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

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Ratifying Committee	**Clinical Governance Committee**	
Date Ratified	**January 2024**	
Next Anticipated Review	**January 2027**	
Executive Director	**Executive Medical Director**	
Policy Lead	**Head of Research and Development**	
Policy Author	**Research Governance Manager**	
Exec Sign off Signature		
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 Development (R&D) 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&D 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&D 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&D 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&D department and confirmation of capacity and capability will be issued before its commencement.

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

Contents

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 (not just as participants, but also as advisers, collaborators, and as leaders of their own research projects), 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&D 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 all research studies taking place within the responsibility of BSMHFT. This means research which intends to recruit BSMHFT staff or service users as participants or utilise BSMHFT data or premises.

Who

This policy is intended to be read and understood by clinical, academic and lived experience researchers wishing to conduct research within BSMHFT.

It is not intended for internal Research and Development (R&D) department staff, who should instead refer to the internal R&D Handbook.

When

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

1.3 Principles

The R&D department aims to ensure that:

- Service users and carers are given the opportunity to take part in research, not only about them but also with them and by them, throughout the entire lifecycle of research from conceptualisation to dissemination and feel safe when they do.
- Applying to the R&D department is simple and receiving a decision is quick and predictable.
- Researchers value the role of the R&D department and LEAR (Lived Experience Action Research group—BSMHFT's patient and public involvement (PPI) research group) 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&D 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 website (**http://www.hra-decisiontools.org.uk/research**) 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&D 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&D 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&D 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&D department must be provided with the research protocol.

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&D Department recommends that they are contacted at least eight weeks prior to the grant application deadline. The R&D department must be provided with the research proposal/research protocol and the draft grant application form at a minimum.

When BSMHFT is the Lead NHS Trust, the R&D Department expects researchers to consult with, when relevant, the Trust's lived experience research group, LEAR, at the earliest possible opportunity—ideally when the idea is being initially discussed. The LEAR group's Terms of Reference can be found at **Appendix 3**.

Lived experience involvement in research (also known as PPI) has been embedded in policy and guidance in the NHS since the 1990s and is now required by the National

Institute for Health Research (NIHR) and NHS Research and Ethics Committees (NHS REC). While not mandatory for all funding organisations, it is strongly encouraged by the vast majority of them. LEAR's written approval of projects has been previously included in successful applications. When BSMHFT are the lead NHS Trust, researchers and LEAR will work collaboratively to complete the PPI/Lived Experience Plan and Feedback Form which will outline LEAR's recommendations and the researchers' proposed involvement of PPI in their project. This is a form (**Appendix 4),** which once agreed by both parties, will be returned to R&D, and can demonstrate evidence of the applicant's consultation and future work plans (if relevant) with the LEAR and/or other PPI groups. Please refer to **Appendix 5** to reflect the process for researchers seeking support of LEAR.

For studies where BSMHFT are the Lead NHS Trust, the R&D 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.
- An introduction to, and help in working with LEAR, who have a track record of beneficially impacting the Trust's research projects, including helping projects to obtain funding. As well as there being a strong moral case to engage with PPI, there is substantial evidence that it also helps to improve research by (i) ensuring findings are genuinely useful for patients and carers, (ii) shaping or reshaping study design, (iii) increasing study success by enhancing recruitment, (iv) transforming data analysis, (v) eliciting better and fuller information from participants, and (vi) assisting with dissemination of the findings.

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&D department

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

Integrated Research Application System (IRAS) Form The IRAS Form includes 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) for the R&D department to commence their review.
Protocol

Version and date controlled.

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.

Version and date controlled.

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.

For Non-commercial studies:

Organisational Information Document (OID) and

Schedule of Events/Schedule of Events Cost Attribution Template (SoECAT)

The OID and the SoE 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:

Model Agreement.

NIHR validated costing template (via the National Contract Review Process/Interactive Costing Tool).

Any relevant contracts or agreement (if required)

Copy of the national regulatory body approval letters

National regulatory body approval letters should be provided to R&D once received. Not having these yet should not prevent submission to the R&D department. Researchers are in fact encouraged to submit to R&D in parallel to make the most efficient use of time.

Generally, 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 who requires access to service users.

Documentation should be submitted by email to:
bsmhft.researchandevelopment@nhs.net

The submission will be brought to the attention of the research governance team who will acknowledge submission within three working days of receipt. A Single Point of Contact in the R&D team will be assigned to the researcher.

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 or groups (i.e., Pharmacy, LEAR) 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 2 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).

Researchers will be issued with a 'Confirmation of Local Capacity and Capability at Birmingham and Solihull Mental Health NHS Foundation Trust' email. Recruitment can then begin.

Please note, studies are not presented to an internal committee for review.

3.4 Record Keeping – Research Governance

The R&D 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&D Department will log all research projects (be they pending, open, closed or archived) on the department's local management system, EDGE. 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. Guidance on site file set up and maintenance can be sourced via the R&D department
- Inform the R&D Department of any amendments to the research study. This includes both substantial and non-substantial amendments. In the case of substantial changes to studies where BSMHFT are the lead NHS Trust, the R&D Department expects researchers to reconsult with LEAR, especially when amendments may have an impact of the involvement of lived experience in the study.
- Inform the R&D 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&D Department.
- Inform the R&D Department when the study has completed.
- Inform the R&D Department of the total recruitment number.
- Submit a final report to the R&D 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 the above should be sent to

bsmhft.researchanddevelopment@nhs.net

3.6 Timeframes

The R&D 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&D 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&D Department of any amendments or breaches of the protocol, and to provide the R&D Department with any necessary progress reports (including recruitment activity updates) and subsequently notification of study end.
R&D 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&D 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.
Head of R&D/ Research Delivery Manager	• To identify responsibility for portfolio studies including governance, budget, and risks
Lived Experience Advisory Research Group (LEAR)	• To review studies where BSMHFT is the Lead NHS Trust.

5 DEVELOPMENT AND CONSULTATION PROCESS

Consultation summary	
Date policy issued for consultation	30/10/2023
Number of versions produced for consultation	1
Committees / meetings where policy formally discussed	
PDMG	13/12/23

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/**
- National Institute for Health Research (2021): Briefing notes for researchers – public involvement in NHS, health, and social care research: **https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371**

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, to include, where relevant for studies where BSMHFT is the Lead NHS Trust, a summary of LEAR/PPI	Research Governance Manager	Studies logged on the Master Tracker will be compared to the files held on the R&D shared drive.	Monthly	R&D Management Board

input into the research project.				
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&D shared drive.	Monthly	R&D Management Board
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&D Management Board
Research studies are reviewed by the R&D 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&D Management Board

10 APPENDICES

Appendix 1 – Equality Analysis Screening Form
Appendix 2 – Research governance considerations during review by the R&D department
Appendix 3 – LEAR group's Terms of Reference
Appendix 4 – Researchers Evidence Form: Confirmation of LEAR recommendations /agreed actions with Researcher
Appendix 5 – Process for researchers seeking expertise from LEAR Group.

Appendix 1 - Equality Analysis Screening Form

A word version of this document can be found on the HR support pages on Connect
http://connect/corporate/humanresources/managementsupport/Pages/default.aspx

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	Corporate	**Service Area**	Research and Development
Date Started	18.10.23	**Date completed**	18.10.23

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 Development (R&D) department at Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) works proactively with local research teams to assess whether 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&D 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&D 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&D 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 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, in whatever capacity, 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 as participants, but also as collaborators on the Trust's research projects and as originators of their own research.

Do the proposals affect service users, employees or the wider community? ***Add any data you have on the groups affected split by Protected characteristic in the boxes below. Highlight how you have used the data to reduce any noted inequalities going forward***				
All may be involved in research as participants, thus this policy would apply to all.				
Do the proposals significantly affect service delivery, business processes or policy? ***How will these reduce inequality?***				
No				
Does it involve a significant commitment of resources? ***How will these reduce inequality?***				
No				
Do the proposals relate to an area where there are known inequalities? (e.g. seclusion, accessibility, recruitment & progression)				
No				
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.				
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&D 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&D 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&D 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&D 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&D 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	**High Impact**	**Medium Impact**	**Low Impact**	**No Impact**

level of negative impact to be?				✓
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 published 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&D 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&D 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?
In cases where BSMHFT is the lead Trust, does the proposal have provision (both financial and in terms of timeframe) for lived experience input?
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?

Appendix 3: LEAR Terms of Reference

Birmingham and Solihull Mental Health NHS Foundation Trust
Lived Experience Action Research (LEAR)

Terms of Reference
December 2021

Purpose

To be a trusted and highly valued service user and carer research group that is an asset regarding research and other matters in the Trust, and that is able to advise and challenge when necessary.
We will do this by using our experiential/lived experience knowledge to inform policy by engaging in research and other matters in a variety of ways.
To promote and support the recovery for all strategy through the activities of the group. To produce original research relating to mental health. To tackle prejudice, stigma and discrimination and enable a much-needed cultural change.

To achieve this, we will:

REVIEW AND ADVISE

- Embed service user and carer involvement at the beginning of research applications and service evaluations.

- Evaluate existing research and research applications from a service user/carer viewpoint. This includes ethical matters and equality and diversity considerations.

- Advise on research study protocol and documentation.

- Represent service users and carers to shape and validate research projects by providing a point of contact for people who have lived experience.

PARTICIPATE

- Actively support the recruitment of research participants.
- Have an active presence throughout the Trust and be visible to staff, service users, carers, and families online and via other communications.
- Be part of the approval of research process as set out in the Trust's Approval of Research Projects Policy

DISSEMINATE

- Ensure that research findings and outcomes are disseminated to staff, service users and carers.

- Hold researchers to account to disseminate their findings and outcomes.

LEAD AND GENERATE

- Influence how research and evaluation is understood by service users, carers and families and our involvement in research.

- Generate our own Research and Development ideas (including digital developments).

KNOW

- Know about and keep up to date with research activity in the Trust. This will be a monthly standing agenda item.

- Influence and align with the Trust research strategy.

- Access a range of training, research knowledge and skills development opportunities within and outside the Trust.

Membership and roles

- The group will be a pool of people who are available via email and MS Teams channel as well as those who attend meetings.

- The group is for people who have used mental health services and/or cared for someone who has.

- The group is open to staff who want to make use of their lived experience to support the group's purpose.

- The group is open to approaches from staff and academic guests who would like to gain the expertise of the group in relation to their research ideas.

- People will be invited as guests to present their research.

- The current chairperson is Max Carlish. The Terms of Reference will be reviewed yearly.

- Minutes to be taken and administrative support provided by the recovery and experience team.

• Honorary members: lead for recovery and service user, family and carer experience, and Research and Development implementation and performance manager. • Governor members of LEAR will represent the group at Board level.
Quoracy 6 members (not including Trust staff).
Agenda The agenda will be circulated a week before the meeting. There will be a minimum of one research presentation at each meeting, up to an hour**.**
Frequency and times **Monthly, 2 hours, Second Wednesday of the month: 10.00-12.00, to be extended as necessary according to the agenda.**
Governance A quarterly report will be submitted to the Trust Clinical Governance Committee as part of the Recovery and Participation Report. The group will also be incorporated within the quarterly Research Report. *A member of the group will attend the research committee to ensure collaboration and two-way information flow (to be agreed).*
Monitoring and Evaluation The group will monitor and evaluate its activity and impact against its purpose on a 6 monthly basis. The impact of the group is monitored and evaluated as part of an ongoing formal service evaluation that incorporates pre and post surveys.

Appendix 4: Researchers Evidence Form: Confirmation of LEAR recommendations /agreed actions with researcher

Confirmation of LEAR (*Lived Experience Action Research*) Recommendations.

Full Title:	
Project presented to LEAR by:	**Name:** **Job Title:** **Email:**
Date of LEAR meeting attended:	
Outcome and recommendations from LEAR:	
Future lived experience participation plans:	

Report Author:	
Date of Report:	

Confirmation that LEAR Service Evaluation Details provided: [ ]

Appendix 5: Process for Researchers seeking expertise from LEAR Group