**WITHDRAWAL OF INFORMED CONSENT FOR HUMAN SUBJECT RESEARCH**

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Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

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**PURPOSE:**

A subject enrolled in a research project may decide to withdraw from the research, or an investigator may decide to terminate a subject's participation in research regardless of whether the subject wishes to continue participating. In these circumstances, questions sometimes arise about:

whether the investigator may use, study, or analyze already collected data about the subject who withdraws from the research or whose participation is terminated by the investigator; and

whether the investigator can continue to obtain data about the subject and if so, under what circumstances.

**POLICY:**

Federal guidance has been developed to guide Investigators regarding data use and retention when a subject withdraws consent from a clinical trial. As a part of the continuing informed consent process, Investigators should discuss with subjects the use and retention of data, if they choose to withdraw from a project.

When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial.

When applicable, the investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.

11. FDA-regulated research, the retention and analysis of already collected data, including PHI, are always considered necessary to protect the integrity of the research project.

**Investigator withdraws subject from further participation**

1. If an Investigator decides to terminate a subject's participation in a clinical trial without regard to the subject's consent because, for example, of concern that the primary research intervention is exposing the subject to an unacceptable level of risk, the investigator should ask the subject whether the subject is willing to continue participation in other research activities described in the IRB-approved protocol and informed consent document that involve participation of the subject, such as
    a. Obtaining data through interaction with the subject; or
    b. Obtaining identifiable private information from the subject's medical records or healthcare providers.
2. The investigator should explain to the subject the importance of obtaining follow-up safety data about the subject. If the subject agrees, research activities involving these other types of participation for which the subject previously gave consent may continue.
3. The investigator should explain to the subject the reasons for this action and, as appropriate, other treatment options.
4. For research greater than minimal risk the Investigators should document the determination to withdraw a subject from further participation.
    a. Whether the withdrawal of the subject resulted from a decision by the investigator,
    b. The reasons for the withdrawal, if known; and
    c. Whether the withdrawal was from all components of the research project or just the primary interventional component.

**REFERENCES:**
N/A

**SUPPORTING DOCUMENTS:**
N/A

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