Government of Pakistan
Health Research Institute-NIH
National Bioethics Committee

REGULATORY FRAMEWORK FOR VIOLATIONS OF NBC-HRI DATA SHARING APPROVAL REQUIREMENTS

Prepared By

Ms. Tayyaba Rahat

Dr. Faiz Bashir (HRI NIH)

Dr. Nighat Murad (HRI NIH)

Reviewed by

National Bioethics Committee Members

Approved by

TAC HRI NIH

1. Preamble

This Regulatory Framework is issued under the powers conferred by the Health Research Institute – NIH Act, 2021. It is aligned with the Personal Data Protection Bill 2023, the Prevention of Electronic Crimes Act (PECA) 2016, and international ethical standards for data governance.

The National Bioethics Committee (NBC-HRI) is the sole statutory body mandated to oversee the ethical governance of health research in Pakistan.
As stated in the Guidelines: *"No health-related research, data collection, or sharing—whether conducted within Pakistan or across international borders—may be undertaken without the explicit approval of the National Bioethics Committee (NBC-HRI)."*
Consequently, health research data is a critical national resource. Initiating any health research data-sharing activities without the explicit approval of the NBC-HRI is a violation of national regulations.

2. Purpose: The purpose of this framework is to:

i. Define prohibited acts regarding the unauthorized sharing of health research data.
ii. Establish a tiered penalty structure for violations.
iii. Ensure the protection of participant privacy and national data sovereignty.
iv. Deter malpractice and enforce compliance among Principal Investigators (PIs), institutions, and collaborating partners regarding health research data sharing process.

3. Scope: This framework applies to all:

- Public and private research institutions in Pakistan.
- Principal Investigators (PIs) and research staff.
- International collaborators receiving data generated in Pakistan.
- Sponsors and funding agencies involved in health related research.

4. Definition of Violations (Offenses):

A violation occurs when an individual or entity fails to adhere to the *Health Research Data Sharing Guidelines*. Specific offenses include:

- Unauthorized Data Sharing: Transferring, publishing, or sharing health data (including IPD, HBM data, or genomic data) without obtaining prior written approval from the NBC-HRI.
- Non-Compliant Cross-Border Transfer: Sending data outside of Pakistan without NBC-HRI clearance or without verifying the recipient country's compliance standards (e.g., GDPR, HIPAA).
- Breach of Consent: Sharing data for purposes outside the scope of the Informed Consent obtained from participants.
- Failure to Anonymize: Sharing identifiable data without applying the required anonymization or de-identification standards (Safe Harbor or Pseudonymization).
- Missing Data Use Agreements (DUA): Sharing sensitive data without a legally binding Data Sharing Agreement (Annex-I) or Metadata Statement (Annex-II).
- Concealment of Data Breaches: Failing to report a data breach to the NBC-HRI and relevant authorities within the mandated timeframe.

5. Classification of Offenses and Penalties:

Violations are classified based on the severity of the risk to participant privacy and national security.

Category A: Minor Violations (Administrative Non-Compliance):

- *Description:* Procedural lapses, such as minor delays in submitting documentation (DMSP) or inadvertent sharing of non-sensitive metadata without NBC approval, provided no harm occurred.
- Penalties:
- Written Warning: Notice to Show Cause (NTC) issued to the PI:
- Remediation: Mandatory submission of corrected documentation within 14 working days.
- Monitoring: Increased scrutiny of future projects by the Institutional Review Board (IRB):

Category B: Major Violations (Ethical Breaches):

- *Description:* Sharing identifiable data without consent, failing to anonymize data before sharing, or sharing data internationally without NBC approval, where no malicious intent is proven but negligence is evident.
- Penalties:
- Suspension of Research: Immediate suspension of the ongoing research project and data freezing.
- Institutional Fine: Financial penalty imposed on the research organization (up to PKR 1,000,000 or as defined by the Personal Data Protection Bill).
- Mandatory Retraining: All research staff must undergo NBC-HRI certified ethics training.
- Retraction: Order to retract published papers resulting from the illicitly shared data.

Category C: Severe Violations (Criminal Offenses):

- *Description:* Willful violation of data sharing laws, selling data without authorization, sharing genomic data for unauthorized commercial gain, or causing significant harm to participants/national security due to negligence.
- Penalties: Criminal Prosecution:

  i. Reference to the Federal Investigation Agency (FIA) Cyber Crime Wing for prosecution under PECA 2016 (Section 16 - Offenses against dignity of a person; Section 3 - Unauthorized access).

  ii. Blacklisting: Permanent blacklisting of the PI and/or institution from receiving government grants, NBC-HRI approvals, or participating in national health programs.

  iii. License Revocation: Recommendation to cancel the license or registration of the offending research body.

  iv. Imprisonment: As per the Personal Data Protection Bill 2023, penalties may include imprisonment for up to 3 years and/or substantial fines.

6. Enforcement and Adjudication:

- Detection: Violations may be detected through NBC-HRI audits, IRB reporting, whistle-blower complaints, or public data breach reports.
- Investigation: The NBC-HRI shall constitute an *Inquiry Committee* to investigate allegations. The Committee has the power to summon records, interview personnel, and inspect data banks.

Due Process: The accused party shall be given an opportunity to respond to the allegations (Show Cause Notice) before penalties are imposed.

Additional Guidelines for Enforcement and Adjudication

a) Policy on "Zero Tolerance" for Unapproved Data Sharing.

The NBC-HRI operates under a strict interpretation of national law. When reviewing cases of unauthorized data sharing, the Committee must apply the following principles regarding exemptions and defenses.

i. No Retroactive Justification: The Committee does not accept "Public Interest" as a valid defense if it was raised *after* the data was shared. A claim of public benefit is only valid if the researcher applied for a Consent Waiver (Ex-Ante) *before* the data transfer occurred. Retrospective claims are automatically invalid.
ii. Primacy of National Law: External policies from foreign sponsors or universities are null and void if they conflict with Pakistani law. The NBC-HRI must reject any defense claiming that a "Funder Agreement" or "University Policy" compelled the researcher to bypass national protocols.
iii. Burden of Compliance: The responsibility lies solely with the Pakistani entity to ensure NBC-HRI approval is secured *before* any transfer takes place. Ignorance of this requirement is not admissible as a defense.

b) FOR RESEARCHERS AND ORGANIZATION:
(What You Need to Know to Protect Yourself)

Important Warning: "I Didn't Know" is Not an Excuse

As a researcher or institution in Pakistan, you are required by law to get NBC-HRI approval before sharing any health data. Please read these three rules carefully to avoid penalties:

i. The "Public Interest" Rule:
   - If you believe sharing data is an emergency or urgently needed for public health, you must apply for a special "Consent Waiver" *before* you share the data.
   - Do not share the data first and ask for forgiveness later. If you share data without approval, saying it was "for the public good" will not protect you from penalties.
ii. The "Foreign Sponsor" Rule:
   - Your international sponsors or partner universities might have their own rules about sharing data. However, their rules do not overwrite Pakistani laws.
iii. No Exceptions:
   - There are no "emergency" exemptions for the approval process itself. You always need approval *before* you act. Failing to get approval is a violation, regardless of your good intentions or external contracts.

c) Liability of Stakeholders
   - Principal Investigator (PI): Bears primary responsibility for ensuring compliance. Claims of "ignorance of guidelines" are not admissible as a defense.
   - Institutional Head: The head of the institution is vicariously liable for creating an environment that facilitates data sharing without proper oversight.
   - International Collaborators: Collaborators receiving data without the required NBC-HRI approval will be reported to their respective national ethics bodies and relevant authorities in their jurisdiction.

7. Reporting Violation:

- Mandatory Reporting: IRBs are legally mandated to report any suspected Category B or C violations to the NBC-HRI within 72 hours.
- Whistleblower Protection: Individuals reporting violations in good faith shall be protected against retaliation under the NBC-HRI protection policy.

8. Reinstatement:

Institutions or PIs blacklisted under Category C offenses may apply for reinstatement after a minimum period of 3 years, subject to:

- Completion of all legal penalties.
- Evidence of structural reform in data governance.
- Successful audit by the NBC-HRI.

Metadata Statement Template for Health Research Data Sharing Approval

1. Study Information

- **Study ID**: (Unique identifier for the research project, protocol version number , assigned by the Institution)
- **Detail Principal Investigator (PI)**
- **Detail all Co-Investigator's (Co-PI)**:
- **Study Title**: Full title of the research study.
- **Structured abstract** including background, Objective, setting(Name of the institution or organization conducting the research),Study Design, brief methodology, expected outcomes, recommendation and policy message(not more than 300 word):
- **Funding Source**: The entity funding the study (e.g., government grant, private organization).
- **Study Duration**: Start and end dates of the study.
- **Institutional IRB Approval Number**: Unique approval number assigned by the IRB/NBC).
- **Approval Date**: Date when IRB/NBC approval was granted.

Review and Approval History

- **Previous Approvals**: Details of previous IRB or Bioethics Committee approvals if applicable.
- **Amendments to Approval**: Any amendments made to the original approval (e.g., changes to data collection, new consent requirements).
- **Review and Approval History**: A timeline of the approval process (e.g., initial review, amendments, final approval).

3. Data Details

- **Data Type**: Specific type of data to be shared (e.g., clinical, genomic, biological samples, imaging).
- **Data Format**: Format in which data will be shared (e.g., CSV, JSON, DICOM, FHIR).
- **Data Collection Method**: Description of how the data was or will be collected (e.g., surveys, clinical trial results, lab tests , mixed).
- **Data Anonymization**: Whether the data is anonymized, pseudonymized, or identifiable.
- **Data Security Measures**: Specific measures for ensuring data security (e.g., encryption, access controls).
- **Data Retention Period**: Duration for which data will be retained before deletion.
- **Data Sharing Duration**: How long the data will be available for sharing (e.g., one year, 5 Years,indefinite).

4. Consent Information

- **Consent Method**: Type of consent obtained from participants (e.g., written, electronic), available or not.
  .

5. Data Sharing Protocol

- **Data Sharing Purpose**: The intended purposes for sharing the data (e.g., academic research, public health studies, others).
- **Sharing Parties**: List of individuals, institutions, or organizations national and international that will have access to the data.
- **Sharing Conditions**: Conditions under which the data will be shared (e.g., academic use,public health initiatives, commercial, non commercial use).
- **Sharing Mechanisms**: Mechanisms or platforms for data sharing (e.g., secure server, cloud storage, direct transfer).
- **Data Use Agreement**: a formal agreement will be signed outlining the terms of data usage and limitations.
- **Privacy and Confidentiality**: Steps taken to ensure privacy and confidentiality of participant data.
- **Data Protection Measures**: Specific measures taken to protect sensitive data (e.g., encryption, anonymization, access control).

7. Contact Information

- **Primary Contact**: Name and contact details of the person managing the data sharing process.

Annexure –II: HEALTH RESEARCH DATA SHARING AGREEMENT

This **Health Research Data sharing Agreement (DSA)** (the "Agreement") is made and entered into by and between:
[Name of Institution/Researcher]
Address
City, Pakistan
(Hereinafter referred to as "Data Provider")
AND
[Name of Recipient Institution/Researcher]
Address
City, Pakistan
(Hereinafter referred to as "Data Recipient")
WHEREAS, the Data Provider is custodian of certain health research data("Data") collected in Pakistan.
AND WHEREAS, the Data Recipient wishes to receive such data to conduct advance analysis or otherwise.
NOW, THEREFORE, in consideration of the mutual understanding both parties wishes to ensure that Data is shared and used in compliance with applicable ethical regulations and standards.

Definitions are same as

Purpose of Data sharing

The purpose of this Agreement is to facilitate the transfer of health research data from the Data Provider to the Data Recipient to enable the Recipient to conduct health-related research under the ethical oversight of the Institutional Review Board (IRB)/National Bioethics Committee of Pakistan. The data will be used solely for the following research purposes:

- [Describe …….]

Description of Data

The health research data being shared includes:

- [Detail the type(s) of data: clinical, demographic, biological samples, genomic data, etc.]
- [Specify whether the data is anonymized or identifiable]
- **Data format**:[e.g., CSV, JSON, DICOM, etc.].
- **Data Source**: The data has been collected from [insert details about the study or research project from which the data originates].

Provision

Both parties agree to adhere to the following:

- The Data Provider confirms that the data has been collected in compliance with ethical guidelines, including the approval of their Institutional Review Board (IRB)/ /NBC.
- The Data Provider confirms that appropriate informed consent has been obtained from the individuals whose data is being shared, or that the data has been anonymized to ensure that participants' privacy is protected.
- Both parties commit to ensuring that the transfer and use of the data comply with national data sharing guidelines of NBC –HRI and data protection laws .

- The Data Recipient agrees to keep all data received confidential and not to disclose or share it with any third parties without prior written consent from the Data Provider and study subjects.
- The Data Recipient agrees to implement adequate security measures to protect the data from unauthorized access, loss or misuse. This includes data encryption, access control, and regular security audits.
- The Data Recipient agrees to retain the data only for the duration necessary for the research project and to securely dispose of the data once it is no longer required under intimation to all regulatory bodies and primary provider.
- Data recipient use data only for the specific research purposes outlined in this Agreement. Any deviation from this purpose, including use of the data for commercial purposes or any unapproved secondary use, is prohibited.
- The Data Recipient agrees to acknowledge the Data Provider in any publications or presentations arising from the research using the shared data.
- The Data Recipient agrees to provide updates to the Data Provider and relevant bodies IRB/NBC on the progress of the research and any significant findings arising from the data.
- The Data Recipient will also inform the Data Provider of any changes in the research that could affect the use or security of the data.
- Any breach of this Agreement, including unauthorized use or transfer of data, may result in the immediate termination of the Agreement and will subject to the legal and ethical action.
- This Agreement may be terminated by either party with written notice. Upon termination, the Data Recipient must return or securely destroy all data provided by the Data Provider.
- Any disputes arising from this Agreement will be resolved through mutual consenses
- The undersigned hereby agree to the terms outlined in this Health Research Data sharing Agreement:

For the Data Provider:

Name: _____
Position: _____
Institution: _____
Signature: _____
Date: _____

For the Data Recipient:

Name: _____
Position: _____
Institution: _____
Signature: _____
Date: _____