

Biosample Access Policy

1. Introduction

- 1.1. onCore UK is a national cancer biobank - a collection of human tissue samples donated by cancer patients for use in cancer research. We are a charity funded by the Department of Health (England), the Medical Research Council and Cancer Research UK.
- 1.2. Our mission is:

“To serve as a national biosample and information resource to enable research towards the discovery and development of new interventions against cancer.”
- 1.3. Donor samples are precious resources and onCore UK has a duty to donors to make sure the best possible value is derived from their kind gift. This document outlines the principles under which we will provide access to samples and supportive information.

2. Eligibility for access

- 2.1. **We will make samples available to bona fide researchers, wherever their research is conducted.** We consider bona fide researchers to be those directed or supervised by a recognised public, charitable or industrial body. Where we are unsure of a researcher’s bona fides (for example, where requests are from smaller industrial bodies or private laboratories) we will look for a track record in the field or other unambiguous means of validating their credentials in making our decision.
- 2.2. **Any use of samples must fall under the consent given by our donors.** This allows samples to be used for biomedical research on the prevention, diagnosis and / or the treatment of cancer and associated diseases.
- 2.3. Applicants must also satisfy us that the stated research objectives are in line with the mission of onCore UK and that the research presents no undue risks to the donors of the samples.
- 2.4. **We will only supply samples for ethically acceptable research. It is our intention to seek ethical approval for the supply of samples.** This will remove the need for researchers to seek approval for projects that fall within its scope, and we anticipate that our approval will cover most projects.
- 2.5. Where projects fall outside of our ethics approval we will require applicants to provide evidence of project specific approval from an appropriate Research Ethics Committee.
- 2.6. **We will only supply samples for research that has been appropriately reviewed and validated.** We expect that most applications will be supported by funders who carry out peer review of scientific merit or that applicants will be able to provide evidence of other review. Where we are not satisfied that a study has been adequately reviewed, we will commission a review on our behalf.

3. Requesting access

Timing of requests

- 3.1. **We will accept applications at any time and, in general, we will provide access on a 'first-come, first-served' basis.** However, in situations where there is competition for access to limited resources we will put in place arrangements to prioritise applications. Prioritisation will be based on each proposal's fit with onCore UK's mission and perceived scientific merit.
- 3.2. **From time to time, we may also issue open calls for applications.** In these cases we may consider all applications together, rather than in the order in which they are received.
- 3.3. We have a duty to ensure that maximum value is obtained from the samples. We may, therefore, put applicants who propose similar studies in touch with one another and suggest that they collaborate. This will not prevent the researchers involved pursuing separate applications if they wish.

Technical review

- 3.4. **We will need to know that applicants have the facilities to store the samples correctly and safely and will make the best use of the samples that they possibly can.** For this reason, we will ask to see copies of policies or standard operating procedures for storing and handling tissues and the associated data as part of the application.

Evidence of funding

- 3.5. **We will only release samples to projects with funding or evidence of institutional support and resource.** Applicants will need to supply evidence (e.g. a letter from the funding body) that the research is sufficiently funded and otherwise resourced before we release samples.
- 3.6. We recognise that some funders may require evidence that applicants will be able to access the samples necessary to a study before they will agree funding. We will consider requests both before and after funding is secured but will not release samples until we receive evidence of funding.
- 3.7. If access is agreed subject to funding this will reserve the samples requested. Any such agreement will be valid for a limited time and, if funders require significant changes to the proposed study or its protocol, we may require a further application.

4. Fees

- 4.1. **We will pass on our costs to researchers.** onCore UK operates on a not-for-profit basis and does not buy or sell human tissue. Our expenses to acquire, store and provide the tissues will be passed on to researchers via a cost-contribution charging system. The fees levied from researchers will be based on the accepted ethical principle of recovering the fair costs of obtaining the samples and the running costs of onCore UK acting as custodians of the samples.
- 4.2. Researchers who request samples for work that is funded by the NIHR, MRC or CR UK will pay a lower fee as these bodies already support the running of onCore UK.

5. Conditions of access

- 5.1. Applicants must agree to our conditions of access and demonstrate that their research project is supported by the institution or organisation in which it will take place. To ensure this is the case we will require the researcher's organisation to enter into a contract that governs the transfer and use of the biosamples supplied.

Usage limitation

- 5.2. We will oblige researchers to use the samples provided only for the purpose specified in their application and agreed by onCore UK.

Onwards transfer

- 5.3. We will place a restriction on researchers to prevent the onward distribution of any samples or information obtained from onCore UK without our prior authorisation. Where we supply to another biobank, this limitation can be waived in the agreement between onCore UK and the other biobank but not between the other biobank and the end user.

Data identifiability

- 5.4. We will not provide researchers with any identifiable personal information about our donors. To further protect our donors' privacy, researchers will be required to agree that they will not attempt to identify our donors in any way.

Maintaining safety, security and quality

- 5.5. We will handle, store and transport all samples in a safe and secure manner that will maintain the quality and the dignity of the gifts entrusted to us.
- 5.6. We will require researchers to work in the same fashion; transporting and storing the samples and data received in accordance with written Standard Operating Procedures, as well as complying with all appropriate local legislation and regulations.

Withdrawal of consent

- 5.7. We will respect our donors' right to withdraw their consent at any time. While we cannot recall samples or information once they have been used, we will require recipients to destroy any unused samples and delete any associated data that we have supplied unless it is in use.

End of study

- 5.8. We would normally expect all samples supplied by onCore UK to be consumed in the course of a research study. However, we will require researchers to destroy any unused samples remaining at the end of their study and to sign a declaration that have disposed of all samples. While we regret any waste of our donors' gifts, our commitment to quality standards means that we cannot use biosamples once they have been released from the collection.

Intellectual property

- 5.9. We will not restrict the freedom of researchers and their organisations to protect and pursue any intellectual property derived from their research using the samples. We expect them to use this freedom to further the development of new interventions for cancer medicine in line with the mission of onCore UK and the intentions of the donors.

Publication and acknowledgement

- 5.10. We will require researchers to return data and knowledge gained from their research using onCore UK's services to the public domain in a timely fashion and, if applicable, as soon as intellectual property rights have been protected. We expect that this will occur through submission to peer reviewed publications or other publically accessible resources in most cases.
- 5.11. We will ask researchers to acknowledge onCore UK, our partners and our donors in any publications based on work using samples that we have supplied.

Transparency

- 5.12. We will make information available to patients and donors, the general public, healthcare professionals and the research community about what happens to samples in general: where they are going, what researchers are doing with them – and most importantly, the results and outcomes that have been achieved.
- 5.13. To support this, we will request lay summaries of their work from researchers in their applications and, at the end of their study, will ask them for a lay summary of their results and their significance.

Compliance with these conditions

- 5.14. We will require researchers to complete a regular declaration that they have complied with the conditions under which samples were supplied and detailing the number of samples used and remaining. We may also audit researchers' handling and use of samples if this is considered necessary.
- 5.15. We will deny future access to any recipients who are found to be in breach of the agreed conditions, and we will inform their institutions and funders of the circumstances.

6. Complaints and dispute resolution

- 6.1. If researchers are not happy with the way that their application is handled, we will first attempt to resolve the problem with them in accordance with our complaints policy statement. If we are unable to reach agreement, we will refer the dispute to onCore UK's Chief Executive Officer and Board for a final decision.



Signed:

Date: 28th September 2009

Chief Executive Officer