Informed Consent and Assent

Purpose

The purpose is to outline the policies and procedures for the informed consent and child assent of human subjects (participants) in research.

General Requirements | Basic Elements | Additional Elements | Waiver or Alteration | Documentation | Waiver of Documentation

Parent/Guardian Permission and Child Assent | Posting of Clinical Trial Consent Form to Federal Website | Screening/Determining Eligibility

Definitions

Assent is an agreement to participate in a research study by subjects who are not competent to give legally-valid informed consent (e.g., children or cognitively impaired individuals); does not involve mere failure to object by the individual, absent affirmative agreement

Benefits are valued or desired outcomes that will be advantageous to the subjects participating, and/or to the field of study. Compensation or other incentives are not to be considered as benefits for subjects to weigh against risks when deciding whether or not to participate.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted, and who are usually under the age of eighteen (nineteen in Alabama and Nebraska, or twenty-one in Mississippi).

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo

or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Coercion is an overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance.

Debriefing is part of the informed consent process where the investigator provides subjects with previously undisclosed information (e.g., research employing deception or incomplete disclosure) about the research project following completion of their participation.

Deception is an intentional misleading of others through misrepresentation or falsehood, which may happen when an investigator provides research subjects with false information in order to obtain unbiased results.

Documentation of Informed Consent refers to use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to research or general medical care.

Human Subject (or Participant) means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Incomplete Disclosure occurs when an investigator withholds information about the specific purpose or nature of the research, usually to prevent bias in results.

Informed Consent is a process by which a knowing, legally effective agreement to participate in research is made by any individual or the individual's legally

authorized representative (LAR), and which may be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Legally Authorized Representative (LAR) means an individual or 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.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For prisoners, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Permission of a Parent/Guardian means the legally effective agreement of parent(s) or guardian to the participation of their child or ward in research.

Parent means a child's biological or adoptive parent.

Undue Influence is an offer of excessive or inappropriate compensation or other overture in order to obtain compliance.

NOTICE - Revised Common Rule (45 CFR 46)

Revisions to Federal regulations became effective January 21, 2019. While informed consent updates are included below, revisions largely involve:

- Inclusion of a summary of key information (for consent forms longer than three pages or involving complex procedures and/or risks)
- Presentation in sufficient detail for understanding reasons why or why not to participate
- For collection of identifiable, private information or specimens, what will happen regarding identifiers and use of de-identified data
- When appropriate for biospecimens:
    - Whether or not identifiers will be removed, and a statement about use for commercial profit and subject profit sharing
    - Whether the research will (if known) or might include whole genome sequencing
- When appropriate, a statement concerning return of clinically relevant results and conditions
- For informed consent waivers or alterations with identifiable information or biospecimens, justification for why the research could not practicably be carried out without using identifiers
- For screening, recruiting, or determining participant eligibility, added flexibility regarding informed consent requirements
- For Federally-funded clinical trials (new clinical trial definition), posting of one, IRB-approved informed consent form to one of two Federal websites

Policy

In order to ensure that all required elements and language are included, Marywood University's informed consent, parental/guardian permission, assent form or script, and advertising templates must be used. Templates may be found on the IRB or ERC's web pages. Documents which are part of the consent process should not include any type of organizational logos or word marks to ensure that undue influence to participate is minimized.

General Requirements for Informed Consent

The general requirements for informed consent are described below. Because no federal guidance has been issued, broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens at §46.116(d) is not being implemented at this time.

(1) Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the LAR shall be in language understandable to the subject or LAR. Language includes spoken communication and/or readability of informed consent materials, if included. Readability levels may be checked using most word processing software. Investigators should refer to our consent form readability tips for further information.

(4) The prospective 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.

(5) Presentation of Information:

(i) 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. This part of informed consent must be organized and presented in a way that facilitates comprehension. **NOTE:** Many IRB studies contain brief consent documents (two or three pages) that meet this new requirement without need of a separate key information section. However, if a project is complex or involves numerous research procedures and/or risks, this summary is required.

(ii) Sufficient detail about the research, organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

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

Basic Elements of Informed Consent

The following information shall be provided to each subject or the LAR:

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

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

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

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (e.g., medical treatments; ability to earn credits through an assignment for the Psychology Department's participant pool);

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; This includes an explanation of the retention period (at least 3 years; See Records Retention policy), who will have access to the records (i.e. if it is being shared with an agency or other investigators), where records will be stored (i.e. locked file), and if, when and how data will be destroyed;

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

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

(8) 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; for prisoner research, inclusion of a statement that the decision whether or not to participate will not affect parole or probation; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) 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 the LAR, if this might be a possibility; or

(ii) 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.

Additional Elements of Informed Consent (When Appropriate)

Except when an IRB allows a waiver or alteration of elements of informed consent, one or more of the following elements shall also be provided to each subject or the LAR, when 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) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR'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 that 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 the subject's biospecimens (even with removed identifiers) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) 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).

(10) If involving prisoners as a target population, a statement that the decision whether or not to participate will have no effect on his or her parole or probation

Parental/Guardian Permission and Child Assent

Research involving children under the age of eighteen (18) requires parental/guardian permission and its documentation, unless waived by the IRB**.** As with informed consent, information given to parents or guardians shall be in understandable language, including readability of written forms. Readability levels may be checked using most word processing software. Investigators should refer to consent form readability tips for further information.

When parental/guardian permission is to be obtained, the IRB may find that the permission of one parent/guardian is sufficient if:

- the research does not involve greater than minimal risk; or
- the research involves greater than minimal risk but presents the prospect of direct benefit to the individual child participants.

Permission from both parents/guardians must be obtained unless one is deceased, unknown, incompetent, or not reasonably available, or when only one has legal responsibility for the care and custody of the child when:

- the research involves greater than minimal risk with no prospect of direct benefit to individual child participants, but is likely to yield generalizable knowledge about the participant's disorder or condition; or
- the research is not otherwise approvable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the

intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

Where child assent is to be sought, investigators will typically use:

- a child assent form for children chronologically or developmentally aged seven (7) to seventeen (17), to be signed by each child; or
- a child assent script for children chronologically or developmentally under the age of seven (7), to be read to each child.

Wards

Children who are wards of the state or any other agency, institution, or entity may be included in minimal risk research or research which presents the prospect of direct benefit to the individual child, only if such research is:

- related to their status as wards, or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

The IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

General Waiver or Alteration of Informed Consent or Parental/Guardian Permission

Waiver

An IRB may fully waive the requirement to obtain informed consent or parental/guardian permission provided the IRB satisfies the requirements for a waiver or alteration listed below.

Alteration

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent or parental/guardian permission described in the basic and additional elements of informed consent sections above, provided the IRB satisfies the below requirements. An IRB may not omit or alter any of the requirements described under general requirements of informed consent.

Criteria for Waiver and Alteration

In order for an IRB to waive or alter consent, the IRB must find and document that:

(1) The research involves no more than minimal risk to the subjects;

(2) The research could not practicably be carried out without the requested 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 it 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 legally authorized representatives will be provided with additional pertinent information (debriefing) after participation.

IMPORTANT CONSIDERATIONS

- The FDA, which regulates studies of drugs, biologics, and medical devices, only allows full waivers or alterations of informed consent:
    - in life-threatening situations, when certain conditions are met (21 CFR 50.23)
    - in emergency research, when certain conditions are met (21 CFR 50.24)
    - when no more than minimal risk is posed, appropriate safeguards to protect the rights, safety and welfare of the subjects are present, and the IRB finds and documents the five above criteria for waivers or alterations
- Passive consent, whereby informed consent is assumed unless a subject, LAR or parent/guardian "opts out," is prohibited. For example, an investigator conducting school research cannot send a note home with a child and automatically enroll him/her unless the parent/guardian declines. Instead, a waiver of parental/guardian permission must be requested if it meets the above criteria. See OHRP's FAQs for Research with Children.

Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed (including in an electronic format) by the subject or LAR and the person obtaining consent, unless such documentation is waived by the IRB. A written copy shall be given to the person signing the informed consent form.

Federal regulations do not define "electronic format." However, it is important to note that just proceeding from an electronic informed consent form to a survey is not an electronic "signature" in and of itself. Several survey platforms offer

features which allow a subject to use a computer mouse or a finger to create an e-signature (e.g. REDCap or Qualtrics), and there may be other systems which identify and authenticate a particular person as the source of the electronic consent. It is the investigator's responsibility to become familiar with the features of his/her chosen platform or system, and to describe and enable them accordingly.

Except where waived, the informed consent form may be either of the following:

(1) A written informed consent form that meets the general requirements of informed consent (§46.116). The investigator shall give either the subject or the subject's legally authorized representative 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 legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Marywood University's informed consent, parental/guardian permission and assent form or script templates must be used to ensure that all required elements are met. Forms may be found on the Forms & Instructions web page. Forms should not include any type of organizational logos or word marks to ensure that undue influence to participate is minimized.

Waiver of Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(1) 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;

(2) 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

(3) If the 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.

This type of waiver is useful in situations where a signed consent document could have a negative consequence for the participants, or for some expedited studies utilizing telephone or Internet survey procedures, if no other law requires written consent or permission [45 CFR 46.117(c)].

Waiver of documentation does not eliminate the requirement for the informed consent process. The IRB may require the investigator to provide subjects or LARs with a written statement regarding the research, which follows our informed consent form template but eliminates the signature lines.

Posting of Clinical Trial Consent Form to Federal Website

For each clinical trial conducted or supported by a Federal department or agency (i.e. Federally funded), one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site which has been established as a repository for such informed consent forms [e.g. clinicaltrials.gov or as a docket folder on regulations.gov (docket ID: HHS-OPHS-2018-0021)]. See Clinical Trial Posting on OHRP's website.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

Preemption

The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

Screening, Recruiting or Determining Eligibility

An 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 subjects without the informed consent of the prospective subject or the subject's LAR, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or LAR, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

History

08/14/2013 - Updated minor language

01/21/2016 - Clarified and added link to OHRP's FAQ on parental permission

08/01/2017 - Added the alteration/waiver note for FDA, per FDA guidance issued July 2017

05/08/2019 - Incorporated Revised Common Rule provisions which were made January 21, 2019

05/16/2019 - Added anchors, information about wards, and prisoner required element

10/31/2019 - Added clarification about electronic signatures