent should be entered in the appropriate section.

- Insert their name, contact details and date. (as designated point of contact for the trial/investigation)

The completed form should then be sent to:

Shirley Nelson
Directorate Administrative and Secretarial Services Manager
Cellular Pathology Office,
Lincoln County Hospital, Greetwell Road, Lincoln. LN2 5QY

The final section of the form is completed by the Cellular Pathology signifying agreement to the proposal. A copy of the completed form will be sent back to the person submitting the form for their records.

Note:

The approval of a particular trial by Cellular Pathology should only be assumed after the receipt of the completed copy of the appropriate proposal form.

This proposal form only refers to trial requirements from Cellular Pathology. Trial requirements from other Pathology departments need to be agreed separately.

Assistance with completing the form can be obtained through:

Shirley Nelson
Directorate Administrative and Secretarial Services Manager
Tel: 01522 573755
shirley.nelson@ulh.nhs.uk

Appendix 4

R&D Pathology Form

Name of study/trial

Length of Trial

Recruitment Target

Name of Principal Investigator

Name of Nurse – Contact Number

Samples to be processed

Samples obtained routinely Blood Sciences	**Samples obtained for research purposes** Blood Sciences
Cellular Pathology	Cellular Pathology

Samples to be stored

Samples obtained routinely Blood Sciences	**Samples obtained for research purposes** Blood Sciences

Cellular Pathology	Cellular Pathology

Sponsor

Proposal Form Submitted by (Name & Contact detail)

Guidance Notes

Pathology Forms are now managed by Sarah Ford who can be contacted on extension 3096 or by email at Sarah.Ford2@ULH.nhs.uk.

Pathology Forms should be completed by the PI, or a delegated member of the research team. Sarah Ford can be contacted for further guidance on Pathology Form completion.

For general queries regarding the requirement for Pathology Forms please contact Maria Tute on extension 7557 or by email at Maria.Tute@ulh.nhs.uk.

Pathology forms are used for internal review, to calculate financial recompense and to obtain pathology sign off, so please provide as much information as possible.

As new trials now require separate Cellular Pathology and Blood Sciences sign-off there is also a separate Cellular Pathology Pathlinks Form to be completed.

Where a protocol amendment affects the pathology processes in a trial, new a R&D Pathology Form *and* a new Cell Path Pathlinks Form need to be completed and submitted.

Details should be provided on which tests will be performed on what samples, and each activity needs to be attributed to the person who will perform it.

The R&D Pathology Form requires details of samples for Blood Sciences and for Cellular Pathology to be distinguished.

Therefore:

- Any details of activity undertaken in the Cellular Pathology department (tumour blocks, biopsies etc.) will need to be entered in the cellular pathology box.
- Any activities undertaken by the blood sciences department (blood tests, urine etc.) will need to be entered in the blood sciences box.
- Bone Marrow Aspirates are signed off by Blood Sciences and Bone Marrow Biopsies are signed off by Cellular Pathology.

Samples to be processed

Samples obtained routinely – enter details of any tests or processes mentioned in the protocol that would be performed as part of routine clinical practice, whether or not the patient was participating in a trial. Please state who will be undertaking each task (e.g. research team or pathlinks).

Samples obtained for research purposes – if the protocol requests any tests to be performed or samples to be processed that would not be done as part of routine clinical care; the details need to be entered into this box. Please state who will be undertaking each task (e.g. research team or pathlinks).

For example:

Samples obtained routinely	**Samples obtained for research purposes**
Blood Sciences Routine tests to be processed by local blood sciences department. - FBC - serum biochemistry: sodium; potassium; chloride; biocarbonate; calcium; phosphate; urea; creatinine; total protein; uric acid; total bilirubin; ALP; gamma-GT; AST or ALT; LDH; albumin; glucose (random) and haptoglobin - eGFR, using MDRD formula - Serology for HIV, HbsAg, HBcAb and HCV - Direct antiglobulin (Coombs) test - CMV serology (anti-CMV IgG status) - Serum ß2-microglobulin - Serum immunoglobulins (IgG, IgA, IgM) - pregnancy test for women of child-bearing potential	Blood Sciences All venepuncture, centrifuging, freezing and shipment to be performed by research team. At baseline and disease recurrence - 1 x 5ml EDTA whole blood sample – aliquot into 5 red top freezer tubes. - 2 x 5ml EDTA plasma sample – centrifuge at 2500 rpm for 15 minutes and aliquot the plasma into 5 green top freezer tubes. - 1 x 10ml Serum sample – allow the sample to clot for 30 minutes then centrifuge at 2500 rpm for 15 minutes and aliquot the serum into 5 blue top freezer tubes. Samples need to be centrifuged and separated within 1 hour, and the aliquots frozen immediately after processing. Each aliquot should be 0.8-1ml. Tubes (filled and unfilled) should be labelled with patient trial number, patient initials and collection date and placed into sample bag with the white copy of the Lab Requisition forms, then frozen at -80°C. If a sample is insufficient to fill all the freezer tubes then indicate this on the Lab Requisition form. These will be transported (on dry ice) as required, to the Endocrine Cancer Group, Edinburgh via courier which will be paid for by the trial centre. Packaging materials and dry ice will be provided by the trial centre. Order of priority of samples is - Serum (1 x 10ml SST) - Plasma (2 x 5ml EDTA) - whole blood (1 x 5ml EDTA) Fewer aliquots of 0.8ml are preferable to more aliquots of a smaller volume. NCR format Lab Requisition forms, freezer tubes and pipettes will be provided by the trial centre. EDTA and Serum Separator tubes to be provided by the local research team.
Cellular Pathology None	Cellular Pathology At baseline and disease recurrence or first diagnosis of contra-lateral breast cancer (if available) 1 x representative tumour block from mastectomy or wide local excision for each patient to be sent to Endocrine Cancer Group Edinburgh via post where 0.6mm cores will be extracted for tissue micro-array construction. Blocks will be returned to source pathology dept. on completion of processing or sooner if required. Tumour blocks will be packaged and dispatched by the local cellular pathology department.

	NCR format Pathology Request forms and packaging materials will be provided, and shipment paid for by trial centre.

Samples to be stored

Enter details of any samples which will be stored (e.g. bloods/urine in freezer.) You need to indicate:

- how many there will be per patient
- what needs to be done to them before they are stored (centrifuging etc.)
- where they will be stored
- how long they will be stored for
- when they will be shipped
- where to
- who will be responsible for each action

Samples obtained routinely - Samples which would be taken and stored as part of the routine clinical care for the patient.

Samples obtained for research purposes – Samples which the protocol specifies as wanting in addition to those that would be taken as part of normal treatment.

For example:

Samples obtained routinely	**Samples obtained for research purposes**
Blood Sciences None	Blood Sciences As above - 5 x 0.8ml whole blood aliquots - 5 x 0.8ml plasma aliquots - 5 x 0.8ml serum aliquots To be stored in freezer tubes/cryovials in a -80°C freezer in the local pathology lab. Samples will be obtained, processed, frozen and shipped by research team.
Cellular Pathology None	Cellular Pathology

Appendix 5

Feasibility Meeting Attendance Register

Study Title:
Study ID:
Date of Feasibility meeting:
Venue and Time:

Name	Designation	Signature

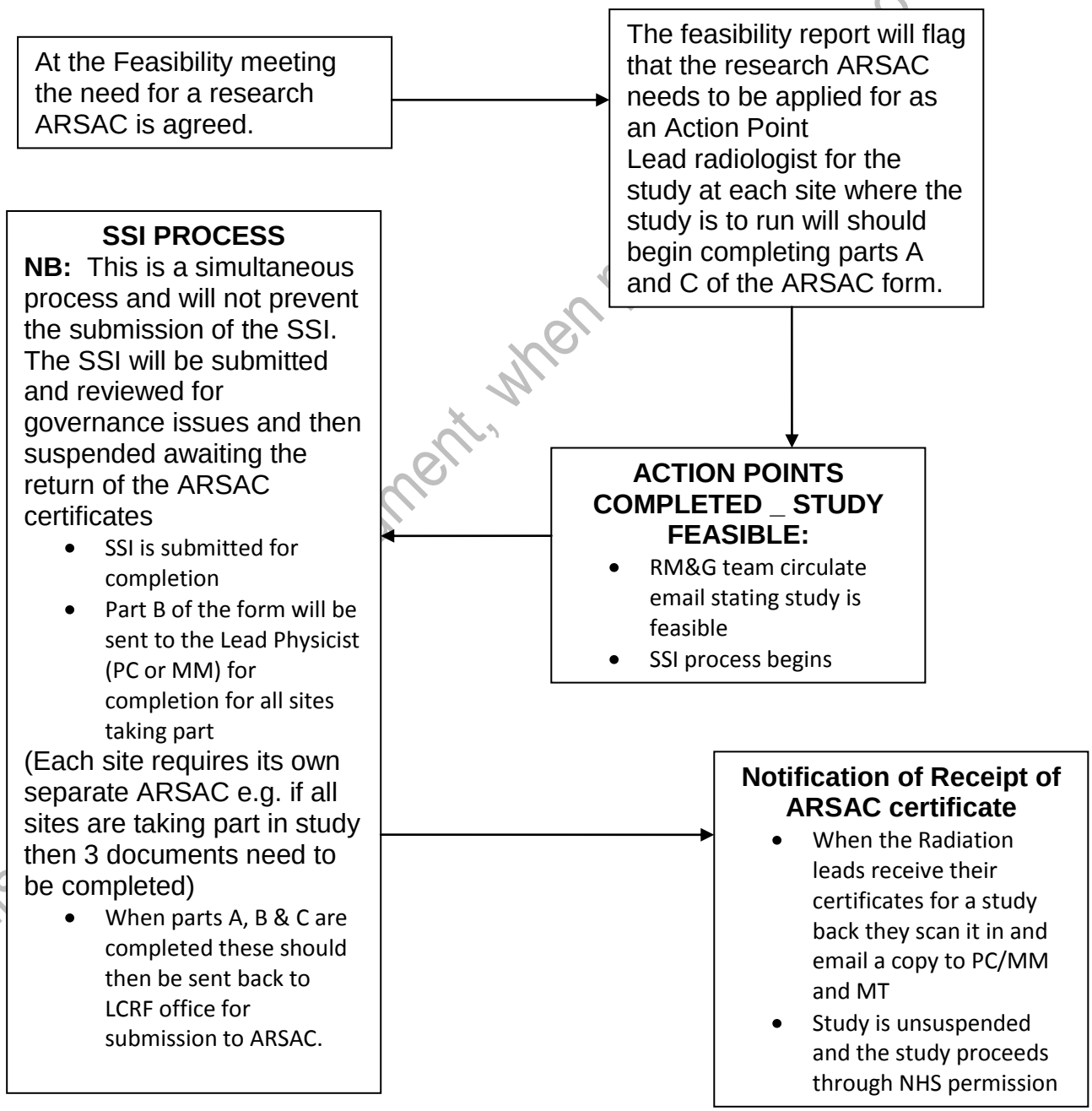
APOLOGIES

Appendix 6

The ARSAC form for research is generated through IRAS by the study centre when they generate the SSI. The most part of this is completed with just the local ARSAC holders name and details to be entered for each site.

The guidance (on IRAS) states that it is the ARSAC license holder's responsibility to check the dosages stated in the IRAS/ARSAC form are correct and they are happy with them. This is then printed off and you need to include a copy of parts A and C of your main ARSAC license with the research form for submission.

The ARSAC form will not be generated unless we have agreement (at feasibility) that we have capacity to perform the research requirements and at the required dose level.



Appendix 7

Nottingham University Hospitals NHS
NHS Trust

R&D Imaging Support Unit
Study imaging summary sheet

Project title				
R&D number		Short title / acronym		
Protocol number		CSP number		commercial funding ☐ non-commercial funding ☐

Please complete the following with responses specific to NUH participation in the trial

Proposed start date		Number of patients to be recruited	
Proposed end date		NUH campus to be used for imaging	

Who should we contact with queries about this form?

Name		Contact location	
Email		Contact phone number	

Have you discussed trial requirements with imaging support department?
Check! Have you included with your application?

	Tick
R&D form or REC form	☐
SSI form	☐
Trial protocol	☐
Participant information sheet	☐

Send this completed form and the supporting documents to mpe@nuh.nhs.uk

lease complete the following information for each imaging or radiation procedure required by the trial at this site. Copy and paste the table for any further procedures.

	Frequency and proposed total number of exams	**How many of these are routine?**	**How many are additional to routine?**	**Dose Constraint or Target Dose**	**Signature of IRMER Practitioner (where required)**	**ARSAC**
Procedure 1						
Procedure name and protocol to be used	-					
Normal / modified reporting protocol?						
Copy of images required? What format?						
Costing for this investigation						

	Frequency and proposed total number of exams	**How many of these are routine?**	**How many are additional to routine?**	**Dose Constraint or Target Dose**	**Signature of IRMER Practitioner (where required)**	**ARSAC**
Procedure 2						
Procedure name and protocol to be used						

Normal / modified reporting protocol?	
Copy of images required? What format?	
Costing for this investigation	

Appendix 8

Research Risk Assessment Matrix Version 5 19.02.13
Trial:
Protocol Reviewed:
Reference number:
Adapted for use by ULHT with kind permission of the University Hospitals Coventry & Warwickshire NHS Trust

	1	2	3	4	5	Score	Comment
Scale of Research	0-20	21-50	51-100	101-250	>250		
Study Phase	None	IV	III	II	I		
Patient Population	No research involvement of human subject groups	Subject group not considered vulnerable – able to give informed consent, may benefit from taking part. Subjects are NHS staff rather than patients	Patients with potential limited capacity to consent e.g. early stages of cognitive impairment limited English. Specialist clinical areas with limited treatment options. Areas with high/rapid turnover of patients. Healthy volunteers in studies with moderate risk attached to the intervention Patients with poorly controlled / complex illnesses	Patients with severely compromised capacity to consent – unconscious, cognitively impaired. Patients with poor prognosis / terminal disease & patients not likely to gain any benefit from taking part Healthy volunteers in studies with high risk attached to the intervention	Any study where side effects of the intervention have a realistic chance of being fatal or causing serious harm (more than 30%) Studies involving a target group of pregnant women, or women of childbearing age		
Intervention	Non invasive procedures Questionnaire / interview or survey research on non contentious subjects	Minor intervention e.g. taking blood or skin samples Questionnaire/ interview or survey work on sensitive	Involves a clinical intervention which represents only a slight deviation from normal treatment and / or basic safety and efficacy testing has	Involves a clinical intervention which represents a significant change from standard care or withholding of all / elements of standard	Significant risk derived from single highly invasive clinical intervention or combination of interventions – e.g. surgical techniques,		

		subjects e.g. sexual behaviour	been carried out e.g. Phase 3 or 4 trials. Treatment is licensed for this indication.	care Basic safety and efficacy data not yet available for the investigational product e.g. Phase 1 and 2 trials	radiotherapy, cytotoxic drugs or combinations of the above. Significant numbers of adverse events expected.		
Assessment measures	Non-invasive	Minor intervention e.g. taking additional blood samples	Additional tests which represent a slight deviation from normal practice, i.e. additional outpatient visits, series blood sampling	Fully justified additional radiation or additional invasive tests that would not usually be part of patient care	Additional radiation or additional invasive tests with insufficient justification		
Follow-up	One-off intervention with no follow up	May be more than one intervention, no follow up	Follow up in line with / similar to clinical practice	Additional follow-up to standard care, may be for extended period	Extended follow-up for many years, may include ONS flagging, GP or relatives		
Investigator	No local investigator, or minimal involvement, e.g. recruitment only	Experienced Principal / Chief Investigator supported by well trained and experienced team Study team have up to date training in GCP / governance	Limited experience of leading a study May have small research team / limited support from collaborators, sponsors Some awareness of governance issues	No prior experience of leading a study Inexperienced / stretched team No evidence of governance / GCP awareness	Previously investigated for fraud/misconduct or there is evidence to suggest the team is dysfunctional.		
Adverse Event reporting	Very low risk project - Not required	Few adverse events anticipated, reporting to CI within local team	Formalised system in place for reporting adverse events	Full pharmocovigilence and safety reporting mechanism required	High risk intervention with likely numbers of SUSARs / SAEs requiring frequent review.		

Information / Personal Data	No personal data being used	Data anonymised or pseudonymised No data sent outside EU Data stored in secure site	Poorly defined processes of data recording and storage. Poorly defined result dissemination. Data to be stored in open environment. No clear process for un-blinding subjects	Data to be sent to sites outside EU Discrepancy between ethics application, patient information, consent and/or protocol/trial information. Potential for fabrication, falsification, distortion/omission or corruption of research data. No provision for result dissemination. No limits on data access.	Previous breaches of data protection / confidentiality		
Protocol Design	Minor or insignificant patient involvement with clear rationale and scientific justification.	Clear complete rationale and scientific justification. Clearly defined proposal. Independent expert and peer review with written summary. Clear developmental background for investigational drug or device.	Some rationale and scientific justification. Protocol is unclear on first reading, potential ambiguity Independent statistical review Some developmental background / rationale	Limited scientific background for study intervention. Incomplete / draft protocol requiring additional work Poor/no documentation of review process.	New/experimental treatment without clear scientific background. Complex protocol or invasive procedure. No independent, expert review.		
Protocol Deviation	Straight forward study with low risk of non-adherence to protocol	Clear guidance for protocol violation	Poor guidance for potential protocol deviations or errors	Potential for deviation from protocol No protocol violation contingency defined. Research to be	Major potential for deviation from protocol, which may result in harm to study subject. Previous instances of		

				conducted out of hours	inappropriate / unauthorised deviation from protocol.		
Consent	Consent not necessary / REC approval to go ahead without it	Clearly defined process for informed consent with named designation of responsibility. Clear defined recruitment process. Patient given sufficient time to consider taking part Clearly identified risk and benefits. Clear consent form and PIS	Assent process in place Consent from vulnerable groups Patients given limited time (less than 48 hours) to consider taking part.	Consent does not cover all aspects of research. Multiple consents for a single study Unclear process for recording consent. No explanation of recruitment process. Patient required to consent same day (i.e. no time to reflect) Complex patient information sheet.	Prior instances of poor consenting procedures.		
Finance	No cost ramifications/ minor implications implications (<10K) Fully funded research Costed by R&D with contract in place	Unfunded research with costs of £10-35k Partially funded research with division picking up the excess	Under-costed Partially funded unclear - Who is picking up the remainder? No divisional support	Not costed by R&D office No defined contract with or between research organisations	Previously identified issues of poor costing or use of funds Previous instances of PI signing off contract without R&D		
	Low Score 0-28	**Moderate Score 29-40**	**High Score 41-54**	**Extreme Score 55-65**			
		Efforts should be made to reduce risks by completing the Risk Management Plan.		**Escalate to R&D Director to consider whether risks can be managed; or whether Trust should not support**	**Score**	0	

Signature……

Date……

Trial Steering Committee required?	Yes/ No
Independent Data Monitoring Committee required?	Yes/ No

To determine whether IDMC is required (consider if 1 'YES', mandatory if 2 or more 'YES':	
1. Is the trial intended to provide definitive information about effectiveness and/or safety of a medical intervention?	Yes/ No
2. Is there prior data to suggest that the intervention being studied has the potential to induce potentially unacceptable toxicity?	Yes/ No
3. Is the trial evaluating mortality or another major endpoint such that inferiority of one treatment arm has safety as well as effectiveness implications?	Yes/ No
4. Would it be ethically important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not fully addressed?	Yes/ No