Use of Human Tissues in Research Policy

Documentation Control

<table>
<thead>
<tr>
<th>Reference</th>
<th>GG/CM/040</th>
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<tr>
<td>Approving Body</td>
<td>Trust Board</td>
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<tr>
<td>Date approved</td>
<td>2 September 2010</td>
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<td>Implementation date</td>
<td>2 September 2010</td>
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<td>Version</td>
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<td>Consultation undertaken</td>
<td>Human Tissues Management Group</td>
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<tr>
<td>Date of Completion of Equality Impact Assessment</td>
<td>August 2010</td>
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<tr>
<td>Target audience</td>
<td>All those involved with working with human tissues for research</td>
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<td>Supporting Procedure(s)</td>
<td>N/A</td>
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<tr>
<td>Review Date</td>
<td>August 2012</td>
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<tr>
<td>Lead Executive</td>
<td>Dr Fowlie, Medical Director</td>
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<tr>
<td>Author/Lead Manager</td>
<td>Prof James Lowe, Chair Human Tissues Management Group</td>
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<tr>
<td>Further Guidance/Information</td>
<td>Mrs Lianne Finnerty, Quality manager, Human Tissues Management Group, <a href="mailto:Lianne.finnerty@nuh.nhs.uk">Lianne.finnerty@nuh.nhs.uk</a></td>
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1.0 Policy Statement

1.1 The Trust has a Duty of Care to any patient who has donated tissue, blood or other human material for research purposes to ensure that the tissue is treated with respect and is handled in accordance with the appropriate national legislation and good practice. This policy has been produced to provide instruction to any individual(s) or organisation who has responsibility for human tissue, which has been donated for research purposes, and to any researcher who wishes to gain access to such samples. Relevant material from a human body according to the Human Tissue Act 2004 is defined as: material which consists of, or includes, human cells. It does not include gametes, embryos outside the human body, or hair and nails from the body of a living person. For the purposes of this policy relevant material will be referred to as ‘human tissue’.

2.0 Donation of tissue for research purposes by patients of this Trust

2.1 Human tissue originating from a Trust patient may come into the stewardship and oversight of one of the following groups

- A laboratory service of this Trust
- A research group in the Trust (eg a Biomedical Research Unit)
- The University of Nottingham.
- A group outside the Trust or University of Nottingham

2.2 The Department of Histopathology - Tissue may have been donated to Histopathology for research purposes by one of the following three methods:

- Tissue may originate from the living via a formal consent process as specified in the Trust Consent Policy
- Tissue from the deceased with consent as specified in the Trust Consent to Post Mortem policy.
- A patient may consent to the use of their tissue samples as part of their consent to take part in a specific research project. Signed consent forms will be
Histopathology holds tissue samples in the diagnostic archive from the living that is not associated with specific consent for use in research. Under certain circumstances it is acceptable that these samples may be used in research provided that approval for the study has been granted by an NRES Committee and that the workers have no direct access to the patient identity.

2.3 Laboratory services apart from histopathology may receive samples such as tissue, blood, urine or other human material

- Tissue may originate from the living via a formal consent process as specified in the Trust Consent Policy.

- Blood and fluids may have been taken with implied consent

- Tissue from the deceased with consent as specified in the Trust Consent to Post Mortem Policy.

- A patient may consent to the use of their tissue samples as part of their consent to take part in a specific research project. Signed consent forms will be retained by the research Chief/Principal Investigator and a copy held in the patients’ medical case notes.

2.4 University of Nottingham (UoN) – Tissue surplus to diagnostic requirements is sometimes taken for research purposes at the time a patient undergoes a specific procedure, with consent. It may then be transferred directly to an academic department of the UoN.

When this occurs, the custodianship of the tissue transfers from the Trust to the UoN, and as such the UoN accepts responsibility for its management, storage and disposal. When tissue samples are transferred directly to the UoN it must be done such that:
a. Any tissue taken will not compromise the remaining tissue sent to Histopathology for diagnostic purposes
b. The patient has given consent valid under the codes of practice of the Human Tissue Authority
c. The research project has received Trust R&D and NRES Committee approval
d. If the material is transferred to a tissue bank, that this tissue bank is included in a license under the Human Tissue Act (2004)
e. That an appropriate Material Transfer Agreement is in place between NUHT and UoN (see Appendix A)
f. That the tissue is archived and/or disposed of according to procedures specified by the NUHT Human Tissues Management Group.

3.0 Function of Histopathology with regards to research tissue samples

The Department of Histopathology has been acknowledged as the Trust’s custodian of patient tissue samples in the diagnostic archives. It will ensure that access, storage and archiving, is compliant with current good practice and legislative requirements. It will not release any tissue samples unless it can be demonstrated that the sample required is appropriate for the intended use and that the sample is going to an individual or organisation that has received ethical (when required) and organisational approval. Prior to the release of any human tissue, histopathology will:

a. Request that researchers comply with departmental policies and procedures established within Histopathology to track and manage human tissue used for research purposes.
b. Request copies of NHS R&D approval and ethical approval, where relevant
c. Ensure that internal records relating to the storage, release, use, or disposal of human tissue is adequately maintained.
d. If the only Trust involvement in the research process is to provide tissue to an organisation outside of this Trust, the following process will be followed:
i. Establish a MTA between the Trust and the organisation as appropriate

ii. Establish a service agreement between Histopathology and the organisation as appropriate and recover costs with R&D approval

iii. If the outside organisation is another NHS Trust, a copy of the R&D approval letter from that Trust will be requested prior to release of any human tissue.

iv. Request a copy of the research ethics committee approval letter relevant to that organisation, if relevant to the project

v. Maintain a record of all organisations outside of this Trust, supplied with patient tissue samples of this Trust.

4.0 Human Tissue taken from outside the Trust

A person seeking to bring human tissue into the Trust, originating from outside the Trust, must first establish a Material Transfer Agreement (MTA) with the provider which will specify that appropriate consent has been obtained and that the use and supply of the tissue is approved by the originating organisation. A copy of the Material Transfer Agreement should be sent to the chair of the Trust Human Tissues Management Group.

The storage and use of such human tissue must either be within premises licensed under the Human Tissue Act (2004) or must be associated with an NRES ethical approval and local NHS R&D approval.

5.0 Function of R&D with regards to research tissue samples

A research project will require approval from the R&D department of this Trust if the research involves the use of any Trust resource, its patients, staff, their data, tissue or organs. All projects are reviewed by the R&D department prior to giving approval. If a project involves the use of tissue samples the review process will expect to see documented evidence of:
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Nottingham University Hospitals NHS Trust

- What tissue samples are required and the quantity.
- What process is to be employed to gain access to such samples.
- Details of consent.
- What the tissue disposal process will be.
- Inclusion of a MTA if samples are to be transferred to an organisation outside of this Trust as appropriate.
- Inclusion of a signed costing proforma.
- Evidence that Histopathology will facilitate the consent procedure with bereaved relatives/legal guardians if post mortem tissue samples are required.

If the submitted project fails to answer these questions sufficiently, the researcher will be contacted to provide further clarification or to make appropriate amendments as requested.

6.0 Tissue Banks and Biobanks

Some research requires the transfer of tissue samples, blood samples, or samples of other bodily material obtained from Trust patients to a tissue bank or bio-bank facility. The Trust has a duty of care to protect its patients by providing a robust system governing how such research tissue is managed. The following process has been established not to hinder research, but to implement a policy to provide clarity. It describes the procedure to be followed when transferring a tissue sample(s) from a Trust patient, to a Tissue Bank. The following system is therefore in operation:

- Individual tissue banks are required to be in licensed premises under the Human Tissue Act (2004) and optionally approval as a Research Tissue Bank by an NRES committee.
- Individual tissue banks, including those in the University of Nottingham that receive Trust samples, require approval from the Trusts R&D department. R&D approval is required to ensure that the Trust meets its duty of care to its patients by ensuring that the following conditions are met:
An MTA is in place to acknowledge and oversee the transfer of tissue from the Trust (via the patient) to the University, and that the University accepts the conditions of transfer.

Written approval is sought from the R&D Department and the Trust Human Tissues Management Group to establish the bank. It is advisable to consult the R&D department regarding this process.

Storage and use of tissues is according to the codes of practice specified by the Human Tissue Authority, compliant with the Human Tissue Act (2004).

Subsequent research projects will require approval from R&D if the project involves:

- contact with, or identification of the tissue donor,
- uses further Trust resources such as Trust patients, staff, their tissue, organs or data.

Tissue surplus to requirements will be disposed of according to procedures that meet requirements of the Human Tissues Act (2004).

7.0 Relevant legislation

Human Tissue Authority codes of practice (hta.gov.uk)

8.0 Implementation and Monitoring Plans

Responsibility for implementation of this policy lies with the Human Tissues Management Group and NHS R&D

All Designated Individuals and Persons Designate named on Trust HTA Licenses will be issued with a copy of the Policy.

9.0 Equality and Diversity Statement

9.1 All patients, employees and members of the public should be treated fairly and with respect, regardless of age, disability, gender, marital status, membership or non-membership of a trade union, race, religion, domestic circumstances, sexual orientation, ethnic or national origin, social & employment status, HIV status, or gender re-assignment.
9.2 All trust polices and trust wide procedures must comply with the relevant legislation (non exhaustive list) where applicable:

- Sex Discrimination Act (1975 amended 1986)
- Race Relations (Amendment) Act 2000
- Disability Discrimination Act (1995)
- Employment Relations Act (1999)
- Rehabilitation of Offenders Act (1974)
- Trade Union and Labour Relations (Consolidation) Act 1999
- Code of Practice on Age Diversity in Employment (1999)
- Civil Partnership Act 2004
- Fixed Term Employees - Prevention of Less Favourable Treatment Regulations (2001)
- Employment Equality (Sexual Orientation) Regulations 2003
- Employment Equality (Religion or Belief) Regulations 2003
- Employment Equality (Age) Regulations 2006
- Equality Act (Sexual Orientation) Regulations 2007

9.3 Equality Impact Assessment Statement

NUH is committed to ensuring that none of its policies, procedures, services, projects or functions discriminate unlawfully. In order to ensure this commitment all policies, procedures, services, projects or functions will undergo an Equality Impact Assessment.

Reviews of Equality Impact Assessments will be conducted inline with the review of the policy, procedure, service, project or function

10.0 Environmental Impact Assessment Statement

10.1 An environmental impact assessment is not deemed relevant for this policy
11.0 We Are Here for You

11.1 We Are Here For You standard mission statement:

This Trust is committed to providing the highest quality of care to our patients, so we can pledge to them that ‘we are here for you’. This Trust supports a patient centred culture of continuous improvement delivered by our staff. The Trust established the Values and Behaviours programme to enable Nottingham University Hospitals to continue to improve patient safety, outcomes and experiences. The set of twelve agreed values and behaviours explicitly describe to employees the required way of working and behaving, both to patients and each other, which would enable patients to have clear expectations as to their experience of our services.
Material Transfer Agreement

This Agreement is made by and between:

NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST with principal offices at, E11 Curie Court, Queens Medical Centre Campus, Derby Road, Nottingham NG7 2UH, hereinafter (“the Donor Institution”)

And;

INSERT RECIPIENT SCIENTIST’S INSTITUTION with principle offices at, Insert Recipient’s Institution Address, hereinafter (“the Recipient Institution”)

This Agreement records the terms under which the Donor Institution will make available Insert Details of Material (the “Material”). The term “Material” includes all unmodified progeny generated from the material supplied and that part of all derivatives and the derivative’s progeny which contains any of the material supplied or its progeny. The Recipient Institution will hold the Material on the terms of this Agreement and solely for the purpose of Insert Long Title of Study (“the Research Project”) within the research group of Insert Recipient Scientist’s Name (“the Recipient Scientist”).

1. The Donor Institution warrants that the Material being transferred has been obtained with appropriate consent and in accordance with all local regulatory and ethical requirements notwithstanding that Material derived from living persons has been anonymised. Wherein specific conditions regarding return or disposal of the Material are attached the Donor Institution must provide such information to the Recipient Institution.

2. The Recipient Institution warrants that the Material shall be stored in premises licensed by the Human Tissue Authority (HTA) or in the absence of such licence that the Material shall only be stored for use in the “Research Project” which [has received approval/has approval pending] by the National Research Ethics Service (NRES). The Donor Institution may request copies of the Recipient Institution’s
3. The Material may only be used by those under the Recipient Scientist’s direct supervision in the Recipient Institution’s laboratories under suitable containment conditions, and in compliance with all applicable statutes and regulations. [DELETE AS APPROPRIATE THE MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS OR FOR CLINICAL OR DIAGNOSTIC PURPOSES/THE MATERIAL BEING TRANSFERRED UNDER THIS AGREEMENT IS FOR USE AS A LABORATORY CONTROL MATERIAL.]

4. The Recipient Institution will not transfer the Material to any other body, or permit its use within the Recipient Institution other than by the Recipient Scientist’s research group, without (in each case) prior written consent from the Donor Institution. The Material may not be used by the Recipient Scientist in research which is subject to the provision of any rights to a commercial third party without prior written consent.

5. The Recipient Institution understands that the Material is experimental in nature, and may have hazardous properties. The Donor Institution makes no representations and gives no warranties either express or implied in relation to it: for example, no warranties are given about quality or fitness for a particular purpose; or that the use of the Material will not infringe any intellectual property or other rights of third parties. The Donor Institution will not be liable for any use made of the Material.

6. Except to the extent prohibited by law, the Recipient Institution assumes all liability for damages which may arise from its receipt, use, storage or disposal of the Material. The Donor Institution will not be liable to the Recipient Institution for any loss, claim or demand made by the Recipient.
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Institution, or made against the Recipient Institution by any other party, due to or arising from the use of the Material by the Recipient Institution, except to the extent the law otherwise requires.

7. The liability of either party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

8. The Recipient Scientist will acknowledge the source of the Material in any publication reporting on its use. If the Recipient Scientist wishes to include in a publication any information which has been provided by the Donor Institution with the Material and which was clearly marked as “Confidential” and “Proprietary” at the point of disclosure (“Confidential Information”), the Recipient Scientist will request permission from the Donor Institution, providing a copy of the text before publication takes place.

9. Nothing in this Agreement grants the Recipient Institution any rights over the Material (other than as specifically granted by this Agreement) or under any patents, nor any right to use, or permit the use of, any products or processes containing, using, or directly derived from the Material for profit-making or commercial purposes (“Commercial Use”). If the Recipient Institution wishes to make Commercial Use of the Material or a product directly derived from the Material it agrees to negotiate in good faith with the Donor Institution or its representative for the grant of an appropriate licence or the conclusion of a revenue sharing agreement, if justified. The Donor Institution will have no obligation to grant a licence.
10. Nothing in this Agreement shall prevent the Donor Institution from being able to distribute the Material to other commercial or non-commercial entities, including any intellectual property protection being undertaken by the Recipient Institution on any new use made with the Material.

11. This Agreement shall commence on the date of the last signature below and will (subject to earlier termination pursuant to clause 10) continue for the duration of the Research Project.

12. The Donor Institution may terminate the Agreement if the Recipient Institution is in material breach of any of the terms of this Agreement and, where the breach is capable of remedy, the Recipient Institution has failed to remedy the same within one month of service of a written notice from the Donor Institution specifying the breach and requiring it to be remedied.

13. Upon completion of the Research Project or earlier termination under clause 10 the Recipient Institution will discontinue all use of the Material, and [delete as appropriate - return/destroy] the Material, unless permission to retain the Material is specifically provided in writing by the Donor Institution to the Recipient Institution. Any permission to retain the Material shall be made in accordance with appropriate Donor consent having been obtained for subsequent use of the Material. Where the Material being transferred has been obtained post mortem the Recipient Institution shall dispose of the Material in accordance with the HTA’s Code of Practice [http://www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm]
14. This Agreement shall be governed by English Law, and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Letter Agreement.

Accepted and Agreed by an authorised Signatory on behalf of:  

Recipient Institution

Name:  
Position:  
Signature:  
Date:

Donor Institution

Name:  
Position:  
Signature:  
Date:

Please contact the Quality Manager for the Human Tissues Management Group who will give advice

Lianne.finnerty@nuh.nhs.uk
Appendix 2

Equality Impact Assessment Report Outline

1. **Name of Policy or Service**
   
   Use of Human Tissues in Research Policy

2. **Responsible Manager**
   
   Prof James Lowe

3. **Name of Person Completing Assessment**
   
   Lianne Finnerty & Prof James Lowe

4. **Date EIA Completed**
   
   04 August 2010

5. **Description and Aims of Policy/Service**
   
   This document specifies the Trust policy in relation to the use of human tissues in research.

6. **Brief Summary of Research and Relevant Data**

7. **Methods and Outcome of Consultation**
   
   Human Tissues Management Group
   NHS R&D
   Directors Group

8. **Results of Initial Screening or Full Equality Impact Assessment:**

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<th>Equality Group</th>
<th>Assessment of Impact</th>
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<td>Age</td>
<td>No Impact Identified</td>
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9. **Decisions and/or Recommendations**

Following the initial screening this policy does require a full impact assessment as the policy sets out the use of human tissues in research in accordance with the Human Tissue Act (2004) and Human Tissue Authority Code of practice 9 (September 2009).

Human Tissues used for research are overseen by NHS R&D, the Designated Individual for the Trust and the Human Tissues Management Group.

10. **Equality Action Plan (if required)**

   **N/A**

11. **Monitoring and Review Arrangements**

    The policy will be reviewed by the HTMG and NHS R&D. All Designated Individuals and Persons Designate named on the Trust HTA Licenses will be issued with a copy of the policy.
### We Are Here For You Policy and Trust-wide Procedure Compliance Toolkit

The We Are Here For You service standards have been developed together with more than 1,000 staff and patients. They can help us to be more consistent in what we do and say to help people to feel cared for, safe and confident in their treatment. The standards apply to how we behave not only with patients and visitors, but with all of our colleagues too.

They apply to all of us, every day, in everything that we do. Therefore, their inclusion in Policies and Trust-wide Procedures is essential to embed them in our organization.

This toolkit has been designed for Policy Owners to assess the compliance of their Policy or Trust-wide Procedure in light of the We Are Here For You values. It is now mandatory for all Policies and Trust-wide Procedures to incorporate the We Are Here For You Values and undergo this compliance assessment.

Please complete the grid below to assess your Policy or Trust-wide Procedure. The toolkit will then advise Policy-owners on the steps they need to take to become We Are Here For You compliant.

**To what extent is your Policy or Trust-wide Procedure affected by the following We Are Here For You values?**

**Please rate each value from 1 – 3 (1 being not at all, 2 being affected and 3 being very affected)**

<table>
<thead>
<tr>
<th>1. Polite and Respectful</th>
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<tbody>
<tr>
<td>Whatever our role we are polite, welcoming and positive in the face of adversity, and are always respectful of people’s individuality, privacy and dignity.</td>
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<tr>
<th>2. Communicate and Listen</th>
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<td>We take the time to listen, asking open</td>
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<td><strong>questions, to hear what people say; and keep people informed of what's happening; providing smooth handovers.</strong></td>
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<tr>
<td><strong>3. Helpful and Kind</strong></td>
<td>All of us keep our 'eyes open' for (and don't 'avoid') people who need help; we take ownership of delivering the help and can be relied on.</td>
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<td><strong>4. Vigilant (patients are safe)</strong></td>
<td>Every one of us is vigilant across all aspects of safety, practices hand hygiene and demonstrates attention to detail for a clean and tidy environment everywhere.</td>
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<td><strong>5. On Stage (patients feel safe)</strong></td>
<td>We imagine anywhere that patients could see or hear us as a 'stage'. Whenever we are 'on stage' we look and behave professionally, acting as an ambassador for the Trust, so patients, families and carers feel safe, and are never unduly worried.</td>
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<tr>
<td><strong>6. Speak Up (patients stay safe)</strong></td>
<td>We are confident to speak up if colleagues don’t meet these standards, we are appreciative when they do, and are open to ‘positive challenge’ by colleagues.</td>
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<td><strong>7. Informative</strong></td>
<td>We involve people as partners in their own care, helping them to be clear about their condition, choices, care plan and how they might feel. We answer their questions without jargon. We do the same when delivering services to colleagues.</td>
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<td><strong>8. Timely</strong></td>
<td>We appreciate that other people’s time is valuable, and offer a responsive service, to keep waiting to a minimum, with convenient appointments, helping patients get better quicker and spend only appropriate time in</td>
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9. Compassionate
We understand the important role that patients’ and family’s feelings play in helping them feel better. We are considerate of patients’ pain, and compassionate, gentle and reassuring with patients and colleagues.

10. Accountable
Take responsibility for our own actions and results

11. Best Use of Time and Resources
Simplify processes and eliminate waste, while improving quality

12. Improve
Our best gets better. Working in teams to innovate and to solve patient frustrations

TOTAL 17

If your Policy or Trust-wide Procedure scores 16 or more, you are required to review the document and make changes to ensure the values are reflected in the document. In addition to this, you are required to insert a We Are Here for You standard mission statement, as outlined below.

If your Policy or Trust-wide Procedure scores 15 or less, you are required to insert a We Are Here for You standard mission statement, as outlined below.

We Are Here For You standard mission statement:

This Trust is committed to providing the highest quality of care to our patients, so we can pledge to them that ‘we are here for you’. This Trust supports a patient centred culture of continuous improvement delivered by our staff. The Trust established the Values and Behaviours programme to enable Nottingham
University Hospitals to continue to improve patient safety, outcomes and experiences. The set of twelve agreed values and behaviours explicitly describe to employees the required way of working and behaving, both to patients and each other, which would enable patients to have clear expectations as to their experience of our services.

We Are Here For You Policy Sub Group members are available for guidance relating to this toolkit. Their contact details are below.

**We Are Here For You Policy Sub-group members:**

The We Are Here For You Policy Sub-Group are all willing to help Policy-Owners when re-working Policies in-line with this toolkit. The contact details for the group are below:

Jennifer Mitham, Directorate HR Manager, X64633, jennifer.mitham@nuh.nhs.uk

Jackie Wilbourn, Directorate HR Manager, X55697 jackie.wilbourn@nuh.nhs.uk

Mike O’Daly, Trust Secretary, X66429/62349/62908 mike.odaly@nuh.nhs.uk

Alyson Packham, Named Nurse Safeguarding Team, X63432/56809 alyson.packham@nuh.nhs.uk

Isabella Furse, Safeguarding Vulnerable Adults Consent Manager, X61627 isabel.furse@nuh.nhs.uk

Sue Arnold, Matron – Neuro & Spinal, MSKN, X67579 sue.arnold@nuh.nhs.uk
EMPLOYEE RECORD OF HAVING READ THE POLICY

Title of Policy/Procedure:

POLICIES AND PROCEDURES - DEVELOPMENT, APPROVAL, IMPLEMENTATION AND REVIEW POLICY

I have read and understand the principles contained in the named policy.

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