GUIDANCE DOCUMENT
Withdrawal of Subjects from Research
Aurora Health Care’s Research Subject Protection Program (RSPP)

This guidance document describes how the Aurora Health Care IRB manages subject withdrawal from research studies. Subject withdrawal occurs when a subject voluntarily withdraws his or her consent to participate in a study, or when a Principal Investigator (PI) ends a subject's study participation.

The ethical principles guiding research with human subjects require that subject participation in research is voluntary, based upon a full disclosure of the procedures, and that their continued right to withdraw at any time is ensured.

Regulatory requirements regarding the retention and use of data after subject withdrawal or termination differ depending on whether or not the research is subject to FDA regulations.

When seeking informed consent from subjects, the following information regarding data retention and use must be included:

- For FDA-regulated clinical trials, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.
- For research not subject to FDA regulations, the investigator should inform subjects whether the investigator intends to either: (1) retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or (2) 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.

Federal regulations state that the informed consent documents must include a statement relating to withdrawal. These include statements that participation in the research is voluntary, that participation may be discontinued at any time without penalty or loss of benefits to which the subject is otherwise entitled, a description of any circumstances whereby an investigator may terminate a subject's participation, consequences of withdrawal and procedures for orderly withdrawal. The Aurora RSPP consent template found on the RSPP website includes language for all of these required statements.

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Data retention when data participants withdraw from a clinical trial

- When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.

- A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-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 participant's information.

- The Researcher must obtain the participant’s consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.

- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Researcher must not access for purposes related to the study the participant’s medical record or other confidential records requiring the participant’s consent. However, a Researcher may review study data related to the participant collected prior to the participant’s withdrawal from the study, and may consult public records, such as those establishing survival status.

Issues pertaining to the withdrawal of biospecimens

- Discontinuation of participation in research may be complete or partial. In some cases, the subject may wish to discontinue some elements of the research project, such as activities involving intervention or interaction, but may want other activities to continue, such as further testing and analysis of biospecimens already collected. When a subject seeks to discontinue participation in medical research that has included collection of biospecimens and associated clinical data, the principal investigator should determine whether the withdrawal is limited to future interventional and/or interactional activities, or is a full and complete discontinuation of participation.

- When a subject discontinues participation in research, further collection and distribution of biospecimens or associated clinical data for research purposes should cease. In addition, if the withdrawal applies to previously stored biospecimens and associated clinical data, the biospecimen resource should not distribute for further research any remaining stored biospecimens or

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associated data. However, analysis of data generated from biospecimens distributed to researchers prior to the date of discontinuation of participation may occur, provided that such analysis falls within the scope of the analysis described in the IRB-approved protocol.

- If a subject who is discontinuing participation in research requests that previously stored but unused biospecimens be destroyed, biospecimen resources and recipient investigators, if applicable, should respect that request. The consent document should clarify whether it is the policy of the biospecimen resource to destroy biospecimens in the event of a subject’s discontinuation of participation in research.

- With respect to any request for removal of data from a biospecimen resource by a subject who is discontinuing participation subjects may be prevented from removing their stored data from a biospecimen resource if such removal would compromise the scientific validity of the study. In considering any request to purge stored data, biospecimen resources should consider whether such action would undermine the integrity of data collected from other subjects who made an informed choice to contribute biospecimens to research. Biospecimen resources should be sensitive to cultural issues and work with affected groups to develop mechanisms for the proper destruction of biospecimens or as appropriate and practicable, the return of biospecimens to the affected group.

**Reporting Subject Withdrawals to the IRB at Time of Continuing review.**

- At the time of continuing review of ongoing research studies and studies in long term follow up, the PI will be asked to identify to the IRB the number of subjects who withdrew from the study (for that continuing review period), and the reasons for withdrawal.

**References**

45 CFR 46.116(a)(8), 45 CFR 46.116(b)(2) and (4)

OHRP: Guidance on Withdrawal of Subjects from: Data Retention and Other Related Issues
http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html

FDA: Guidance for Sponsors, Clinical Investigators, and IRBs Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials

https://admin.share.aahrpp.org/Website%20Documents/2015%20Evaluation_Instrument_for_Accreditation(v2).pdf