

Ethics and Standards Statement for onCore UK



onCore UK has been established to serve as a national cancer biosample and information resource for research into new interventions against cancer. Its core values are of *safety, quality, service* and *ethics*.

The statement below is intended to summarise the means by which onCore UK expects to comply with its core values in pursuit of this mission.

onCore UK:

1. Is a registered charity that is organisationally external to the NHS and independent of the research community.
2. Focuses on fulfilling the wishes of cancer patients who donate tumour tissues and other biological samples (biosamples), such that these donations may aid cancer research towards the discovery and development of new interventions for cancer medicine and alleviate the burden of cancer on future patients.
3. Works with patients and the NHS to provide services to cancer researchers, which include the provision of human biosamples from cancer patients and associated supporting information.
4. Provides education and support to donors and researchers related to good practices and the benefits of the use of human biosamples in research.
5. Works to high standards and establishes benchmarks for the collection, storage, provision and use of donated human biosamples in research.
6. Accords with the strategic direction of the National Cancer Research Institute (NCRI), is supported by the NCRI partners and was founded through joint funding by the Department of Health (England), Medical Research Council and Cancer Research UK.
7. Has a strategy for involving patients and the public in its activities and for taking account of their opinions in guiding how it operates its business.
8. Will operate its business with the approval of a Research Ethics Committee and under the guidance of the UK National Research Ethics Service (NRES).
9. Operates an external Ethics and Standards Advisory Panel to provide additional specific independent advice to the Executive and Trustees of onCore UK.

V4 February 2008

10. Complies with all applicable regulation in the UK (including the Human Tissue Act 2004, the regulations subsidiary to this Act and the Codes of Practice issued by the Human Tissue Authority, the Health and Social Care Act 2003 and the Data Protection Act 2003).
11. Works with the support of the Department of Health and within the Research Governance Framework of the Department of Health (England). It complies with comparable systems applying in the devolved administrations of the United Kingdom insofar as it operates in these countries.
12. Works with the knowledge of the Human Tissue Authority. It defers to the Authority to obtain all necessary approvals relevant to its business activities and will comply with all inspections by this Authority when necessary.
13. Acquires human biosamples and associated information about donors, their disease, their treatment and their response to treatment through contracts with the NHS. These contracts govern the responsibilities of the NHS Trusts to:
 - 13.1. gain consent of the patients for donation,
 - 13.2. only provide biosamples to onCore UK when they are excess to the needs of high quality patient care,
 - 13.3. only provide biosamples for research when they are collected and handled to high quality standards prescribed by onCore UK,
 - 13.4. always collect and provide donor information that is necessary to make the tissue a powerful research tool and, thus fulfil the wishes of the donor,
 - 13.5. protect patient interests above those of the Trust, onCore UK or researchers,
14. These contracts also define the responsibilities of onCore UK to:
 - 14.1. protect patient interests above those of the NHS Trusts, onCore UK or researchers,
 - 14.2. safeguard patient identity and confidentiality in line with the Data Protection Act, the consent given by the donors and the approval given by the research ethics committee,
 - 14.3. safeguard the quality and research potential of the donated biosamples and information through the operation of systems that ensure security, minimise risks and use technologies that preserve the potential for the donors wishes to be fulfilled,
 - 14.4. act as an honest broker between the donors of biosamples and the research community,
 - 14.5. operate its business with observance to its duties under the Human Tissue Act 2004, the subsidiary regulations and in compliance with the relevant Codes of Practice issued by the Human Tissue Authority,
 - 14.6. operate its business with the approval of a Research Ethics Committee,
 - 14.7. supply donated biosamples and information to any researchers who have a demonstrable opportunity to make good use of these resources to fulfil the mission of onCore UK and the intentions of the donors,
 - 14.8. supply biosamples to researchers through a fair and equitable access system,
 - 14.9. govern the terms under which biosamples and information are supplied to researchers through legal contracts with researchers and the institutions in which they work.

V4 February 2008

15. Strives to make biosamples from cancer patients and supportive information available to bona fide researchers, wherever the research is conducted, as long as:
 - 15.1. the stated research objectives are in line with the mission of onCore UK,
 - 15.2. the proposed research is covered by the scope of the donor consent covering the uses of the biosamples,
 - 15.3. the specific research plans are covered by an approval by an appropriate Research Ethics Committee,
 - 15.4. the research presents no undue risks to the donors of the biosamples,
 - 15.5. the research is sufficiently funded and otherwise resourced,
 - 15.6. the necessary biosamples can be sourced and supplied,
 - 15.7. the research project is supported by the institution or organisation in which it will take place,
 - 15.8. the researcher's organisation enters into an agreement that governs the transfer and use of biosamples supplied
 - 15.9. and the specific project is deemed to be of high priority in situations where there is competition for access to limited tissue resources.

16. The contract between onCore UK and a researcher's organisation for provision of biosamples and services provides the framework for the transfer and use of human cancer biosamples and associated information. The contract:
 - 16.1. protects the interests of the donor,
 - 16.2. assigns limits to the uses to which the tissue may be put,
 - 16.3. confers responsibilities on the researchers to work within the legal and ethical frameworks covering the acquisition and use of the biosamples,
 - 16.4. assures researchers that onCore UK has complied with its legal and ethical obligations and is authorised to transfer the samples and information to the researchers,
 - 16.5. defines the obligations on the researchers to account for the use and disposal of all samples supplied to them by onCore UK,
 - 16.6. assigns to researchers and their organisations, with the consent of the donors, full rights to protect and pursue any intellectual property derived from their research using the samples, and to use this to further the development of new interventions for cancer medicine in line with the mission of onCore UK and the intentions of the donors,
 - 16.7. puts an obligation on 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,
 - 16.8. places a restriction on researchers to prevent the onward distribution of any samples or information obtained from onCore UK without prior authorisation of onCore UK.

17. Operates its overall business through a not-for-profit financial model and specifically does not buy or sell human biosamples.
 - 17.1. It does, however, reimburse reasonable expenses to NHS Trusts to cover the

costs of any activities involved in the provision of biosamples to onCore UK that are additional to the costs of standard patient care. It passes these costs on to researchers via a cost-recovery charging system.

- 17.2. It also provides services to the research community that are additional to, although related to, the provision of biosamples alone. Such services add utility to the samples and enhance the opportunity for researchers to make significant discoveries from studying the biosamples. onCore UK provides these additional services for additional fees. All profits generated in this way are reinvested in the organisation to maintain its ability to provide a quality service, to further enhance the services it offers and to generally further its mission. In this respect, onCore UK operates a not-for-profit financial model for such services.

BJ Clark
Chief Executive Officer

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V4 February 2008