1. OBJECTIVE

The informed consent document and process is central to the responsible conduct of human subjects research. This policy identifies the key components of the informed consent document and process.

Specific Procedures

Researchers may not involve human beings as subjects in research unless the researcher has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). Exception to this policy requires that the IRB grant a waiver or modification of the informed consent requirement.

- A researcher shall seek informed consent from the prospective subject or LAR only under circumstances that provide sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the prospective subject or LAR (whether orally or in writing) shall be in language understandable to the subject or LAR.
- The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision, and an opportunity to discuss that information.
- 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 subject's or LAR's understanding of the reasons why one might or might not want to participate.
- **For consent forms longer than 3 pages**, informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research, and must be organized and presented in a way that facilitates comprehension. Research which is regulated by the FDA (i.e. subject to 21 CFR 50 and 21 CFR 56), and not conducted, supported, or otherwise subject to regulation by another Federal department or agency, is encouraged but not required to include the concise and focused presentation in the consent process.
- Informed consent (whether oral or written) may not include any exculpatory language through which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or that releases or appears to release the researcher, the sponsor, the institution, or its agents from liability for negligence.

Elements of informed consent

Unless altered or waived by the IRB, the following information shall be provided to each subject or LAR:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subjects.
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, including a statement that notes the possibility that specific regulatory authorities (e.g., HHS, FDA, ED, DoD, DOJ as applicable) may inspect the records;
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Language limiting the subject's right to withdraw from the study is not permitted; and
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - 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 researcher for future research studies without additional informed consent from the subject or the 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.

Unless altered or waived by the IRB, one or more of the following additional elements shall also be provided to each subject or the LAR, when appropriate:

- 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) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's or the LAR's consent;
- For studies involving payment for subject participation, a payment statement explaining details and any conditions of payment;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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;
- The approximate number of subjects involved in the study;
- 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;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- 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).

The following information must be provided when applicable:

- When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), a statement notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act;

- If a researcher has a financial interest related to a research study, a statement regarding the financial interest and its management;
- If NIH-funded or a Certificate of Confidentiality has been granted, statement regarding Certificate of Confidentiality protections;
- If the research involves genetic information, statement describing the Genetic Information Nondiscrimination Act (GINA); or
- If the radiation/radioactive materials are used for research purposes, radiation risk language.
- For studies conducted or supported by the U.S. Public Health Service (PHS) involving HIV testing, PHS requires that subjects whose test results are associated with personal identifiers be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception under special circumstances.

The IRB may require that additional information be given to subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

Waiver or alteration of consent

The IRB may waive the requirements to obtain informed consent, or approve a consent procedure that omits some, or alters some or all, of the elements of informed consent if the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the requested waiver or alteration; and
- Whenever appropriate, the 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, the IRB may waive the requirement to obtain informed consent, or approve a consent procedure that omits some, or alters some or all, of the elements of informed consent if the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine:
    - public benefit of service programs;
    - procedures for obtaining benefits or services under those programs;

    - possible changes in or alternatives to those programs or procedures; or
    - possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

Documentation of informed consent

Unless the IRB grants a waiver of documentation of informed consent as described below, informed consent will be documented by the use of an IRB-approved, written consent form, signed and dated by the prospective subject or prospective subjects' LAR at the time of consent. A copy shall be given to the person signing the form.

The consent document should be a written informed consent form that meets the requirements of this policy. The researcher shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's LAR.

Unless waived, informed consent should be documented as follows:

- Subjects who are willing to participate in research must sign a copy of the IRB-approved and electronically stamped informed consent statement prior to participating in research procedures.
    - Signature may be provided via physical, "wet" signature, a physical or digital copy of a wet signature, or verified electronic signature via encrypted digital signature, observed electronic signature, electronic signature pad, voice print, digital fingerprint, or signature made with a fingerprint on a touchscreen.
    - If the consent conversation is not conducted face-to-face, the subject may electronically submit or mail a signed copy of the informed consent document to the research site (preferably to the interviewer and/or researcher). Unless the IRB approves otherwise, the study team must receive a copy of the signed document prior to beginning research procedures.
    - If the subject is physically unable to provide a signature, they should make a mark on the informed consent document and the study team should document the circumstances. If the subject is unable to make a mark, an impartial witness should witness the documentation process and sign the consent document.

- The subject (or LAR) must enter the date of signature on the consent document to permit verification that consent was actually obtained before the subject began participation in the study. The subject's research record and/or medical records should document that the consent process occurred prior to participation in the research.
- The person conducting the consent interview must also sign and date the informed consent document as the "person obtaining consent". The signature of the PI is not required on the consent document, unless he/she is the person conducting the consent interview.
- If the subject wishes to take the consent document home in order to review it and/or further consider participation in the research study before signing, the person obtaining consent may sign the consent document when the consent is presented to the subject. The subject may sign the consent document at a later time after making a decision to participate.

The IRB may waive the requirement for the researcher to obtain a signed informed consent form for some or all subjects if it finds either of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

For FDA-regulated research, the IRB may waive the requirement that the subject or the subject's LAR sign a written consent form only if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In cases in which the documentation requirement is waived, the IRB may require the researcher to provide subjects or LARs with a written statement regarding the research.

IRB review and approval

The informed consent process shall be described in the BYU IRB Questionnaires and an informed consent document provided for the IRB's review and approval, when appropriate. The IRB will review the information and ensure that all requirements consistent with this policy are met. To ensure that subjects' consent is voluntary, the IRB will consider whether any undue pressures, including

excessive payment, will be brought to bear on potential subjects. Such pressure may be subtle as, for example, when a teacher asks his/her own students to become subjects of his/her research. Upon approval, the consent statement will be electronically stamped.

Informed consent process

The PI is ultimately responsible for ensuring consent is obtained but may delegate this responsibility to members of the study team who are appropriately trained to obtain consent and provide information about the study.

The informed consent process should be conducted via a conversation between the study team and the prospective subject, unless the IRB approves a consent process which does not include a conversation. The informed consent document provides a guide for the informed consent conversation and provides the subject with information which can be referenced later. If the consent conversation cannot be conducted face-to-face, the informed consent process may be conducted over the telephone or via other electronic means. The subject should be provided with a copy of the informed consent document prior to the conversation so they can review during the discussion.

Subjects who can understand and comprehend spoken English but are unable to read the informed consent document for any reason (e.g. illiteracy, blindness or diminished vision, dyslexia, unable to obtain a copy of the consent document for review, etc.) may be enrolled in a study; however, special care must be taken to ensure the individual is able to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained orally.

- The study team must present the information orally and document the circumstances.
- An impartial witness must observe the entire consent process and sign the consent document. Although not required, a video recording of the consent interview is recommended.

Informed Consent Procedures for Non-English-Speaking Subjects

- Informed consent information provided to subjects or the subjects' LAR must be in a language understandable to the subject or the LAR. As such, the consent conversation and informed consent document should be in a language understandable to the subject (e.g. in the subject's first language or a language in which the subject is fluent).
- If the researcher anticipates that non-English-speaking individuals will likely be enrolled in the study, plans for language-appropriate consent procedures should be considered and described in the IRB submission. If a non-English consent document is provided for IRB

review and approval, the IRB will require certification that the translated documents are correct or documentation that the non-English versions have been reviewed by an expert in the required language.

Informed Consent Procedures with Special Populations

Because of the special vulnerability of certain populations of subjects (including children, prisoners, pregnant women, individuals lacking consent capacity, and transnational participants), federal regulations, state and local laws, and institutional policies require additional protections regarding their consent to participate in a research study.

Revisions to the Informed Consent Document

- Revisions to the informed consent document must be reviewed and approved by the IRB prior to implementation.
- Newly enrolled subjects must sign the most recently approved version of the consent document.
- When submitting a revised consent document for IRB review and approval, the study team must notify the IRB whether previously-enrolled subjects will be notified of the new information and, if so, the timing and mechanism of the notification. The IRB will consider the study team's plan for notification and ensure its appropriateness.
- If the study team is aware of new or increased risks that are not reflected in the current IRB-approved consent document, study teams must not enroll new subjects until the revised informed consent document is available.
- If the IRB agrees that previously-enrolled subjects should be re-consented using the new informed consent document, the re-consent process should be documented and a note made in the subject's record when the re-consent process is completed. The original, signed new consent document must be retained in the study records and a copy provided to the subject (or LAR). Any previously signed consent documents should be retained and not discarded.

When a Subject Withdraws from Research

If a subject wishes to discontinue participation in the research, data collected on the subject to the point of the subject's withdrawal from a study remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

If a subject wishes to discontinue participation in the research and the researcher would like to continue to follow the subject's health and collect clinical data from his/her medical records, a

separate IRB-approved informed consent containing all required elements must be developed and presented to the subject at the time of his/her withdrawal from the study requesting this follow-up to be done. The subject must give permission (i.e., sign this separate informed consent document) in order for clinical data to be collected. If the subject declines to consent to the follow-up, the researcher must not access the subject's medical record or other confidential records for purposes related to the research, but may consult public records, such as those establishing survival status.

2. SCOPE

The policies and procedures apply to all non-exempt human subjects research conducted by BYU researchers that include informed consent document(s) and process.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116, 46.117
21 CFR 50.25, 50.27, 56.109(b)-(d)
FDA Guidance, IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects (July 2017)
82 Fed. Reg. 7,149, 7,265 (Jan. 19, 2017) (to be codified at § _.116).
83 Fed. Reg. 2,885 (Jan. 22, 2018).

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.