

Research Ethics Committees - Expectations and Requirements of Registration for Biobanks

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HRA – Who are we and what do we do?

- Established in 2011 – Recommendation made by the Academy of Medical Science
- Established as a non departmental public body in the Care Act 2014

(2) The main objective of the HRA in exercising its functions is-

(a) to **protect** participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and

(b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical **(including promoting transparency in research)**

HRA – Who are we and what do we do?

- Research Ethics Service (responsible for UK wide SOPs)
- NHS Governance approvals in England
- Confidentiality Advisory Group
- Publishing guidance on:
 - principles of good practice in the management and conduct of health and social care research;
 - requirements, whether imposed by enactments or otherwise, to which persons conducting health or social care research are subject.

HRA – Who are we and what do we do?

- **Transparency**

Promoting transparency in research includes promoting—

- the registration of research;
- the publication and dissemination of research findings and conclusions;
- the provision of access to data on which research findings or conclusions are based;
- the provision of information at the end of research to participants in the research
- the provision of access to tissue used in research, for use in future research.



HRA – Who are we and what do we do?

- Transparency agenda
- Working with stakeholders



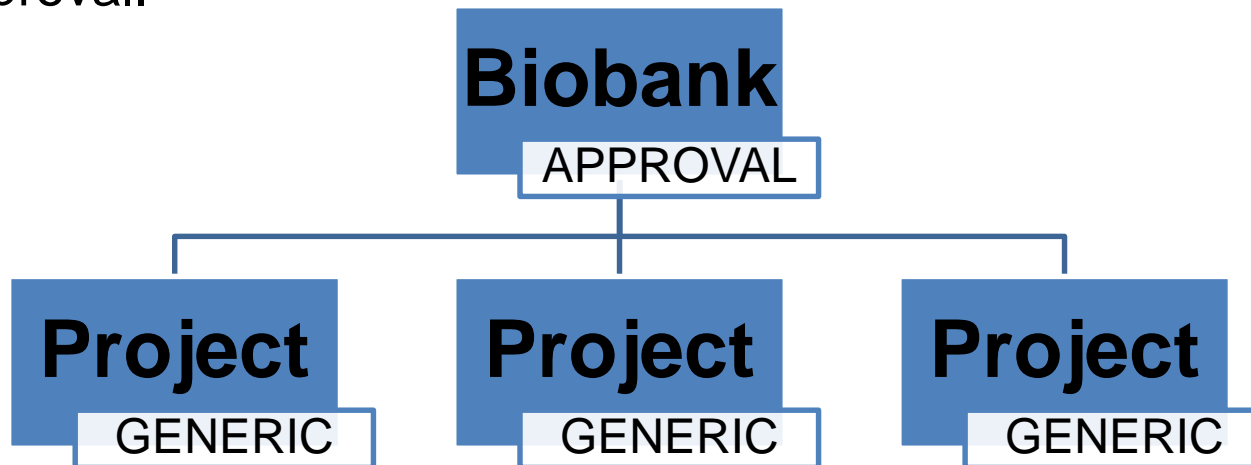
Tissue Directory and
Coordination Centre

- UKCRC Tissue Directory and co-ordination centre.
- 2016 – UK wide agreement to make registration on the Directory a standard condition for a favourable opinion for a research tissue bank
- Commenced from February 2017

HRA – Who are we and what do we do?

RES SOP 12.21

“There is no requirement for tissue banks to obtain ethical approval under the HT Act or under NHS research governance systems or GAfREC. Applications will therefore be made on a voluntary basis, but ethical approval for a bank may have benefits by facilitating programmes of research without a need for individual project-based ethical approval.”



Condition: Favourable opinion

Registration of Research Tissue Banks

It is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory. The Research Tissue Bank should be registered no later than 6 weeks after the date of this favourable ethical opinion letter or 6 weeks after the Research Tissue Bank holds tissue with the intention to provide for research purposes. Please use the following link to register the Research Tissue Bank on the UKCRC Directory: <https://directory.biobankinguk.org/Register/Biobank> Registration is defined as having added details of the types of tissue samples held in the tissue bank.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment or when submitting an annual progress report. We will monitor the registration details as part of the annual progress reporting process.

How we monitor

Through standard contact/reporting processes (long term)

- Annual progress reporting
- Substantial amendment






Active communication (short term)

- Audit of registration
- Reiteration of requirement



Active communication

- RTBs with a favourable opinion for a new of renewal between February 2017 and August 2017

Number of RTB applications	17	
Found on the Directory	7	
Not found on the Directory	10	

Following up where not found

For those not found on the Directory – e-mail to the tissue bank manager:

1. Is your Tissue Bank registered on the UKCRC Research Tissue Bank Directory?

If not,

- a. Were you aware of the condition to register the tissue bank on the UKCRC Tissue Bank Directory?
- b. Were you aware the existence of the UKCRC Tissue Bank Directory?

Following up where not found

For those not found on the Directory – e-mail to the tissue bank manager:

2. Are you aware of or do you perceive any barriers to registering on the UKCRC Tissue Bank Directory?

Following up where not found

For those not found on the Directory – e-mail to the tissue bank manager:

3. If you have not registered, is this because you are not yet required to (it's less than 6 weeks since the favourable opinion or the point at which you hold tissue with the intention of providing for research)? If there is another reason, please could you provide this?

Responses received

All responders said they were happy to register



1 – registered but different name

3 – Haven't started collecting tissue

Responses received

“We simply do not have enough staff or resources to supply samples to researchers who are not collaborating closely with our members.”

“No barriers as such, however, the nature of our RTB meant that some of the registration questions were not applicable. The services section of the registration could also be improved to include more services.”

“It was not a requirement that I was aware of before your email prompted me to look back at the REC approval letter.”

Reflections and next steps



Reflections and next steps

- Continue to work closely with the UKCRC Tissue Bank Directory and Co-ordination Centre
- Stakeholder engagement
- Encourage RECs to have the conversation at the review stage
- Include as a question in IRAS to raise awareness

Thank you