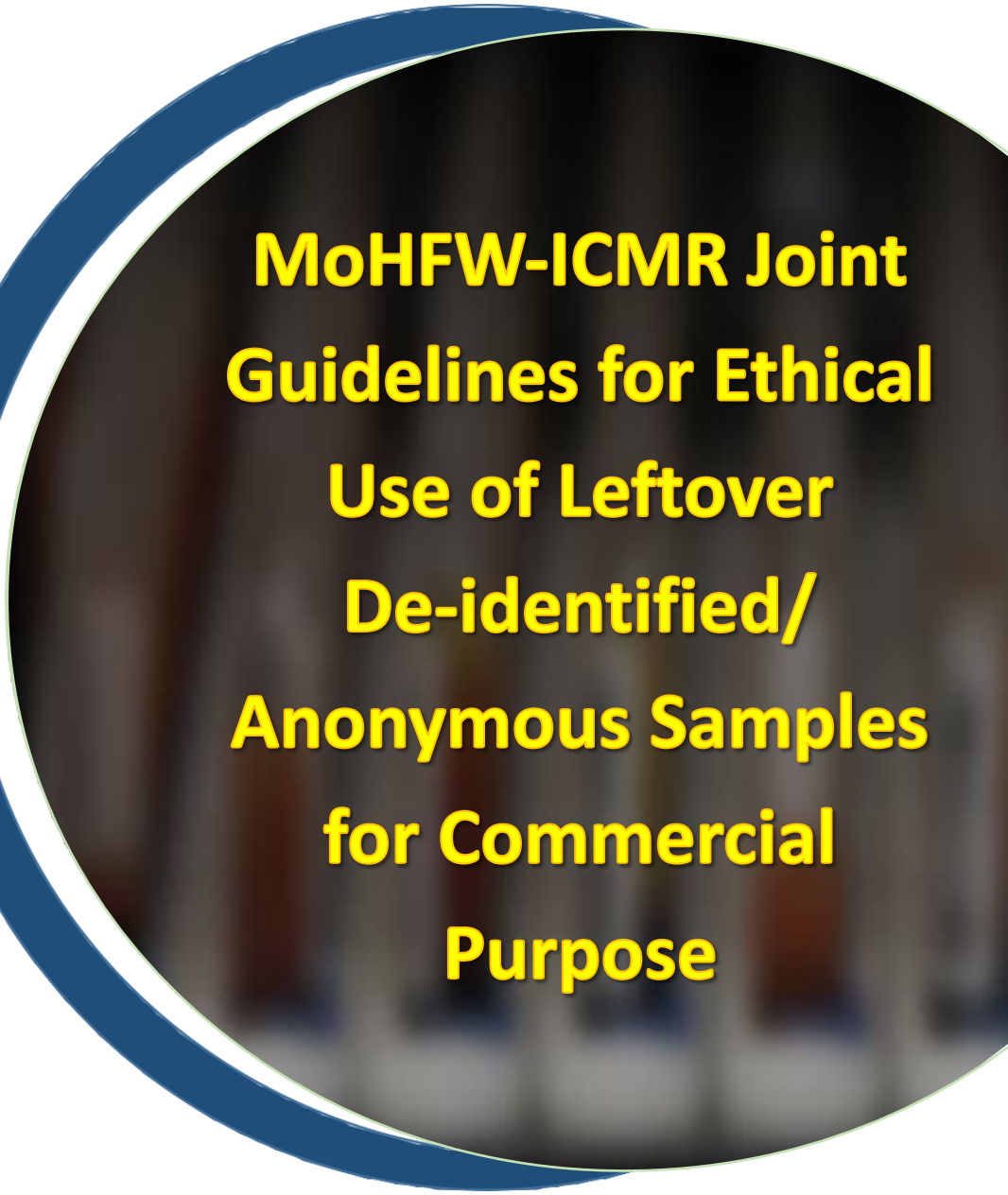
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
MINISTRY OF HEALTH & FAMILY WELFARE
स्वास्थ्य एवं परिवार कल्याण विभाग
DEPARTMENT OF HEALTH & FAMILY WELFARE

सत्यमेव जयते

Ministry of Health & Family Welfare



MoHFW-ICMR Joint Guidelines for Ethical Use of Leftover De-identified/ Anonymous Samples for Commercial Purpose

October, 2024

Indian Council of Medical Research

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Ministry of Health and Family Welfare

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Table of Contents

1. BACKGROUND

Human Biological Samples

These are samples or specimens that are any material generated from a diagnostic, therapeutic, or surgical procedure on patients. These include organs, parts of organs, cells, tissues, sub-cellular structures, cell products such as blood, blood products (even positive for eHBsAG/HCV/ HIV/Syphilis and expired blood), urine, saliva, DNA/RNA, hair, Nail clippings, or any other cells, body fluids (Ascitic fluids, pleural fluids, cord blood, etc). The source for these specimens may be patients, autopsy specimens, abandoned wastes, tissue banks, IVF clinics, organ donation centers etc.

Leftover Samples

After these samples have undergone the required clinical and laboratory testing for the patient, there are large quantities of leftover samples that may remain available in hospitals. These samples may be referred to as a biomedical waste, sometimes may be a biohazard, and require appropriate methods for disposal. The hospital itself may have no added value for these samples, nor the capacity to store these samples after the provision of patient care. Such samples are usually discarded as hospital waste.

De-identified Samples*

These leftover samples if de-identified/ anonymous can serve as a precious resource for R&D activities to develop diagnostics, advance innovations, or for the development of kits, identify specific disease markers, or determine relevant health parameters and other such purposes and may have huge value.

Commercial Use

There has been keen interest from commercial companies in procuring and using these leftover de-identified samples for the development of commercial kits/ products or technologies that have the potential to improve future patient outcomes, provide diagnostic accuracy, or offer therapeutic advancements ultimately benefitting society.

* In this document, de-identified samples refer to samples with no identifying information or link to patient identity, and cannot be re-linked.

2. SCOPE

2.1 The present guidance ONLY addresses the Ethical Use of leftover, irreversibly de-identified samples, or pooled samples, that are non-identifiable and collected for clinical care (non-research) for development of future product/ technology and or commercial purposes.

2.2 This guideline is NOT applicable for use of leftover 'research' samples, since their secondary use must be aligned with the original informed consent given by the research participant.

3. ETHICAL CONSIDERATIONS FOR LEFTOVER SAMPLES IN COMMERCIAL USE

3.1 Guiding principles

3.1.1 The hospitals must ensure that the samples are completely anonymous/ de-identified irreversibly/ non-identifiable material/ leftover biological samples/ not specifically intended for research purposes/ are going to be discarded after clinical diagnostics/ care.

3.1.2 These could be pooled samples/ or samples without any traceable link/ or without any identifiers that could potentially lead back to the patient. Robust data security measures must be in place to protect any residual information associated with the samples.

3.1.3 Companies should maintain transparent and open communication with the relevant institutions/ hospitals

3.1.4 Commercial kits and technologies that are prepared should be affordable, ensuring broader accessibility for patients and healthcare providers in the country.

3.2 Rights of Donors/ Autonomy/ Informed Consent

3.2.1 Patients own the biological samples and data collected and the Institutions are the custodians acting on their behalf and as per ICMR National Ethical Guidelines, 2017, Informed consent is required from the patients for any secondary use of samples for 'research'.

3.2.2 However, if the clinical samples are anonymous / de-identified irreversibly/ left over after clinical care, they lose identity and there is no way for the institutions to go back to patients to obtain informed consent for any secondary use.

3.2.3 Therefore, for the use of de-identified/ anonymous left over samples, use may be permitted with a 'waiver of informed consent'.

3.2.4 There would be no loss to patient's rights or autonomy in such case as the left-over samples are de-identified and cannot be traced to the patient.

3.2.5 The leftover sample for commercial use could be permitted for the following types of samples:

a) Anonymous; have no clinical/ personal information/ unlabelled/ pooled and there is no way to link with the source.

b) Anonymised; De-identified irreversibly and all clinical/ personal/ identifying information has been removed and anonymised and therefore there is no way to re-link with the source.

3.3 Limitations:

3.3.1 It may be noted that de-identified samples that contain clinical information, could still become identifiable and therefore could lead to a breach in the confidentiality of the patient.

3.3.2 If the samples are Identified/ coded/ can be reversible to identify the patient, and samples are not leftover, samples contain clinical/ personal information or they are research samples this guideline will not be applicable.

3.4 Role of Hospitals in Commercial use:

3.4.1 De-identified and Leftover samples going to be discarded by the hospital can be provided by hospital to commercial companies for future commercial activity.

3.4.2 Robust data protection and security measures should be in place to safeguard against de-identification.

3.4.3 The hospital must sign appropriate MoUs/ MTAs with the commercial company stating the plan, types of samples, defined duration and proposed outcomes. The quantity, duration for which the samples will be stored and any limitations on their use should be specified.

3.4.4 The hospital may decide to seek regular progress reports from the company to ensure compliance with the signed agreements regarding the use of provided leftover samples.

3.4.5 If any institution has a stake in the clinical samples or plays a role in kit or technology development, adequate provisions be specified in the agreements and shared between the hospital and the company.

3.5 Role of Ethics Committee in Commercial use:

3.5.1 The ethics committee may determine if the proposed leftover samples were collected for clinical care (and NOT research) and the samples will be discarded by the hospital.

3.5.2 Assess that the benefits of using leftover samples would outweigh the risks and privacy concerns and would serve the public interest.

3.5.3 Most R&D activities of Commercial companies may not be clearly defined in advance and individual research proposals may not be available for ethics review. However, the company may provide an overview of the purpose, the plan, and expected outcomes and seek a one-time approval from the hospital/ institutional ethics committee.

3.5.4 An expedited ethics review can be conducted in view of no potential risk to research participants and a waiver of consent granted for anonymous/de-identified samples.

3.5.5 The ethics committee may review the plan along with the MoU/ MoA/ MTA and can provide a 'one-time' review and approval to allow the use of leftover de-identified biological samples for potential commercial use over a defined period of time.

3.5.6 ECs may want to review the detailed plan to ensure that the samples are de-identified irreversibly at the hospital and cannot be tracked back to the patient.

3.6 Role of Commercial Company

3.6.1 Companies must adhere to local, national, and international regulations governing the collection, storage, and secondary use of biological samples. This includes obtaining necessary approvals, such as ethical clearance, as well as establishing formal agreements such as MoUs/ MoA and MTAs.

3.6.2 The companies should contribute to scientific knowledge and medical advancements useful for mankind. The companies must engage in good ethical practices, regular audits, and handling procedures to maintain regulatory compliance.

3.6.3 The company must provide information on the intended use of the samples, declare the nature of product development, and display transparent policies that indicate the source, handling, purpose, financial interests, and robust scientific methods, safety, and destruction of samples when they complete the intended purpose.

3.6.4 The companies must make the products/ kits/ others be easily accessible to the people in the country at affordable costs.

3.7 MoA/MoU/ MTA

The agreement shall accordingly include following details:

3.7.1 Purpose and Scope:

a) Define the profile of each party involved in ref to proposed commercial activity
b) Role of each collaborator (Technical, financial or other)
c) Details of any ongoing R&D activity

3.7.2 Roles and Responsibilities of Parties

a) Left over samples (Type, duration, quantity, purpose, method, frequency of collection, place for final processing, procedures to be followed for processing, expected output).
b) Ensure samples are anonymous, describing de-identification process/ anonymisation/ irreversibility to linking back to individual and privacy and security of samples.
c) Overview of procedures/ methods to be followed/ spectrum of proposed products.
d) Details of various possible outputs from the collected specimens/ samples (including those which can be possible, but not aimed currently by the party).
e) The spectrum of Therapeutic use of 'output' from these specimens/ samples, to be listed in detail, and out of all, what the party is aiming for.
f) Transparency and statement on Financial benefits/ sharing between hospital/ company/ copyright agreements/ patents/ others as applicable.
g) Ensuring access to products developed and making them affordable at low cost to the public.

3.7.3 Points of contact of each party responsible for the execution of MOA:

a) Name of Contact person
b) Designation
c) Contact details for regular correspondence

3.7.4 Regulation:

a) Duration of Contract

a) Termination of Agreement
b) Date of expiration after it has been signed
c) Financial details pertaining to each party
d) Future commercial exploitation to be addressed through appropriate acts/ law and licensing authority like State Blood Transfusion Councils, DCGI, CPCB, IMA, Clinical Establishment act, etc

3.7.5 Dispute:

In case of deviation/ violation of regulations/ disputes between parties, govt regulatory agencies take action, through appellate bodies like High Court of State/ Supreme court.

(Provision of punishment/ fine to be kept in case of violation of regulation, loss of confidentiality of data/ information, commercial exploitation, safety norms).

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