



Application for Waiver of Consent & Undertaking for Accessing Retrospective Data/Stored Human Samples

IEC Ref. No.:

Title of Study:

Principal Investigator (Name, Designation, and Affiliation):

Request for Waiver of Consent

The Principal Investigator seeks an exemption from obtaining informed consent for accessing retrospective data or stored human samples for the following reasons:

1. Justification for Waiver of Consent:

- The data to be accessed has been irreversibly anonymized, ensuring that no identifiable patient information will be disclosed.
- The research involves the use of retrospective data or previously collected human biological samples, where obtaining consent is not feasible without compromising the validity of the study.
- The study is low-risk, and the waiver of consent would not adversely affect the rights or welfare of the individuals whose data/samples are being accessed.
- The research contributes significantly to scientific knowledge or patient care, justifying the waiver request.

2. Category of Research for Exemption from Review (if applicable): [Select appropriate category as per National Ethical Guidelines for Biomedical & Health Research Involving Human Participants]

- Research on data in the public domain/systematic reviews or meta-analyses
- Observation of public behaviour/information recorded without linked identifiers
- Public health programs by government agencies
- Other: [Provide detailed justification]

Signature of PI: _____

Date: _____



Undertaking for Use of Retrospective Data/Stored Human Samples

I, the undersigned, _____ as the Principal Investigator, hereby undertake the following with regard to the use of retrospective data or stored human samples for research within the Department of [Insert Department] at AIIMS Raipur:

1. Ethical Compliance:

I affirm that all data/samples accessed will be used strictly in adherence to the ethical standards prescribed by institutional guidelines and applicable laws.

2. Anonymity and Confidentiality:

I ensure that all patient data or sample information will be irreversibly anonymized, and no identifiable information will be disclosed to any third party.

3. Consent and Authorization:

I confirm that all necessary permissions and authorizations have been obtained for the storage and use of the retrospective data/samples.

4. Data Security and Access Control:

I commit to implementing robust security measures to protect the stored data/samples and associated records. Access will be regulated and provided only to authorized personnel for legitimate research purposes.

5. Compliance with Regulations:

I pledge to stay informed and comply with any changes in regulations regarding the ethical use of human biological samples or retrospective data.

6. Reporting and Accountability:

I undertake to immediately report any non-compliance or ethical concerns related to the use of these data/samples to the Institutional Ethics Committee.

7. Responsibility:

I accept full responsibility for the management, ethical use, and security of the data/samples accessed under this undertaking.

Signature of PI: _____

Date: _____