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## Section 6: Informed Consent



### 6.1 General Policy

Researchers must describe in the research protocol how the informed consent process will be conducted, the setting in which it will occur, a description of the waiting period between informing the prospective participant and obtaining consent, and methods in place to prevent undue influence on a potential participant to enroll in a study.

The following are points to consider when conducting the consent process.

Researchers should consider obtaining informed consent as a process, not just a consent form, by which the research study is thoroughly explained to the potential subject. The requirement to obtain informed consent should be seen as not only a legal obligation, but also as an ethical obligation. Documentation of informed consent is accomplished through the use of a consent form. Prior to enrolling subjects in a research activity, researchers are required to obtain legally effective informed consent from a potential subject or their LAR and, if the research involves children, a parent's permission or child's consent. (see **Section 6.6** Parental Permission/Child Assent).

As part of the informed consent process, researchers are responsible for ensuring subjects (or LARs) are given sufficient opportunity to consider whether or not to participate in the study and must seek to avoid coercion or undue influence. Information given to potential subjects (or LAR) must be in language that is understandable to the subject or representative. Non-English speaking subjects must have information presented in a language they understand (**Section 6.4.1 Non-English Language Informed Consent** and other Study Documents).

No process or consent form used to obtain and document consent may include exculpatory language through which the subject waives any of their legal rights or releases, or appears to release, the researcher, sponsor, or institution or its agents from liability for negligence. Any consent form used to enroll subjects in a research protocol must be reviewed and approved by an IRB prior to enrollment. In addition, the IRB may request to observe the informed consent process to ensure adequate consent when the research involves particularly vulnerable populations.

Researchers should be aware that the setting in which consent is sought may introduce a feeling of undue influence. For example, students in an educational setting may feel that refusal to participate will affect their grades. Prevention of these sorts of pressures should be addressed in the research design, as the process must always preserve the right to refuse participation.

In all cases, consent forms must be consistent with state laws and federal regulations regarding content. The informed consent requirements stated in this manual are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

Procedures for requesting a waiver of the requirements for obtaining and/or documenting informed consent are delineated in **Section 6.7**.

## 6.2 Elements of Informed Consent

The IRB will determine that the required disclosures will be provided to each subject or a legally authorized representative in accordance with legal and regulatory requirements listed below as required elements of informed consent. The IRB will also consider whether additional disclosures are required for inclusion in the consent process.

1. It is expected that researchers will use the DU IRB informed consent form templates with required sections and verbiage for preparing consent forms. Other formats may be considered provided that all required elements and applicable additional elements are present. Research-related consent forms must contain all the basic elements of informed consent, regardless of the risk level of the study unless a request for waiver or alteration of some or all of the elements is requested by the researcher and the waiver is approved by the IRB. The consent form template contains all the required elements of consent. In addition, the IRB requires that all consent forms be written at a level appropriate to a minimum expected educational level of the target population and in the second person, e.g., “You will be required to …”

Per the revised Common Rule, implemented January 21, 2019, the following key information must receive priority by appearing at the beginning of the consent form and be presented first in the consent discussion. The following five elements must be included at the beginning of the consent form, and informed consent process, encompassing the required key information.

1. The fact that consent is being sought for research and that participation is voluntary.
2. The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research,
3. The reasonably foreseeable risks or discomforts to the prospective subject,
4. The benefits to the prospective subject or others that may reasonably be expected from the research, and
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

The following are the basic required elements (extracted from 45 CFR Part 46.116):

1. A statement that the study involves research.

2. An explanation of the purpose of the proposed research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. Identification of which procedures are experimental. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.
6. A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable.
7. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that if it is an experimental treatment or procedure, no benefits can be guaranteed.
8. A disclosure of appropriate alternative procedures or treatments, if any, which are available and might be advantageous to the subject. One alternative might be to choose not to participate in the research. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.
9. A statement describing the manner and extent, if any, to which confidentiality of records identifying the subject will be maintained, a statement that the IRB and other entities may inspect the records, and, if the research is Food and Drug Administration (FDA)-regulated, FDA may inspect the records.
10. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and if so, what they consist of or where further information may be obtained. For studies that are not greater than minimal risk and are not HHS-funded, this element may be omitted.
11. A description of whether or not reimbursement for time, inconvenience, etc. will be given, including the schedule of payments.
12. Information regarding who to contact for answers about the research and in the event there is a research-related injury (this is generally the principal investigator (PI) or another staff member closely associated with the study). A separate contact, typically this is the Office of Research Integrity & Education and the IRB Chair, must be named for questions concerning the subject's rights to provide input, comments, or complaints.
13. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.
14. If the research involves collection of identifiable private information or identifiable biospecimens, one of the following statements must be included as appropriate:

    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or LAR, if this might be a possibility; or

    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Note: for FDA regulated *applicable clinical trials* (See definition in HRPP Policy 201) the following statement must be included:

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

The following additional elements of informed consent must be added to the consent form when appropriate:

1. A statement that the particular treatment and/or procedure may involve risks to the subject (or to the embryo or fetus, if the subject becomes pregnant) that are currently unforeseeable. This element should be included when the research involves an investigational drug or device or involves procedures for which the risk profile is not well known.
2. Anticipated circumstances under which the subject's participation may be terminated by the PI, with or without the subject's consent. Include when there are known circumstances under which the subject's participation may be terminated by the PI or sponsor.
3. A description of additional costs for which the subject will be responsible, that may result from participation in the research study. Include when there are additional costs to subjects, over and above standard of care, e.g., additional MRIs, radiographs, DEXA scans, additional visits that may not be covered by insurance/Medicare/Medicaid.
4. A description of the consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject. This element should be included when there is a likelihood that abrupt termination from the research is likely to result in adverse events to the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject. Include when there is a likelihood that interim findings might indicate increased risk and a reasonable person would wish to reconsider participation.
6. The approximate number of subjects that will be involved with the study, in totally and at the University. Include when such information might affect a subject's willingness to participate**.**
7. Other additional information may be required by the IRB.

## 6.3 Other Requirements for Obtaining Informed Consent

1. The IRB must be made aware of the person(s) who will be conducting the informed consent process. All faculty, staff, and students should be listed in the application, and are the only personnel allowed to obtain consent. The IRB requires that the person obtaining consent be appropriately trained in human subjects research (See **Section 3.16 Training Requirements**) and fully knowledgeable about the project and be able to answer questions that potential subjects may ask regarding the project and/or procedures performed as a part of the project.
2. If potential subjects are deemed as decisionally impaired, informed consent must be obtained from a LAR (See **Section 6.5: Third Party/Surrogate Consent**). They should be told that their obligation is to try to determine what the subject would do if they were competent, or if the subject's wishes cannot be determined, what they think is in the best interest of the decisionally impaired subject. The IRB must approve the inclusion of decisionally impaired subjects.
3. The consent form is only part of the total consent process in which the researcher conducting the informed consent process, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject's questions. The person obtaining consent is responsible for assuring that research subjects understand the research procedures and risks. Each subject (or LAR) must be provided adequate time to read and review the consent form, in addition to being advised of the procedures, risks, potential benefits, alternatives to participation, etc. Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.
4. The IRB has the authority to observe the consent process at any time. Depending on the perceived risk of the research procedures, the IRB may wish to observe the consent process for that protocol. In these cases, the PI will be contacted and the time and place for observing the process will be scheduled.
5. Obtaining informed consent from subjects must be accomplished prior to performing the research activity and using only an IRB-approved consent form. Written requests for

amendments to an existing consent form must be approved prior to implementation, at which time the revised consent form will be updated with a revised consent version date in the header of the document and be accompanied by a formal approval notification.

6. Upon receipt of an IRB approved consent form, copies of all old versions should be discarded to prevent inadvertent use of an outdated consent form. Copies of the most recently approved consent form may be made and should be used until superseded by an amended consent form. Any research project that undergoes a continuing review must submit a copy of any consent forms currently used for recruitment as part of the continuing review process. It is advised that the researchers retain a copy of the original, and any IRB-approved revised consent form(s) for their records.
7. For long-term studies, researchers are reminded that the informed consent process is ongoing and that it does not end with the signing of the consent form. Subjects should be kept apprised of events that might affect their willingness to participate.
8. Researchers are reminded that the informed consent process and form must be in a language understandable to the subject. Therefore, if it is anticipated or known that there will be non-English speaking potential subjects who might be interested in enrolling in a study, the consent form must be translated. It will then have to be reviewed and approved by the IRB. Translation of the consent form should be conducted by a certified translator or if performed by someone who is not a certified translator but is fluent in the translated language, the PI must certify that it is an accurate translation by completing Appendix K: Certificate of Translation.

## 6.4 Documenting Informed Consent

Federal regulations governing the use of human subjects in research activities require written documentation of informed consent (handwritten signature of the subject) unless the research meets the criteria for waiver of documentation. The subject should sign and date the IRB approved consent form.

1. After completing the consent process and assuring that the subject (or LAR) has no further questions and agrees to participate in the research activity, the person obtaining informed consent should instruct the subject (or LAR) to sign and date the consent form in the appropriate spaces.
2. Each subject (or LAR) must be given a copy of the signed consent form. The original consent form should be filed in such a manner as to ensure immediate retrieval when required by auditing entities (e.g., OHRP, FDA, IRB).

### 6.4.1 Non-English Language Informed Consent and other Study Documents

It is neither ethically justifiable to exclude potential subjects in a research study solely on the basis of language spoken nor ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective. In order to address these considerations, when enrolling subjects who do not speak English in research, the subject must be provided with:

1. A written consent document in a language understandable to them.
2. An interpreter fluent in both English and the subject's spoken language.

A consent form translated into the appropriate language should be submitted to the IRB. The IRB will accept non-English documents that are:

1. Professionally translated by a certified translator, or
2. Translated by someone who is fluent in the non-English language. The PI must review the document and complete Appendix K: Translation and Interpreter Form, verifying the translation is accurate and correct.

A certificate from the certified translator or a description of the proposed translation procedures, including the PI's certifying statement, must be provided to the IRB with the non-English documents.

### 6.4.2 Use of a Short Form Written Consent Document

A short form is a written document stating that the elements of informed consent required by 45 CFR 46.116 have been presented to and understood by the subject or the subject's legally authorized representative. A short form may be used when the majority of subjects in a study are English speakers, but there are a portion of the subjects who will not be able to understand the consent form written in English.

However, if the majority of the anticipated subjects to be enrolled do not speak English or will be unable to understand the consent form written in English, the consent form must be translated into a language understandable to the subjects.

#### 6.4.2.1 When following DHHS regulations, the IRB must determine

1. The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
2. A written summary embodies the basic and required additional elements of disclosure.
3. There will be a witness to the oral presentation.
4. For participants who do not speak English, the witness is conversant in both English and the language of the participant.
5. The participant or the participant's legally authorized representative will sign the consent document.
6. The witness will sign both the short form and a copy of the summary.
7. The person actually obtaining consent will sign a copy of the summary.
8. A copy of the signed short form will be given to the participant or the legally authorized representative.
9. A copy of the signed summary will be given to the participant or the legally authorized representative.

#### 6.4.2.2 When following FDA Regulations, the IRB must determine

1. The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
2. A written summary embodies the basic and required additional elements of disclosure.
3. There will be a witness to the oral presentation.
4. For participants who do not speak English, the witness is conversant in both English and the language of the participant.
5. The participant or the participant's legally authorized representative will sign the consent document.
6. The witness will sign both the short form and a copy of the summary.
7. The person actually obtaining consent will sign a copy of the summary.
8. A copy of the signed short form will be given to the participant or the legally authorized representative.
9. A copy of the signed summary will be given to the participant or the legally authorized representative.

### 6.4.3 Informed Consent Process for Online Survey-Based Research

1. Internet based consent documents, also referred to as an implied consent, should include all the elements of a regular signed consent.
2. Researchers should maintain the format of the template consent document, with study specific information added, as much as possible.

## 6.5 Third Party/Surrogate Consent

1. The regulations are clear that written documentation of informed consent (or permission of the parents if the subject is a child) of the subject (or LAR) is required.
2. When a PI proposes to conduct a research project utilizing adult subjects who by virtue of age, physical impairment, mental impairment, or any other reason, may not be able to personally execute legally effective informed consent, the IRB shall review the project on the basis of risk and benefit. This policy is not meant to imply that the requirement for written documentation of consent is waived. Rather, it applies to those studies in which third party/surrogate consent is obtained from a LAR.

## 6.6 Parental Permission/ Assent

If the research involves minors under the age of 18 years or individuals over the age of 18 who are decisionally impaired, the federal regulations require the assent of the child or minor or decisionally impaired adult and the permission of the parent(s) or guardian(s) (45 CFR 46.408). While children and some adults may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent. The assent process should involve taking the time to explain to a child or adult, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being done, what will be done to them, and that if they object, the research will be terminated. *Assent* means the potential subject's affirmative agreement to participate in the research. Mere failure to object should not, in the absence of affirmative agreement, be construed as assent.

To obtain informed consent for children under the age of 18 years or for adults over the age of 18 who may be decisionally impaired, submit the Parental Permission Form for Child Participation and Child Assent form. For more information refer to **Section 12.4 Research Involving Children**.

## 6.7 Waiver of Informed Consent and Waiver of Documentation of Consent

Obtaining informed consent from research participants or their legally authorized representatives is required for all expedited and full board research unless the IRB determines that the regulatory criteria for a waiver or alteration of consent or a waiver of documentation of consent is justified based on study specific criteria. The IRB will document its determination to approve a consent waiver in the IRB determination letter.

Waivers cannot be granted for FDA-regulated research and the DU IRB does not approve requests for "Planned Emergency Research" or exceptions to the requirement to obtain consent for "Planned Emergency Research."

### 6.7.1 Waiver of Informed Consent

Federal regulations include provisions for approval of a waiver or alteration of part or all of the consent process. There are two general instances when an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 45 CFR 46.116, or waives the requirement to obtain informed consent. In the first general instance (45 CFR 46.116(c)) the IRB must find and document that:

1. The research is to be conducted by or subject to approval of state or local

government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not be practicably carried out without the waiver or alteration.

In the second general instance (45 CFR 46.116(d)) an IRB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent, or that waives the requirement to obtain informed consent, provided that the IRB finds and documents that:
1. The research involves no more than minimal risk to the subjects.
2. The research could not practicably be carried out without the waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects, and;
5. Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participation.

### 6.7.2 Waiver of Written Documentation of Consent

Documentation of Consent cannot be waived if the research is FDA regulated.

The IRB has the authority to waive the requirement for written documentation of informed consent. When waiving the requirement for a consent form, the IRB must review a written description of the information that will be provided to subjects and consider whether to require the researcher to provide subjects with a written statement regarding the research. If required, the IRB encourages researchers to use the consent template, or a reformatted version, with the signature sections removed. The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if it finds that (45 CFR 46.117 (c)):

1. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; and that the research presents no more than minimal risk of harm to subjects and involves no procedure for which written consent is normally required outside of the research context; or
2. If the subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The IRB will also consider granting a waiver of documentation in special circumstances involving international research if the research meets the other regulatory requirements.

The determination of the applicability for waiver of the consent process must be documented in the IRB determination letter as to the specific paragraph and subparagraph(s) under which the waiver was approved.

### 6.8 Broad Consent

In the revised Common Rule, implemented in January 2019, broad consent is an alternative consent process for use only for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be specified research. In order to

utilize broad consent, the study team and/or the department/biorepository responsible for the storage of the identifiable information/biospecimens are required to identify the types of research that may be conducted with the data/biospecimens, record and track who has agreed to or refused consent, and to track the terms of consent to determine whether proposed future research use falls within the scope of the identified types of research.

**At this time, the DU IRB will not mandate nor implement the institutional use of broad consent, as the tracking requirements may be burdensome**. Exempt categories 7 and 8, which rely on broad consent will not be utilized by the IRB. The DU IRB will continue to support investigators seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through other processes, including comprehensive IRB review and consent procedures as appropriate.

## 6.9 Posting of Clinical Trial Consent Forms

For research studies that meet the NIH definition of clinical trials are required to register on ClinicalTrials.gov through the Protocol Registration System (PRS). The PRS is an electronic database that is used to post and manage clinical trials as required by NIH. For each clinical trial supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the PI on a publicly available Federal website that will be established as a repository for such forms. The form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

*Applicable clinical trials* (ACTs) must be registered with ClinicalTrials.gov if the answers to the questions below are all "YES":

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated on a health-related biomedical or behavioral outcome?

### Background

ClinicalTrials.gov is a databank or registry of federally funded, privately supported, and unfunded clinical trials involving human subjects. It is managed by the National Library of Medicine within the National Institutes of Health (NIH). ClinicalTrials.gov is the result of a federal law requiring that clinical trials be registered to improve public access to information about clinical research, promote public trust in research, and inform future research. In some cases, registration is also required for journal publication. This guidance document provides information about clinical trial registration requirements set forth by the Food and Drug Administration, the National Institutes of Health, and the International Committee of Medical Journal Editors.

### Definitions

**Applicable Clinical Trials**:

- **Drugs and Biologics**: A controlled clinical investigation, other than a Phase 1 clinical investigation, of a drug or biologic product subject to FDA regulation.

- **Medical Devices**: A prospective clinical study of health outcomes comparing an intervention with a medical device against a control, or pediatric postmarket surveillance required by the FDA.

*Applicable clinical trials* generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE)
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

Registration is *not* required for small trials to determine the feasibility of a device or to test prototype devices where the primary outcome measure relates to feasibility, and not to health outcomes.

[If Applicable]: 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.

**Resources**

ClinicalTrials.gov FDAAA

Guidance for drugs and biologics

Guidance for devices

**National Institutes of Health Registration Requirements**

Effective January 18, 2017, National Institutes of Health (NIH) requires registration at ClinicalTrials.gov for all clinical trials funded wholly or partially by NIH.

Effective March 23, 2018, US Congress directs NIH to delay enforcement of new clinical trials policy. The policy includes a new definition of *clinical trial* that would have required that many basic and behavioral studies be registered with clinicaltrials.gov.

**Definitions**

**Clinical Trial**: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-

related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. **[See note above regarding delayed enforcement]**

**Prospectively Assigned**: A pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

**Intervention**: A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

**Health-related biomedical or behavioral outcomes**: The pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. **Examples** include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

## 6.10 Authorization to Use or Disclose Protected Health Information

Researchers may perform research activities in which they collect or have access to Protected Health Information (PHI). To use or disclose PHI, researchers must obtain an authorization signed by the subjects.

### 6.10.1 Required Elements

1. A description of the information to be used or disclosed presented in a specific and meaningful fashion.
2. The name or other specific identification of the person(s), or class of persons, to whom the use or disclosure will be made.
3. A description of each purpose of the requested use or disclosure.
4. An expiration date or event that relates to the individual or the purpose of the use or disclosure.
5. A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization.
6. A statement indicating when the authorization for use and disclosure occurs; e.g., at the end of the research.
7. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

In addition to the core elements, the authorization is required to contain statements

adequate to place the individual on notice of all of the following:

1. The individual's right to revoke the authorization in writing, and either:
    a. The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or
    b. To the extent that the information in **Section 6.7.1** is included in the notice required by 45 CFR 164.520, a reference to the covered entity's notice.
2. The ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization, by stating either:
    a. The covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations applies; or
    b. The consequences to the individual of a refusal to sign the authorization, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.
3. The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected.
4. The authorization must be written in plain language.
5. The individual must be provided with a copy of the signed authorization.

### 6.11 Waiver of Authorization for Use and Disclosure of PHI

In order to use or disclose PHI without an authorization signed by the research subject, the researcher must obtain one of the following:

1. Documentation that an amendment or waiver of the research subjects' authorizations, for use/disclosure of PHI has been approved by the IRB. This provision of the rule might be used, for example, to conduct records research when researchers are unable to use de-identified information; or

2. Where researchers represent:
    a. That the research is only for purposes of preparing a research protocol or similar uses preparatory to research.
    b. That he or she will not remove any PHI from the covered entity and
    c. That PHI is necessary for the research purpose; or

3. To disclose PHI of decedents, where the researcher represents that the use or disclosure of PHI is:
    a. Solely for research on the PHI of decedents,
    b. Necessary for the research, and
    c. Documentation of the death of the individuals about whom PHI is sought and provided.

### 6.12 Authorization of FERPA

At the University of Denver, the Office of Institutional Research & Analysis (IR) has been designated by the Registrar to review and approve requests for the use of student records for research purposes. If you intend to use student records for research purposes, including grades, course assignments, and other FERPA protected education records, you must complete the Student Records Request Form and submit it to IR for review and approval. That signed document must be submitted with your IRB application and other materials via IRBNet before IRB approval can be obtained. See the FERPA Guidance document on the ORIE website for more information.

### 6.13 Re-Consenting Subjects

Researchers have the responsibility to inform subjects of any new information that might affect subjects' willingness to continue participation in the research. In these cases, an amended consent form, delineating the findings and the changes to research risks/benefits, must be reviewed and approved by the IRB. Subjects should then be briefed on the changes, asked if they wish to continue participation and signify their willingness to continue participation by signing the amended consent form. For minor changes to the consent form that will not change risk/benefit, re-consenting is generally not required.

## 6.14 Record Retention Requirements for Subject Consent Forms

The PI shall maintain, in a designated location, the original copy of all executed subject consent forms. The signed consent forms, along with all research-related files, are to be available for inspection by authorized officials of the University administration, the IRB, regulatory agencies, sponsors, and, if applicable, the FDA or HHS.

For non-FDA regulated studies, forms should be retained for **at least three years** after completion of the study.

For FDA-regulated studies, all signed subject consent forms shall be retained by the PI for the appropriate period(s) specified below:

1. Drugs: 2 years following the date a marketing application is approved or the study is discontinued.

2. Devices: 2 years after a study is terminated or completed and the records are needed to support FDA approval.

Should a PI or project director depart the University prior to the completion of an activity or less than the time specified above, the PI is responsible for initiating mutually satisfactory

arrangements with their department and the University administration as to the disposition of executed subject consent documents.