The ethical principals guiding research with human subjects require that that no subject participates in research unless their individual participation is voluntary, based upon a full disclosure of the procedures, and their continued right to withdraw at any time.

An important caveat to the right to withdraw however is that data collected from a subject up to the point of withdrawal remains part of the study database. A consent document cannot give a subject the option of having data removed from the study dataset. FDA law and regulations require the collection and maintenance of complete clinical study data. This includes information on subjects who withdraw from a clinical investigation, whether the subject decides to discontinue participation in the clinical trial (21 CFR 50.25(a)(8)) or is discontinued by the investigator because the subject no longer qualifies for the research.

Depending on the nature of the study a research subject has options when withdrawing from the research. If the intervention is a one-time interaction and the subject wishes to discontinue their participation that request should be honored immediately and completely by the investigator. However, when a subject in a longitudinal study wishes to discontinue a specific component of the research the investigator may ask the subject if they wish to provide continued follow-up and/or be involved in future data collection. 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 non-invasive chart review and address the maintenance of privacy and confidentiality of subject’s information. Similarly, when a subject withdraws from the interventional portion of a clinical trial an investigator may discuss having the subject provide continued follow-up information and/or provide further data subsequent to their withdrawal. This continued participation would generally be limited to clinical outcome information such as lab results, chart review, future medical care and/or quality of life surveys. The aforementioned scenario may also be referred to as partial withdrawal. A consent form can be designed to incorporate the option for partial withdrawal and is recommended for long term studies. If limited and optional continued participation was not discussed in the initial consent document, the investigator must obtain the subjects’ separate and additional informed consent. The IRB must approve the consent document. See HRPP Manual 6-4 “Informed Consent.”

If a subject withdraws from the interventional portion of the study and does not consent to continued follow-up the investigator must not access the subject’s medical record or
other confidential records for research purposes. This is true even if there is valid HIPAA authorization (to access protected health information) in effect. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study and may access public records to establish survival status etc.

When an individual's participation in research includes the collection or retention of biological samples for future research separate permission for such use must be detailed in the consent document. When biological samples are banked for future research use and continue to contain direct identifiers the subject who provided the samples has the option of withdrawing permission for the future use of the specimens. Biological samples that are labeled in such a way that the subject from which the sample was obtained can be identified must be destroyed upon request, regardless of whether the sample is currently being used in an ongoing research project. The investigator has the option of removing all identifiers from the sample and continuing to use it, but only if the subject is informed of this intent during the consent and authorization process.

References: