FAQs related to Research Approvals and the use of secondary clinical/research data

Contents

Scope and purpose of this document

This document was prepared by the Research and Innovation (R&I) department at University Hospitals Bristol and Weston (UHBW). It is intended as a guide for carrying out research in an NHS setting that involves use of patient data; both routinely collected, and data collected for purposes of research.

In this document "research" refers to clinical research studies as defined in the UK Policy Framework for Health and Social Care Research.

1. What approvals are needed for carrying out research in the NHS?

1.1 What is Health Research Authority (HRA) Approval?

HRA and HCRW (Health Care Research Wales) Approval is the process that brings together the assessment of governance and legal compliance, and applied for via the Integrated Research Application System (IRAS) online portal. Dedicated HRA and HCRW staff undertake review of applications centrally, and independent Research Ethics Committee (REC) opinion is provided through the UK Research Ethics Service.

You can apply for HRA and HCRW Approval if the project meets all of the following criteria:

- The lead NHS R&D Office is in England or Wales (IRAS project filter question 3a answered “England” or "Wales").
- It is a project-based study type. That is a study described by any of the IRAS filter question 2 categories except ‘research tissue banks’ and ‘research databases’.
- NHS premises and/or NHS patients and/or NHS staff in England and/or Wales are participating in the project.

Please note that only projects that are considered research should be submitted to the HRA. If you are unsure whether your project is considered research as defined by the UK Policy Framework for Health and Social Care Research, please use the decision tool available on the HRA website. The HRA also provides a table detailing the differences between research projects, audits and service evaluations.

Some research projects may require HRA Approval but not REC review. Examples can be found on the HRA/IRAS sites .

Further information including approvals for sites outside of England and Wales can be found on the HRA website.

2. Who is responsible for identifying potential research participants?

The searching of patient or service user records for potential research subjects can be done legally by fulfilling any of the following criteria (information available in the HRA Approval standards):

- The researcher gains the explicit consent of every patient with a record in the population pool being assessed
- The search is conducted by a health or social care professional who has a 'legitimate relationship' with the patient, such as a clinical or social worker
- The search is conducted by a researcher who is part of the "direct care team" (see section 2.3 below)
- The search makes use of 'privacy enhancing technologies'
- Support under section 251 regulations is granted through the Confidentiality Advisory Group (CAG) for the research (in England and Wales)

2.1 Who are the Confidentiality Advisory Group (CAG?)

If a researcher needs to access identifiable information and is not able to fulfil the criteria mentioned above, they will need to apply to the Confidentiality Advisory Group (CAG) and obtain 'Section 251 support'. In IRAS, the research team will be able to select whether they wish to submit an application to the CAG. The CAG reviews applications where confidential patient information is to be processed in England and Wales without consent for *research and non-research projects*.

The (CAG) is a specialised body that advises the Health Research Authority (HRA) and the Secretary of State for Health on requests for access to confidential information, in the absence of informed consent from its owners. Please note that Section 251 Support and CAG review will only apply for English and Welsh sites. If your project requires access to NHS Scottish data, please refer to the HRA Approval standards for further information or the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care. In Northern Ireland, there is no equivalent legislation in place that enables confidential personal information to be shared without consent for research.

2.2 Who is considered part of the direct care team?

There are a range of different staff groups delivering research across UHBW and for the purpose of transparency it is important to define who is considered part of the direct care team. As UHBW is a research-active Trust and research is embedded in our Trust's tripartite mission, research is considered part of clinical care. Our patients would therefore expect to be contacted about research studies that they may be eligible for.

The direct care team can include different staff groups, such as nurses, trial co-ordinators, data managers, administrators etc. as well as doctors. They may access patient identifiable information

prior to consent, for the sole purpose of eligibility screening, **providing the following conditions are met**:

- They must have substantive or honorary contracts with UHBW NHS Foundation Trust;
- They must only work under the remit of those contracts, for the role they are employed to do and under the supervision of an NHS line manager in the Trust;
- They must follow the principles of the Data Protection Act 2018 and only access identifiable information for the approved research studies to which they are allocated;
- They are not allowed to access patient identifiable information for any other purposes, e.g. for personal or other academic reasons.

For example, it would not be expected that a UHBW Neurologist would be able to access the medical records of a patient seen at the UHBW Cardiology department. They would not have the legal basis to access this information to screen and identify potential participants for a research study. They would be expected to ask someone within the Cardiology team who has a legal basis to access the medical records (e.g. patients' Cardiologist or a nurse/ward administrator). They would then be responsible for undertaking this search and the Cardiology team would need obtain verbal patient consent for the Neurology team to approach them about taking part in their study.

2.3 Can I review participant identifiable information prior to consent for pre-screening purposes if I have an Honorary contract or Letter of access with the Trust?

Please note that having a Letter of Access/Research Passport does not provide the researcher with a legal basis to access personal identifiable information without prior consent. Only members of the direct care team can review personal information to identify and initially approach potential participants. If the participant provides verbal/written consent confirming that they are happy for the researcher to contact them about the study, the direct care team member can then provide the researcher the participant's contact details. If members of the research team who are not part of the clinical/direct care team need to review personal identifiable information without consent, they will most likely require Section 251 Support from CAG.

3. Research using data collected as part of routine care

A member of a patient's or service user's direct care team may render confidential patient information anonymous without breaching the duty of confidentiality. As described in section 2.3, the care team includes registered health and social care professionals and other staff that directly provide or support care to patients.

Anonymised information can then be used in health and care research. There are three main scenarios that are likely to apply to health and care research.

3.1 Scenarios

The following scenarios are available on the HRA and IRAS websites.

- **Scenario 1**: A member of the care team enters information about patients into a database (for example, using a secure web-based system) without any identifiers, where the primary purpose of the database is to support public health surveillance or clinical decision-making. That database would then hold information that would be anonymous to the person analysing the data (where appropriate controls about linking that data to other data are put in place). The establishment of a database for public health or clinical purposes does not require HRA Approval/ review by a REC and should be managed under clinical and information governance arrangements. This anonymous data may then be used for *research* without REC approval (as the data was not collected with the intension to be used in research*) but will require HRA Approval*. HRA Approval will not be required if the data is used for a non-research project (for example a service evaluation).
- **Scenario 2**: A member of the clinical care team enters information about patients into a study-specific database (for example, using a secure web-based system) without any identifiers, where the primary purpose of the database is to support an individual research project. Where the purpose of new data collection is for research, it requires HRA approval and review by a REC, even if the data analysed by researchers will be anonymous to the researcher.
- **Scenario 3**: Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by direct care staff using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised, before conducting the research (by entering into a secure database). HRA Approval will still be required if the project is a research study (but not if the data is used for audit or service evaluation purposes).

4. Useful Links

HRA/IRAS

http://www.hra-decisiontools.org.uk/research/ (HRA decision tool)

http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf (HRA 'Defining research table')

https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-approval-assessment-criteria-standards-document.pdf (link to HRA Approval standards)

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/ (HRA information about CAG)

ICO

https://ico.org.uk/for-organisations/guide-to-data-protection/introduction-to-data-protection/about-the-dpa-2018/ (ICO- Further information about the DPA 2018)

https://ico.org.uk/media/1061/anonymisation-code.pdf (ICO - Further information about the process of anonymising data)

UHBW Site

http://www.uhbristol.nhs.uk/research-innovation/for-researchers/is-it-research,-audit-or-service-evaluation/ (UHBW – Is my study considered research, audit or service evaluation?)