Informed Consent

Purpose

1) This policy describes the general requirements for obtaining and documenting informed consent.

Policy

1) Researchers may only involve human participants in research when the legally effective informed consent has been obtained from the participant or the participant's legally authorized representative (LAR) (45 CFR 46.116, 21 CFR 50.20).

2) Exceptions to this policy include:

   a) Exempt research (since use of an information sheet would suffice)

   b) In circumstances where the IRB grants a waiver or modification of the informed consent requirement.

3) Researchers shall seek prospective informed consent from a participant or LAR after the individual has sufficient opportunity to discuss and consider their participation. Researchers must also minimize the possibility of coercion or undue influence.

   a) Researchers must describe how the informed consent process will be conducted, the setting in which it will occur, how long individuals have to consider participation, and methods to prevent undue influence.

   b) Researchers should consider informed consent as a process, not just a form, by which the research study is thoroughly explained to the potential participant. The requirement to obtain informed consent is an ethical obligation. Documentation of informed consent is accomplished through the use of a signed consent form. Electronic signatures are acceptable however for FDA-regulated research, the electronic record must comply with 21 CFR part 11. Marking a checkbox (or similar mechanism) by itself does not suffice as documentation of informed consent.

   c) If the research involves children and the investigator has not requested or the IRB has not granted a waiver or alteration of informed consent, permission from a parent (either one or two, depending on the risk level) and assent of children aged 7 years or older must be obtained. See Chapman's Policy on research involving vulnerable populations for additional information.

   d) Researchers should be aware that the setting in which consent is sought may introduce a feeling of undue influence. For example, students in an educational setting may feel that refusal to participate will affect their grade. See Chapman's IRB guidelines on research involving vulnerable populations for additional information. Individuals must have the right to refuse participation without penalty.

      i) If a study includes subordinate positions (e.g., students, employees) PIs should take steps to ensure that individuals do not experience (or perceive) pressure to participate. Inclusion of language within the informed consent (for example, explaining that the decision to participate will not impact a course grade or their relationship with the PI) may be one way to address and mitigate this concern. See the IRB's guidelines on Vulnerable Populations.

4) The information that is given to the prospective participant or LAR (whether orally or in writing) shall be in language understandable to the participant or LAR.

5) The prospective participant or LAR must be provided with the information that any reasonable person would want to have to make an informed decision about whether to participate.

6) The informed consent form (ICF) 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 understanding of the reasons why one might or might not want to participate.

7) The informed consent form cannot include any exculpatory language through which the participant or LAR is made to waive or appear to waive any legal rights or that releases or appears to release researchers, the sponsor, the institution, or its agents from liability for negligence.

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

8) Prospective participants' informed consent may not be required for screening, recruiting, or determining eligibility of potential participants when researchers obtain information from the participants through oral or written communication (i.e., interaction with potential participants) or access identifiable records or stored biospecimens.

9) Participants or LAR's must give the researcher specific written consent before the participant's identifiable information is shared publicly, e.g., through a publication or to meet a sponsor's data-sharing requirements.

IRB Submission and Review

The researchers describe the informed consent process in the Cayuse IRB submission and provide an informed consent form for the IRB's review and approval, when appropriate. Submitted informed consent forms and related documents (e.g., recruitment material, debriefing) are recommended to be on the current template from Chapman's IRB in order to facilitate IRB review. The IRB reviews the information and ensures that all requirements consistent with this policy are met.

Informed Consent Process

1) Informed consent is an ongoing process of information exchange that provides the prospective participant or participant's LAR with adequate information pertaining to the research study; sufficient opportunity to consider aspects of the research, including the risks and benefits, and whether to participate; and the opportunity for the participant to ask questions and receive answers to those questions, thus minimizing the possibility of coercion or undue influence.

    a) To ensure a complete and compliant consenting process, it is important that the person consenting participants be knowledgeable about the research and if relevant, the condition being studied

2) The informed consent process is often conducted via a conversation between the researcher and the prospective participant or participant's LAR. The informed consent form provides a guide for the informed consent conversation and provides the participant or LAR with information that can be referenced later. If the informed consent conversation cannot be conducted face-to-face, the informed consent process may be conducted over the telephone or via other electronic means. In this situation, it is recommended that the participant be provided with a copy of the informed consent form in advance.

3) Participants who can understand and comprehend spoken English but are unable to read the informed consent form for any reason (e.g., illiteracy, vision impairment, dyslexia) may be enrolled in a study; however, special care must be taken to ensure such individuals are able to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained orally.

    a) The study team must present the information to the participant orally following an IRB-approved consent form. The research team will keep a record of the fact that oral consenting procedure was used in this instance and the reasons for it. An impartial witness must observe the entire consent process and sign and date the ICF consent form.

Informed Consent for Exempt Studies

1) Studies deemed by the IRB to be exempt under the federal regulations present low or no risk to the human research participant. Therefore, Chapman can apply best practices and other flexibilities to the informed consent process.
2) Unless specifically waived, Chapman researchers are expected to inform participants and the LAR, when applicable, of the following details of the study and get their agreement before participating in a study.
    a) a statement that the project involves research
    b) a general description of study procedures and time commitment
    c) any potential discomfort or risk related to participation (e.g., discomfort responding to sensitive or personal questions, privacy concerns, disclosure risks)
    d) an indication that participation is voluntary and that they may skip any questions they do not feel comfortable answering in an interview or survey
    e) how their privacy and confidentiality will be protected
    f) an outline of plans for data-sharing or future research use of their information
3) When applicable, PIs should also describe:
    a) any use of information about participants obtained from records (e.g., student coursework, medical information, data from a prior study)
    b) plans to audio/video record or photograph participants and how recordings/images will be used and retained, including their approval to be recorded in accordance with California law
    c) information about participants' use of software or apps, including any privacy issues, incurred costs, etc.
    d) any plans for capturing information via screen-recording, key-stroke-logging, etc.
    e) In exempt studies only, if deception about the purpose or nature of the study is planned, prospective subjects must be informed that they will be unaware of, or misled about, the nature or purposes of the research, and agree to proceed.

4) For exempt studies, researchers are not required to document informed consent, for example, through a signed consent form. However, an information sheet about the study should be provided to the prospective participant before the start of a survey or any study procedure . See the Chapman website for templates and examples.
5) For exempt studies that involve photography, audio, and video recording, the information sheet must include the destruction timeframe (of the recordings), who will have access to the recordings and where they will be destroyed.
6) As with nonexempt research, the decision to participate in a research study belongs entirely to the potential participant. This choice must be voluntary and free from any undue influence – real or perceived.

Documentation of Informed Consent

1) Informed consent is documented by the use of an approved, written consent form described in 21 CFR 50.25 and 45 CFR 46.116(a), that is signed and dated by the prospective participant or LAR at the time of consent.

2) For studies reviewed by Expedited of Full procedures, unless the IRB grants a waiver of documentation of informed consent, informed consent must be documented as follows:

    a) For Expedited or Full studies, participants who are willing to participate in research must sign a copy of the IRB-approved informed consent form prior to participating in research procedures unless a waiver of documentation of informed consent is approved by the IRB.

        i) Signature may be provided via

            (1) a physical “wet” signature on a paper document or

            (2) a digital signature using Adobe Sign or DocuSign for a verified electronic signature. Note that typing one’s name or checking a box to acknowledge participation **does not** fulfill the signature requirement.

        ii) If the consent conversation is not conducted face-to-face, the participant may send electronically (e.g., fax, email, mail, upload onto a secure website, etc.) a signed copy of the informed consent form to the researcher.

        iii) If the consent is obtained face-to-face, the participant should sign a consent form that has been approved by the IRB. In online studies, whenever possible, the researcher should provide the participant with a digital copy of the consent form. In phone interviews, if possible and relevant to the nature of the study, the PI should offer to send the participant a physical or digital copy of the IRB approved consent form for their record.

        iv) Unless the IRB approves otherwise, the study team must receive a copy of the signed informed consent form prior to beginning research procedures.

        v) If participants are physically unable to provide a signature, they can make a mark on the informed consent form and the researchers must document the circumstances. If participants are unable to make a mark, a witness must observe the documentation process and sign the consent form as the witness to the consent process.

b) For research involving greater than minimal risk, the person conducting the consent discussion must also sign and date the informed consent form as the "person obtaining consent." The signature of the principal investigator is not required unless they are the person conducting the consent discussion.

c) Research personnel shall give either the participant or LAR adequate opportunity to read the informed consent form (or have the form read to them) and deliberate before deciding whether to participate in the study.

d) For photography, audio, and video recording, a separate signature should be obtained indicating permission for the recording and acknowledging its permissible uses.

e) In cases where the participant's identifiable data will be shared, researchers must secure the approval of the participant or the LAR. Researchers must provide details about the identifiable information that will be shared, the location of the data, and for how long the data will be publicly available.

Waiver of Documentation of Informed Consent

1) If identifiable data is shared, documentation of informed consent cannot be waived.

2) The IRB may waive the requirement for researchers to obtain a signed informed consent form for some or all participants if the IRB determines **at least one** of the following criteria are met:

   a) That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant or LAR is asked whether they want documentation linking themselves with the research, and the participant's wishes govern.

   b) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

      i) This is the only criteria that the IRB may use to waive the requirement that the participant or LAR sign a written consent form for Food and Drug Administration (FDA) regulated research.

   c) If the participants 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 participants and provided that there is an appropriate alternative mechanism for documenting that informed consent was obtained.

3) All the elements of elements of informed consent should be present in the ICF unless waived by the IRB (regardless of waiver of documentation of informed consent).

4) Justification for the waiver documentation must be outlined in the Cayuse IRB application. The IRB may require researchers to provide participants or LARs with a copy of the unsigned informed consent form regarding the research.

Elements of Informed Consent

1) Informed consent forms exceeding three (3) pages in length must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. A key information section is included in Chapman's IRB templates.

2) Unless altered or waived by the IRB, the following information shall be provided to each prospective participant or LAR who is considering participation in a research study. The IRB may require that additional information be given to participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.

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

    b) A description of any reasonably foreseeable risks or discomforts to the research participant.

    c) A description of any benefits to the research participant or to others that may reasonably be expected from the research.

    d) A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the research participant.

    e) A statement describing the extent to which, if any, confidentiality of records identifying the research participant will be maintained and for FDA regulated research, notes the possibility that the FDA may inspect the records.

    f) For research involving more than minimal risk, an explanation as to whether any compensation is provided 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.

    g) An explanation of whom to contact for answers to pertinent questions about the research and participants' rights, and whom to contact in the event of a research-related injury to the research participant.

    h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

    i) 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 researcher for future research studies without additional informed consent from the participant or LAR, if this might be a possibility; or

        ii) A statement that the participant'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.

3) The following additional elements shall also be provided to each participant or LAR, when appropriate:

   a) A statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus if the research participant is or may become pregnant), which are currently unforeseeable (this is usually limited to biomedical research involving clinical treatment or procedures).

   b) Anticipated circumstances under which participation may be terminated by the researchers without regard to the participant's consent (e.g., if a participant fails to comply with research procedures).

   c) Any additional costs to the participant that may result from research participation (this is usually limited to biomedical research involving billing participants or participants' health insurance for services provided as part of research).

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

   e) A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant.

   f) The approximate number of research participants involved in the study.

   g) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.

   h) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions (this is usually limited to biomedical research).

   i) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen; this is usually limited to biomedical research).

4) The following additional information must be provided in consent forms when applicable:

   a) When seeking informed consent for certain clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement notifying the participant 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: "A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

   b) If research personnel have a conflict of interest related to a research study, a statement regarding the conflict of interest as determined by the Conflict of Interest Management Plan.

   c) For studies where a Certificate of Confidentiality has been granted, including any study funded by the National Institutes for Health (NIH), a statement regarding Certificate of Confidentiality protections.

   d) If the research involves genetic information, a statement describing the protections provided by the Genetic Information Nondiscrimination Act (GINA) of 2008.

e) When seeking informed consent from participants who will participate in a study involving a "medical experiment," investigators must provide participants (or LARs) with a copy of the "Chapman University Experimental Participant's Bill of Rights" along with a study specific informed consent form. Participants must be provided with a copy of the Experimental Participant's Bill of Rights form in a language in which the participant is fluent.

i) A "medical experiment" study includes one or more of the following procedures:

(1) The severance or penetration or damaging of tissues of a human participant or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human participant in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the participant or otherwise directly benefiting the participant.

(2) The investigational use of a drug or device

(3) Withholding medical treatment from a human participant for any purpose other than maintenance or improvement of the health of the participant.

ii) When the Experimental Participant's Bill of Rights is provided to participants, the following statement should be included: "You have been given a copy of this form to keep."

iii) Participants need not sign the Experimental Participant's Bill of Rights form; however, a research team member should document that each participant received the form.

Waiver or Alteration of Consent

1) The IRB may waive the requirement to obtain informed consent in its entirety, or approve a consent procedure that omits or alters some of the elements of informed consent if the IRB determines **all of the following criteria are met**:

a) The research involves no more than minimal risk to the participants.

b) The research could not practicably be carried out without the requested waiver or alteration.

c) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable manner.

d) The waiver or alteration will not adversely affect the rights and welfare of the participants.

e) Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation. (This criterion is specific to research involving deception.).

2) The FDA has adopted the same criteria for waiving or altering informed consent for FDA regulated research.

3) Investigators must justify their request to waive or alter some or all of the elements of informed consent in the Cayuse IRB application. In addition, the IRB must find and document that a study satisfies all of the waiver criteria.

Informed Consent Procedures for Participants Who Can Read and Write but in a Language other than English

1) The consent conversation and informed consent form must be in a language understandable to the participant (e.g., in the participant's first language or a language in which the participant is fluent).

2) If researchers plan to enroll non-English-reading individuals, plans for language-appropriate consent procedures must be described in the Cayuse IRB submission. If a non-English informed consent form is provided for IRB review and approval, the IRB requires certification that the translated documents are complete and accurate translations of the English version of the informed consent form that is approved by the IRB.

Informed Consent Procedures involving Surrogate Consent

1) Federal regulations require that consent be sought from a research participant or LAR and defer to "applicable law" to define who is legally authorized (45 CFR 46.116 and 21 CFR 50.20). In California, Health and Safety Code 24178 describes who may serve as a LAR to give consent for an incapacitated prospective research participant.

   In accordance with both federal regulations and California law, the following guidelines must be taken into account when considering whether to enroll participants via surrogate consent methods:

   a) The IRB has to specifically approve the use of surrogates in a research study.

   b) The submission must include a process for formal evaluation of the prospective participant's ability to participate in the consent process, unless it is clear that the prospective participant cannot participate in the consent process (e.g., an unresponsive individual).

   c) If surrogate consent will be sought for a responsive participant, the participant must be told of the researcher's plan to consult a surrogate.

   d) If a participant in any way objects to or resists study participation or the use of surrogate consent, that participant may not be included in the study.

Informed Consent Procedures with Special Populations

1) Certain populations of participants require additional protections regarding their consent to participate in research. Please see applicable IRB guidelines on vulnerable populations for additional consent requirements when involving these populations in research (e.g., research involving individuals with diminished mental capacity).

Revisions to the Informed Consent Form

1) Revisions to the informed consent form must be reviewed and approved by the IRB prior to implementation.

2) Newly enrolled participants must sign the most recently approved version of the informed consent form, unless the IRB approved the study with waiver of signed consent. While a copy of the previously approved informed consent must be maintained in the research files, all additional copies should be discarded to prevent inadvertent use by researchers.

3) When submitting a revised informed consent form for IRB review and approval, the researchers must notify the IRB whether previously enrolled participants will be notified of the new information and, if so, the timing and mechanism of the notification (e.g., email or other written correspondence, telephone). The IRB will consider the researchers' plan for notification and ensure its appropriateness.

4) If the researchers are aware of new or increased risks that are not reflected in the IRB-approved informed consent form, they must not enroll new participants until the revised informed consent form incorporating these risks is reviewed and approved by the IRB.

5) If the IRB agrees that previously enrolled participants must be notified of new or different information or re-consented using a new informed consent form, the notification or re-consent process should be documented. Any previously signed consent forms must be retained in the research records and not discarded. Please refer to the institutional records retention policies for more information.

When Participants Withdraw from Research

1) If a participant wishes to discontinue participation in the research, data collected on the participant to the point of the participant's withdrawal from a study typically remains part of the study records.
    a. The Office of Human Research Protections (OHRP) provides guidance on this topic which states that investigators can retain and analyze already collected data related to participants who choose to withdraw from the research or whose participation is terminated by the investigator provided that all analyses falls within the scope of the research approved by the IRB.
    b. The Food and Drug Administration (FDA) also has guidance on this topic which states data collected on participants up to the time of withdrawal must remain in the study database for a study to be scientifically valid.
    c. When research involves deception or incomplete disclosure, the IRB typically requires participants to be debriefed and asked if they wish for their data to be withdrawn from final analysis. ***The wishes of the participants take precedent.*** For more information regarding this requirement, please see the Chapman IRB guidance research involving deception.
    d. There may be other regulatory requirements that take priority as well. For example, when conducting research in the European Union (EU), or when enrolling individuals who are EU residents in research, the General Data Protections Regulations (GDPR) applies. The GDPR allows individuals the right to erasure (also known as the right to be forgotten) which requires investigators (data controllers) to erase all personal data concerning the individual.
2) Chapman investigators are encouraged to outline in the informed consent form what may happen with the data provided by participants in situations where they may withdraw their participation or where their participation is withdrawn by investigators.

Revision history:

18Mar2025 – various updates:

- 4 pages as minimum ICF length requiring a key information section
- that following Chapman IRB ICF templates is strongly recommended
- greater clarification as to what suffice as documentation of consent
- deleted text requiring use of IRB-stamped ICF
- clarified the process for consenting participants who cannot read
- clarified that prospective agreement to deception is required only for exempt category 3 studies
- removed need for a separate signature (in the information sheet) for audio/videorecording in exempt studies) and specified required content (specific to recordings) in information sheet

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