

<b>ELEMENTS OF THE INFORMED CONSENT</b>	<b>SOP 5.1.01</b>
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## 1. Purpose & Policy

The purpose of this SOP is to outline the necessary elements that must be included in Informed Consent documents. IRB Policy *Section 5.1*.

## 2. General Information

The Informed Consent Form (ICF) is central to the responsible conduct of human subject's research. The ICF typically follows the template generated in the IRB Protocol Application System (PAS). This is an automated process intended to help generate an initial ICF draft consistent with the rest of the protocol, but it is not intended as a final version. Investigators are responsible for editing their ICF, and ensuring that all text is easily understandable, is generally well-written, and provides a prospective participant with the key information that is most likely to assist them in understanding why one might or might not want to participate in the research. Generally, ICFs for adults should be written at an eighth-grade comprehension level, though the level may be higher or lower based on the participant population. Scientific or technical terms, if necessary, should be defined in lay language. It is essential that the ICF is clear, simple, and in grammatically flawless English. Investigators may wish to use the help of online resources for this purpose.

## 3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with elements of the informed consent; however, investigators should carefully read and follow this guidance.

## 4. Informed Consent Document

### A. Elements of the Informed Consent

ICFs must include the following elements:

1. Research Description

The ICF must state that the study involves research. It must also give an explanation of the purpose(s) of the research, the expected duration of participation, a description of the procedures to be followed, and identification of any procedures that are experimental. It is also important to state any requirements for inclusion or exclusion of participants from the study.

2. Reasonably Foreseeable Risks

The ICF must provide a description of any reasonably foreseeable risks or discomforts to the participant. If applicable, the ICF should also state that the risks might not be fully known.

3. Benefits

The ICF must include a description of any benefits to the participant or to others that may reasonably be expected from the research. Based on the study, the ICF may state that there is no direct benefit to the participant, but that there is a broader benefit to science and society; such benefit needs to be briefly articulated in the ICF.

4. Alternative Procedures or Treatment

The ICF must include a disclosure of alternative procedures or courses of treatment, if any, that might be available to the participant. Often the ICF for basic research studies will state that an alternative is for the participant not to participate in the study.

5. Confidentiality of Record

The ICF must include a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. It may be appropriate to include a statement that federal, state or local government agencies having authority over the research, may have access to the records. For FDA regulated research, the ICF must also include a statement that there is a possibility that the FDA may inspect the record. If identifiable research data are kept for a limited time, this should be stated clearly (e.g., “the video recordings will be destroyed after one year”).

If applicable, the ICF should also include a statement that a COC has been granted as part

of a PHS award, has been applied for in accordance with NIH provisions, or has been obtained from NIH.

6. Compensation and Treatment for Injury

The ICF will include an explanation as to whether any compensation will be provided for participation. Additionally, the ICF should provide a separate explanation as to whether any medical treatment or compensation for injury are available if injury occurs. If medical treatment or related compensation are available, the ICF should describe what is covered, whom to contact, and where further information may be obtained. The Caltech ICF template provides specific text for these sections that must be used.

7. Contact Information

The ICF must provide an explanation of whom research participants can contact and how for (1) answers to pertinent questions about the research and research participant's rights, (2) requests to withdraw, and (3) notification in the event of a research-related injury to the participant.

8. Voluntary Participation

The ICF must include 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 the participant is otherwise entitled. This is particularly important for any research involving clinical populations or a hospital setting, where it is critical to ensure that prospective participants understand the distinction between their clinical treatment as patients, and their voluntary participation as research participants.

a) Withdrawal Procedures for Studies Participant to the General Data Protection

Regulation (GDPR) of the European Union (EU) or the European Economic Area (EEA) and the Personal Information Protection Law (PIPL)

If participants are recruited from the EU, EAA, or China, the ICF must provide the appropriate language to comply with GDPR and PIPL, which set forth the framework for

various individual rights on how personal data gathered from participants in these areas can be used, process, transmitted, and protected. Follow [SOP 5: GDPR & PIPL](#)

## 9. Collection of Identifiable Private Information or Identifiable Biospecimens

If researchers are collecting Identifiable Private Information<sup>1</sup> (IPI) or Identifiable Biospecimens<sup>2</sup> (IB) the ICF must include, as applicable:

- a) A statement that identifiers might be removed from the IPI or IB 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 participant; or
- b) 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. If the information or biospecimens will not be used again, the investigator should provide a description of and timeline for destruction.

## 10. Support

All financial sponsors of the research must be disclosed in the ICF.

## 11. Conflicts of Interest

When applicable, a disclosure statement by the investigator(s) involved in the research that they may have a potential or actual financial conflict of interest, along with any further explanation of the conflict, as deemed appropriate by the IRB.

## 12. Date of Approval/Expiration Date

The ICF must clearly state the date of the IRB approval and date of expiration. These dates may be left blank on the ICF template submitted to the IRB, but must be present on the IRB-approved ICF, which will be used to consent participants.

## 13. No Clinically Relevant Research Results

The ICF must include a statement that the study is for research purposes only and that no

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<sup>1</sup> Identifiable private information is private information for which the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

<sup>2</sup> Identifiable biospecimens are biospecimens for which the identity of the participant is or may readily be ascertained by the investigator or associated with the biospecimen.

clinically relevant results will be collected nor will individual research results be disclosed to the participants.

#### 14. Number of Participants

The ICF should provide the approximate number of participants involved in the study.

### **B. Additional Informed Consent Elements**

Depending on the nature of the research, the following additional elements may be required in the informed consent document:

#### 1. Unforeseeable Risks

If applicable, the ICF should include a statement that the particular study or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable. It is recommended that investigators consider this addition for all studies that are more than minimal risk.

#### 2. Termination of Participation by the PI

If applicable, the ICF should include any anticipated circumstances under which the participant's participation may be terminated by the PI without the participant's consent.

#### 3. Additional Costs

If applicable, the ICF should include any additional costs to the participant that may result from participation in the research (such as travel costs).

#### 4. Consequences of Participant's Withdrawal

If applicable, the ICF may need a statement reflecting the consequences of the participant's decision to withdraw from the research and procedures for safe and orderly termination of the participation of the participant.

#### 5. Significant New Findings

If any significant new findings may arise during the course of the research which could relate to the participant's willingness to continue participation, a statement that these

- findings will be provided to the participant and a description of the method of dissemination.
6. California Experimental Participant's Bill of Rights  
For medical experiments and other experiments where the IRB deems it appropriate, prior to consent, participants must be provided with an Experimental Participant's Bill of Rights in accordance with California Health & Safety Code § 24172. This is typically generated automatically as a section of the ICF by the online IRB system when investigators submit their protocols.
  7. Incidental Findings  
If applicable, include a statement as to how incidental findings will be handled. (See Incidental Findings V(I)(8) and [SOP: Incidental Findings](#))
  8. HIPAA Authorization  
If applicable, a written authorization to use identifiable health information for research purposes in accordance with the Health Insurance Portability and Accountability Act (HIPAA) should be included in the informed consent document or a separate HIPAA Authorization Document.
  9. Photographing and Recording  
If applicable and deemed appropriate by the IRB, the ICF should include a statement that the participant will be photographed or audio or video recorded and whether or not the participant will be identifiable. The ICF should also include where such photographs or recordings will be kept, and the planned duration of retention. It is often appropriate to have the participant initial next to the relevant section of the ICF to indicate their understanding of such procedures.
  10. Physical Contact  
If applicable, and the research requires any physical contact with participants, the nature of the contact needs to be disclosed in the protocol and the ICF. Follow [SOP: Physical Contact with Study Participants](#).

## 11. Fasting

As applicable, if a protocol requires the participant fast for any length of time prior to completing the written informed consent process, the investigator must receive general consent from the participant before the participant begins to fast. The ICF for the study must include a complete description of the fasting requirements. Follow [SOP: Fasting in Human Participants Research](#).

## 12. Future Contact to Continue Data Collection

If applicable, the ICF should include a request for consent from the participant to be contacted in the future:

- a. to obtain additional information, or
- b. to arrange to collect additional data (e.g., another visit to the lab, or a questionnaire to fill out on the internet), or
- c. to request participation in other research studies at Caltech by the same or different researchers.

It is important to identify what contact information will be preserved (name, phone, email, etc.), where it will be stored, by whom, for what length of time and, as applicable, state that this contact information may be made available to and they may be contacted by other researchers at Caltech. It is often appropriate to have the participant initial to indicate their understanding of such future contact.

## 13. Data Sharing

If applicable, the ICF should include information about any data sharing, the purpose of the data sharing, and whether the participant's identity will be ascertainable. If specific data repositories are contemplated, they should be included by name. It is strongly recommended that PIs include a data sharing plan in their protocols whenever feasible. For de-identified generic data sharing, template text should be considered. Follow [SOP: Data Management & Sharing](#).

## 14. Commercial Use

If applicable, the informed consent document should state that the participant's

biospecimens (even if identifiers are removed) may be used for commercial profit and whether or not the participant would share in such profit.

15. Biospecimens

For research involving biospecimens, the informed consent shall include whether the research will (if known) or might include whole genome sequencing.

16. Broad Consent

If the study will require the storage, maintenance, and secondary research use of *identifiable* private information or *identifiable* biospecimens (collected for either research studies other than the proposed research or non-research purposes), researchers can elect to obtain “Broad Consent”. The elements of a Broad Consent must include Elements b, c, e, h, and, if applicable, aa and bb, above as well as:

- a. A general description of the types of research that might be conducted with the identifiable private information or identifiable biospecimens.
- b. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
- c. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (can be indefinite) and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (can be indefinite.).
- d. Unless the participant will be provided details about specific research studies, the Broad Consent must include a statement that the participant will not be informed about the details of any specific research studies that might be conducted using the participant’s identifiable private information or identifiable biospecimens. The participant must be told that this includes not knowing the



purposes of the research, and that, their Broad Consent, includes consent to a research study that they might otherwise have chosen not to consent to.

- e. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the participant in all circumstances, the Broad Consent should include a statement that such results may not be disclosed to the participant.
- f. An explanation of whom to contact for answers to questions about the participant's rights and about storage and use of the participant's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.