**Consent Form Checklist
and Model Language**

*This checklist is designed to be used with the Consent Form Template available on the HSC website. Use it to see which additional information (if any) needs to be added to your consent document. The model language provided below may be modified when appropriate, but be sure that the result is clear and conveys all of the necessary information.*

GENERAL CONSIDERATIONS FOR WRITING CONSENT FORMS:

* Avoid technical language.
* Keep the reading level low (usually no higher than 6th grade). Most word processing software includes a tool to measure this.
* Avoid big blocks of text. Your consent form will be more readable if text is broken into smaller sections, perhaps using bullet points or other techniques.
* Use diagrams, photos, flow charts, etc. as necessary to help you communicate.

**INCLUDE THE FOLLOWING ELEMENTS AS APPROPRIATE:**

**Purpose of the Study**

Brief description of what you’re trying to learn (without technical language).

**Study Sample:**

We hope to include \_\_\_ people in this study. (Or, if appropriate: We hope to include \_\_\_ people with your medical history – or your age, or whatever – in this study.)

*Are you recruiting students for this study?*

* If YES, then you must make VERY clear that participation in this study is completely separate from any course requirements, and that declining to participate would have no effect on one’s grade.
* This statement must be emphatic and must appear *above the Purpose heading* in the consent document. Use a text box, bold-face type, underscoring, or similar means to draw attention to it. Here is a sample statement:
* Explain which procedures are part of the study, and which (if any) are course requirements.

PARTICIPATION IN THIS STUDY IS COMPLETELY SEPARATE FROM COURSE
REQUIREMENTS. DECLINING TO PARTICIPATE WILL HAVE NO EFFECT
ON YOUR GRADE OR YOUR STANDING IN THE PROGRAM.

* *Will you offer extra course credit to participants?* If YES, then ensure that the same amount of credit can be obtained by non-participating students by some non-research activity (without having to spend more time or effort than participants will for research procedures). Explain how much extra credit will be received by participants, and how to get that much credit without participating.
* *Will you be using test scores, GPA, or other information from the student’s academic record?* If YES, then explain what information will be used and how it will be obtained.

*Are you recruiting your own patients, clients, supervisees, or anyone over whom you have authority?*

* If YES, then you must make VERY clear that participation in this study is completely separate from any clinical relationships, workplace responsibilities, etc.
* This statement must be emphatic and must appear above the Purpose heading in the consent document. Use a text box, bold-face type, underscoring, or similar means to draw attention to it. A text box similar to the one above for students would be appropriate.

**Who is doing this study?**

Provide the name of the principal investigator (or the lead investigator at this site, for multi-site studies). Also provide this person’s contact information (e.g., email).

*Does your study involve 2 or more institutions?*

* If YES, then state that this is one of [two, or several, or many] sites involved in this study.

*Is this a multi-site study?*

* If YES, say: You are one of \_\_\_ people to take part in this study here, out of \_\_\_ nationally [*or internationally, if appropriate*]*.*

*Does your study have a sponsor?*

* If YES, include the following: “The study is supported by \_\_\_\_.”

*Does any investigator involved with this study have a financial conflict of interest?*

* If YES, then include the following language:
The following disclosure is made to help you decide whether this relationship affects your willingness to participate in this study: [*Explain the conflict of interest and the steps taken to minimize its effects.*]

**What you would be asked to do:**

*Will you be taking photos or participants, or making audio or video recordings of them?*

* If YES, make that clear.
	+ Explain what will be photographed/recorded.
	+ Explain who will see/hear these, how they will be used, and how they will be stored and protected.
		- Participants are often very sensitive to whether their photos/videos might be seen by people they know. If any photos/recordings will be used in courses, local presentations, etc. where members of the participants’ community might see them, make that very clear.
	+ If these materials might be used in teaching, presented at conferences, used in other research, etc., make that very clear.
	+ If it is possible for participants to opt out of being recorded/photographed and still participate in the study, explain that.

*Are there 2 or more arms/groups in this study?*

* If YES, *are you using the same consent form for all arms/groups?*
	+ If YES, make clear the research procedures for each group. (If separate consent documents are used for each group, then describe only the procedures for this group.)
	+ If there are multiple arms/groups but each will have its own consent form, then explain only the procedures for this group.
	+ Use a subtitle for each consent form indicating which group it will be used for.
* *Will participants be randomly assigned to groups?* If YES, include this: The group you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what intervention you get. You will have an [equal/one in three/etc.] chance of being assigned to any given group.
* *Will there be double or single blinding?*
	+ If SINGLE BLINDING, add this: You will not be told which group or intervention you are getting, however your study team will know.
	+ If DOUBLE BLINDING, add this: Neither you nor the study team will know which group or intervention you are in.

*Are you recruiting patients or clinical clients for this study?*

* If YES, then make clear which procedures are standard care and which are investigational.

*Will (or might) the study 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 the bio specimen)?*

* If YES, say so. Be sure to avoid technical language. Make clear the implications this has for incidental findings, limitations on confidentiality, etc.

*Will (or might) participants be contacted again for follow-up or to seek consent to participate in further research?*

* If YES, explain who will contact them, (approximately) when, and how often.
* If one can participate in the study but decline further contact, offer that option.

**Will being in this study help you?**

* *Do not discuss or describe payments to participants in this section. That has its own section (study reimbursement, below).*
* *Address only the benefits arising from the research procedures themselves. E.g., If you are interviewing people at a rock-climbing competition, list only the risks associated with the interview (such as breach of confidentiality) and not those associated with rock climbing.*
* *If your consent form has a Key Information cover sheet and the benefits are all described there, then omit this section in the main body of the consent document.*
* *If participants will not benefit directly from the research procedures, say this: You should not expect to benefit from being in this study.*
* *If others might benefit from this study, explain that.*
	+ *Don’t make unwarranted assumptions or unsupported claims.*

**Will you receive anything for participating in this study?**

If NO, then say something like, “You will not be paid for your participation in this study.”

*If participants WILL receive anything of value, describe it. If payment will be made, explain whether it will be cash/check/gift card, and whether it will be given immediately upon completion or sent later.*

* + *Make clear how incomplete participation will be compensated.*
	+ *Explain whether the researchers will reimburse participants for any expenses incurred as part of their study participation. (e.g., meals, parking, lab tests) If participants need to provide receipts or other documentation, make that clear.*
	+ *If you will be collecting participants’ names or other information for tax purposes or other financial records, explain this. Idaho State University’s policy requires tax forms be completed by subjects who receive more than $75 for participating (including situations in which 2 or more payments for participation total more than $75).*

**Will it cost you anything to be in this study?**

* *If any of these costs will be reimbursed by the researcher, say so. Describe any receipts or other documentation participants will need for reimbursement.*
* *If the participant’s insurance will be billed for any of these costs, explain that. Also explain what will happen if the insurance company will not cover these costs.*

**Who will see your information:**

*Could any IDENTIFIABLE data from this study be presented in a publication, presentation, teaching, or other forum?*

* If YES, explain that researchers would first seek that person’s separate consent first.

*Does your study meet the NIH definition of a clinical trial?*

Use this decision tree to find out: <https://grants.nih.gov/policy/clinical-trials/ct-decision-tree.pdf>

* If your project meets the definition of a clinical trial, include the following: “A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.”

*Could participants be removed from the study by the investigator?*

* If YES, include this: The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include [*describe reasons why the participants may be withdrawn, if appropriate*].

*Will de-identified data or samples be made available to other researchers?*

* If YES, include this: “De-identified information (or samples) could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.”
* If NO, say, “The information or samples collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.”

**Signature block:**

* *Not all studies require signed consent. There is a decision tree at the end of this document to help you make that determination. If your study requires signed consent, then include lines for the name and signature of the participant, and for the date. A signature line for the researcher may also be added.*
* *If you want a witness to observe the consent process and sign as well, consult first with the IRB chair (**humsubj@isu.edu**) to discuss what the witness would be certifying and how it would be conducted.*
	+ *If you will be collecting participants’ names or other information for tax purposes or other financial records, explain this.*
* *If your study will include focus groups, please include the following language (or similar wording) in your consent form:* “Although we ask everyone in the group to respect everyone’s privacy and confidentiality, and not to identify anyone in the group or repeat what is said during the group discussion, please remember that other participants in the group may accidentally repeat what was said.”
* *If there will be audio or video recording or photos of participants, make that clear.*
	+ *Explain who will see/hear these, how they will be used, and how they will be stored and protected.*
	+ *If these materials might be used in teaching, presented at conferences, used in other research, etc., make that very clear.*
	+ *Explain whether it is possible for participants to opt out of being recorded/photographed and still participate in the study.*

*Are some components of the study procedures (e.g., being photographed or recorded) optional?*

* IF YES, include the following, with whichever optional components apply to your study:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity:

The researcher may [*audio or video*] record me to aid with data analysis. The

researcher will not share these recordings with anyone outside of the

immediate study team. (Specify which or both will occur. If recording is a

requirement of participation, delete this element.)

I agree \_\_\_\_\_\_\_\_\_\_ I disagree\_\_\_\_\_\_\_\_\_

The researcher may [*Specify which or both will occur:*]audio or video record me for use in scholarly presentations or publications. This is done because sometimes showing my face or hearing my voice might serve to help other professionals understand the research. I may be identifiable as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

I agree \_\_\_\_\_\_\_\_\_\_ I disagree\_\_\_\_\_\_\_\_\_

The researcher may contact me in the future to see whether I am interested in

participating in other research studies by the principal investigator of this

study. I will decide at that time whether to participate; this is only an agreement to be contacted about other studies.

I agree \_\_\_\_\_\_\_\_\_\_ I disagree\_\_\_\_\_\_\_\_\_

* Anticipated circumstances under which the subject’s *participation may be terminated by the investigator* without regard to the subject’s (or the legally authorized representative’s) consent.
* The consequences of a *subject’s decision to withdraw* from the research and procedures for orderly termination of participation by the subject.
* If the research involves *collection of identifiable private information or identifiable bio-specimens*, there must be a statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens *could be used for future research* or distributed to another investigator for future research without additional informed consent from the subject (or the legally authorized representative).
* 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*.
* 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.
* If you wish to ask participants to consent to *future contact about additional research*, please include check boxes for participants to accept or decline to be contacted about other studies in the future.
* If an NIH Certificate of Confidentiality is or will be issued, that the appropriate language is included:
	+ This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use [*information/ documents/ or biospecimens*] that may identify you in any federal/ state/ or local civil/ criminal/ administrative/ legislative/ or other action, suit, or proceeding, or be used as evidence (e.g., if there is a court subpoena) unless you have consented to this use. [*Information/ documents/ or biospecimens*] protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal/ state/ or local civil/ criminal/ administrative/ legislative/ or other proceedings/ see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
	+ [Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.
	+ [Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported/ such as child abuse and neglect/ or harm to self or others].
	+ [Language such as the following should be included if researcher intends to disclose information covered by a Certificate with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed/ such as including research data in the medical record].

Reporting Obligations: When describing confidentiality, include whichever of the following statements is appropriate:

If we learn about current or ongoing child (or elder) abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

*Or*

An exception to our promise of confidentiality is when law or policy permits us in good faith to report evidence of child [or elder] abuse or neglect.

*Or*

We will not ask you about child [or elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

[Describe any other limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover drug use or other sensitive information (like HIV diagnosis), explain that this information may be disclosed to appropriate authorities.]

Data Sharing: Data from this study may be shared with other researchers to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

If data is being collected in, or transferred from, the European Union (GDPR) or another country or state that has its own data security or privacy requirements, ensure that those have been met. See: https://gdpr.eu/what-is-gdpr/

STUDIES INVOLVING GREATER THAN MINIMAL RISK: In addition to the basics, include the following.

* Clear, non-technical description of the risks. Explain what it would be like to experience such an outcome.
* Is any treatment or compensation available from the researcher (or the researcher’s institution) for any harms resulting from study participation?
	+ *No exculpatory language is allowed*. Participants must *not* be told that they are waiving rights by participating or that they are not entitled to compensation. It is permissible to say that there is no plan or funding for compensating those harmed by research participation, but that they may seek compensation through the courts.
* If you need medical care because of taking part in this research study, please seek medical treatment through [*include if relevant:* the investigator or] a treatment center of your choice. If you seek treatment from someone other than the investigator, contact the investigator to inform her/him about any related injury or illness. Generally, this care will be billed to you, your insurance or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury. [*Describe any compensation available for research related injury*.]

**BIOMEDICAL RESEARCH:**

In addition to the basic information listed above, include the following elements as appropriate.

* If there are courses of treatment or other procedures (not included in the study methods) that are available to the participant, make that clear. This generally covers the non-research treatment options available to the patient.
	+ If any of these are compatible with research participation, explain that.
* Emphasize that participation in the study is voluntary, and that declining to participate would have no negative effect on one’s relationship with clinicians or institutions.
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
* Explain whether any information in the participant’s medical record will be used for the study.
* Explain whether any information gathered as part of the study will be added to the medical record.
* If participants will be charged for any drugs, devices, procedures, tests, etc., then make that clear.
	+ If their insurance will be billed for any research-related expenses, make that clear. Include an honest estimation of the likelihood of whether their insurance would cover those costs, and whether they would be responsible for any uncovered portion.
* A statement that the subject’s bio-specimens (even if the identifiers are removed) may be used for commercial profit, and whether the subject will or will not share in this commercial profit.
* For research involving bio-specimens, whether the research will (or might) include whole genome sequencing.
* That the research consent form and information will be posted on clinicaltrials.gov if applicable.
* If the protocol is FDA sponsored research, include language that FDA personnel may review any and all documents related to the research including subject medical records, in either a directed or routine audit of the investigator, the institution or IRB.
* When applicable indicate that the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product.
* When applicable indicate when and how the participant will be informed of the results of the research.
* When applicable, include whether assessment, educational or clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.] Most tests done in research studies are only for research and have no clear meaning for [developmental, educational or health care.] If the research with your identifiable information or biospecimens 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 appropriate:] If the researchers return biomedical 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, or get professional genetic counseling. You may have to pay for those additional services yourself.

If the study sponsor will be paying any portion of the participant’s medical expenses, include this:

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

If your biomedical study recruits prisoners, include the following:

If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Does your consent form require a signature line, or do you qualify for a waiver of documentation of consent? Here’s a decision tree:

