**REQUEST FOR REVIEW**

 **Last Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**This form is to be used for requesting review and approval of a new project before it is initiated. Full details must be given and all necessary documentation submitted.**

**For students: Each student research/project proposal must be read and endorsed by the student’s advisor.**

Full name/mailing address of principal investigator:

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| --- |
|  |
|  |
|  |
|  |
| Phone number: |  |  | Email address: |  |

Check one:

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Faculty member: | Department/School: |  |
| [ ]  | Student: | Candidate for degree of: |  |
| [ ]  | Staff: | Position: |  |
| [ ]  | Other (specify): |  |

**Advisor: By submitting this form to the IRB, I attest to having read it and endorse it.**

|  |  |  |  |
| --- | --- | --- | --- |
| Date: |  | Advisor’s name: |  |

Short title of the study/project:

|  |
| --- |
|  |

 **(Please use no more than ten words)**

|  |  |
| --- | --- |
| **Names of co-investigators (if any):** |  |
|  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Will this study/project extend beyond one year?** | **Yes** | [ ]  | **No** | [ ]  |
| * **If approved, study/project will start on:**
 |  |
| * **Projected end date:**
 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Will this study/project receive financial support from a Federal agency?** | **Yes** | [ ]  | **No** | [ ]  |
| ***If yes, which agencies are providing support?*** |  |

*I certify that the statements made in this request are accurate and complete, and if I receive IRB approval for this project, I agree to inform the committee in writing of any emergent problems or proposed procedural changes. I further agree not to proceed in the research/project until the problems have been resolved or the IRB has reviewed and approved of the changes.*

|  |  |  |  |
| --- | --- | --- | --- |
| Date: |  | Name of Investigator: |  |

**I. IN LAY LANGUAGE, STATE CONCISELY THE HYPOTHESIS, PURPOSE, AND/OR OBJECTIVES OF THE PROPOSED RESEARCH/PROJECT (a few sentences only):**

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**II. THE HUMAN SUBJECTS INVOLVED IN THIS RESEARCH/PROJECT:**

*1. Who are the subjects? How many will be involved in the study/project?*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*2. How will you recruit or select the subjects, or how will you gain access to them? Be specific. Indicate whether the subjects will be recruited from your place of employment and, if so, how this research/project relates to your job role and any other information pertinent to your relationship with the subjects (e.g., how will you ensure against the possibility of coercion?)*

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*3. Are you advertising/posting notice for subjects/volunteers?* **Yes**[ ]  **No**[ ]

 ***If yes, submit a copy of the advertisement or notice.***

*4. For how much time will each subject be involved in the study/project? If you are using your subjects on more than one occasion, indicate the number of such occasions and their duration.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*5. Are you paying your subjects?* **Yes**[ ]  **No**[ ]

 ***If yes, indicate how much and describe how you will prorate the payments to subjects who withdraw before the study/project ends:***

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*6. Are your subjects students?* **Yes**[ ]  **No**[ ]

 ***If yes, name the institution in which they are enrolled:***

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*7. Typically, signed informed consent is required from adult subjects. For children under the age of 18, signed informed consent must be obtained from the child’s parent or legal guardian. In addition, verbal assent from the child must be obtained prior to participation. (For teenagers capable of reading and understanding the parental consent form, written signed assent should be obtained as well.)*

*However, the need for signed informed consent and assent may be waived for research/projects conducted in common educational settings examining education practices, or research/projects observing public behavior, examining publically available data, and other situations outlined in Title 45 Section 46.101. Additionally, the requirement for signed informed consent may be waived if the lack of signed consent would not adversely affect the rights and welfare of subjects* ***and*** *any of the following apply:*

1. *The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;* ***or***
2. *The only record linking the subject and the research would be the consent document and the principal risk of the research to subjects would be potential harm resulting from a breach of confidentiality caused by signing the consent document;* ***or***
3. *The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

*If signed informed consent is* ***NOT*** *obtained, adult subjects should receive written information about the research/project and that participation is completely voluntary. Further details are located on the IRB website at* <https://www.up.edu/irb/how-to-initate-a-review/informed-consent.html> *or in Appendix A of this document.*

 *This research/project will include:*

 *Signed informed consent form* **Yes**[ ]  **No**[ ]

 *Parental/Guardian signed informed consent form* **Yes**[ ]  **No**[ ]

 *Assent form* **Yes**[ ]  **No**[ ]

 *Written information sheet (if not using consent form)* **Yes**[ ]  **No**[ ]

 ***Please submit a copy of these forms/documents. (Note: forms should be in a reader-friendly format and provided at a reading level appropriate to the majority of study/ project subjects.)***

**Where the requirement of signed informed consent is waived, the researcher must provide written information to potential subjects that includes all the applicable elements of the informed consent form.**

*8. Do your subjects include any of the following?*

 *Pregnant women, human fetuses, and neonates (Subpart B, 46.201)* **Yes**[ ]  **No**[ ]

 *Inmates or prisoners (Subpart C, 46.301)* **Yes**[ ]  **No**[ ]

 *Children (Subpart D, 46.401)* **Yes**[ ]  **No**[ ]

*9. Are any subjects in this study vulnerable to the possibility of coercion or undue inﬂuence when making a decision whether to participate in the research project or as a participant in the research project?*

**Yes**[ ]  **No**[ ]

 ***If yes, address why inclusion of the identified vulnerable population(s) is crucial to the research design of this project and what has been done to ensure equity in selection of vulnerable subjects. Any power differentials that have the potential to create vulnerability in subjects must be addressed explicitly.***

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*10. How will you protect the subjects’ confidentiality in your study/project?*

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**III. THE RESEARCH /PROJECT PROCEDURES**

1. *Describe in sufficient detail and in lay language the procedures you will be doing to or with your subjects. (For faculty conducting research, please describe the planned roles and activities of students used as research assistants.)*

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1. *Are you obtaining from your subjects information about their private behavior, economic status, sexual activity, religious beliefs, or other matters which, if made public, might negatively impact their self-esteem or reputation, or could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing or employability?*

**Yes**[ ]  **No**[ ]

 ***If yes, describe the means you will use to ensure that all your data are kept secure and confidential until they are destroyed. Refer to Appendix B for guidance on considerations related to data collection and storage that should be addressed below.***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*3. Does your study/project involve withholding of the true purpose and procedures of the study/project from your subjects?* **Yes**[ ]  **No**[ ]

 ***If yes, describe the procedure you will use to debrief your subjects, indicating the willingness to allow subjects to withdraw after debriefing and to remove from your data all records of their involvement:***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*4. Are there potential subjects who, if selected for this project, would be especially vulnerable to risk because of the procedures you will be using?* **Yes**[ ]  **No**[ ]

 ***If yes, describe the process you will use to screen and eliminate all such vulnerable subjects from the study/project:***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*5. Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce high levels of stress or anxiety beyond what is expected in everyday life?* **Yes**[ ]  **No**[ ]

 ***If yes, describe your plans for counseling or making referrals for distraught subjects:***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*6. In three or four sentences, summarize the probability of possible risk, the magnitude of possible risk, and the risk/benefit ratio of the proposed research/project, with regard to the human subjects, the risks to them, and the potential benefits to knowledge or society.*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*7. Are you using a questionnaire and/or an interview as part of your procedure?* **Yes**[ ]  **No**[ ]

 ***If yes, submit a copy of the questionnaire(s) and/or interview questions.***

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1. *Will you keep study/project materials, records, and documents secure for at least three years, (as requested by the IRB)?* **Yes**[ ]  **No**[ ]

***If not, please explain****:*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. *How and to whom will data/results be distributed?*

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## Appendix A – Information Required in the Informed Consent Process

Title 45 Part 46 Section 116 of the federal Office of Human Research Protection regulations outlines the required components of the informed consent process. Below the requirements are summarized, but the full regulatory text can be found at:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>.

All information sheets and informed consent documents submitted to the University of Portland IRB are expected to contain the elements listed below. Regardless of the expected outcome of an IRB review, investigators are expected to submit an informational sheet with every submission, at minimum.

**The document begins with the presentation of Key Information.** (46.116(a)(5)(ii)

Key information constitutes a concise and focused presentation of the information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

**The document contains the Basic Elements of Consent.** (46.116(b))

The nine basic elements of consent must be included when applicable to the research project submitted for IRB review.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and 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;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
	1. 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 or the legally authorized representative, if this might be a possibility; **or**
	2. 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.

**The document contains the Additional Elements of Informed Consent, where appropriate.** (46.116(c))

1. 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;
2. 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;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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;
6. The approximate number of subjects involved in the study;
7. 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;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) 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).

## Appendix B – Privacy Protection

It is the responsibility of the person submitting the request for review to ensure that the research data are collected, stored, transmitted, and shared in the most secure manner possible and communicate the privacy protection plan in the IRB Request for Review document. In addition, researchers must also address risk of reidentification and data breaches in the consent process.

**Definitions**

*Anonymous data* – data that have no ability to be traced to the person providing the data and have never had a linked identifier associated with it during the research process.

*De-identified data* – data that researchers, or others, cannot readily connect to the identity of a specific research participant.

*Coded data* – data that have personal identifiers, such as name or email, removed and replaces blatant personal identifiers with a code that is used to connect data points about subjects over time.

**Common Mistakes Seen in IRB Submissions that Require Revisions**

The IRB Request for Review form:

* Fails to adequately describe the data collection, transmission, storage, and retention/destruction plan.
* Identifies data as anonymously collected, but provides no supporting evidence for how anonymity is secured.
* Identifies data collected electronically as anonymous.
	+ One should assume that data collected electronically are never anonymous due to data stored by the software provider, such as IP addresses, during the data collection process.
* Fails to address how coded data are stored other than saying the data are stored on a password-protected device.
* Fails to adequately describe the quantity of research participants and/or how the venue of recruitment may create unintentional linked identifiers.
* Fails to communicate risk of data breach by software vendor in the consent process and other computer related harms that may be a risk (hacking, phishing, breach, lack of appropriate security measures, etc., as among those risks encountered in daily life).
	+ One should assume that the use of software provided by a third party, such as Survey Monkey, gives the software provider access to the data collected.

**Addressing Privacy Protections in Your IRB Submission**

The questions below should be addressed, at minimum, when applicable to your research methods.

* What is the specific method(s) you are using to collect data from research subjects?
* How are the collected data recorded?
* How are recorded data transferred between locations or devices?
* Where are recorded data stored?
	+ Best practice is to never store or transport electronic data on personal devices.
* Who has access to the spaces and/or devices where data are stored?
* Are spaces/devices where data are stored for any amount of time locked and password protected?
* When is data encryption used?
	+ Best practice would be to encrypt any non-anonymous data both during storage and transit.
* How are data transferred between members of the research team?
* What data are shared outside of the research team?
* What privacy protections are in place for ensuring that the code for coded data is not accessed by unauthorized people?
* How will the research team break the connection between the coded data and the code when the connection is no longer needed?