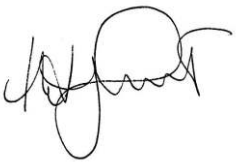
The approval of research projects within Birmingham and Solihull Mental Health NHS Foundation Trust

POLICY NUMBER & CATEGORY	**C39**	**Clinical**
VERSION NO & DATE	**3**	**February 2020**
RATIFYING COMMITTEE	**Clinical Governance Committee**	
DATE RATIFIED	**June 2020**	
NEXT ANTICIPATED REVIEW DATE:	**June 2023**	
EXECUTIVE DIRECTOR	**Executive Medical Director**	
POLICY LEAD	**Head of Research and Innovation**	
POLICY AUTHOR	**Research Governance Manager**	
Exec Sign off Signature (electronic)		
Disclosable under Freedom of Information Act 2000	**Yes**	

POLICY CONTEXT

Nationally, NHS organisations are required to Assess, Arrange and Confirm (AAC) their capacity and capability to deliver a research study before its commencement. The Research and Innovation (R&I) department at Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) works proactively with local research teams to assess whether or not the Trust has the capacity and capability to participate in the research, puts in place any practical arrangements to deliver the research, and subsequently confirms that the research can begin.

The Trust has a reputable research portfolio and the R&I department continually strives to ensure that research is reviewed, approved and subsequently carried out within a safe and transparent framework. With due regard to relevant UK legislation, this policy sets out the principles, requirements and processes which will be implemented by the R&I department. It ensures that the advice given, and the processes experienced by researchers, is consistent and exceptional. This policy also sets out the responsibilities of researchers in contributing to a successful review, and in ensuring that the R&I department are kept informed of developments as the study progresses.

POLICY REQUIREMENT

All research conducted in the Trust must be reviewed and approved by the R&I department and confirmation of capacity and capability will be issued before its commencement.

In addition, researchers are obliged to notify the R&I department of any amendments or breaches of the protocol, and are required to provide the R&I department with any necessary progress reports and subsequently notification of study end.

Contents

1 INTRODUCTION 4

1.1 Rationale (Why) 4
1.2 Scope (Where, Who, When) 4
1.3 Principles 4

2 POLICY (What) 5

3 PROCEDURE 5

3.1 For studies where BSMHFT is the Lead NHS Trust 5
3.2 All studies – submission for review and approval by the R&I department 6
3.3 The issuing of capacity and capability at BSMHFT 8
3.4 Record Keeping – Research Governance 8
3.5 During the study – Research Team Responsibilities 9
3.6 Timeframes 9

4 RESPONSIBILITIES 9

5 DEVELOPMENT AND CONSULTATION PROCESS 10

6 REFERENCE DOCUMENTS 10

7 BIBLIOGRAPHY 10

8 GLOSSARY 10

9 AUDIT AND ASSURANCE 10

10 APPENDICES 11

1 INTRODUCTION

1.1 Rationale (Why)

Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) believes that research is a core function of health and social care; that it is essential to the health and wellbeing of our service users and carers, and that it can lead to improvements in the future care provided by the Trust. BSMHFT wishes for all service users and carers to be given the opportunity to participate in high-quality ethical research, and to feel safe when they do.

With due regard to relevant UK legislation, this policy sets out the principles, requirements and processes which will be implemented by the R&I department and followed by researchers to ensure that research is accessible to both researchers and service users/carers alike, and that high-quality, ethical research is supported and approved.

1.2 Scope (Where, Who, When)

Where

This policy applies to <u>all</u> research studies taking place within the responsibility of BSMHFT.

Who

This policy is intended to be read and understood by researchers wishing to conduct research within BSMHFT. It is not intended for internal Research and Innovation (R&I) department staff, who should instead refer to the internal R&I Handbook.

When

This policy should be followed prior to the commencement of any research activity at the Trust.

1.3 Principles

The Trust positively supports individuals with learning disabilities and ensures that no-one is prevented from accessing the full range of mental health services available. Staff will work collaboratively with colleagues from learning disabilities services and other organisations, in order to ensure that service users and carers have a positive episode of care whilst in our services. Information is shared appropriately in order to support this.

The R&I department aims to ensure that:

- Service users and carers are given the opportunity to take part in research and feel safe when they do.
- Applying to the R&I department is simple and receiving a decision is quick and predictable.
- Researchers value the role of the R&I department in being efficient and supportive.
- Trust staff appreciate the importance of research to the delivery of Trust services.

- Research conducted within the Trust is of high quality and ethically sound

.

2 POLICY (What)

All research conducted in the Trust must be reviewed and approved by the R&I department, and confirmation of capacity and capability will be issued before its commencement.

A research study is defined as *'the attempt to derive generalisable and/or transferrable new knowledge by addressing clearly defined questions with systematic, rigorous and repeatable methods. This excludes audits of practice, service evaluations and market research.'*

Please note that this policy does not apply to projects deemed as Service Evaluation or Clinical Audit. The Health Research Authority (HRA) has a decision tool on its website which can assist in confirming which of the three categories (research, service evaluation or clinical audit) the project is deemed as **however the final decision will be made by the R&I department.**

If a research study involves undertaking research on:

- BSMHFT premises and/or
- with BSMHFT service users and/or
- with BSMHFT staff and/or
- with BSMHFT data

then it must be reviewed and approved by the R&I department before its commencement i.e. before participants can be actively screened and approached or before data can be prepared and released.

3 PROCEDURE

3.1 For studies where BSMHFT is the Lead NHS Trust

For studies where BSMHFT is the Lead NHS Trust, the R&I Department strongly encourages researchers to get in touch with the department at the earliest availability so that key discussions regarding conducting research within the NHS can happen upfront and support can be provided. The R&I department must be provided with the research protocol and, ideally, an Integrated Research Applications System (IRAS) Form.

Early engagement is a **must** when BSMHFT is the Lead NHS Trust **and** an external application for funding is being made (i.e. a grant application). The R&I Department recommends that they are contacted eight weeks prior to the grant application deadline. The R&I department must be provided with the research proposal/research protocol and the draft grant application form at a minimum.

For studies where BSMHFT are the Lead NHS Trust, the R&I Department can provide the following:

- Advice and support on cost attribution following Department of Health Attributing the Cost of Health and Social Care Research (AccORD) guidance, including identifying the NHS Support Costs and NHS Treatment Costs.

- A Letter of Support for a grant application.
- Support to the researcher though the HRA approval process, and if applicable the Research Ethics Committee approval process and the process for adoption onto the NIHR CRN Portfolio.
- A local NHS feasibility assessment to ensure successful study delivery.

N.B. For research studies requiring BSMHFT research sponsorship, please refer to the 'Applying for and maintaining Research Sponsorship from Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT)' Standard Operating Procedure.

3.2 All studies – submission for review and approval by the R&I department

The UK Local Document Pack, as defined nationally by the Health Research Authority (HRA), should be provided to the R&I department which includes the following documentation:

Integrated Research Application System (IRAS) Form The IRAS Form requires comprehensive information about the study and the associated research governance considerations. The information in the form should be consistent with the Protocol and all other study documentation. It should be electronically signed by both the Chief Investigator and the Research Sponsor and should list BSMHFT as a participating site in Part C (unless approved in a subsequent amendment) in order for the R&I department to commence their review.
Protocol Current version and date. The Protocol is a full description of the research study and acts as a 'manual' for members of the research team to ensure that everyone adheres to the method outline. It should describe as much detail about the research project as possible. No two research protocols are the same, but there are common elements and items that need to be addressed. The HRA has various protocol templates on their website.
Participant Information Sheet (PIS), Consent Form and additional participant documentation. Current version and date. It is imperative that participants are fully informed about their involvement within a research study. The Participant Information Sheet supports the consent process by helping to ensure that all of those invited to take part have been adequately informed. The HRA have a vast resource, including templates, to assist with these documents. Additional participant documentation may include GP Letter, questionnaires, interview topic guides or leaflets and posters.
<u>For Non-commercial studies:</u> **Organisational Information Document (OID)** and

Schedule of Events/Schedule of Events Cost Attribution Template (SoECAT) The OID and the SoEs is used to provide site specific information to each participating NHS Trust. It allows the Trust to be clear on what activities will be undertaken locally and if applicable, how those costs will be covered. The SoECAT is a requirement for all research studies funded by the NIHR and is completed **instead of** a SoE in these circumstances.
For commercial studies: **Organisational Information Document** and **NIHR validated costing template.**
Any relevant template or model agreement (if required)
Copy of the national regulatory body approval letters National regulatory body approval letters should be sent once received. Not having these yet should not prevent submission to the R&I department. Researchers are in fact encouraged to submit to R&I in parallel to make the most efficient use of time. As a general rule, the following national regulatory body approval letters will apply for different studies: • All NHS research requires HRA Approval. • All NHS research involving service users as participants requires NHS REC Approval. • All NHS research involving investigational medicinal products or medical devices requires approval from the Medicines and Healthcare Products Regulatory Agency (MHRA). • All NHS research involving the Prisons or Probation Trust will require approval from Her Majesty's Prison and Probation Service (HMPPS).
Any research study amendments and their associated national regulatory body approval letters

A small amount of additional documentation is requested above that provided in the initial UK Local Document Pack. This includes the following:

Recently (last six months) signed and dated CV for the Principal Investigator (PI) and where requested, a Good Clinical Practice (GCP) certificate (completed within the last two years).
Recently (last six months) signed and dated CV for the local research team and where requested, a Good Clinical Practice (GCP) certificate (completed within the last two years).

A Research Passport application for any member of the research team who is external to the Trust and whom requires access to service users.

Documentation should be submitted by email to **bsmhft.researchandinnovation@nhs.net** and will be brought to the attention of a member of the research governance team who will remain the researcher's single point of contact throughout the research study review process. The application will be acknowledged within three working days of receipt.

Following receipt of the UK Local Document Pack, the research governance team will begin their capacity and capability assessment. Whilst this will be led by the research governance team, it is important that the individual who made the submission is readily available to answer any outstanding queries and to provide any additional documentation. Depending on the study in question, the review may also involve communication with various support departments (i.e. Pharmacy) or service areas/wards/departments that are to be involved in the study delivery.

Following a review of the submission by the research governance team, the applicant will receive notification of any outstanding documents/queries required to complete the review.

Appendix 1 covers some of the considerations of the research governance team during the review.

3.3 The issuing of confirmation of capacity and capability at BSMHFT

Findings from the capacity and capability review will be inputted into an internal 'Summary of Findings' document by the research governance team. The Summary of Findings will be presented to the Research Governance Manager/Implementation and Performance Manager for Trust sign-off (the issuing of capacity and capability). Please note, studies are not presented to an internal committee for review.

Responses will then be fed back to the Research Governance Manager/ Implementation and Performance Manager and should the review be favourable, the researcher(s) will be issued with a 'Confirmation of Local Capacity and Capability at Birmingham and Solihull Mental Health NHS Foundation Trust' email. Recruitment can now begin.

3.4 Record Keeping – Research Governance

The R&I Department will hold a comprehensive electronic study file for each research study containing the research submission and the subsequent Trust sign-off on the departments' electronic shared drive.

The R&I Department will log all research projects (be they pending, open, closed or archived) on the departments local management system; EDGE. In order to ensure that EDGE records remain up to date, researchers will be contacted by the research governance team when the study is approaching the planned study end date to assess:

- Whether the study has indeed closed and therefore obtain the actual study end date, the participant recruitment total and the final report.
- Whether the study requires an extension and obtain the national regulatory approval for the extended study end date.

3.5 During the study – Research Team Responsibilities

During the study researchers are required to fulfil the following duties:

- Maintain a Site File.
- Inform the R&I Department of any amendments to the research study. This includes both substantial and non-substantial amendments.
- Inform the R&I Department of any breaches to the research protocol.
- Submit the annual progress report (as required by the HRA on the anniversary date of when HRA Approval was received) to the R&I Department.
- Inform the R&I Department when the study has completed.
- Inform the R&I Department of the total recruitment number.
- Submit a final report to the R&I department, this may be in the form of a dissertation/thesis, or an end of project report submitted to the national regulatory body. This should be received within one year of study end.

All of the above should be sent to **bsmhft.researchandinnovation@nhs.net**

3.6 Timeframes

The R&I Department are expected to issue approval within 40 calendar days of receipt of the UK Local Document Pack as defined in point 3.2. Early engagement with the R&I team will assist in a quicker turnaround.

4 RESPONSIBILITIES

Post(s)	Responsibilities
Researcher	• To provide all the necessary and up-to-date documentation relating to the research project as detailed in *the procedure*. • To answer outstanding queries and to provide any additional documentation during the review process. • To notify the R&I Department of any amendments or breaches of the protocol, and to provide the R&I Department with any necessary progress reports (including recruitment activity updates) and subsequently notification of study end.
R&I Department – research governance team	• To ensure that upon receipt of the relevant and up-to-date documentation relating to the study as referred to in *the procedure*, the review is conducted. • On confirmation from the Research Governance Manager, to confirm to the researcher that the study can begin.
R&I Department - Research Governance Manager	• To review the findings from the review and to subsequently confirm that the research can commence. • To oversee the Trusts research study review process.

5 DEVELOPMENT AND CONSULTATION PROCESS

Consultation summary		
Date policy issued for consultation	10/03/2020	
Number of versions produced for consultation	1	
Committees / meetings where policy formally discussed	**Date(s)**	
Research & Innovation Committee – virtual	10/02/2020	
PDMG	21/05/2020	
Where received	**Summary of feedback**	**Actions / Response**

6 REFERENCE DOCUMENTS

- The Health Research Authority: **https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/**
- The UK Policy for Health & Social Care (2017): **https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/**
- Department of Health Attributing the Cost of Health and Social Care Research (AcoRD): **https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research**
- Governance arrangements for research ethics committees: **https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/**
- Integrated Research Application System: **https://www.myresearchproject.org.uk/**

7 BIBLIOGRAPHY

No documents.

8 GLOSSARY

All specialised terminology has been defined within the main body of the policy.

9 AUDIT AND ASSURANCE

'The approval of research projects within Birmingham and Solihull Mental Health NHS Foundation Trust' will be reviewed every two years.

The Research Governance Manager will oversee the Trusts Assess, Arrange and Confirm (AAC) process.

Element to be monitored	Lead	Tool	Frequency	Reporting Committee

All research studies undergo a review and a Summary of Findings is completed.	Research Governance Manager	Studies logged on the Master Tracker will be compared to the files held on the R&I shared drive.	Monthly	R&I Committee
All research studies have a comprehensive electronic study file.	Research Governance Manager	Studies logged on the Master Tracker will be compared to the files held on the R&I shared drive.	Monthly	R&I Committee
All research studies are recorded on EDGE.	Research Governance Manager	Studies logged on the Master Tracker by the Research Manager will be compared to data held on EDGE	Monthly	R&I Committee
Research studies are reviewed by the R&I department within 40 calendar days	Research Governance Manager	EDGE will act as the reporting mechanism. A standard report has been created allowing the calculation of turnaround times.	Monthly	R&I Committee

10 APPENDICES

Appendix 1 –. Equality Analysis Screening Form.

Appendix 2 - Research governance considerations during review by the R&I department

Appendix 1 - Equality Analysis Screening Form

Title of Proposal	The approval of research projects within Birmingham and Solihull Mental Health NHS Foundation Trust		
Person Completing this proposal	Katie Williams	**Role or title**	Research Governance Manager
Division	Core	**Service Area**	Research and Innovation
Date Started	09.03.2020	**Date completed**	09.03.2020
Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation.			
Research is one of the Trusts strategic ambitions. Nationally, NHS organisations are required to Assess, Arrange and Confirm (AAC) their capacity and capability to deliver a research study before its commencement. The Research and Innovation (R&I) department at Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) works proactively with local research teams to assess whether or not the Trust has the capacity and capability to participate in the research, puts in place any practical arrangements to deliver the research, and subsequently confirms that the research can begin. The Trust has a reputable research portfolio and the R&I department continually strives to ensure that research is reviewed, approved and subsequently carried out within a safe and transparent framework. With due regard to relevant UK legislation, this policy sets out the principles, requirements and processes which will be implemented by the R&I department. It ensures that the advice given, and the processes experienced by researchers, is consistent and exceptional. This policy also sets out the responsibilities of researchers in contributing to a successful review, and in ensuring that the R&I department are kept informed of developments as the study progresses.			
Who will benefit from the proposal?			
Researchers, both internal and external, will benefit from this policy because they will have a clearer understanding of the process to follow in order to recruit from within BSMHFT. Service users will benefit from this policy because they will be assured that all research studies that they will be asked to take part in have been reviewed by the necessary external and internal regulatory bodies. By supporting researchers, this policy will also enable more research to take part in the Trust, providing Service Users with more opportunities to take part.			

Impacts on different Personal Protected Characteristics – *Helpful Questions:*	
Does this proposal promote equality of opportunity? *Eliminate discrimination?* *Eliminate harassment?* *Eliminate victimisation?*	*Promote good community relations?* *Promote positive attitudes towards disabled people?* *Consider more favourable treatment of disabled people?* *Promote involvement and consultation?* *Protect and promote human rights?*

Please click in the relevant impact box or leave blank if you feel there is no particular impact.

This policy has no impact on personal protected characteristics. This policy confirms the process that researchers, both internal and external, need to go through in order to conduct their study at the Trust. This policy is not about the potential participant themselves.

Personal Protected Characteristic	**No/Minimum Impact**	**Negative Impact**	**Positive Impact**	**Please list details or evidence of why there might be a positive, negative or no impact on protected characteristics.**
Age	✓			This policy is not about the potential participant themselves, however, Services Users may be excluded from taking part in a particular research study due to not meeting the inclusion/exclusion criteria which is stated in the research protocol received by the R&I Department. For example, a study may be aimed at young adults, in which case Service Users over 24 may be excluded. However this exclusion will be because the research question is aimed at that particular Service User group. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria.
Including children and people over 65 Is it easy for someone of any age to find out about your service or access your proposal? Are you able to justify the legal or lawful reasons when your service excludes certain age groups				
Disability	✓			This policy is not about the potential participant themselves. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria for taking part. A study excluding participation due to disability would not receive national approval.
Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability?				

Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?				
Gender	✓			This policy is not about the potential participant themselves, however, Services Users may be excluded from taking part in a particular research study due to not meeting the inclusion/exclusion criteria which is stated in the research protocol received by the R&I Department. For example, a study may be aimed at females, in which case males may be excluded. However this will be because the research question is aimed at that particular Service User group. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria.
This can include male and female or someone who has completed the gender reassignment process from one sex to another Do you have flexible working arrangements for either sex? Is it easier for either men or women to access your proposal?				
Marriage or Civil Partnerships	✓			This policy is not about the potential participant themselves. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria for taking part. A study excluding participation due to relationship status is very unlikely.
People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?				
Pregnancy or Maternity	✓			This policy is not about the potential participant themselves, however, Services Users may be excluded from taking part in a particular research study due to not meeting the inclusion/exclusion criteria which is stated in the research protocol received by the R&I Department. For example, a clinical trial on a new drug would exclude pregnant females for safety purposes. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria.
This includes women having a baby and women just after they have had a baby Does your service accommodate the needs of expectant and post natal mothers both as staff and service users? Can your service treat staff and patients with dignity and respect relation in to pregnancy and maternity?				
Race or Ethnicity	✓			This policy is not about the potential participant themselves, however, Services Users may be excluded from taking part in a particular research study due to not meeting the inclusion/exclusion criteria which is stated in

				the research protocol received by the R&I Department. A recent research study is aimed at the African community, excluding other race or ethnicity. Exclusion on these grounds will be because the research question is aimed at that particular Service User group. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria.
Including Gypsy or Roma people, Irish people, those of mixed heritage, asylum seekers and refugees What training does staff have to respond to the cultural needs of different ethnic groups? What arrangements are in place to communicate with people who do not have English as a first language?				
Religion or Belief	✓			This policy is not about the potential participant themselves, however, Services Users may be excluded from taking part in a particular research study due to not meeting the inclusion/exclusion criteria which is stated in the research protocol received by the R&I Department. A recent research study was aimed at the Sikh community, excluding other religions. Exclusion on these grounds will be because the research question is aimed at that particular Service User group. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria.
Including humanists and non-believers Is there easy access to a prayer or quiet room to your service delivery area? When organising events – Do you take necessary steps to make sure that spiritual requirements are met?				
Sexual Orientation	✓			This policy is not about the potential participant themselves. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria for taking part. A study excluding participation due to relationship status is very unlikely.
Including gay men, lesbians and bisexual people Does your service use visual images that could be people from any background or are the images mainly heterosexual couples? Does staff in your workplace feel comfortable about being 'out' or would office culture make them feel this might not be a good idea?				
Transgender or Gender Reassignment	✓			This policy is not about the potential participant themselves. The Research Ethics Committee will have reviewed and approved the inclusion and exclusion criteria for taking part. A study excluding participation due to relationship status is very unlikely.

This will include people who are in the process of or in a care pathway changing from one gender to another Have you considered the possible needs of transgender staff and service users in the development of your proposal or service?				
Human Rights	✓			This policy is not about the potential participant themselves however all research studies involving Trust Service Users are approved by the Research Ethic Committee who reviews each research study in line with human rights.
Affecting someone's right to Life, Dignity and Respect? Caring for other people or protecting them from danger? The detention of an individual inadvertently or placing someone in a humiliating situation or position?				
If a negative or disproportionate impact has been identified in any of the key areas would this difference be illegal / unlawful? I.e. Would it be discriminatory under anti-discrimination legislation. (The Equality Act 2010, Human Rights Act 1998)				

	Yes	**No** ✓		
What do you consider the level of negative impact to be?	**High Impact**	**Medium Impact**	**Low Impact**	**No Impact**
				✓

If the impact could be discriminatory in law, please contact the **Equality and Diversity Lead** immediately to determine the next course of action. If the negative impact is high a Full Equality Analysis will be required. If you are unsure how to answer the above questions, or if you have assessed the impact as medium, please seek further guidance from the **Equality and Diversity Lead** before proceeding. If the proposal does not have a negative impact or the impact is considered low, reasonable or justifiable, then please complete the rest of the form below with any required redial actions, and forward to the **Equality and Diversity Lead.**
Action Planning:
How could you minimise or remove any negative impact identified even if this is of low significance?
N/A

How will any impact or planned actions be monitored and reviewed?
N/A
How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact other people as a result of their personal protected characteristic.
N/A
Please save and keep one copy and then send a copy with a copy of the proposal to the Senior Equality and Diversity Lead at **bsmhft.hr@nhs.net** . The results will then be publihed on the Trust's website. Please ensure that any resulting actions are incorporated into Divisional or Service planning and monitored on a regular basis.

Appendix 2 - Research governance considerations during review by the R&I department.

Has the Principal Investigator (PI) at the Trust confirmed their involvement and are they suitably qualified? Do we have their CV on file?
Is the study adopted onto the NIHR CRN Portfolio and does the study require support from the R&I Departments Clinical Studies Officers (CSOs) and if so, what support is required?
Have the local research team confirmed their involvement and are they suitably qualified?
Is there any conflict of interest arising in the Trust taking part?
Is any study specific training and/or supervision required before the research can begin and have arrangements been put in place for this?
Are any external research staff having direct contact with service users/carers/staff or will they have access to identifiable data or tissues? Will an Honorary Research Contract or Letter of Access be required?
Does the study require the support of any support departments such as Pharmacy, Pathology, Radiology or support from other sites (such as the Clinical Research Facility) or Trusts? Have they agreed to support?
Is the study compliant with the Data Protection Act? Will personal information be shared with researchers outside of the direct care team? Where will data be stored? Is the Participant Information Sheet and Consent Form clear in terms of what personal information will be collected as part of the research study?
Is the study feasible in terms of clinical space and/or equipment required?
Will the study be taking samples and if so, where will they be stored and processed?
Will participants lack the capacity to consent?
Has a recruitment target been agreed?
Have patient documentation been localised?
Are financial arrangements in place? Is a contract required?
Does the research have the necessary regulatory approvals?