EORTC
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The future of cancer therapy

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Human Biological Material collection and use

POL020

Version 3.0

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Table of Contents

1 PURPOSE

To define the collection or acquisition, processing, and storage of Human Biological Material (HBM) in EORTC clinical studies and research projects, as well as the conditions of use of the HBM.

The principles developed in this policy apply to all EORTC clinical studies and research projects, as well as intergroup studies for which EORTC is the coordinating group. However, the section 3.2 concerning the conditions of use are limited to those studies when EORTC is the coordinator of the chain of custody of the HBM.

This policy refers to the technical aspects of HBM collection or acquisition, processing, storage and use but excludes the ethical considerations, which are described in POL002.

Data sharing (including clinical and molecular data generated from HBM analyses) is described in POL008.

2 DEFINITIONS

- **Human Biological Material (HBM)**: Any type of human tissue, body fluid or derivative, including (but not limited to) nucleic acids.
- **HBM collection**: process developed in EORTC studies to acquire HBM from patients.
- **HBM acquisition**: process set-up to acquire already existing HBM collection.
- **Chain of custody**: The flow of HBM between the different parties involved in collecting, processing, storing and using HBM (e.g. the hospital/site, service providers, storage facilities and labs performing translational research (TR)).
- **Coordinator of the chain of custody**: An individual, company, institution, or organisation (i.e. Sponsor or its delegate) responsible for ensuring all parties participating in the chain of custody act in compliance with the study, applicable legislation and existing contractual agreements.
- **Sponsor**: an individual, company, institution or organization, which takes responsibility for the initiation, management of a clinical study and/or financing of a clinical study.

3 POLICY

All collections of HBM in EORTC studies and projects shall comply with all applicable ethical, legal, regulatory and quality assurance requirements.

EORTC shall process all HBM and associated personal data in compliance with its Data Protection Policy (POL021).

EORTC is committed to ensuring that the HBM generated from its studies be put to good use by the cancer research community and, whenever possible, are translated to deliver patient benefit.

It is therefore EORTC's policy to share HBM generated from its studies upon request from qualified scientific and medical researchers whilst safeguarding intellectual property, the protection of personal data, confidentiality, and the privacy of patients, in line with EORTC POL002.

3.1 Collection/acquisition, processing and storage

3.1.1 Sample collection

Best practices for sample collection and processing are detailed in "HBM guidelines for sites" defined and updated by EORTC HQ, in collaboration with expert pathologists, molecular biologists, etc. The library containing the best practice guidelines, to be implemented in all EORTC studies and shared with clinical sites and partners, is maintained by the EORTC HQ.

The processes are updated regularly based on scientific advancements and development of new analysis techniques.

HBM should be traceable to the patient it originates from and its actual location must be tracked all along the chain of custody.

Should the HBM be needed at any time for the purpose of confirmation of patient diagnosis or choice of treatment plan, pertinent HBM (if not yet used) will be returned to the institution.

3.1.2 Sample storage

All HBM collections should be stored in a certified/accredited storage facility (e.g. biobank), and evaluated by EORTC in relation to the following criteria:

- Capabilities such as sample collection kit producing, shipment organisation, conformity check, relabelling, aliquoting, sample destruction, storage and processing of HBM including emergency storage, fitting the needs of EORTC.
- Accreditation under the up-to-date ISO 9001 norm and/or ISO/IEC 17025; other accreditations are a plus (e.g. ISO 15189).
- Assigned administrator responsible for the facility and designated contact person to facilitate communications; up-to-date organizational chart detailing all roles and responsibilities and the persons in charge;
- A barcode labelling system and an inventory of HBM and status of the collection, including location of HBM or other relevant information such as collection and processing procedures (ideally a LIMS system). EORTC must be able to access the status of HBM at any time.
- Compliance with GxPs and any international, national or other applicable legislation.
- Data Protection Officer (DPO) and all the requirements set by the applicable legislation for the protection of personal data.

For all storage facilities, the quality management system of HBM shall cover all the following key processes: staff training, infrastructure, equipment maintenance and repair, safety and contingency plans, assessment of HBM quality, processing, storage management and distribution, document and record management, personal data protection measures and compliance with ethical and legal regulations. Some of these processes may be installed nationally to ensure compliance with local legislation.

EORTC storage facilities (procedures, infrastructures and resources) are subject to audit by EORTC.

3.1.3 Processing and analysis of samples

Processing of samples shall happen upon EORTC request, for projects approved by EORTC, either described in the scope of a clinical trial or approved research projects (see section 3.2).

Laboratories will be selected based on the scientific relevance and following a vendor assessment. To note, laboratories are not limited to service providers. Academic labs or clinical sites can also be selected to perform the analysis, when scientifically relevant (e.g., central pathology review).

The analysis plan will be developed prior to start of analysis. The lab will share their processing guidelines with EORTC HQ. If no guidelines are defined, HBM guidelines for laboratories defined and updated by EORTC HQ, in collaboration with expert pathologists and molecular biologists could be issued.

EORTC labs are subject to audit by EORTC.

3.2 Use of HBM

Use of HBM is limited to what has been defined contractually between EORTC and the laboratory/third party. Any further research on HBM material will need to be approved by EORTC HQ and an independent ethics committee.

All raw and analysed data generated from HBM, including but not limited to further use, will be shared with EORTC, and EORTC will be granted access for research use on those data.

3.2.1 In the scope of clinical studies

The description of the HBM collection (e.g. type, quantities, timepoints), the scope (optional, mandatory or future TR) and purpose of the collection shall be described in the protocol of the clinical study or a separate document. A scientific review will be performed by TRAC (as described in EORTC POL016 and EORTC POL014) and the required regulatory approvals (as applicable) will be obtained (POL002).

3.2.2 In the scope of further use of collected samples

TR projects developed when a/multiple study(ies) have reached their end will have to follow this process.

Instructions and a request form are available at http://www.eortc.org/investigators/data-sharing/. All questions concerning EORTC HBM and data sharing should be addressed to TR@eortc.org and DataSharing@eortc.org, respectively.

Review of the requests shall follow EORTC POL008.

Each request will be evaluated for its scientific merit and its feasibility.

Administrative review

- The data request form is complete
- The qualifications and experience of the research team to conduct the proposed proposal
- The researcher plans to publish the analysis results

HBM availability

- The HBM required for the planned analysis is available at the EORTC storage facility
- If clinical data are requested, POL008 and POL009 shall be followed.
- The research proposal does not compete with Sponsor/Funder's publication plan; for HBM acquired or collected in studies that have not reach their end, the study coordinator(s) or study steering committee shall approve the project. The relevant EORTC-disease group(s) will be informed if the project is approved.

Scientific review

- The ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives.
- This is done by an external independent committee and further described in POL014.

Regulatory and legal compliance

- EORTC will check the compliance with the EORTC POL021, POL016, existing contractual agreements, patient consent and applicable legal/regulatory requirements, such as but not limited to ethical and data privacy protection compliance such as EU General Data Protection Regulation.
- The Research Proposal is compatible with study informed consent and any regulatory or ethical constraints. The HBM may be shared whilst preserving Individual patient's rights to privacy and compliance with applicable legislation, including but not limited to EU General Data Protection Regulation.
- It is the responsibility of the requestor to ensure an appropriate ethical review of the project is performed.

A conflict of any of the parts results in a decline of the Research Proposal, or a request for re-work or further information from the researcher. If HBM access is declined, the rationale will be provided to the researcher. If all checks pass, then the HBM sharing will proceed.

The EORTC will notify the data applicant of the final decision by e-mail within two (2) months of the application.

Once approved, a contract describing the obligations between parties will be set-up and the shipment of the HBM will be organized. The EORTC costs for review of the request, as well as the shipment of HBM should be covered by the requestor, prior to shipment of material. Additional costs might apply and will be defined in the contract.

3.3 Publications, and IP

If the publication is co-authored by an EORTC Headquarters staff or is published "on behalf of EORTC" or as "EORTC Research", it must be processed in compliance with EORTC Publication policy (POL009).

Otherwise, the EORTC must be acknowledged for sharing the data for the research, in compliance with EORTC Datasharing policy (POL008). The publication must also contain the following disclaimer *"The contents of this publication and methods used are solely the responsibility of the authors and do not necessarily represent the official views of the EORTC"*.

Additionally, the applicant must provide the references (at least DOI) of any publication resulting from research to the EORTC within two (2) months of the publication through an email addressed to DataSharing@eortc.be.

IP terms will be set on a project-specific basis in the contractual agreements, prior to sharing of the HBM.

4 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Protection of human subjects participating in medical research	EORTC POL002
Release of data from EORTC studies for use in External Research Projects	EORTC POL008
Publication Policy	EORTC POL009
Translational Research Advisory Committee (TRAC)	EORTC POL014
Protocol Development Process, Selection and Approval Procedures for EORTC Studies	EORTC POL016
Protection of Personal Data	EORTC POL021

5 REFERENCES

- Declaration of Helsinki - Medical Research Involving Human Subjects (2013)
- Declaration of Tapei - Research on Health Databases, Big Data and Biobanks (2016)
- Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine, Oviedo, 4.IV.1997.
- Recommendation Rec (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin – (CoE Rec (2006)4).
- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 25.I.2005.
- OECD Guidelines on Human Biobanks and Genetic Research Databases (2009).
- EU Clinical Trials Directive 2001/20/EC.

6 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.00	Initial version	Jacqueline Hall and the EORTC PathoBiology Group	31 Jan 2011
2.00	Custodianship remains with institution. Custodianship differentiates from geographical storage. EORTC is responsible to	Jacqueline Hall and the EORTC PathoBiology Group	29 Mar 2012

	ensure the integrity of the chain of custody. Definition of Biological material includes 3 types: additional material (collected for research purposes), pre-existing material of diagnostic value and pre-existing material not of diagnostic value.		
2.1	EORTC storage facilities updated to validated storage facilities. Assessment process of validated storage facilities update. Administrative changes.	Emilie Varin	05 Jun 2015
2.1	No change	Marie Morfouace	22 May 2018
3.0	Adaptation of assessment process for storage facilities Adaptations of process of request of HBM to match EORTC internal process Limitations of HBM control by study coordinator(s)	Marie Morfouace	29 Mar 2021