

Guidance on Avoiding the Transmission of Protected Health Information (PHI) and Private Identifiable Information (PII) to the Human Research Protection Office or Institutional Review Board (IRB) at Virginia Commonwealth University's Human Research Protection Office.

Purpose:

This guidance document aims to provide a clear set of instructions to the research community (i.e., principal investigator, research coordinators, and other research personnel) involved in conducting human subject research on emphasizing the need to securely handle the PHI and PII of human subjects when submitting documents to the Human Research Protections Program via e-IRB system, email, fax or mail.

Guidance:

The Virginia Commonwealth University's (VCU) Human Research Protections Program (HRPP) provides leadership and administrative support to the Institutional Review Board (IRB) and Institutional Official in the protection of the rights, welfare, and well-being of human subjects involved in research conducted at VCU.

The VCU's HRPP and the IRB are vital in overseeing research activities involving human subjects to ensure ethical and legal compliance. Thus, it is crucial to protect the sensitive health information and private identifiable information of human subjects when conducting research involving human subjects. It is imperative to avoid intentionally or inadvertently transmitting Protected Health Information (PHI) or Private Identifiable Information (PII) to these bodies, as it may pose significant risks to individuals' privacy and lead to regulatory non-compliance.

IRB's Role and Purpose:

The IRB's primary responsibility is to review and approve research protocols to protect human subjects. They do not need access to PHI or PII to fulfill this role. Instead, they assess the study's ethical considerations, informed consent process, and data protection measures without requiring access to individual-specific data.

Data De-identification Requirement:

IRBs generally expect researchers to submit de-identified data for review. De-identification removes or obscures direct and indirect identifiers, minimizing the risk of individuals being identified from the data. Transmitting de-identified data aligns with best practices in research ethics.

Investigators should not send Protected Health Information (PHI) or Private Identifiable Information (PII) to the HRPP office and IRB for several critical reasons:

Privacy and Confidentiality:

PHI and PII contain sensitive information about individuals' health and identity. Sending such information to the IRB office could compromise the privacy and confidentiality of research participants, leading to potential harm or unauthorized access to personal data.

HIPAA Compliance:

The Health Insurance Portability and Accountability Act (HIPAA) establishes strict rules and regulations for protecting PHI in healthcare and research settings. Transmitting PHI to the IRB office without proper authorization or safeguards may result in HIPAA violations and legal consequences for the institution and its representatives.

Ethical Considerations:

Respecting the ethical principles of research is fundamental to safeguarding the rights and well-being of study participants. Transmitting PHI or PII to the HRPP office and IRB could breach the trust between researchers and participants, potentially leading to a reluctance to participate in future research.

Data Security Risks:

Transmitting sensitive information through email or other insecure channels poses security risks. Unencrypted communication or unsecured file transfers could lead to data breaches, exposing individuals' sensitive information to unauthorized parties.

Legal Compliance:

Apart from HIPAA, many countries and regions have data protection laws governing personal information handling. Sending PHI or PII to the IRB office without a legitimate purpose and proper consent could lead to non-compliance with these laws.

Institutional Policies:

Most research institutions have policies regarding the handling and transmission of PHI and PII. Violating these policies may lead to disciplinary actions and reputational damage for the investigator and the institution.

The core reasons for not sending PHI or PII to the IRB office are to protect the privacy and confidentiality of research participants, ensure compliance with relevant regulations and laws, and uphold the highest ethical standards in research conduct. Instead, investigators should focus on providing de-identified data and pertinent documentation necessary for the IRB's ethical review process.

For more information regarding HIPAA, please see [“What is Covered by HIPAA at VCU?”](#) guidance on VCU's HRPP website.

Definitions:

1. *De-Identified Data*: Refers to information that has been processed or modified to remove or obscure specific identifiers, making it no longer possible to link the data directly to an individual or to re-identify the individuals to whom the data originally pertained. De-identification is a privacy protection technique used to safeguard sensitive information while allowing the data to be used for various research, statistical analysis, or public health purposes without compromising individuals' privacy.
2. *Protected Health Information*: also referred to as personal health information, is the demographic information, medical histories, test and laboratory results, mental health conditions, insurance information, and other data that a healthcare professional collects to identify an individual.
3. *Private Identifiable Information*: any information that permits an individual's identity to be directly or indirectly inferred, including any other information linked or linkable to that individual.
4. *Principal Investigator*: individual responsible for preparing, conducting, and administering a research protocol.
5. *Human Subject*: a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information