



MCW Office of Research Standard Operating Procedure

WITHDRAWAL OF INFORMED CONSENT FOR HUMAN SUBJECT RESEARCH

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

Applies to: Faculty and Staff involved in human research

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.

PROCEDURE:

Subject Withdrawals and Research Data Retention

1. When a subject withdraws from a project, the data collected on the subject to the point of withdrawal remain part of the project database and may not be removed. The consent document cannot give the subject the option of having data removed.
2. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the project. Under this circumstance, the discussion with the subject would distinguish between project-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
3. If a subject withdraws from the interventional portion of the project, but agrees to allow the investigator to continue other research activities described in the IRB-approved protocol and informed consent document that involve participation of the subject, such as:
 - a. obtaining data about the subject through interaction with the subject; or

- b. obtaining identifiable private information from the subject's medical, educational, or social services agency records or from the subject's healthcare providers, teachers, or social worker.
 - c. When a subject's withdrawal request is limited to discontinuation of the primary interventional component of a research project, research activities involving other types of participation for which the subject previously gave consent may continue.
 - d. The investigator must obtain the subject's informed consent for this limited participation in the project (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
4. If a subject withdraws from the interventional portion of a project and does not consent to continued follow-up of associated clinical outcome information, the investigator must discontinue the following activities involving that subject's participation in the research project.
 - a. Interacting or intervening with the subject in order to obtain data about him or her for the research project, and
 - b. Obtaining additional identifiable private information about the subject for the research project by collecting or receiving such information from any source, and
 - c. Obtaining additional identifiable private information about the subject for the research project by observing or recording private behavior without interacting or intervening with the subject
 5. An investigator may review project data related to the subject collected prior to the subject's withdrawal from the project, and may consult public records, such as those establishing survival status.
 6. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.
 7. Under applicable FDA law and regulations, data collected on human subjects enrolled in an FDA-regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the project to be scientifically valid.
 8. Documentation of the subject's request for withdrawal from further participation in biomedical research greater than minimal risk is recommended.
 - a. Withdrawal of the subject resulted from a decision by the subject,
 - 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.
 9. Report the withdrawal of subjects to the IRB. Depending on the circumstances, this information may be reported with the continuing progress report or may require reporting as a Reportable Event.
 10. HHS conducted or supported research that is also subject to the HIPAA Privacy Rule: if a subject chooses to withdraw from that research and also revokes authorization in writing for continued use or disclosure of his or her PHI that was already obtained in the research, analysis of that PHI may only continue to the extent necessary to protect the integrity of the research project.
 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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