**Human Subject Protection Program**
**Investigator Guidance**
**June 4, 2020**

# PRIVACY AND CONFIDENTIALITY IN RESEARCH

## Overview

- This guidance is intended to aid investigators to ensure that adequate provisions exist for the protection of research participant privacy and the maintenance of confidentiality of identifiable research data.

## Protecting Participant Privacy

**Privacy is about people.**

- Privacy is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

- Privacy is:
  - ☐ A sense of being in control of access that others have to ourselves;
  - ☐ A right to be protected; and
  - ☐ Is in the eye of the participant, not the researcher or the IRB.

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| **Subject Population** | **Considerations:**<br>➢ What are the cultural norms of the proposed subject population?<br>➢ Some cultures are more private than others.<br>➢ What are the ages of the proposed subject population? There may be age differences in privacy preferences (e.g., teenagers less forthcoming than older adults) |
| **Recruitment Methods** | **Considerations:**<br>➢ How are potential participants identified and contacted?<br>☐ **Acceptable methods:** |

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| | ✓ Brochures, flyers, newspaper/magazine/newsletter advertisements, telephone, email, websites, and/or social media platforms<br>✓ Sending an introduction letter to colleagues to distribute to eligible individuals – interested individuals contact investigator.<br>✓ Primary care staff contacting their patients that qualify to determine interest.<br>☐ **Unacceptable methods:**<br>✓ Searching through medical records to identify eligible patients to contact for participation, but the investigators are not involved in the care of the patients (aka "cold-calling"). |
| **Sensitivity of the Information Being Collected** | **Consider:**<br>➢ Studies that involve the collection of sensitive (e.g., pregnancy, sexuality, sexual activity/behavior, HIV status) or illegal (e.g., drug and/or alcohol use) information involves a greater need for participant privacy. |
| **Method of Data Collection (Focus Group, Individual Interview, Covert Observation)** | **Considerations:**<br>➢ Will participants feel comfortable providing the information in this manner?<br>➢ If passively observing the participant; could the individuals have an expectation of privacy (e.g., online threads, forums, chat rooms, or comment sections about living with HIV)? |

## Maintaining Confidentiality

**Confidentiality is about data.**

- Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

- Confidentiality is:
  - ☐ About identifiable data;
  - ☐ An extension of privacy; and
  - ☐ An agreement about data storage and who has access to identifiable data.

☐ Confidentiality protects patients from inappropriate disclosures of "Protected Health Information" (PHI).

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| **Research Design** | **Considerations:**<br>➢ Protocols should be designed to minimize the need to collect and maintain identifiable information about research participants.<br>➢ When feasible, data should be collected anonymously, or the identifiers should be removed or stored separately from the data and destroyed as soon as possible.<br>➢ Access to identifiable research data should be based on a “need to know” and the "minimum data necessary" standard be followed. |
| **Collecting and Maintaining Identifiable Data** | **Considerations:**<br>➢ The investigator needs to ensure that:<br>☐ The study includes the necessary safeguards to maintain confidentiality of identifiable data, and<br>☐ There are data security provisions in place appropriate to the degree of risk from disclosure. |
| **Limit Access to Data** | **Considerations:**<br>➢ When FDA-regulated test articles are a used in the study, participants must be informed that the FDA may have access to their study records to protect their safety and welfare.<br>➢ Any information derived from the research project that personally identifies the participant will not be voluntarily released or disclosed by these entities without the participant’s separate consent, except as specifically required by law.<br>➢ Research records provided to authorized, non-CHLA entities should not contain identifiable information about the participant.<br>➢ Research consent forms should include who will have access to identifiable data. |