BERKELEY LAB

STANDARD CONSENT FORM FORMAT

- **This template is intended as a guideline, with suggested language. Alternative consent forms are also allowed so long as the regulatory requirements are still met.**
- **Consent forms should be printed on letterhead, including LBNL logo unless justified otherwise.**
- **Statements in blue are provided for guidance, be sure to remove or replace as needed.**
- **Flesch-Kincaid reading level should be at an 8th grade level or lower.**

STUDY TITLE

Key Information *(Required for consent forms longer than 3 pages or 2000 words)*	
Researchers	*Include key researcher names and organizations participating in the research*
Funding	*Funding Source*
Purpose	
Participants	*Population description, Ex. Healthy men and women between the ages of 22 and 65*
What Will Happen	
Potential Risks	
Potential Benefits	
Contact Information	

[The purpose of the Key Information box: The revised Common Rule regulations on human subjects require that subjects be given a concise and focused presentation of key study information before being given other information. The goal of the Key Information is not simply to provide an abstract or executive summary of the rest of the consent form, but to assist potential subjects with understanding the reasons why one might or might not want to voluntarily participate in the research.]

You are being invited to participate in a research study.

What should I know about participating in a research study?

- Whether you choose to participate in this research study is strictly up to you.
- You can always choose not to take part. Your participation is voluntary.
- You can ask and have answered all of the questions you want before you decide.
- You can agree to take part and later change your mind without giving any reason.
- Your decision will not be held against you, and there will be no penalty or loss of benefits.
- You do not waive any of your legal rights by signing this form.
- You will get a signed copy of this consent form to keep. *[Remove "signed" if requesting a waiver of documentation of consent.]*

Why is this research being done?

[Provide the potential subject with a short and simple explanation of the goals of the research in lay language consistent with the general population from which the subjects will be recruited and, if possible, at no greater than an eighth-grade reading level. Set out the questions that the research seeks to answer, the expected duration of participation, how many people will be studied, and the organization funding this study. Include any experimental procedures or therapies and identify them as such.]

What happens if I agree to participate in this study?

[Explain to the potential subject in lay language no greater than an eighth-grade reading level what will happen to the participant or what they will be asked to do in the study. Be sure to include where, when and how the research will be done. Also include any data that will be collected about them. Whenever appropriate, include the following items:]

- *A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 step(s)/visit(s).*
- *The drugs or biologics that will be given to the subject and any devices that will be used.*
- ***The length and duration of each visit and procedure.***
- *What data will be collected about them.*
- *[Include for a study that involves randomization. Otherwise delete.]* The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researchers will choose what treatment you get. You will have a _____ *[equal/one in two/etc.]* chance of being given each treatment.

Is there any way being in this study could be harmful? What are the predicted risks?

[All risks to participants should be described here, preferably in bullet points, including the mitigation methods being put in place to protect participants. Confidentiality risks may be included in this section or separately summarized, as appropriate. Two examples are given below]

[For studies where no special confidentiality risks exist.] Participation in research may involve a loss of privacy. Your records will be kept as confidential as possible under the law. When the results of the research are used in reports or papers, no information will be included that would reveal your identity.

[For studies where LBNL co-workers will be used as research subjects.] Participation in research may involve a loss of privacy. Your data will be given a code number. The records will be kept …*[where]*… and the code key will be kept locked in ……*[a separate location of greater security.]* However, because the researchers work here at Berkeley Lab it is possible that others may find out if you take part in the research and may guess which data is yours. Your records will be kept as confidential as possible under the law. When the results of the research are used in reports or papers, no information will be included that would reveal your identity.

Is there any way being in this study could help me? What are the predicted benefits?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- *[Describe any direct benefits to the subject, then any benefits to others.* ***Monetary reimbursement for participation is not a benefit.]***
- *If benefits from participation may not continue after the research has ended, describe them here.*

[ALTERNATIVE] There will be no benefit to you from participating in this study. However, it is hoped that information gained in this study will help others by _____. *(Describe how the information gained in this study will help society, advance knowledge, etc.).*

Will I be paid to participate in the study?

If you agree to take part in this research study, we will pay you _____ [amount] for your time and effort. If you are paid $600 or more a year as a research subject, your earnings will be reported to government tax agencies. You also will have to fill out and submit a federal W-9 form if you are nearing this limit. [*include details on how, when, conditions for non-payment*]
OR You will not be paid for your participation, nor will you be charged.

How are my information or samples stored and used for the research?

The information that you provide in the study will be handled confidentially, and every effort will be made to protect the data and limit the use and disclosure of your personal information.

- *If identifying data is collected, clarify whether any coding system will be used, and when and how it will be de-identified.*
- *State where the data will be stored. Provide details of how the data will be kept confidential, e.g., locked filing cabinet, password protected computer files, and how access will be controlled.*
- *State who will have access to the data both during the research and after the research is over, e.g., only the research team will have access to the identifying information. If any data is to be collected through Survey Monkey, Mechanical Turk, or similar services, clarify whether that organization will retain any data once the study is complete. Be specific.*
- *State whether the data will be disposed of following the research and, if so, how. Proper destruction of PII must be carried out when it is no longer necessary to support the project.*
- When we share the results of this study *[insert details here, e.g., when published in scientific journals, professional publications and/or educational presentations*], we will not include your name *[insert other information that will not be disclosed and if data will be presented in aggregate form].*
- There may be circumstances when this information must be released or shared as required by law. Other individuals/organizations that may have access to information from this study include the Human Subjects Committee, representative(s) of the Department of Energy Human Subjects Protection Program and its accrediting organization, other federal regulatory agencies, the sponsor of the study, and/or the following_____. *[Add other organizations that may have access to the subject's records during the study, for what purpose, and for how long.]*
- Information collected about you will NOT be used or shared for future research. [*OR]* All identifiable information, e.g., your name, date of birth, will be removed from the information and/or samples collected in this project. After we remove the identifiers, the information and/or samples may be used for future research or shared with other researchers without your additional consent.
- Your information and samples may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you and/or your family.

Though not expected, what would happen if I were injured? *[Required for all studies with physical intervention or greater than minimal risk. <u>This statement must be used without changes</u>.]*

Should you be injured as a result of being in this study, if you are treated at Lawrence Berkeley National Lab (LBNL) there will be no cost to you. If treatment outside of LBNL is required, the costs of the treatment may be billed to you or your insurer just like other medical costs, and potentially reimbursed, depending on a number of factors. LBNL [and name of study sponsor may also be inserted here] does not normally provide any other form of compensation for injury. For more information about this, you may call the office of the Human Subjects Committee at (510) 486-6005 or contact harc@lbl.gov.

Who can I talk to if I have questions?

If you have questions or concerns talk to the research team at _____. *[Insert contact information for the research team.]*
This research has been reviewed and approved by the Berkeley Lab Human Subjects Committee (HSC), an administrative group of people who oversee the rights and welfare of human-research subjects participating in research activities conducted by Berkeley Lab researchers. For questions about your rights as a participant, you may call the office of the HSC at (510) 486-6005 or contact harc@lbl.gov.

Are there alternative procedures if I do not want to be in this research?

Participation in this research is completely voluntary. You can decide to participate or not to participate. Your decision will not be held against you, and there will be no penalty or loss of benefits.
[Include if there are alternatives other than participating.]
Instead of being in this research study, your choices may include: *[List alternative procedures.]*

[Include if there are no alternatives other than participating.]
Your alternative to participating in this research study is not to participate.

[Optional for all projects:] You may be asked to participate in other research in the future, but will be free to refuse to do so.
If you wish to participate, you should sign below.

_____

AUTHORIZATION: I have read this consent form. All of the questions I have asked have been answered to my satisfaction. I volunteer to participate in this research.

_____	_____
Date	Subject's Signature
	_____
	Subject's Name (print legibly)
_____	_____
Date	Person Obtaining Consent (Signature)
	_____
	Name (print legibly)

[STOP! Do not use the following signature lines unless third party consent is being requested and has been addressed in detail in the protocol.]

AND/OR:

Date	Legally Authorized Representative (i.e., parent, legal guardian, conservator, or individual with power of attorney for health care of the subject)
	Name (print legibly)
Date	Person Witnessing Signature of Representative
	Name (print legibly)

ADDENDA FOR EXTRA SECTIONS WHEN APPLICABLE

Audio/and/or Photographic and/or Video Recording

[If audio and/or photographic and/or video recording devices will be used, Explain why the records are needed for the research and what will be done with them upon completion of the research, e.g., kept indefinitely, archived after transcription, destroyed after X years. For a photograph or video recording, explain if the face and/or identifying markings, e.g., tattoos, can/will be obscured. If audio and/or photographic and/or video recording will not be used, delete this section.]

Please sign below if you are willing to have XXX recorded/photographed. You may still participate in this study if you are not willing to have the XXX recorded/photographed.

☐ I do not want to have XXX recorded/photographed.

☐ I am willing to have XXX recorded/photographed.

Signed: _____

Date: _____

If you plan to take photographs or make audio, video, or other types of recordings, and you want to use the photographs/record for activities beyond research analysis, e.g., in publications, presentations, or other promotional purposes, include a section that does the following:

- *Informs the participant that you are making a [type(s) of media used] recording in which the person's name, likeness, image and/or voice will be included;*

- *Asks the participant to grant you the right to make and use recordings in whole or in part in media forms now known (such as film, slides, or digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*
- *Explains that the participant will not receive any financial compensation from commercial and/or non-commercial (as appropriate) uses of the images/recordings.*

The same signature line above may be used for this performance release information.

Will I get to see my results if I participate?

[Disclose whether the participants will be able to see the results of their own study participation, and whether they will receive a copy of published reports or articles. When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects or their healthcare providers, and if so, under what conditions; include also for research involving biospecimens.]

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information and/or samples gives results that do have meaning for your health, the researchers *will/will not* contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor and/or get professional genetic counseling. You may have to pay for those additional services yourself.

Can I be removed from the research study without my consent?

[Include for studies with factors that will eliminate them from continued eligibility.]

The principal investigator (and/or the sponsor) can remove you from the research study without your approval. Possible reasons for removal include that you no longer meet the eligibility criteria, if it is in your best interest to do so, or if you do not follow study procedures. *[Describe any other reasons why the subject may be withdrawn if appropriate.*] You will be notified if you are removed from the research study.