

Elements of Informed Consent and Authorization

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The Consent Process

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

The consent process begins when a potential research subject is initially contacted. Although an investigator may not recruit subjects to participate in a research study before the IRB reviews and approves the study, an investigator may query potential subjects to determine if an adequate number of potentially eligible subjects is available.

The IRB should be aware of who will conduct the consent interview. FDA does not require the Principal Investigator to personally conduct the consent interview, but the Investigator remains ultimately responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. If delegating the task of obtaining informed consent to another individual, the Investigator must ensure that this person is sufficiently qualified to answer questions about the research, including questions about the medical treatment to be delivered as part of the research, if applicable.

The IRB should be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed.

In addition to signing the consent document, the subject/representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the subject began participation in the study. If consent is obtained the same day that the subject's involvement in the study begins, the subject's medical records/case report form should document that consent was obtained prior to participation in the research. A copy of the consent document must be provided to the subject and the original signed consent document should be

retained in the study records. Note that the FDA regulations do not require the subject's copy to be a signed copy, although a photocopy with signature(s) is preferred.

Passive Consent or Implied Consent

Terms such as “passive” or “implied” consent are not referenced in the HHS regulations. However, OHRP is aware that these terms are sometimes used by investigators or IRBs to describe a process in which consent or parental permission requirements have been altered or waived, or for which the requirement to document consent or parental permission has been waived.

The term “implied informed consent” is sometimes used for situations where a subject has implied that he or she consents to participate (by sending back a completed survey) but has not signed an informed consent document. OHRP would consider this to be a permissible informed consent process if the IRB has approved the informed consent alteration and waived the requirement for documentation of informed consent.

The term “passive consent” is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an opt out procedure, which is not consistent with the regulatory requirement for seeking and obtaining parental permission [emphasis added]. If the IRB determines that the conditions for waiver of parental permission can be met, then the IRB could waive the requirement for parental permission under 45 CFR 46.408(c) or 45 CFR 46.116(c) or (d). Even though not required by the regulations, an IRB may require that parents be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission. (<http://answers.hhs.gov/ohrp/questions/7249>)

Third Party Consent

Although the Federal regulations do not deal with this issue explicitly, the question has received increasing discussion over the last several years. Many IRBs would conclude that, when an investigator conducting research obtains identifiable private information about a living individual, that individual becomes a research subject, regardless of whether that person is the individual with whom the investigator is having an interaction. For example, if the research involves asking the primary subject to provide identifiable private information about a third party (also known as a secondary subject), that third party then becomes a subject in the research. As such, all of the regulatory requirements for protecting that individual obtain.

IRBs may differ in their interpretations of "identifiable private information." To better understand the issues of interpretation, consider two examples: (1) an unemployed person provides household income information for a two-person household in which only one household member is employed; (2) a mother provides health information about the father of her child. In the first example, the information is identifiable, but may not be considered private. In the second example, the information is private, but may not be considered identifiable if no identifying information was gathered about the father. However, if an IRB determines that these examples represent "identifiable private information" (as it may reasonably do), then the Federal regulations require informed consent from the employed person or the father before such questions are asked of the unemployed person or the mother.

The IRB can determine whether informed consent needs to be sought from third party subjects. The IRB can also determine whether this consent may be waived. The Federal regulations (45 CFR 46.116(d)) state that IRBs may approve a waiver of consent if the IRB determines that the research poses no more than minimal risk to the secondary subject, that the rights or welfare of the secondary survey would not be adversely affected, that the research could not be practicably conducted if consent from the secondary subject were required, and that, if appropriate, there be a plan to provide the waived consent information to the secondary subject after the conclusion of the study.

Investigators whose research may involve secondary subjects are encouraged to contact the IRB to discuss how to best protect the rights and welfare of these subjects in a given project. Other information on the issue of third party information is available at: http://www.nih.gov/sigs/bioethics/nih_third_party_rec.html.

Information from this section was copied from: <http://www.aapor.org/irbfaqsforsurveyresearchers>.

21 CFR 50.25 and 45 CFR 46.116 Elements of informed consent

Most of the information about the elements of informed consent elements was gleaned from the FDA website: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>.

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.*

The statement that the study involves research is important because the relationship between patient-physician is different than that between subject-investigator. Any procedures relating solely to research (e.g., randomization, placebo control, additional tests) should be explained to the subjects. The procedures subjects will encounter should be outlined in the consent document, or an explanation of the procedures, such as a treatment chart, may be attached to and referenced in the consent document.

Consent documents for studies of investigational articles should include a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety. In studies that also evaluate the effectiveness of the test article, consent documents should include that purpose, but should not contain claims of effectiveness.

If the Investigator plans to collect perform testing for HIV or Infectious diseases, to be compliant with Colorado statutes, he must obtain the subject's explicit permission. Researchers at National Jewish Health may use a clinical HIV/Infectious diseases testing consent form or augment the research consent form with this additional testing information that describes the required disclosures to state authorities. Because

Colorado requires written consent for testing, National Jewish Health requests an additional signature line for initial lines for this purpose.

Notes: National Jewish Health requires a description of all five of the subparts to this element.

The expected duration of the subject's participation should include an estimate of the amount of time for each visit to enable subjects to make a more informed decision about their possible time commitment.

National Jewish Health also considers "collection of medical records" to be a description of the procedures to be followed. If the Investigator plans to collect health information from the medical record, the Investigator must state that he/she will be accessing the medical record and must provide a description of the nature of information that will be collected.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

The risks of procedures relating solely to research should be explained in the consent document. The risks of the tests required in the study protocol should be explained, especially for tests that carry significant risk of morbidity/mortality themselves. The explanation of risks should be reasonable and should not minimize reported adverse effects.

The explanation of risks of the test article should be based upon information presented in documents such as the protocol and/or investigator's brochure, package labeling, and previous research study reports. The IRB should make an assessment based on the information provided in the submission instead of making assumptions based on familiarity with the drugs, devices, or procedures.

For IND studies, the IRB should compare the risk information against the Investigator's Brochure.

Note: For federally-funded studies, OHRP cites/penalizes institutions that do not describe a risk of "loss of confidentiality." This implies that they require a statement pertaining to loss of confidentiality. National Jewish Health requires this risk to be listed in all studies for consistency.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

The description of benefits to the subject should be clear and not overstated. If no direct benefit is anticipated, that should be stated.

The IRB should be aware that this element includes a description not only of the benefits to the subject, but to "others" as well, such as for the advancement of science. This may be an issue when benefits accruing to the investigator, the sponsor, or others are different than that normally expected to result from conducting research. Thus, if these benefits may be materially relevant to the subject's decision to participate, they should be disclosed in the informed consent document.

- (4) *A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*

To enable a rational choice about participating in the research study, subjects should be aware of the full range of options available to them. Consent documents should briefly explain any pertinent alternatives to entering the study including, when appropriate, the alternative of supportive care with no additional disease-directed therapy. While this should be more than just a list of alternatives, a full risk/benefit explanation of alternatives may not be appropriate to include in the written document. The person(s) obtaining the subjects' consent, however, should be able to discuss available alternatives and answer questions that the subject may raise about them. As with other required elements, the consent document should contain sufficient information to ensure an informed decision.

- (5) *A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (for FDA regulated research). [Note that National Jewish Health IRB also requests that there be a statement that National Jewish Health IRB may review the records.]*

Study subjects should be informed of the extent to which the institution intends to maintain confidentiality of records identifying the subjects. In addition, they should be informed that the agency with regulatory authority or the IRB may inspect study records (which include individual medical records). If any other entity, such as the sponsor of the study, may gain access to the study records, the subjects should be so informed.

The consent document may, at the option of the IRB, state that subjects' names are not routinely required to be divulged to regulatory agencies. When a regulatory authority requires subject names, the agency will treat such information as confidential, but on rare occasions, disclosure to third parties may be required. Therefore, absolute protection of confidentiality should not be promised or implied.

Consent documents should not state or imply that a regulatory agency needs clearance or permission from the subject for access. When clinical investigators conduct a study for submission to FDA (for with federal funding from NIH), they agree to allow the appropriate regulatory agency access to the study records. Informed consent documents should make it clear that, by participating in research, the subject's records automatically become part of the research database. Subjects do not have the option to keep their records from being audited/reviewed by others.

- (6) *For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*

Informed consent documents should describe any compensation or medical treatments that will be provided if injury occurs. If specific statements cannot be made (e.g., each case is likely to require a different response), the subjects should be informed where further information may be obtained. The consent document should also indicate whether subjects will be billed for the cost of such medical treatments.

Note: National Jewish Health requires use of its research injury template. If a sponsor requests a modification, the modification should be pre-approved by the Director of Grants administration and the Director, Research Regulatory Affairs.

[See the description of Exculpatory Language at the end of this form.]

Compensation v. Waiver of Subject's Rights

The consent document must explain whether there is compensation available in case of injury but must not waive or appear to waive the rights of the subject or release or appear to release those conducting the study from liability for negligence.

When costs will be billed, preferred statements include:

- "...will be billed to you or your insurer in the ordinary manner,"
- "The sponsor has set some funds aside for medical costs related to..."
- "Here's how to apply for reimbursement if you think you might be eligible..." or
- "No funds have been set aside..."

Statements such as: "...will be the responsibility of you or your insurance company" or "compensation is not available," could appear to relieve the sponsor or investigator of liability for negligence, see 21 CFR 50.20. Further, descriptions pertaining to the responsibilities of insurance companies have been erroneously interpreted by some subjects to mean that the insurance companies are required to pay.

Note: For commercially-sponsored studies, National Jewish Health cannot accept language that requires initial billing to a third party payor, such as the health insurance provider or the Center for Medicare Services (CMS). CMS explicitly prohibits such payments. Further, it would violate National Jewish Health's contracts with insurance companies to bill them for the commercial sponsor's cost of doing business. National Jewish Health also requires a statement that if insurance companies are incorrectly billed for a research-related injury, the payment must be returned and the commercial sponsor must cover the charges. Some exceptions to this requirement are permitted on a case-by-case basis, but all exceptions must be pre-approved by the Director of Grants administration and the Director, Research Regulatory Affairs.

[Again, see the description of Exculpatory Language at the end of this form.]

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

This requirement contains three components, each of which should be specifically addressed. The consent document should provide the name of a specific office or person and the telephone number to contact for answers to questions about: 1) the research subjects' rights; 2) a research-related injury; and 3) the research study itself. It is as important for the subject to know why an individual should be contacted as it is for the subject to know whom to contact.

Note: The National Jewish Health IRB must always be listed in this section as a resource for questions about research subjects' rights. Studies conducted in the CTRC may also list the contact information for the research subject advocate.

- (8) *A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*

This element requires that subjects be explicitly informed that they may decline to participate or to discontinue participation at any time without penalty or loss of benefits. Language limiting the subject's right to drop out of the study should not be permitted in consent documents.

If the subjects who drop out will be asked to permit follow-up of their condition by the researchers (e.g., complete an early termination visit), the process and option should be outlined in the consent document.

If subjects wish to drop out of all future participation, they may do so verbally or in writing. However, to stop ongoing use or disclosure of their health information, they must revoke their HIPAA authorization in writing. At National Jewish Health, subjects are instructed to write to the Corporate Compliance Officer.

(b) Additional elements of informed consent

It is up to the IRB to determine in a particular instance whether some or all of the above additional elements must be included as part of the informed consent process for a particular study. The IRB should make this determination based on the nature of the research and its knowledge of the local research context. If the IRB determines that additional elements are appropriate to the research study, this additional information should be considered just as essential as the eight basic elements of informed consent described in the FDA regulations at 21 CFR 50.25(a) or in the HHS regulations at 45 CFR 46.116(a).

Furthermore, an IRB may require that additional information beyond the basic and additional elements be given to subjects during the informed consent process, when in the IRB's judgment the additional information would meaningfully add to the protection of the rights and welfare of the subjects 45 CFR 46.109(b)).

- (1) *A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.*

A statement that there may be unforeseen risks to the embryo or fetus may not be sufficient if animal data are not available to help predict the risk to a human fetus. Informed consent documents should explain that mutagenicity (the capability to induce genetic mutations) and teratogenicity (the capability to induce fetal malformations) studies have not yet been conducted/completed in animals. [Note: The lack of animal data does not constitute a valid reason for restricting entry of women of childbearing potential into a clinical trial.]

Subjects, both women and men, need to understand the danger of taking a drug whose effects on the fetus are unknown. If relevant animal data are available, however, the significance should be explained to potential subjects. Investigators should ensure that the potential risks that the study poses are adequately explained to subjects who are asked to enter a study. If measures to prevent pregnancy should be taken while in the study, that should be explained.

FDA guidance on the inclusion of women in clinical trials [58 FR 39406] gives IRBs broader discretion to encourage the entry of a wide range of individuals into the early phases of clinical trials. FDA urges IRBs to question any study that appears to limit enrollment based on gender and/or minority status. Statements such as, "you may not participate in this research study if you are a woman who could become pregnant" should not routinely be included in informed consent documents.

Note: When discussing pregnancy testing of minors, some consent forms state how the results will be disseminated. Remember that Colorado statutes are interpreted such that pregnant minors have control over health information pertaining to their pregnancy status, including results of pregnancy tests. The consent form cannot state that pregnancy tests on minors will be provided to the parents/guardians.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

When applicable, subjects should be informed of circumstances under which their participation may be terminated by the investigator without the subject's consent. An unexplained statement that the investigator and/or sponsor may withdraw subjects at any time, does not adequately inform the subjects of anticipated circumstances for such withdrawal.

A statement that the investigator may withdraw subjects if they do not "follow study procedures" is not appropriate. Subjects are not in a position to know all the study procedures. Subjects may be informed, however, that they may be withdrawn if they do not follow the instructions given to them by the investigator.

(3) Any additional costs to the subject that may result from participation in the research.

If the subjects may incur an additional expense because they are participating in the research, the costs should be explained. The IRB should consider that some insurance and/or other reimbursement mechanisms may not fund care that is delivered in a research context.

If there is no cost to participate in the research, this should be explicitly stated.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

When dropping out of from a research study may have deleterious effects on the subject's health or welfare, the informed consent should explain any procedures that are necessary for the subject's safety and specifically state why they are important to the subject's welfare. An unexplained statement that the subject will be asked to submit to final tests does not adequately inform the subjects why the tests are necessary for the

subject's welfare. Consent forms should describe what an early termination visit will consist of.

- (5) *A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.*

When it is anticipated that significant new findings could occur that would be pertinent to the subject's continued participation, the IRB should determine that a system, or a reasonable plan, exists to make such notification to subjects.

- (6) *The approximate number of subjects involved in the study.*

If the IRB determines that the numbers of subjects in a study is material to the subjects' decision to participate, the informed consent document should state the approximate number of subjects involved in the study.

Note: National Jewish Health IRB also requires an additional phrase specifying how many subjects will be enrolled under National Jewish Health's jurisdiction.

- (7) *A statement that the study will be posted on ClinicalTrials.gov.*

The FDA, under the Food and Drug Administration Amendments Act (FDAAA) of 2007, requires online listing and disclosure of "applicable trials." These trials involve drugs, devices, or biologics regulated by the FDA. For a flowchart to help determine whether a study is considered an applicable trial, review:

http://grants.nih.gov/ClinicalTrials_fdaaa/docs/Flow_chart-ACT_only.pdf.

The following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials.

<http://grants.nih.gov/grants/guide/notice-files/not-od-08-014.html> and

<http://clinicaltrials.gov/ct2/manage-recs/background>.

"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The four required sentences fulfill the need for a standardized, specific statement concerning the availability of trial data on www.ClinicalTrials.gov for every applicable clinical trial. The FDA formulated the statement after consideration of all comments submitted to the proposed rule docket, and input from Institutional Review Board (IRB) members, clinical trial directors, ethicists, and communication experts. Requiring word-for-word reproduction of the statement avoids the need for individual analysis and determination of what is appropriate to be included. The use of the statement also avoids different statements for different trials.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf>

It is important to note that the International Committee of Medical Journal Editors (ICMJE) now requires trial registration for any interventional clinical trial as a condition for the publication in an ICMJE journal, and this requirement covers more types of trials

than the FDA requirement. Researchers may register in *ClinicalTrials.gov* or another data registration site approved World Health Organization (WHO).

http://www.icmje.org/faq_clinical.html

Exculpatory Language

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

<http://www.hhs.gov/ohrp/policy/exculp.html>

Examples of Exculpatory Language:

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

Elements of HIPAA Authorization

National Jewish Health, together with the University of Colorado, Denver, has developed standard template wording for the authorization section that identifies the parties who can use and disclose the PHI as well as the parties to whom the PHI may be disclosed. It also includes the following required information:

45 CFR 164.508(c)(1) Authorization Core Elements:

Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).

Protected health information may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

Note: National Jewish Health prefers that the nature of health information be as descriptive as reasonably possible.

The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.

The authorization may list specific health care provider(s) or description of classes of persons (e.g., the study doctor) who may request use of the PHI.

Note: At National Jewish Health, the consent template references “the research team.”

The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.

Where a covered entity conducts the research study, the Authorization must list ALL names or other identification, or ALL classes, of persons who will have access through the covered entity to the protected health information (PHI) for the research study (e.g., research collaborators, sponsors, and others who will have access to data that includes PHI).

Examples may include, but are not limited to the following:

- Principal Investigator and his/her staff
- Data coordinating centers that will receive and process PHI;
- Institutional Review Boards;
- Sponsors who want access to PHI or who will actually own the research data;
- Contract Research Organizations who will monitor the data; and/or
- Data Safety and Monitoring Boards.

Description of each purpose of the requested use or disclosure.

An authorization is limited to a single purpose. Most authorization forms simply state that the purpose is to collect and store health information for a research study.

Researchers should note that this element must be research study-specific, and cannot include the purpose of “future, unspecified research.”

Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository).

Expiration of authorization may be governed by state law.

Note: In Colorado, there is no limitation on use or disclosure of health information. It is also permissible to list an event that will indicate expiration of authorization, such as “end of the research study.”

Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

Note: If there is a standalone authorization, there is no requirement to capture the signature of the person administering the authorization, although many institutions prefer to capture this information.

45 CFR 164.508(c)(2) Authorization Required Statements

The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.

An authorization must be revoked in writing. Subjects should be with provided an address to which to send the revocation or told which section of the Notice of Privacy Practices contains the address.

Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.

When the research involves treatment and is conducted by the covered entity, or when the covered entity provides health care solely for the purpose of creating protected health information to disclose to a researcher, subjects can be told that if they do not sign the Authorization, they cannot participate in the study.

Be aware that when the research does not involve research-related treatment by the covered entity or when the covered entity is not providing health care solely for the purpose of creating protected health information to disclose to a researcher, the covered entity may not condition treatment on whether they sign the Authorization.

The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.

Third party recipients, such as Contract Research Organizations, may not be considered covered entities and may not be required by the Privacy Rule to protect the information. However, there may confidentiality protections imposed by state laws or organizational policies.

Some organizations also add cautionary statements about disclosure:

- Your health information will be used or disclosed when required by law.
- Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.
- No publication or public presentation about the research described above will reveal your identity without another authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

A research subject may revoke his/her Authorization at any time. However, a covered entity may continue to use and disclose PHI that was obtained before the individual revoked Authorization to the extent that the entity has taken action in reliance on the Authorization.

In cases where the research is conducted by the covered entity, this would permit the covered entity to continue using or disclosing the PHI as necessary to maintain the integrity of the research, as, for example, to account for a subject's departure from the research study, to conduct investigations of scientific misconduct, or to report adverse events.