Penn
University of Pennsylvania
Human Research Protections Program

Social-Behavioral Consent Form Completion Guidance

Contents

Informed Consent

General Requirements of Informed Consent

The 2018 Common Rule [§46.116(a)] states that these broad points about the consent process and documentation:

- Consent must be obtained from the participant or their legally authorized representative (LAR) before the participant may be involved in the research.
- The prospective participant 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.
- The prospective participant or LAR must have sufficient opportunity to consider whether to participate, and an opportunity to discuss the information presented. The possibility of coercion or undue influence must be minimized.
- The information that is given to the participant or LAR must be in language that is understandable to the participant or LAR.
- No informed consent, whether oral or written, may include any exculpatory language through which the participant or the LAR is made to waive or *appear to waive* legal rights, OR releases or *appears to release* the investigator, the sponsor, the institution, or its agents from liability for negligence. For examples, see: www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent- documents/index.html.

- Consent must be documented unless a waiver of documentation of consent is requested and approved by the IRB.
- Informed consent must present information in sufficient detail and must be organized and presented in a way that facilitates understanding of why one may or may not want to participate.

Consent Requirements for Exempt Research
If your human subjects' research study qualifies for exempt review under one of the eight categories outlined in the federal regulations, generally a simpler consent document will suffice. The IRB recommends the following elements below are covered. If these items are applicable but not present, the IRB will request revisions accordingly.

- Study Title and PI's Name
- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the procedures to be followed (experimental or investigational procedures must be identified);
- A description of any reasonably foreseeable potential risks or discomforts related to the research procedures;
- A description of any benefits to the participant or to others (including both direct & indirect benefits);
- Disclosure of alternatives (i.e., not to participate, or other procedures /courses of usual or investigational treatment that may benefit the participant);
- A statement that participation is voluntary;
- A statement that the participant may refuse to participate/withdraw without penalty or loss of benefits;
- A statement describing how confidentiality of the participant's data will be maintained;
- Storage of data for future research uses: Language about whether the research involves any plans to store data for future uses. Options:
    - A statement that data will not be stored or distributed for future research studies; OR
    - A statement that data will be de-identified prior to storage, and could be stored and distributed for future research studies without additional informed consent.
- Contact information for questions about the study (study team), research participant's rights (IRB of Record), and who to call if injury occurs.

Required Elements of Informed Consent

The 2018 Common Rule [§46.116(b)] outlines several basic elements of consent that should be provided to each subject or the legally authorized representative. These must be present in any consent form undergoing expedited or convened review for it to receive IRB approval. If they are not, the IRB will request revisions accordingly.

- Summary of Key Information—Informed consent 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 why one might or might not want to participate. Key information should be organized in a way that facilitates comprehension.
- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the procedures to be followed (experimental or investigational procedures must be identified);
- A description of any reasonably foreseeable potential risks or discomforts related to the research procedures;
- A description of any benefits to the participant or to others (including both direct & indirect benefits);
- Disclosure of alternatives (i.e., not to participate, or other procedures /courses of usual or investigational treatment that may benefit the participant);
- A statement that participation is voluntary;
- A statement that the participant may refuse to participate/withdraw without penalty or loss of benefits;
- A statement describing how confidentiality of the participant's data will be maintained (describe secure methods of data/sample storage and security; *applicable to Penn Medicine/Dental*, HIPAA authorization does not fulfill this consent element)
- Injury Language: For greater than minimal risk research, include an explanation of any injury compensation or any medical treatments available should injury occur and description of injury coverage
    - NOTE: If the study is industry-sponsored, the IRB will check the injury language in the informed consent form to be sure it accurately reflects the contract agreement between the university and the sponsor. As a result:
        - If the sponsor has a master agreement with Penn: the injury language will be assessed at time of initial submission, since the contract is already finalized. You may be asked to make additional edits to this section as an administrative stipulation to align with contract language.

  - If the sponsor does not have a master agreement with Penn: the IRB cannot check the injury language until the contract is negotiated and finalized. Therefore, you will receive a reminder note in the letter that a stamped informed consent form cannot be provided until this occurs. Please also note that the contracts offices are responsible for these contract negotiations and will notify the IRB at time of finalization. ***If finalization happens prior to IRB review, please notify your administrator so that the consent form may be stamped in a timely manner.***

- Storage of data for future research uses: Language about whether the research involves any plans to store data for future uses. Options:
  - A statement that data will not be stored or distributed for future research studies; OR
  - A statement that data will be de-identified prior to storage, and could be stored and distributed for future research studies without additional informed consent; OR
  - Broad consent language noting that coded/ identifiable data will be stored and distributed for future research studies without additional informed consent. Additionally, the following elements are required if coded/ identifiable data may be stored and shared for future use:
    - A statement about which identifiers will be retained and shared with data.
    - The types of institutions or researchers that might conduct research with the data.
    - A description of the period of time that the data may be stored, maintained, and used for research purposes. If indefinite, this should be stated.
    - A general description of the types of research that may be conducted with the data.
    - A statement regarding whether participants will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research.
    - If relevant, statement regarding whether clinically relevant research results, will be disclosed to participants, and if so, under what conditions.
    - Specifically related to the future use: A description of: how confidentiality will be maintained during storage/ sharing, reasonably foreseeable risks and benefits of future research use, and who to contact with any questions about future use/storage and research related harms.
- Contact information for questions about the study (study team), research participant's rights (IRB of Record), and who to call if injury occurs.

Additional Elements of Informed Consent

The 2018 Common Rule [§46.116(c)] outlines several additional elements of consent that should be provided to each subject or the legally authorized representative, when applicable. If applicable, these must be present in any consent form undergoing expedited or convened review for it to receive IRB approval. If they are not, the IRB will request revisions accordingly.

- 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
- The circumstances when participant participation may be terminated by the investigator
- Any additional costs to the participant due to the research
- The consequences of a participant's decision to withdraw/explanation of how to withdraw
- A statement that significant new findings which may affect willingness to continue participation will be provided to the participant
- The approximate number of participants involved in the study.
- Returning Research Results—If relevant, a statement regarding whether clinically relevant research results, will be disclosed to participants, and if so, under what conditions. NOTE: This may apply to research with biospecimens as well as research with any diagnostic devices.
- Collection of Biospecimens—When the study involves the collection of biospecimens (i.e., blood, urine, tissue, hair, sputum, etc.), the following elements of consent are required:
    - A statement that the biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this profit
    - A statement regarding whether the research will 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)"

Required Institutional Consent Language

- Payments / Remuneration for Participation: If participants will receive monetary compensation for their participation by check or an amount of $100 or more, include institutional language in the template ICF about reporting to the IRS.
- Confidentiality section: If your study involves testing for infectious diseases, include institutional language in the template ICF about reporting to Philadelphia and state Health Departments.

- Electronic Medical Record and Release of Study Related Information: Include template institutional language *when research is being conducted within Penn Medicine and research data and results may be placed into the electronic medical record or the study is otherwise built in the EMR*. Studies must be built into the EMR/ PennChart if the study will be utilizing PennChart EMR ordering, billing or recruitment capabilities.

HIPAA Authorization

HIPAA authorization is required only if one of more members of the research team is affiliated with Penn Medicine or Penn Dental.

General Requirements of HIPAA Authorization

HIPAA Authorization must be obtained from participants in the following circumstances:

1. The study is accessing (using), collecting, and/or disclosing (sharing) protected health information (PHI) from Penn Medicine or Penn Dental patients. This includes abstracting information from the medical record for use in a research study.
2. The study will generate participant level data (e.g., survey administration, clinical trial, etc.) and is being conducted under the Penn Medicine or Penn Dental. The data generated/created is considered Protected Health Information because it is generated under a HIPAA covered entity, regardless of whether the targeted participants are Penn patients.

If obtaining consent and HIPAA authorization is infeasible waivers of informed consent and HIPAA authorization must be requested from the IRB.

Required Elements of HIPAA Authorization

The following are the required elements of HIPAA authorization that must be present in either a separate form or, more typically, the consent form. Please ensure that these are included and, if they are not, the IRB will request revisions accordingly. NOTE: it is preferred that Penn's HIPAA Authorization language be used in Penn consent/HIPAA documents.

- A list of the protected health information collected/used
- A description of who may use/disclose the information
- A description of who may receive the information
- A statement to indicate that the duration of authorization does not expire
- A statement to indicate that a participant has the right to revoke authorization, and how to do this
- A statement to indicate information disclosed outside the covered entity may not be protected

Required Institutional HIPAA Language

- Storage of Research PHI: All research undergoing expedited and convened board review involving Penn Medicine must utilize the clinical trial management system (CTMS). Ensure that you include required institutional language on storing research data in the CTMS.
- Who may use/disclose the information: The following bullets must be included in the HIPAA section to ensure appropriate internal access to study data.
  - Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
  - Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB