DREXEL UNIVERSITY
Office of
Research &
Innovation

Obtaining Informed Consent from Research Participants – Standard Operating Procedures

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HRP-090	**002**	**06/02/2026**	**Page 1 of 18**

Table of Contents

1. Overview

No investigator conducting research under the auspices of Drexel University may involve a human being as a subject in research without obtaining the legally effective informed consent of the human research subject or the human research subject's Legally Authorized Representative (LAR) unless a waiver of consent has been approved by the IRB in accordance with Section 11 of these procedures.

Except as provided in Section 12 of these procedures, informed consent must be documented by the use of a written consent form approved by the IRB. For exempt research, requirements regarding the process of providing information to potential participants are outlined in the HRP SOP for Exempt Studies.

The IRB will evaluate both the consent process and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from human research subjects.

The following procedures describe the requirements for obtaining consent from human research subjects participating in research conducted under the auspices of Drexel University.

2. Definitions

Court-appointed legal guardian: (except to the extent any appointed health care agent has authority, unless the health care agent's authority has been suspended by a court order) is a court appointed guardian granted "general" guardianship or "guardian of the person" may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

Durable general power of attorney: grants the agent whatever authority is specified in the power of attorney document and is referred to as an attorney-in fact. Where the power of attorney includes a specific provision stating that it shall survive any period of incapacity or mental incompetence of the principal it is considered a "durable" power of attorney, and the person holding power of attorney may provide surrogate consent for research participation **unless** the research participation includes an activity expressly excluded from the power of attorney. *NOTE that a general power of attorney is only valid when registered with the register of deeds in either the county named in the power of attorney or the county in which the principal resides. Before relying on the decision of a person holding a general power of attorney, investigators should require proof that the power of attorney has been registered and should examine the document to ensure that it expressly survives any period of incapacity or mental incompetence of the principal. For assistance with these determinations, please contact the Office of General Counsel.*

Health care power of attorney (HCPOA): a health care agent pursuant to the execution of health care power of attorney document. A HCPOA document (to the extent of authority granted) grants the agent power to make health care decisions for the individual following a physician's determination that the individual lacks adequate capacity to make their own health care decisions. Therefore, if such a physician determination has been made, the agent under an HCPOA may provide surrogate consent for research participation to the extent this does not contradict the written HCPOA.

Legally authorized representative (LAR): An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

3. Basic Requirements

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by federal regulations and the Drexel University Institutional Review Board (IRB). Investigators are required to obtain legally effective informed consent from a subject or the subject's LAR unless the requirement has been waived by the IRB. When informed consent is required, it must be sought prospectively and properly documented.

The informed consent process involves three key features:

1) disclosing to the prospective human research subject information needed to make an informed decision;
2) facilitating the understanding of what has been disclosed; and
3) emphasizing to the prospective human research subject that participation in the research is voluntary.

Informed consent is more than just a signature on a form. It is a process of information exchange to include reading, discussion, receiving answers to any questions, and signing the consent document. The informed consent process is the critical communication link between the prospective human research subject and an Investigator, beginning with the initial approach of an investigator and continuing through the completion of the Research study. Investigators must have received the appropriate training and be knowledgeable about the study protocol in order that they may answer questions to help provide understanding to the human research subject or prospective human research subject.

The exchange of information between the investigator and prospective human research subject can occur via one or more of the following modes of communication, among others:

- face-to-face dialogue;
- video conference;
- mail;
- email;
- telephone; or
- fax.

However, obtaining informed consent must allow for a dialogue so that the prospective human research subject has sufficient opportunity to ask questions and receive responses when considering whether or not to participate. Investigators must obtain consent prior to entering a human research subject into a study, gathering data about a human research subject, and/or conducting any procedures required by the research plan, unless consent is waived by the IRB.

If someone other than the Principal Investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process and must have the expertise to be able to answer questions about the study including those regarding risks, procedures, and alternatives.

Sample or draft consent documents may be developed by a sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that are presented to the prospective human research subject. The prospective human research subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective human research subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts but rather facilitates the prospective human research subject's or LAR's understanding of the reasons why one might or might not want to participate.

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective human research subject without the informed consent of the prospective human research subject or LAR, if either

1) the investigator will obtain information through oral or written communication with the prospective human research subject or LAR; or
2) the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

These informed consent requirements are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for informed consent to be legally effective.

4. Informed Consent Process

Informed consent must be obtained under the following circumstances:

1) Informed consent may only be obtained from prospective human research subjects who have the legal and mental capacity to give consent. For prospective human research subjects without that capacity, permission must be obtained from a legal guardian or a LAR. See Section 5 below.
2) The informed consent process provides the prospective human research subject (or LAR) with sufficient opportunity to read the consent document, when applicable.
3) The informed consent process must be sought under circumstances that provide the prospective human research subject (or LAR) with sufficient opportunity to consider whether or not to participate.
4) The informed consent process must be sought under circumstances that minimize the possibility of coercion or undue influence.
5) The informed consent information must be presented in language that is understandable to the prospective human research subject (or LAR). To the extent possible, the language should be

understandable by a person at a reading level appropriate for the target population and must use layman's terms to describe the research.

6) For prospective human research subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the prospective human research subject (or the prospective human research subject's LAR). In accordance with these procedures, the IRB requires that informed consent discussions include a reliable interpreter when the prospective human research subject does not understand the language of the person who is obtaining consent.
7) The informed consent process may not include any exculpatory language through which the prospective human research subject is made to waive or appear to waive any of the prospective human research subject's legal rights or through which the investigator, the sponsor, the Organization, or Drexel University employees or agents are released from liability for negligence or appear to be so released.
8) The investigator is responsible for ensuring that each prospective human research subject is adequately informed about all aspects of the research and understands the information provided.

5. Who Can Act as an LAR for a Decisionally Impaired Research Subject in Pennsylvania?

Pennsylvania laws do not directly address human research requirements specific to LARs for decisionally impaired individuals. The Drexel IRB follows federal regulations, guidance from the U.S. Office for Human Research Protections (OHRP), and the Pennsylvania Code, to determine if state laws are relevant in the research context. These procedures will be followed to determine who would be considered an acceptable LAR for purposes of providing surrogate consent for decisionally impaired human research subjects in studies conducted in Pennsylvania.

While Pennsylvania statutory law does not explicitly authorize substituted consent in the absence of a power of attorney or court-appointed guardian, case law strongly supports substituted consent by close family members when patients lack capacity to make medical decisions. When the subject is unable to give informed consent, the subject's close family member or significant partner is in the best position to determine the wishes of the subject regarding participation in therapeutic research.

The following individuals may be considered legally authorized representatives of the subject and capable of providing surrogate consent:

1) Court-appointed legal guardian authorized to consent to the subject's participation in research in a current court order issued within the subject's jurisdiction.
2) A health care power of attorney (HCPOA)
3) A "health care representative" when the subject cannot speak for themselves and where there has been no guardian appointed by the court or HCPOA designated by the patient. Any member of the following classes, in descending order of priority, who is reasonably available may act as the subject's health care representative.
    a) The subject's spouse (unless an action for divorce is pending) and adult children or children of another relationship;
    b) Adult children (18 years of age or older);
    c) A parent;
    d) An adult sibling;
    e) An adult grandchild;

f) An adult who has knowledge of the patient’s preferences and values, including but not limited to religious and moral beliefs, to assess how the patient would make decisions.

If there is any doubt as to which individual is the legally appropriate authorized representative for the subject, the Office of General Counsel must be contacted.

NOTE: The investigator should obtain a copy of the court order, HCPOA, or durable power of attorney and should maintain the copy with the research records as documentation of the authority of the surrogate decision maker.

Beyond the categories described above, others may not give surrogate consent for research enrollment. Institutional custodians or caretakers are not legally authorized representatives in the absence of a specific court appointment granting them guardianship.

6. Determining a Potential Adult Subject’s Ability to Consent to Research

In the absence of a specific legal or medical finding to the contrary, the individual human research subject must be presumed to have decision making power for themselves and must give consent, informed to the best ability of the research team. If there is any doubt as to the human research subject's capacity to consent, the investigator and the IRB should consider the need for independent assessment of capacity (e.g., psychiatric consult). If the human research subject does not have decisional capacity and the IRB has approved enrollment via surrogate consent, consent should be obtained from the highest available surrogate representative as described below.

There is an important distinction between the legal meaning of the term “incompetent” and the broader use of the term “decisionally impaired” in these procedures. Decisionally impaired persons are those who, due to a psychiatric, organic, developmental, or other disorder or situation that affects cognitive or emotional functions, are unable to exercise independent decision making. “Incompetence” is a finding of a court of law that results in the appointment of an LAR for the individual judged incompetent by the court (see “court appointed guardian” below). Persons who have been judged “incompetent” in a court of law are only a subset of the larger group of persons who may be decisionally impaired.

Decisional impairment in a human research subject may be determined in several ways:

1) A court finding of incompetence;
2) A physician’s or, in the case of mental health treatment, an eligible psychologist’s determination; or
3) An investigator or independent consultant’s determination, based on methods described in the IRB application and/or protocol, such as standardized assessments of decisional capacity or a quiz used to assess the prospective participant’s knowledge of the study as described during the informed consent process. Standardized assessments that may be appropriate include MacArthur Competence Assessment Tool for Clinical Research or the University of California, San Diego Brief Assessment of Capacity to Consent.

If a court finding of incompetence is not available, and the methods used to assess decisional capacity described in the IRB-approved protocol are not conclusive such that it’s unclear whether the prospective participant is decisionally impaired, then informed consent should be obtained from both the prospective participant and the appropriate legally authorized representative.

For the purpose of this procedure, a prospective human research subject has the capacity to consent to their own participation in a research activity if the prospective human research subject demonstrates an appreciation:

1) That the activity is research;
2) Of the risks and benefits of a study;
3) Of the study procedures and requirements;
4) Of the alternatives that are available if not participating; and
5) That, by choosing not to participate, this decision will be accepted without penalty.

In reaching a decision about participation, it is essential for the prospective human research subject to demonstrate an ability to use this information in a rational manner. Thus, in considering risks, benefits, and available alternatives, prospective human research subject must show they understand the aspects of these factors that are unique to them as individuals.

See additional procedures for Vulnerable Subjects in Research for further discussion regarding adults who cannot consent for themselves.

The decision-making capacity of a prospective human research subject should be evaluated when there are reasons to believe that the prospective human research subject may not be capable of making voluntary and informed decisions about research participation.

The investigator and research staff must have adequate procedures in place for assessing and ensuring prospective human research subjects' capacity, understanding, and informed consent or assent. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate including consideration of state and local law and organizational policy.

It is often possible for investigators and others to enable persons with some decisional impairments to make voluntary and informed decisions to consent, assent, or refuse participation in research. Potential measures include repetitive teaching, group sessions, audiovisual presentations, and oral or written recall tests. Other measures might include follow-up questions to assess the prospective human research subject's understanding, videotaping or audiotaping of consent interviews, second opinions, use of independent consent observers, allowing a waiting period before enrollment, or involvement of a trusted family member or friend in the disclosure and decision-making process.

Both investigators and IRB members must be aware that for some prospective human research subjects, their decision-making capacity may fluctuate. For prospective human research subject with fluctuating decision-making capacity or those with decreasing capacity to provide consent, periodic reevaluation of capacity and re-consent or consent for continuing participation by a LAR may be necessary.

In the event that a human research subject loses or becomes impaired in decision-making capacity after enrollment, and this is not anticipated in the research plan, the investigator is responsible for notifying the IRB. The investigator is responsible for developing a plan for the IRB's consideration which follows the guidelines outlined above for persons with fluctuating or diminishing capacity.

Whenever a prospective human research subject has the capacity to give consent (as determined by qualified professionals), informed consent should be obtained and documented in accordance with Section 4 above. When a prospective human research subject lacks the capacity to give consent, investigators may obtain consent from the LAR of the prospective human research subject as described in the HRP procedures for Vulnerable Subjects in Research.

When assent is possible for some or all prospective human research subjects, the investigator should provide the IRB with an assent plan that describes when and how assent will be obtained, provisions that will be taken to promote understanding and voluntariness, and how assent will be documented. Under no circumstances may a prospective human research subject be forced or coerced to participate.

If the investigator plans to use audio or videotapes, computer video presentations, or written materials, to promote understanding, these materials must be provided to the IRB for review. If the investigator intends to use audio or video recordings to document assent, provisions to ensure the security of the recordings should be described to the IRB. If the investigator will use an assent form to document assent, this must be submitted to the IRB for review.

7. Basic Elements of Informed Consent

To be valid, the consent process must provide all of the following basic elements of information to prospective human research subjects:

1) For studies regulated under the Revised Common Rule (45 CFR 46) the consent must begin with a concise summary of key information most likely to assist a prospective human research subject or their LAR in understanding the reasons why a prospective human research subject might or might not want to participate in the research.
2) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the prospective human research subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
3) A description of any reasonably foreseeable risks or discomforts to the prospective human research subject.
4) A description of any benefits to the prospective human research subject or to others which may reasonably be expected from the research.
5) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective human research subject.
6) A statement describing the extent, if any, to which confidentiality of records identifying the prospective human research subject must be maintained.
7) 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.
8) 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 prospective human research subject.
9) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the prospective human research subject is otherwise entitled, and the prospective human research subject may discontinue participation at any time without penalty or loss of benefits to which the prospective human research subject is otherwise entitled.
10) For studies regulated under the 2018 Common Rule (45 CFR 46), one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    a) 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 prospective human research subject or the LAR, if this might be a possibility; or

b) A statement that the prospective human research 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.

11) For U.S. Food and Drug Administration (FDA)-regulated studies, a statement that notes the possibility that the Food and Drug Administration may inspect the records;
12) For "applicable" FDA-regulated clinical trials or NIH-funded clinical trials, the following statement must be included verbatim: "A description of this clinical trial will be available on [https://www.ClinicalTrials.gov,](https://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."
   a) In general, "applicable" clinical trials mean:
      i) controlled clinical investigations, other than Phase 1 clinical investigations of a drug or biologic; and
      ii) prospective clinical studies of health outcomes comparing an intervention with a device against a control.
   b) This definition excludes the following:
      i) small clinical trials to determine the feasibility of a device;
      ii) a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes; and
      iii) mandated pediatric post market surveillance activities.

Additional elements of informed consent to be applied, as appropriate:

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;
2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3) Any additional costs to the subject that may result from participation in the research;
4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
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;
6) The approximate number of subjects involved in the study;
7) A statement that significant new findings developed during the course of the research that may related to the subject's willingness to continue participation will be provided to the subject;
8) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
9) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
10) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

8. Documentation of Informed Consent

Except as provided in Section 11 of this document, informed consent must be documented by the use of a written consent form approved by the IRB.

1) Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the prospective human research subject or the prospective human research subject's LAR at the time of consent. The person obtaining consent will also sign and date the consent form.
2) A copy of the consent form must be given to the person signing the form. The investigator should retain the signed original in the research records. Sponsor or funding requirements may require a copy of the signed and dated consent form to be given to the participant per Good Clinical Practice Guidelines.
3) The consent form may be either of the following:
    a) A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the prospective human research subject or the prospective human research subjects LAR, but the prospective human research subject or LAR must be given adequate opportunity to read it before it is signed; or
    b) A short form written consent document stating that the elements of informed consent have been presented orally to the prospective human research subject or the prospective human research subject's LAR.

A *short form* may be used when consenting non-English speakers or illiterate prospective human research subjects. The short form should be used when you do not anticipate enrolling non-English speakers. If you anticipate enrolling non-English speakers, the consent form must be translated into the prospective human research subject's native language. The short form is *not* to be used when a study team has simply failed to make provisions for translated versions of the consent document in commonly spoken languages in the recruitment area/population. If the prospective human research subject is blind, the consent form may be read to the prospective human research subject or the use of an audio version of the consent form (audiotape, digital audio format (e.g., MP3), etc.) should be considered.

Federal regulations (21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2)) permit oral presentation of informed consent information in conjunction with a *short form* written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required and the prospective human research subject must be given copies of both the short form document and the summary.

When this method of consent is used, there are additional regulatory requirements that must be followed. These include:

- The IRB must approve the full version of the consent form documents (or summary of information to be orally presented to the subject) including stored specimens and HIPAA authorization forms.
- The short forms available on the IRB website are considered IRB-approved documents. Several different languages are available. These short forms do not need to be submitted separately to the IRB for approval as *only* the study and contact information should be edited. The short form must be used in conjunction with the IRB-approved consent documents.

- A witness to the oral presentation must be present. The witness may be the interpreter, if one is used, or an independent third party. When consenting non-English speaking prospective human research subjects, the witness must be bilingual in order to verify the exchange.
- **Required signatures:**
    - The short form must be signed by the prospective human research subject (or the prospective human research subject's LAR) and the witness/interpreter.
    - The full version of the consent documents must be signed by the witness/interpreter and the person obtaining consent.

Investigators should carefully consider the ethical/legal ramifications of enrolling human research subjects when a language barrier exists. If a prospective human research subject does not clearly understand the information presented, the prospective human research subject's consent will not truly be informed and may not be legally effective. In addition, interpreters must be available for studies in which there is ongoing contact with the human research subject in order to facilitate study procedures, reporting of problems, etc.

If a short form is not available in the language spoken by the prospective human research subject, investigators must have the full version of the consent document translated prior to enrolling the prospective human research subject.

Requirements for the documentation of informed consent may be achieved through an electronic informed consent process (eIC). The Drexel University IRB follows the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) guidance for the use of eIC.

9. Special Consent Circumstances

The IRB should include procedures to ensure that prospective human research subjects are not excluded from potentially beneficial research due to barriers such as language and physical disabilities. At the same time, in order to ensure that a human research subject's welfare is protected throughout the participation, prospective human research subjects should not be enrolled if they may not be able to communicate with the investigator on an ongoing basis.

9.1 Enrollment of Persons with Limited English-Language Proficiency

Expected Enrollment

In some studies, the investigator may be able to anticipate enrollment of persons who do not speak or read, or have limited proficiency in, oral or written English. When the target subject population includes such persons or the investigator and/or the IRB otherwise anticipates that consent will be conducted in a language other than English, the IRB requires a translated consent document, and other subject materials, to be prepared. In order to ensure that translated documents are accurate, the IRB may choose to require a certified translation, to have an independent back-translation or to have a review of the translated documents by an IRB member or other person who is fluent in that language. When non-English speaking human research subjects enroll, the non-English speaking human research subject and a witness sign the translated consent document. The non-English speaking human research subjects are given a copy of the signed translated consent document.

Unexpected Enrollment

If a person who does not speak, read, or has limited proficiency in English presents for possible enrollment, an IRB-approved translated version of the written consent may not be available for use. Investigators should carefully consider the ethical and legal ramifications of enrolling human research subjects when a language barrier exists. If the prospective human research subject does not clearly understand the information presented during the consent process or in subsequent discussions, the prospective human research subject's consent may not be informed, and therefore, not effective.

If an investigator decides to enroll a human research subject into a study for which there is not an extant IRB-approved consent document in the prospective human research subject's language, the investigator must utilize the IRB-approved short form template, available on the Drexel website and follow procedures for a "short form" written consent process as described in Section 8.

Use of Interpreters in the Consent Process

Unless the person obtaining consent is fluent in the prospective human research subject's language, an interpreter will be necessary to facilitate the consent discussion. Preferably someone who is independent of the prospective human research subject (i.e., not a family member) should assist in presenting information and obtaining consent. Whenever possible, interpreters should be provided copies of the translated consent, or short form and the IRB-approved consent script (typically the English-language version of the consent document) well before (24 to 48 hours if possible) the consent discussion with the prospective human research subject. If the interpreter also serves as the witness, the interpreter may sign the translated consent, or short form consent document and script, as the witness and should note "Interpreter" under the signature line. The person obtaining consent must document that the "short form" process was used in the human research subject's research record, including the name of the interpreter.

9.2 Oral Consent

When prospective human research subjects are unable to read a written consent form (such as blind or illiterate subjects), the IRB may approve an oral consent process, provided the prospective human research subject:

1) retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained orally, and
2) is able to indicate approval or disapproval to study entry.

For research that is no more than minimal risk, documentation of consent may be waived according to the criteria in Section 11.

For greater than minimal risk research, the consent form must be read to the prospective human research subjects and the prospective human research subjects must be given an opportunity to ask questions. An impartial witness should be present during the entire informed consent discussion. An audiotape approved by the IRB may also be used. If capable of doing so, the prospective human research subject signs, or marks an X to signify consent. If that is not possible, the prospective human research subject will provide oral consent. The person obtaining consent and the witness will sign the written study consent form with a statement that documents that an oral process was used and, if necessary, that the prospective human research subject gave oral consent. The consent process will also be documented in the human research subject's research record. Signed copies of the consent form are given to the prospective human research subject and, whenever possible, these documents should be provided to the prospective human research subject on audio or video-tape.

10. Subject Withdrawal or Termination

For a variety of reasons, a human research subject enrolled in a research study may decide to withdraw from the research, or an investigator may decide to terminate a human research subject's participation in research regardless of whether the human research subject wishes to continue participating. Investigators must plan for the possibility that human research subjects will withdraw from research and include a discussion of what withdrawal will mean and how it will be handled in their research protocols/research plans and consent documents.

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

- For FDA-regulated clinical trials: when a human research subject withdraws from a study, the data collected on the human research subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the prospective human research subject the option of having data removed.
- For research not subject to FDA regulations: the investigator should inform prospective human research subjects whether the investigator intends to either:

    1) retain and analyze already collected data relating to the human research subject up to the time of the human research subject's withdrawal, or
    2) honor a human research subject’s request that the investigator destroy the human research subject's data or that the investigator exclude the human research subject's data from any analysis.

When a human research 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 human research subject previously gave consent may continue. Investigators should ask a human research subject who is withdrawing whether the human research subject wishes to provide continued follow-up and further data collection subsequent to the human research subject's withdrawal from the interventional portion of the study.

Under this circumstance, the discussion with the human research subject would distinguish between study-related interventions and procedures and continued follow-up in person, by phone, or via records review, of data and address the maintenance of privacy and confidentiality of the human research subject's information.

If a human research subject withdraws from the interventional portion of the study but agrees to continued follow-up as described in the previous paragraph, the investigator must obtain the human research subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original consent document). IRB approval of consent documents for these purposes would be required.

If a human research subject withdraws from the interventional portion of a study and does not consent to continued follow-up, the investigator must not access or gather private information about the human research subject for purposes related to the study. However, an investigator may review study data related to the human research subject collected prior to the human research subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

11. Waiver of Informed Consent

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the prospective human research subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the prospective human research subjects;
3) The research could not practicably be carried out without the waiver or alteration;
4) If the research involves using identifiable private information or identifiable biospecimens, or the research could not be practicably carried out without using such information or biospecimens in an identifiable format;
5) Whenever appropriate, the human research subjects or LARs will be provided with additional pertinent information after participation.

For research involving public benefit and service programs conducted by or subject to the approval of state or local officials, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1) The research or demonstration project will be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    a) Public benefit or service programs;
    b) Procedures for obtaining benefits or services under those programs;
    c) Possible changes in or alternatives to those programs or procedures; and/or
    d) Possible changes in methods or levels of payment for benefits or services under those programs; and
2) The research could not practicably be carried out without the waiver or alteration.

FDA regulations do not provide for waivers of informed consent except in certain emergency situations.

12. Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all prospective human research subjects, for some or all research activities, if it finds that:

1) The only record linking the prospective human research subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.
    a) *Note 1*: Prospective human research subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the human research subject is talking to investigators.)

   b) *Note 2*: In order to waive written documentation of consent where the only record linking the human research subject and the research would be the consent document, the research cannot be FDA-regulated.

2) The research presents no more than minimal risk of harm to prospective human research subjects and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-investigators (e.g., marketing surveys, telemarketing).
   a) *Note*: The FDA does permit a waiver of documentation of consent if this condition is satisfied. This is most commonly applied in the context of minimal risk screening activities that are necessary to determine eligibility for enrollment in the full trial.
3) If the prospective human research subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that 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.

Unless the IRB has granted a full waiver of the requirement to obtain informed consent, investigators who seek and receive approval for a waiver of documentation of consent still must perform an adequate consent process.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the prospective human research subject, and the IRB will consider whether to require the investigator to provide prospective human research subjects with a written statement regarding the research. The IRB must document its findings justifying the waiver or alteration.

13. Consent for Use of Stored Samples and Genetic Testing

In general, all anticipated uses of collected samples of human tissues, body fluids, or biological products should be carefully delineated in the study procedures section of the consent form. Issues to be addressed might include the specific information to be obtained, whether the information may be of value to the prospective human research subject, whether and how that information will be disclosed or made available to the prospective human research subject and whether genetic counseling will be available at the prospective human research subject's option.

If specimens are to be collected and stored for future unspecified purposes (genetic testing or otherwise), this should be addressed in the study procedures section of the consent form.

The consent form and process for maintaining human specimens in a repository for future research uses must inform the prospective human research subjects explicitly about the unspecified possible future use of the specimens and related personal information. The consent process should consider all of the following:

- The sample will be stored and possibly used in future research studies.
- A description of any personal information about the specimen source that will be maintained (this may or may not include identifiers).
- If no personal identifiers will be used for labeling the stored samples, i.e., if it is impossible for the sample to be linked with the prospective human research subject, the consent form should so state.

- If personal identifiers are to be used that will allow future matching of the prospective human research subject to the collected sample, the consent form should describe how the samples will be used, how privacy and confidentiality will be protected, and whether and under what circumstances identifying information would be disclosed.
- Future research using the samples will be reviewed by the IRB prior to additional use of the samples.
- Whether and how researchers may contact human research subjects whose specimens are in the repository.
- A statement about any potential commercialization and that there are no plans for human research subjects to share in financial proceeds that may accrue from products derived from the specimens.
- Whether, how, and under what circumstance results from research studies using the specimens would be communicated to the human research subjects and, where relevant, to their family members).
- If specimens are individually identifiable, how the specimens and associated data may be withdrawn from the repository. If the specimens are not individually identifiable, a statement that they may not be withdrawn for that reason. Specimens that have already been used and the data derived from their use cannot generally be withdrawn.
- The planned length of storage for specimens.
- Storage location.

14. Consent for Inclusion in Research Registry

A research registry is a database of prospective human research subjects who have indicated their willingness to participate in research studies. Prospective human research subjects must consent to inclusion in the registry. However, researchers may use a staged consent process in which preliminary consent is granted by prospective human research subjects when they are included in the registry and additional consent is obtained when those prospective human research subjects participate in a study.

15. Disposition of Consent Documents

As noted above, each prospective human research subject or their LAR must sign and date the consent form prior to participating in the study, unless this documentation is waived by the IRB. A copy of the signed consent form (photocopy or duplicate signed original) must be given to the person signing the form. An original signed consent form should be retained in the investigator’s files. See HRP procedures for Investigator Responsibilities for additional information regarding investigator responsibilities related to record retention.

15.1 Research Consent Forms in Health Care Records

An informed consent document for research participation is not a health care document and ordinarily would not be included in a health care record. Similarly, other forms of information about research interventions that are not health care would not ordinarily be included in an individual’s health care record. There may be additional requirements of the applicable health system regarding the inclusion of signed authorizations in the electronic medical record.

However, some clinical research includes health care. Additionally, information about some research interventions, whether or not treatment-related, may be relevant to a health care provider's diagnosis and treatment decisions about the individual. For example, it may be important for a health care provider not associated with the research study to know that a patient is receiving drugs or interventions as part of a research protocol. In these circumstances it may be appropriate for the consent form to be included in the health care record.

At the time of the review, the IRB, in consultation with the PI, should make a determination as to the appropriateness of including the consent form in the human research subject's health care record. Conversely, there may be circumstances where it is inappropriate to include the consent form in a human research subject's health care record, and specific mechanisms should be in place to exclude research information from the health care record (e.g., when research participation is not relevant to ongoing health care but might disclose sensitive personal information such as sexual preferences). If the decision is made to include the consent form in the human research subject's health care record, then the informed consent and HIPAA authorization for the study should state that this information will be placed in the human research subject's health care record.

In determining whether research participation records will be placed in the health care record, IRBs and investigators should consider several points. Although protection of the human research subject's health and safety by providing research participation information to a health care provider is an appropriate concern, there are also other human research subject welfare issues to be considered, particularly privacy and confidentiality. Some human research subjects will not want information about their research participation to be shared with their healthcare provider for a variety of reasons including personal privacy or the concern that the information may be transmitted to a health insurer or employer. These are the very privacy and confidentiality concerns that underlie the HIPAA regulations giving patients the right to know what is in their health care record and to control disclosure of their PHI from the health care record.

16. Record Retention of Informed Consent Forms

As with all protocol related materials, a copy of the approved consent documents (not the signed consent forms themselves) should be retained by the IRB for a minimum of three (3) years following the end of the study. Refer to additional HRP procedures on Investigator Responsibilities and Drexel University's Records Management Program Master Schedule for more information on records retention requirements.

17. Responsibilities

17.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, approving waivers, and monitoring. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

17.2 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate approvals and oversight, obtaining informed consent from research participants, and submitting the applicable documentation to the HRPP/IRB and study sponsor.

18. Resources

- DHHS Use of Electronic Informed Consent
- Drexel Records Management Program Master Schedule
- Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) guidance for the use of eIC
- U.S. Code of Federal Regulations - 21 CFR 50.27(b)(2): Documentation of Informed Consent
- U.S. Code of Federal Regulations - 21 CFR 312.57: Recordkeeping and Record Retention
- U.S. Code of Federal Regulations - 21 CFR 812.140: Records
- U.S. Code of Federal Regulations - 45 CFR 46: Protection of Human Subjects
- U.S. Code of Federal Regulations - 45 CFR 46.117(b)(2)): Documentation of Informed Consent

19. Revision

*Please note that this document corresponds to former guidance documents HRP-802 Informed Consent and HRP-803 Documentation of Informed Consent.

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