5.13 Subject Withdrawal or Termination

For a variety of reasons, a subject enrolled in a research study 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: (1) 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 (2) whether the Investigator can continue to obtain data about the subject and if so, under what circumstances. The following addresses these and related questions. Investigators must plan for the possibility that subjects will withdraw from Research and include a discussion of what withdrawal will mean and how it will be handled in their research Protocols and informed consent documents.

Regulatory requirements regarding the retention and use of data after subject withdrawal or termination differ between Research subjects to FDA regulations and that not subject to FDA regulations. 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 study to be scientifically valid. [FDA 21 CFR 314.50(f)(2); FDA 21 CFR 814.20(b)(6)(ii); FDA 21 CFR 601.2(a); and FDA 21 CFR 50.25(a)(8)]. For Research not subject to FDA regulations, 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.

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.

Sometimes, a subject wants to withdraw from the primary interventional component of a study, but is willing 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: (1) obtaining data about the subject through interaction with the subject (e.g., through follow-up interviews, physical exams, blood tests, or radiographic imaging); or (2) 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. When a subject’s withdrawal request is limited to discontinuation of the primary interventional component of a research study, research activities involving other types of participation for which the subject previously gave consent may continue. Investigator should 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 study. Under this circumstance, the discussion with the subject would distinguish 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 subject’s information.

If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous paragraph, the Investigator must obtain the subject’s Informed Consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approved of informed consent documents would be required.

If a subject (a) withdraws from the interventional portion of a study, (b) does not consent to be continued follow-up of associated clinical outcome information, and (c) does not request removal of their data, the Investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

Regulations and Guidance: FDA 21 CFR 314.50(f)(2); FDA 21 CFR 814.20(b)(6)(ii); FDA 21 CFR 601.2(a); and FDA 21 CFR 50.25(a)(8).