

Safeguarding (Preventing Harm) in Research

Division: Trust-Wide

Document No (if Trust-Wide): R&D P07

Contact policiesandguidelines@nbt.nhs.uk for a reference number if required

Specific staff groups to whom this policy <u>directly</u> applies	Likely frequency of use	Other staff who may need to be familiar with policy
All employees of the Trust engaged in research, including individuals employed by a third party, by individual contractors, as students, as locums or as agency staff.	As required	R&D Department staff, Research active staff

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Summary of changes since the previous version	New policy to comply with UKRI and NIHR funder terms. This new policy clarifies the responsibilities of NBT R&D Senior Leadership Team in managing concerns and incidents related to safeguarding within research. The policy also sets out the expectations placed upon our research community to safeguard research participants, collaborators, and partners, and ensure routes for reporting concerns and incidents are in place at a project level.

1. Executive summary

North Bristol NHS Trust is committed to promoting and maintaining safe research environments and preventing and reducing the risk of harm in research. The Trust has a moral and legal obligation to do no harm, to prevent harm and to assure the welfare of staff, participants and any other individuals or communities involved in or affected by research activities. This policy formalises our principles around safeguarding in research. This policy should be read in conjunction with the broader Institutional Safeguarding Policies (CG-197 and CG-134), which outline NBT's approach to preventing and reducing the risk of harm to children and adults at risk.

Contents

1. Executive summary	2
2. Purpose of the policy	3
3. Scope of the Policy	4
4. Definition of terms	4
5. Roles and responsibilities	5
6. Procedures	5
7. Reporting concerns	7
8. Monitoring effectiveness	11
9. Associated policies/documents	12
10. Glossary of Terms	12

2. Purpose of the policy

- 2.1.** All those involved in NBT's research activities have a right to be treated fairly with dignity and respect, and to work or participate in safe research environments which are free from sexual exploitation, abuse and harassment, bullying, psychological abuse, and physical violence.
- 2.2.** NBT's commitment to safeguard children and adults at risk, along with mechanisms to support these commitments, are contained in the NBT Safeguarding Adult and Safeguarding Children Policies (CG-197 and CG-134).
- 2.3.** NBT's commitment to zero-acceptance of unacceptable behaviour in the workplace, which includes discrimination such as racism, violence and aggression, bullying, harassment and abuse, and sexual misconduct are managed through the: Trust Freedom to Speak Up Policy (PEO-22), Trust Disciplinary Policy (PEO-06); Trust Fairness at Work Policy (PEO-33); Trust Prevention, Management and Reduction of Violence and Aggression Policy (HS08), Trust Domestic Abuse Policy (CG-205); Trust Sexual Misconduct Policy (PEO-53), Equality Diversity and Inclusion Policy (PEO-37); High Professional Standards (MHPS).
- 2.4.** Several other processes include mechanisms to ensure safety specifically in the research process including the NHS Research Ethics Framework and Research Code of Practice for Research (UK Research Integrity Office)
- 2.5.** The purpose of this Safeguarding in Research policy is to align these commitments and mechanisms, and to:
 - 2.5.1.** Acknowledge that our duty of care extends to all involved (directly and indirectly) in research activities, where all people may be potentially vulnerable to harm due to a range of intersecting factors.
 - 2.5.2.** Formalise our approach to identifying, preventing, and addressing risks of harm in relation to research activities, accounting for some of the complexities that arise from, and might be specific to, collaborative research processes.
 - 2.5.3.** Formalise a set of key principles to guide researchers and professional staff conducting and/or supporting research.
 - 2.5.4.** Signpost relevant procedures and mechanisms to be used for reporting and addressing concerns/ incidents relating to safeguarding in research.
- 2.6.** This policy is underpinned by the same legal and regulatory frameworks contained in the institutional Safeguarding Policies. Relevant legislation includes Sexual offences Act 2003; Mental Capacity Act 2005; Safeguarding Vulnerable Groups Act 2006; Equality Act 2010; Counter Terrorism and Security Act Data Protection Act 2018; Working together to Safeguard Children 2018.
- 2.7.** This policy has been formulated in response to developments in the research sector. In 2018, UK Research and Innovation (UKRI) and other funders of international research commissioned the UK Collaborative on Development Research (UKCDR) to undertake a review of evidence around safeguarding in this sector, resulting in a set of good practice guidelines and principles. In May 2020, drawing on this work, UKRI published its 'Preventing harm (safeguarding) in research and innovation policy'. In September 2020, the National Institute for Health Research (NIHR) published its policy on preventing harm in research, which applies to all NIHR funded activities.

- 2.8.** Our policy responds to these developments, providing a wider scope to encompass Research within our safeguarding approaches. It also ensures compliance with funder requirements, since the implementation of these principles is now being monitored through assurance processes and organisational audits.

3. Scope of the Policy

- 3.1.** This policy outlines NBT's commitment to taking all reasonable steps to anticipate, mitigate and address potential and actual harms occurring during research.
- 3.2.** This policy applies to all North Bristol NHS Trust staff including, honorary contract holders and others within NBT who are actively involved in any research activities.
- 3.3.** This policy specifically covers taking all reasonable steps to prevent and address incidents of exploitation, abuse, or harm to any:
- 3.3.1.** Individual directly involved in research activity (i.e., staff, students, public collaborators, participants in research, collaborating partners).
 - 3.3.2.** Individual indirectly involved in research activity (i.e., members of the public, family members/associates of research participants, members of communities in which research is being carried out).
 - 3.3.3.** Child, young person, or vulnerable adult who is not directly involved in NBT research activity but may be vulnerable to exploitation, abuse or harm by staff, students or any associated personnel actively involved in NBT research projects or research activities.
- 3.4.** This policy applies to all aspects of the research process, including (but not limited to): project design and development; communication and interactions with partners, stakeholders, and participants; data collection and fieldwork; dissemination activities, the creation of outputs, engagement with the public and communities.
- 3.5.** This policy is concerned with safeguarding concerns, risks or incidents that are directly related to and/or a result of the research process. Where concerns that are not directly related to research arise (for example, where a participant discloses an unrelated concern or incident), procedures in the Trust's Safeguarding Policies should be followed.
- 3.6.** Because research is often collaborative and undertaken with a range of project partners, it is important to hold open discussions about policies on, and approaches to, safeguarding with all parties involved within the research process, and to agree approaches to safeguarding for particular projects.
- 3.7.** All research activities, irrespective of location, fall within the remit of this policy. Sometimes these may take place in countries with distinct regulatory, statutory, or legislative frameworks which require adherence, or in particular cultural or geopolitical contexts that require consideration.

4. Definition of terms

- 4.1. In defining “Safeguarding in Research” we are utilizing UKCDR’s definition of safeguarding as preventing and addressing “any sexual exploitation, abuse, or harassment of research participants, communities, and research staff, plus any broader forms of violence, exploitation, and abuse... such as bullying, psychological abuse and physical violence.”
- 4.2. In defining “Research” we are utilizing the UK Policy Framework for Health and Social care definition “the attempt to derive generalisable or transferable findings” as applies to health and social care research that is within the responsibility of the HRA or Devolved Administrations’ Health Departments.
- 4.3. R&D Senior Leadership Team (SLT) comprises the following roles: Deputy Director of Research, Research Development and Grants Manager, Research Operations Manager, Commercial Research Manager, Research Infrastructure Manager, Research Matrons.

5. Roles and responsibilities

- 5.1. North Bristol NHS Trust (via the Trust Research Group) is responsible for ensuring that appropriate policies, procedures, and support are in place to enable safeguarding in research.
- 5.2. NBT is responsible for taking reports of concerns seriously and acting in a fair and timely manner to address any concerns or incidents. The R&D department, via the Director of Research and Deputy Director of R&D are responsible for supporting this policy and its implementation, and for ensuring that concerns are reported through Trust mechanisms, external funding bodies and external authorities where this is required.
- 5.3. All individual NBT staff members engaged in research must be familiar with and comply with this policy. This includes, as appropriate for their own role, taking personal responsibility for:
 - 5.3.1. treating each other, research participants and members of the general public with dignity and respect, to act with the highest standards of integrity, honesty, and professionalism and to embed good practice in every aspect of their work,
 - 5.3.2. adhering to the highest level of research ethics, in line with requirements set out by national and international regulatory bodies, profession and regulatory research guidance and research ethics frameworks issued in appropriate areas, see Research Councils’ Policy and Guidelines on Governance of Good Research Conduct,
 - 5.3.3. recognising the inherent power imbalances that exist in research activities and take all reasonable steps to mitigate them within the activities that they are involved in,
 - 5.3.4. engaging in equitable partnerships throughout the development, delivery and dissemination of a research and innovation activity to avoid extractive and exploitative approaches,
 - 5.3.5. being aware of relevant policies and procedures within their organisation and

know how to respond to and report concerns about exploitation, abuse, and harm,

- 5.3.6.** raising concerns that they have, or those that are reported to them, through the appropriate channels for their research project, their organisation, and/or the appropriate authorities,
- 5.4.** Chief Investigators have overall responsibility for ensuring that projects within their portfolio are managed in line with this policy, and related policies; and that routes for reporting any concerns regarding safeguarding are communicated to all project contributors.
- 5.5.** Principal Investigators have responsibility for ensuring that research studies are delivered in line with this policy, and related policies; and that routes for reporting any concerns regarding safeguarding are communicated to the staff who are delivering their studies.

6. Procedures

- 6.1.** All staff, students and associated personnel involved in conducting research are expected to:
 - 6.1.1.** Familiarise themselves with this policy and other related policies and procedures (see section 9).
 - 6.1.2.** Treat each other, participants, partners, and the public with respect. Act with integrity, honesty, and professionalism, and embed good practice in every aspect of their research work.
 - 6.1.3.** Contribute to the development and maintenance of a positive research culture, that values transparency and integrity, adheres to the highest level of research ethics, engenders a culture of mutual respect, and enables the prevention of harm.
 - 6.1.4.** Report any safeguarding in research concerns at the earliest opportunity.
 - 6.1.5.** Cooperate with any investigations into safeguarding in research concerns.
 - 6.1.6.** Principal Investigators are also responsible for ensuring that delivery staff working on research studies are aware of their responsibilities regarding safeguarding and are aware of this policy.
 - 6.1.7.** Chief investigators are also responsible for ensuring that project contributors are aware of their responsibilities regarding safeguarding and that routes for reporting any safeguarding concerns are communicated to all project contributors in an accessible and appropriate manner.
- 6.2.** All Chief Investigators of NBT led research should undertake a R&D Preventing Harm in Research risk assessment when planning research activities, working alongside R&D, to identify risks, prepare mitigation and management plans, confirm routes for reporting project specific concerns and communicate these to all project partners. This will include consideration of:

6.2.1. Equality, Diversity, and Inclusion

- NBT is committed to promoting Equality, Diversity, and Inclusion (EDI). This commitment is outlined in our Equality Diversity and Inclusion Policy (PEO-37) and associated 3- year plan which is overseen by our People Team.
- EDI must be considered when assessing vulnerabilities and risk of potential harms. Risks are not experienced equally. All people may potentially be vulnerable to harm due to a range of intersecting factors, including (but not limited to) gender, sexuality, age, race, ethnicity, religion, disability, and socio-economic status.
- Risks are context specific and may be exacerbated in particular settings (for example, where projects are working in conflict affected regions, where research involves working with vulnerable adults or children, etc.). Where research in such scenarios is undertaken, extra care should be taken to manage the risk of harm.

6.2.2. Working Collaboratively with partners

Where research involves collaboration with external partners, it is important that:

- partnerships are developed in a transparent, inclusive, and equitable manner to avoid exploitation and harms within the partnership and
- that the partner is familiar with the principles and processes in this Safeguarding in Research Policy and commits to uphold them during the research process.

It is also important that researchers:

- Engage in equitable partnerships through research, avoiding exploitative approaches and adopting transparent practices, for example sharing full details of and responsibility for projects fairly.
- Recognise inherent power imbalances (e.g., gender imbalances, inequities between research teams based on geographical location, imbalances related to career stage etc.) and take steps to mitigate these.
- Involve all research partners in design and planning of research studies to ensure contextually appropriate activities that reduce risks.
- Agree approaches to safeguarding, in writing, including appropriate methods for reporting, handling, and escalating safeguarding issues that occur throughout the collaborative research process.
- Fairly and appropriately credit all contributors.

- 6.3.** Researchers at all career stages will be supported by R&D to implement this policy; with associated tools to support conducting risk assessments, mitigation, oversight, and reporting.

7. Reporting concerns

7.1. Project Level reporting of concerns

It is important that individual research projects have established and appropriate routes for reporting safeguarding concerns during the research process. Where projects involve human participants, the use of personal data, the use of human tissue, and/or where they will interact

with other public, communities and stakeholders, they must build appropriate mechanisms for reporting, handling, and escalating safeguarding concerns into their design.

7.1.1. For NBT Chief Investigators, project specific approaches to reporting of safeguarding concerns should be led by the Chief Investigator and:

- Include routes for reporting concerns or incidents that are independent of the research team and are accessible to all contributors to the research, including external and public collaborators and contributors (see section 3.3)
- Consider barriers to reporting (e.g., language, fear, power imbalances) and how these might be addressed, and how the team will communicate reporting mechanisms to those who might need to utilise them.
- Include instructions for direct reporting, or escalation, of reported concerns or incidents to the Director of Research, Deputy Director of R&D or other member of the R&D Senior Leadership Team at the earliest opportunity.

7.1.2. For all NBT staff engaged in research, including on externally led research projects on which an NBT member of staff is collaborating or delivering; any concerns or incidents regarding safeguarding must, at the earliest opportunity, be reported directly to:

- the Director of Research, Deputy Director of R&D or other member of the R&D Senior Leadership Team, either alongside, or in the absence of, project specific routes for reporting.
- The Trust Freedom to Speak Up Guardians to receive independent and impartial advice and support at any stage of raising a concern.
- the Trust Safeguarding Team, if a safeguarding concern or incident relates to the welfare of a child or adult at risk in NBT's care or relates to allegations of harm to a child or adult at risk by an NBT staff member.

7.2. Trust Level handling of concerns

These procedures are without prejudice to the normal operation of the relevant disciplinary procedures of the Trust (NBT Disciplinary Policy (PEO-06) and Maintaining High Professional Standards Policy for Medical Staff (PEO-11)). They are set out by way of guidance only and may be varied to suit the circumstances of a particular case. In the event of any conflict between these procedures and the relevant disciplinary procedure of the Trust, the latter shall take precedent.

7.2.1. Reports of Safeguarding in Research concerns or incidents, either experienced, witnessed or suspected, should be made directly to, or escalated to, the Director of Research, the Deputy Director of R&D or, a member of the R&D Senior Leadership Team, at the earliest opportunity and preferably in writing.

7.2.2. Exploitation, abuse, and harm as defined in this policy covers a broad range of possible offences of varying severity, therefore any action taken will be on a case-by-case basis.

- 7.2.3.** On receiving the report of the Safeguarding in Research concern or incident, the Deputy Director of R&D or member of the R&D Senior Leadership Team (case-lead), will assess whether any immediate action is required to prevent further risk or harm to employees, research participants, collaborators or the Trust, or if immediate action is required to protect data and research integrity.
- 7.2.4.** This will be followed by a preliminary review led by the case-lead, to determine which Trust policy/ies are most appropriate for the investigation of the report, this may include either one or a combination of:
- if there is a risk that safeguarding concerns are linked to Research Misconduct these would be referred to the Director of Research and Chief Medical Officer and managed in line with the Trust Research Misconduct Policy, for example, coercing participants into a study without informed consent is both a safeguarding issue (exploitation) and misconduct (ethical breach).
 - if a safeguarding concern or incident relates to a child or adult at risk's welfare in NBT's care or relates to allegations of harm to a child or adult at risk by an NBT staff member, the Trust Safeguarding Team will be notified, and the Trust Safeguarding Adult and/or Safeguarding Children policies will be followed.
 - if a safeguarding concern or incident relates to unacceptable behaviour by, or to, an NBT staff member engaged in research; which may include discrimination, racism, violence, aggression, bullying, harassment, abuse or sexual misconduct; the most appropriate Trust policy will be followed, which may include the Trust Disciplinary Policy, Trust Fairness at Work Policy, Trust Prevention, Management and Reduction of Violence and Aggression Policy, Trust Domestic Abuse Policy Trust Sexual Misconduct Policy, High Professional Standards (MHPS).
 - if a safeguarding concern is raised regarding the behaviour or actions of a person employed outside of NBT but who is engaged in NBT led research or leading research on which NBT is a collaborator or a site; the employing organization of that employee will be notified of the Safeguarding in Research concern or incident, in writing, at the earliest opportunity so that this can be investigated in line with that employers local policy.
 - The Trust will support any individual who has reported, or is affected by, a Safeguarding in Research incident to either continue, pause, or disengage with the research activity depending on their situation, preference and NBT's duty of care to that individual.
- 7.2.5.** The case-lead will notify the individual/s affected by the Safeguarding in Research concern or incident, and individual/s who made the report if not the same person, of the outcome of the preliminary review within 10 days of receipt of the concern or incident. This will include the decision on which Trust policy/ies the concern or incident fall under and the next steps. This includes any decision to investigate formally via Trust Disciplinary procedures and any notifications made, to be made,

to external authorities or Funding Bodies.

- 7.2.6.** If the individual who has raised, or is affected by, a concern or allegation does not wish for further action to be taken, then this will be considered by the Trust sensitively. However, NBT, as a duty of care, will determine what appropriate action will need to be taken and whether external bodies will need to be notified.
- 7.2.7.** In the event of there being a case to answer for breaches of Safeguarding in Research by NBT staff member/s, the investigation of such reports will occur in line with the Trust's Disciplinary Policy (PEO-06).
- 7.3.** Where a breach of Safeguarding in Research is being formally investigated, the Director of Research and Chief Medical Officer will make a decision whether to suspend the research and if it is appropriate to inform the Sponsor (as defined in the UK Policy Framework for Health and Social Care Research) of the ongoing investigation; the sponsor will be responsible for reporting the misconduct to REC/HRA Medicines and Healthcare products Regulatory Authority, if it is appropriate to do so.
- 7.4.** As well as sanctions identified within Trust Disciplinary Policy, other sanctions, through the authority of the Director of Research, may include:
- Withdrawal of pending grant submissions led by the individual concerned.
 - Withdrawal of the individual concerned from Chief Investigator (CI) roles, Principal Investigator (PI) roles, co-applicant roles on partner grants or research delivery roles.
 - Withdrawal of Confirmation of Capacity and Capability for continuation of a research project and, possibly, any research projects in which the individual concerned has involvement.
 - Changes in staffing to relevant research project/s.
 - More frequent and closer monitoring of future work.
 - Barring the individual concerned from conducting research in the Trust for a given period.
 - Revoking an honorary research contract.
 - Implementing a mandatory requirement for training to address unacceptable behaviours.
- 7.5.** Where an NBT researcher feels that they have been unfairly sanctioned, this should be addressed through the NBT Disciplinary Policy appeal process.
- 7.6.** In the case of misconduct related to breaches of Safeguarding in Research, professional groups may also be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers, as well as clinicians. Similarly, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council.

- 7.7.** Irrespective of the individual policy a concern or incident falls under, the following principles apply. NBT will:
- Address any immediate safety concerns and/or offer support to affected individuals.
 - Deal with concerns and complaints in a timely manner.
 - Take a victim/survivor-centred approach, listen, and take concerns seriously.
 - Maintain the highest level of confidentiality.
 - Take appropriate action, including reporting to appropriate authorities (except where this would cause further harm to the victim/survivor).
 - Take appropriate action at individual, departmental or organisational level to ensure, as far as possible, that similar concerns do not arise in the future.
 - Notify funding bodies and other authorities as required/appropriate.
- 7.8.** NBT will not tolerate harassment or victimisation of anyone who has reported a Safeguarding in Research concern or attempts to persuade or force someone not to raise their concerns, regardless of what the outcome is to the investigation.
- 7.9.** No one will be treated less favourably because of being involved in reporting a Safeguarding in Research Concern. NBT has a duty of care to support staff whether the report is upheld or not.
- 7.10.** NBT will not accept any retaliation or victimisation of an individual who is involved in reporting a Safeguarding in Research concern or incident. This will be dealt with under the Trust's disciplinary policy.
- 7.11.** At NBT, there will be no negative consequences for anyone that has reported a Safeguarding concern or incident in good faith, If an NBT member of staff is found to have made deliberate, false allegations of a vexatious nature, they may be subject to disciplinary action.

8. Monitoring effectiveness

- 8.1.** The below table details the monitoring procedures in order that NBT can be assured that compliance with a policy is being met. It identifies both the processes for monitoring compliance and the actions to be taken where deficiencies and non-compliance are identified. This table must be completed in all policies.
- 8.2.** This section describes how the implementation of the policy will be monitored. Audit activity should form part of all policy monitoring; therefore, an audit tool/checklist must be appended (or reference made to a national audit the Trust participates in on a regular basis). The below table should be populated with the key areas currently being monitored in addition to any monitoring criteria as required by regulators such as the CQC. This table can be extended as required.

What will be monitored	Monitoring/ Audit method	Monitoring responsibility (individual/group/ committee)	Frequency of monitoring	Reporting arrangements: (committee/group the monitoring results are presented to)	How will actions be taken to ensure improvements and learning where the monitoring has identified deficiencies
Volume of concerns or incidents	Caseworker tracker	R&D Senior team	Annual	Trust Research Group	Audit of all allegations, identify any trends or patterns from which corrective actions could be implemented.
Compliance with policy	Review volume of formal vs informally resolved cases and outcomes	R&D Senior Team	Annual	Trust Research Group	Audit of all incidents and decision-making processes against policy.

9. Associated policies/documents

9.1. NBT policies referenced in this Safeguarding in Research Policy can be found: [Policies Guidance & Toolkits - LINK](#)

- NBT Safeguarding Adult and Safeguarding Children Policies (CG-197 and CG-134).
- Trust Disciplinary Policy (PEO-06)
- Trust Fairness at Work Policy (PEO-33)
- Trust Prevention, Management and Reduction of Violence and Aggression Policy (HS08),
- Trust Domestic Abuse Policy (CG-205)
- Trust Sexual Misconduct Policy (PEO-53)
- Equality Diversity and Inclusion Policy (PEO-37)
- High Professional Standards (MHPS)
- Research Misconduct Policy (R&D P06)
- NBT Freedom to Speak Up Policy (PEO-22)

10. Glossary of Terms

- **Safeguarding** The process of protecting individuals from harm, abuse, exploitation, and neglect. In research, this includes preventing and responding to any form of abuse or misconduct affecting participants, staff, or communities.
- **Harm** Any physical, emotional, psychological, or reputational damage caused to an individual. In research, harm may result from unethical practices, power imbalances, or unsafe environments.
- **Abuse** A violation of an individual's human and civil rights by any other person or persons. This includes physical, emotional, sexual, and financial abuse, as well as neglect and discriminatory abuse.
- **Exploitation** Taking unfair advantage of a person for personal or institutional gain. In research, this may include using participants' data or contributions without proper consent, recognition, or benefit-sharing.
- **Sexual Misconduct** Any unwelcome sexual advance, request for sexual favours, or other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.
- **Adult at Risk** A person aged 18 or over who may be unable to protect themselves from harm or exploitation due to age, disability, illness, or other circumstances.
- **Child** Anyone under the age of 18, in line with the Children Act 1989.
- **Power Imbalance** A situation where one individual or group holds more influence, authority, or control over another, often seen in researcher-participant or funder-researcher relationships.

- **Chief Investigator (CI)** The lead researcher responsible for the overall conduct of a research project, including ensuring compliance with safeguarding policies.
- **Principal Investigator** The individual responsible for the conduct of a research study at a research site.
- **Research Misconduct** Behaviours that deviate from accepted ethical and professional standards in research, including fabrication, falsification, plagiarism, and unethical treatment of participants.
- **Preventing Harm in Research Risk Assessment** A structured process to identify, evaluate, and mitigate potential safeguarding risks in research activities.
- **Reporting Mechanism** A formal process or channel through which concerns or incidents related to safeguarding can be reported, investigated, and addressed.
- **Equitable Partnership** A collaborative relationship in research where all partners are treated fairly, with shared responsibilities, benefits, and decision-making.
- **Duty of Care** A legal and ethical obligation to ensure the safety and well-being of others, particularly those who may be vulnerable or at risk.
- **UKRI / NIHR / UKCDR** Key UK research funders and bodies that have developed safeguarding policies and frameworks to guide ethical research practices.