Screening for Potential Research Participants Policy

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Executive director	**Medical Director & Caldicott Guardian**	
Policy lead	**Head of Research and Development**	
Policy author *(if different from above)*	**Research Governance Manager**	
Exec Sign off Signature (electronic)		
Disclosable under Freedom of Information Act 2000	**Yes**	

POLICY CONTEXT

As demonstrated in the Trusts strategic ambition, Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT, 'the Trust') 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 improvement in the future care provided by the Trust.

The Trust recognises that practical delivery of research requires extra effort and commitment from the Trust's clinical teams, particularly with regards to identifying potential participants for studies using complex inclusion criteria. For the Trust to provide an effective research service, identifiable Confidential Patient Information (CPI) is required to be accessed by NHS staff beyond the service users immediate care team.

POLICY REQUIREMENT

The Trust is committed to protecting the confidentiality of identifiable patient information whilst simultaneously supporting research and recognising the benefits that research brings to people who use our services. This policy ensures that there is a systematic and structured approach confirming who is permitted to access CPI for the purpose of screening and identification of potential participants for Trust reviewed and approved research studies.

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1. Introduction

This policy ensures that there is a systematic and structured approach confirming who is permitted to access CPI for the purpose of screening and identification of potential participants for Trust reviewed and approved research studies.

1.1 Rationale (why)

As demonstrated in the Trusts strategic ambition, the Trust 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. In supporting this research, the Trust recognises that practical delivery requires extra effort and commitment from the Trust's clinical teams, particularly with regards to identifying potential participants for research using complex inclusion criteria. For the Trust to provide an effective research service, CPI is required to be accessed by NHS staff beyond the service users immediate care team, for the purpose of screening and identification of potential participants.

The term **'personal data'** is defined in the General Data Protection Regulation 2018 and Data Protection Act 2018, and means any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

The term **'Confidential Patient Information (CPI)'** is defined as information to which a duty of confidentiality is owed under common law. Personal data including any health related information or health related information in a context from which personal data can be identified, would be CPI.

Under common law, patients can expect that their personal data will be kept confidential. Within that duty of confidence, the care team can access that data to provide care and for certain other purposes such as research, provided that the confidence is kept; that nobody has access to CPI that they would not normally have access to by virtue of the role they are doing in providing care for patients. Individuals who are not part of the care team are not within the patient's confidence.

For the NHS as a whole to provide an effective service, CPI will need to be accessed by NHS staff beyond the service users immediate care team, for the purpose of screening and identification of potential participants. To support such a process, an organisational policy is required confirming:

- The strict group of research staff who can be involved in identifying potential participants using this procedure.

- The Trusts Research and Development (R&D) transparency plan, ensures that service users and carers are informed about the processing of their personal data; that their health records may be screened by a strict group of research staff for the purpose of potential participation in a research study.

The Trust has engaged in a thorough consultation process concerning this policy and procedure. In particular, this policy and procedure has been written following advice from the Information Governance Department. The Caldicott Guardian has formally approved the groups who can be involved in identifying potential participants using this procedure.

1.2. Scope (when, where and who)

This policy applies to the screening and identification of potential participants for research reviewed and approved by the R&D department. Nationally, NHS organisations are required to Assess, Arrange and Confirm (AAC) their capacity and capability to deliver a research study. Only once a study has received confirmation of capacity and capability from the Trusts R&D department can any research activity begin. The proposed method of patient screening and identification, including an assessment of the individual who has been assigned this duty, is considered as part of the local R&D review and is the responsibility of the R&D Department.

For the purposes of this policy 'screening' involves reviewing caseloads and care records to identify potential participants against study inclusion and exclusion criteria as confirmed in the research protocol.

The strict group of research staff to be involved in identifying potential participants using this procedure are those referred to as the R&D Department Research Delivery Team. This includes:

- **Research Nurses**
- **Senior/Research Fellows**
- **Clinical Studies Officers (CSO)**
- **R&D Assistants**

All individuals have:
- substantive BSMHFT employment contracts, following pre-engagement checks
- attend full Trust Induction.
- a BSMHFT Line Manager who sits within the R&D Department.
- nhs.net email addresses.

The R&D Research Delivery Team also have three further roles which support screening and recruitment on a workload demand basis:

- **BSMHFT Bank R&D Assistant**
- **Honorary R&D Assistant (3rd year placement student with a neighbouring University – typically Aston University, Coventry University or Newman College)**
- **West Midlands Clinical Research Network Research Nurses and Practitioners**

These individuals hold a BSMHFT contract (either a BSMFT Bank Agreement, a BSMHFT Honorary Agreement or a BSMHFT Letter of Access), following pre-engagement checks.

Staff from the West Midlands Clinical Research Network also hold full NHS contracts with Royal Wolverhampton NHS Trust.

The Bank R&D Assistant attends a full BSMHFT induction. The Honorary R&D Assistant and West Midlands Clinical Research Network Research Nurses and Practitioners attend specific BSMHFT modules (including Rio and Information Governance)

All have a BSMHFT Line Manager who sits within the R&D Department and all have nhs.net email addresses.

1.3 Principles (beliefs)

The Trusts takes seriously its duty to protect the information entrusted to it by its service users. The Trust believes that it has a clear duty to protect a service users right to confidentiality. Additionally, the Trust recognises the role mental health research plays in improving services and in promoting evidence-based practice. The Trust therefore recognises the role screening plays in its research activities and is committed to ensuring that this activity is conducted by a strict group of R&D Department staff with appropriate safeguards in place.

This policy and procedure will ensure:

- A service user's identifiable information is safe and its confidentiality respected.
- Service users and their carers are aware that the Trust is research active and that there may be instances when their care records are screened for research eligibility purposes by a strict group of research staff.
- Staff, service users and their carers are aware of the opportunities to participate in research studies and understand the possible benefits that may accrue for themselves and for others.
- The participation of clinical teams in research is facilitated by the screening of care records conducted by R&D Department staff.
- The Trust continues to focus upon improving its services through research and development as reflected in the Trusts strategic ambition.

2. Policy (what)

Outside of the immediate care team, the screening and identification of potential participants for research studies should be conducted only by those groups as described in 1.2.

Individuals involved in screening owe a duty of confidentiality and as confirmed in their HR arrangement with the Trust and are subject to disciplinary procedures if this duty is breached.

Individuals who conduct screening and identification of potential participants are trained in information governance and in the use of Trust IT systems (RiO), and follow the guidance and procedures associated with all Trust policies.

3. Procedure

- On receipt of a research study application, the R&D department will commence the AAC review. The proposed method of patient screening and identification, including an assessment of the individual who has been assigned this duty, is considered as part of the local R&D review. Only members of the direct care team or those individuals who fall within the groups specified above (section 1.2.) will be permitted to screen and identify potential participants. In the instance where the individual falls outside of these groups, a member of the direct care team/those specified in this policy will be identified to complete this task.

- Individuals screening and identifying potential participants will work with the Trust based clinician who is acting in the role of Principal Investigator (PI). The PI will oversee and facilitate the screening of caseloads and care records, will confirm eligibility and will advise on the first approach.

- In line with standard Trust policy, RiO logins are not issued until both information governance training and RiO training has been completed.

- The screening of caseloads and care records will be performed within a 'safe haven' framework, ensuring:

    - Identifiable information obtained during screening should be minimal and the data accessed will only be that relating to the inclusion/exclusion criteria.
    - Identifiable information will not be kept or stored for any other purpose other than informing care teams of potential recruits
    - Identifiable information should only be kept on Trust information systems.
    - Identifiable information obtained during screening should not be used to form research data sets.

- The initial approach to the service user will remain with the immediate care team, unless permitted by the service user's assigned clinician.

3.1 Information for service users and carers

- The Information Governance Department have amended the Trust Privacy Note to include details that care records may be screened by a strict group of research staff to ascertain eligibility for potential research studies.

3.2 Reviewing caseloads and RiO care records to identify potential participants

R&D Department Research Delivery Team staff may not commence any screening of caseloads and care records for a research study until that research study has been reviewed and approved by the R&D department.

- The individual will screen caseloads and care records through RiO and within a 'safe haven' framework to identify possible recruits. National data opt-out will be applied appropriately (section 4).

- The care team will be approached to ask for their opinion on suitability of the service user and to either obtain permission to approach the service users to discuss participation or to ask if they would be willing to do so, subsequently directing the service user to the local research team. The wishes of service users choosing to opt out of the research will at all times be respected.

4. National data opt-out

Where R&D Department staff need to identify people to participate in research studies, the national data opt-out will apply. R&D Departmental staff are not considered by the Trust to fall under one of the agreed mechanisms for identifying the cohort for a research study whereby the national data opt-out would not need to be applied.

National data opt-out information held by the Trust is updated every 24 hours. Rio, the Trusts electronic healthcare system already displays an 'R' for research on each patient record. This will turn **red** for those records where the national data opt-out needs to be applied. These service users cannot be screened further and cannot be approached about research as a result of the screening process. **NB: This does not prevent a clinician or another member of the direct care team approaching a service user to give their consent and to participate in a study. It also does not prevent a service user from asking about and consenting to participate in a research study.**

N.B: National data opt-outs can take up to 21 days from the service user making their choice online/phone, to this filtering down from NHS Digital to the NHS spine. Please see the BSMHFT National Data opt-out SOP for further information.

5. Monitoring

The R&D Department will oversee and monitor these procedures.

On receipt of a research study application, the R&D department will commence the AAC review. The proposed method of patient screening and identification, including an assessment of the individual who has been assigned this duty, is considered as part of the local R&D review. Only members of the direct care team or those individuals who fall within the groups specified above (section 1.2.) will be permitted to screen and identify potential participants. In the instance where the individual falls outside of these groups, a member of the direct care team/those described in this policy will be identified to complete this task. The research study will not be formally approved until this condition has been met.

6. Responsibilities

Post(s)	Responsibilities	Ref
Individual conducting screening and identifying potential participants	The screening for potential recruits is conducted within a 'safe haven' framework.	Section 3
Principal Investigator	Oversee screening. Review findings from screening activity. First approach to participant.	Section 3
Policy Lead	To review this policy. To conduct audit and assurance.	Section 4
Executive Director	To ensure Caldicott principles.	Section 1
Research Governance Manager	Ensure that the proposed method of screening and identification of proposed researchers is reviewed and meets the criteria as defined in this policy.	Section 1.2

7. Development and Consultation Process

Consultation Summary		
Date policy issued for consultation	May 2023	
Number of versions produced for consultation	1.1	
Committees/meetings where policy formally discussed	Research and Development Management Board Meeting – 22nd May 2023	
Where received	**Summary of feedback**	**Actions/Responses**

8. Reference Documents

- Confidentiality Policy, Version 6, January 2021.
- Information Governance Assurance Policy, version 9, January 2021.

9. Bibliography

- The Caldicott Principles, December 2020.

10. Glossary

Assess, Arrange, Confirm (AAC)
The Health Research Authority (HRA) defined the different stages that NHS Trusts participating in a research study must go through before agreeing that a research study can open at the Trust:

- Assess: The NHS Trust must assess whether or not the organisation has the capacity and capability to participate in the study.
- Arrange: The NHS Trust must put in place practical arrangements to delivery the study.
- Confirm: The NHS Trust must confirm that it has the capacity and capability to delivery the study, and will deliver the study, through the signing of an agreement.

Caldicott Guardian
The December 1997 Caldicott Report (named for its author Dame Fiona Caldicott) identified weaknesses in the way parts of NHS handled confidential patient data. The report made several recommendations, one of which was the appointment of Caldicott guardians, members of staff with a responsibility to ensure patient data is kept secure:

Recommendation 3: A senior person should be nominated in each NHS organisation, including the Department of Health and associated agencies, to act as a "guardian". The "guardian" should normally be a senior health professional or be closely supported by such a person. The NHS IM&T Security Manual (Section 18.4) requires each organisation to designate a senior medical officer to oversee all procedures affecting access to person-identifiable health data. This role and that of the "guardian" may be combined, providing there is no conflict of interest. The Department of Health should take the development of this role forward in partnership with interested parties.

It is now a requirement for every NHS organisation to have a Caldicott guardian. The Guardians are responsible for ensuring that their organisation adheres to the Caldicott principles. In the Birmingham & Solihull Mental Health NHS Foundation Trust the Medical Director is the Caldicott Guardian

Confidential Patient Information (CPI)
CPI is defined as information to which a duty of confidentiality is owed under common law. Personal data including any health related information or health related information in a context from which personal data can be identified, would be CPI.

Personal Data
Personal Data is defined in the General Data Protection Regulation 2018 and Data Protection Act 2018, and means any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or

indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Rio
RiO is the electronic care record system that has been rolled out across the trust. RiO will enable the trust to maintain one central electronic care record for each service user, to which staff can electronically record and view up to date clinical and administrative information.

11. Audit and assurance

Element to be monitored	Lead	Tool	Frequency	Reporting Arrangements
Suitability of individual permitted to screen	Research Governance Manager	Summary of Findings utilised	For every research study granted approval by the R&D Department.	Unsuitable requests logged and reported to R&D Committee.

12. Appendices

Appendix 1 – Equality Impact Assessment

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	Screening for Potential Research Participants Policy		
Person Completing this proposal	Katie Williams	**Role or title**	Research Governance Manager
Division	Core	**Service Area**	Research and Development
Date Started	10.10.23	**Date completed**	10.10.23
Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation.			
As demonstrated in the Trusts strategic ambition, Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT, 'the Trust') 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 improvement in the future care provided by the Trust. The Trust recognises that practical delivery of research requires extra effort and commitment from the Trust's clinical teams, particularly with regards to identifying potential participants for studies using complex inclusion criteria. For the Trust to provide an effective research service, identifiable Confidential Patient Information (CPI) is required to be accessed by NHS staff beyond the service users immediate care team. This policy ensures that there is a systematic and structured approach confirming who is permitted to access CPI for the purpose of screening and identification of potential participants for Trust reviewed and approved research studies. This policy is NOT about the participants themselves or the applying of inclusion/exclusion criteria to take part, which is already predefined in the approved Research Protocol.			
Who will benefit from the proposal?			
Firming up who is permitted to screen potential research participants means that NHS Clinicians will be able to offer research within their clinical areas as they will now be confident in the support they are being provided for screening. As a knock on effect, Service Users will be provided with			

the opportunity to take part in research studies related to their diagnosis and have confidence that their CPI is being accessed under strict conditions, for strict purposes.
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. Service users can be confident that their CPI is being access under strict conditions, for strict purposes. Staff can have confidence in the support that they are being provided to screen notes for potentially eligible participants.
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 – the proposal seeks to ease the demands on the clinical team.
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 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	✓			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.
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 sexual orientation 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..

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 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