CAL POLY HUMBOLDT
Office of Research & Sponsored Programs Foundation

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The checklist provided below is presented as guidance for persons developing and reviewing applications to the Humboldt Institutional Review Board (IRB) for approval of activities involving the collection of information from or about human subjects. The intent of the list is to facilitate the process for IRB application approvals.

	For anonymous, minimal risk research, a signature on the consent form is not required. The IRB usually still requires investigators to provide and explain a written consent statement regarding the research.
	Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.
	Statement that the study involves research and an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
	Any possible risks and/or discomforts are indicated, including all of those mentioned in the IRB application form. If none, please state.
	If relevant, the location of where the procedure(s) will be conducted is included.
	The possible benefits of participation are indicated.
	Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
	The method used to insure confidentiality, including how data will be kept, used, and destroyed.
	Identification of whom to contact for subjects' questions about research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
	Contact Information for the Primary Investigator is included: Name, phone number, and e-mail. If the Primary Investigator is a student, the faculty supervisor's contact information must also be provided.
	Include the following statements: The Investigator will answer any questions you have about this study. Your participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; and you may discontinue participation at any time without penalty or loss of benefits. If you have any concerns with this study or questions about your rights as a participant, contact the Institutional Review Board for the Protection of Human Subjects at irb@humboldt.edu or (707) 826-5165. **Optional: When needed, see the translation of this sentence into Spanish below on page 4.**

	Amount of compensation or statement that there will be no compensation for participation. (Please see page three for language related to recruitment incentives, such as entering participants in drawings.)
	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.
	Intention to use direct quotations from participants must be stated on the informed consent form.
	Intention to audio or video record participants must be stated on the informed consent form.
	Intention to share the data collected with other researchers in the future must be stated on the informed consent form.
	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: 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 investigator for future research studies without additional informed consent from the subject, if this might be a possibility; or A statement that the subject'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.
	When signed consent is required, a clear space is provided where the participant or their legally authorized representative will sign and date the consent form.
	Additional elements of informed consent, when appropriate:
	A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable.
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
	Any additional costs to the subject that may result from participation in the research.
	The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
	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.
	The approximate number of subjects involved in the study.
	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

The following is a list of additional considerations if your research involves the use of an online instrument (i.e., survey, questionnaire, etc.).

	If data collection involves sending emails to Humboldt students, staff, and/or faculty, permission should be obtained from Humboldt Institutional Research, Analytics, and Reporting prior to seeking IRB approval. For more information see: http://www2.humboldt.edu/irp/
	In the informed consent, the location of where the procedure(s) will be conducted is described by using the term 'online' followed by the type of instrument and the name of the company or software hosting the survey, (e.g., online survey powered by SurveyMonkey).
	The method(s) used to insure anonymity and/or confidentiality must be described. Note that many online survey companies and software (SurveyMonkey, Snap Surveys, and QuestionPro) allow investigators to track respondents using the participant's email address and unique URL. In addition, some survey companies/software record the IP address of survey participants. Because the investigator cannot guarantee anonymity in this case, the investigator should either indicate that these features will be disabled, or must indicate that the identifying data will remain confidential.
	Describe what will happen to the data after the research is concluded. If data will be stored by a survey company, describe the length of time the company will host the data.
	For an online survey, a signature line is not required. Instead, the elements of informed consent may be incorporated into the survey. The preferred method is to display the full informed consent on the first page of the survey ending with the following statement: "Please print this informed consent form now and retain it for your future reference. If you agree to voluntarily participate in this research as described, please check the box below to begin the online survey. Thank you for your participation in this research." Underneath this statement, include a required question with one checkbox with the following text: "I have read and understood this consent information, and agree to participate in the (survey, questionnaire, etc.)." To see an example, visit: https://www.surveymonkey.com/r/HSU-IRB-IC-Example
	If applicable, recruitment emails should never contain more than one potential participant in the "To" and "CC" field. Doing so may be a privacy violation and/or violate terms of use of your email service (as is the case for Gmail). At minimum, investigators should use the "Bcc" field. The preferred method for sending email is a mail merge or using the survey software to send individual emails.

Additional elements that may be required for review include:

- If research involves working with outside entities (for example, tribes, schools, or businesses), then permission must be obtained from an authorized representative of that entity. Written permission from the outside entity may be required for IRB review and is always required for research involving tribes or vulnerable populations.

- If data collection involves access to Humboldt email lists, permission should be obtained from the Humboldt Institutional Research, Analytics, and Reporting prior to seeking IRB approval.

- Approved IRB protocols may be reviewed by Humboldt Risk Management, who may require further action.

- If the research involves Protected Health Information (PHI), then Health Insurance Portability and Accountability Act (HIPAA) requirements must be considered. Please see the IRB-HIPAA Privacy Rule Summary for more information.

- Regarding recruitment incentives:

  California gambling law (California Penal Code section 319) prohibits rewarding or compensating study participants with entry into a chance giveaway (drawing, lottery, raffle, or the like) for any material prize (cash, gift cards, etc.). However, if the chance to win is not contingent on participating in the study, such drawings can be permitted. Therefore, we suggest adding the following (or similar) message to your recruitment text and consent forms:

  "You can participate in the drawing even if you do not complete or participate in the study by asking the investigator to include you."

- If documents such as the Informed Consent must be in languages other than English, it is the researcher's responsibility to ensure the documents are translated accurately.

- Translation into Spanish of IRB contact information:

  - Si tiene alguna preocupación o preguntas sobre sus derechos como participante, contactar a la Junta de Revisión Institucional para la protección de las personas que participan como sujetos de estudio. Correo electrónico: irb@humboldt.edu, teléfono (707) 826-5165.

Guidelines for Mandated Reporting for IRB:

The following language will be used in consent forms when faculty or staff could be in their mandated reporter role:

- CSU Executive Order 1083 requires Humboldt faculty and staff researchers to follow the Mandated Reporting rules for reporting incidents or concerns about abuse of minors. Although students are not mandated reporters, we encourage students who suspect abuse or neglect of any minor to report this concern to the responsible faculty member, who is a mandated reporter. Thus, the IRB requires that language such as the following be included in the Informed Consent form for research that could involve information from research participants about abuse of minors:

    - We will make every effort to keep your answers confidential. However, because faculty and staff researchers must follow mandated reporting rules, information or concerns you share about abuse or neglect of any minor are reportable under California's Child Abuse and Neglect Reporting Act (CANRA).

- Additionally, CSU Executive Order 1096 requires all HSU employees (*with limited exceptions*) to report any instances of or information regarding discrimination, harassment, or retaliation involving the CSU in any way. The IRB requires that language such as the following be included in the Informed Consent form for research which is *not conducted by those employed in confidential healthcare or law enforcement settings as defined in EO 1096, Article I, H* and that could involve information from research participants about discrimination, harassment, or retaliation:

    - We will make every effort to keep your answers confidential. However, because Humboldt employees are required to report information regarding discrimination, harassment, or retaliation involving the CSU, information you share about discrimination, harassment, or retaliation may be reportable under CSU Executive Order 1096. Humboldt employees are also encouraged to contact Human Resources regarding information from third parties not affiliated with the CSU regarding discrimination, harassment, or retaliation.

- All questions or complaints may be referred to the Office of the Dean of Students or the Human Resources office.

The IRB will endeavor to notify Human Resources of the following:

- The names of faculty or staff who will come into contact with minors at least once per week. This will include the beginning and end of the potential contact.