

**Institutional Review Board Application Form**

**PLEASE NOTE THAT THE IRB DOES NOT REVIEW APPLICATIONS DURING FINALS’ WEEK OF EACH SEMESTER**

**For copies of forms, policies, and procedures, go to the** [**IRB website**](https://www.ursinus.edu/offices/institutional-review-board/)**.**

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| --- | --- |
| Date of submission: | Insert today’s date here. |
| Faculty member/Principal investigator (PI) and home department: | Insert PI and department here. |
| Co-Investigator(s): | List if any. |
| Student investigators: | List if any. |
| Title of Project: | Insert title here. |
| Dates of proposed research: | Insert date range here. |
| Is this an honors project? | [ ]  Yes [ ]  No |
| Is this a Summer Fellows project? | [ ]  Yes [ ]  No |
| Is this protocol associated with a sponsored project/external grant? List grant number.  | [ ]  Yes [ ]  No Grant number: Click or tap here to enter text. |
| Is this part of a class assignment? Please list class name and number.  | [ ]  Yes [ ]  No Class number: Click or tap here to enter text. |
| Are you seeking exempt approval for your protocol?  | Please follow the procedures on the [Exempt Research website](https://www.ursinus.edu/offices/institutional-review-board/institutional-review-board/exempt-research/), including filling out a Request for Exemption Form. |

**Certification of Principal Investigator (Students cannot be Principal Investigators)**: Signature certifies that all Investigators have reviewed the proposed protocol and that the research will be conducted in full compliance with federal/state regulations and UC IRB procedures. It is understood that:

1. continuing IRB review may be required annually
2. all changes in the study and/or study personnel must be approved by the IRB prior to implementation;
3. serious, unexpected study related adverse events must be promptly reported to the IRB.

Principal Investigator: Date: Click or tap here to enter text.

Checklist of Required Items (**Please note that if any of the following forms are missing, your application can not be processed**):

[ ]  All Investigators have current IRB/CITI training (within the last 5 years) [per UC policy](https://www.ursinus.edu/offices/institutional-review-board/training/)

[ ]  IRB Application Form (this document)

[ ]  Informed Consent/Assent Form(s)

[ ]  Copies of questionnaires, surveys, or other materials to be given to subjects

[ ]  Any other relevant materials that would aide in review of the study (i.e. letters of support from survey sites or external IRB approvals as needed)

**ALL IRB MATERIALS AND QUESTIONS SHOULD BE SENT, VIA EMAIL, TO THE IRB ADMINISTRATOR AT:**

*irbadmin@ursinus.edu**.*

**IRB PROTOCOL**

**A. PURPOSE, RESEARCH VARIABLES, AND POPULATION**

A1. **Purpose of the study**- State concisely and realistically, what the study is intended to accomplish.

Click here to enter text.

A2. **Background**-Briefly state the background of the study, including references when appropriate, and identify the main questions the current study is intended to address.

Click here to enter text.

A3. **Subject Population** – Please provide the following information:

 **Age Range** - What is the age range and why was it chosen?

 Click here to enter text.

**Number** - What is the estimated number of subjects? Click here to enter text.

**Inclusion Criteria** - What are the specific inclusion criteria?

Click here to enter text.

**Exclusion Criteria** - What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.

Click here to enter text.

**Vulnerable Subjects** - If vulnerable Human Subjects are involved in the proposed research, please provide justification of the need to use these subjects in research.

|  |  |
| --- | --- |
| **Minors** |  |
| **Pregnant Women** |  |
| **Fetuses** |  |
| **Illegal Behavior** |  |
| **Cognitively Impaired** |  |
| **Incarcerated** |  |
| **Educationally or Economically Disadvantaged** |  |

 **Justification for use of vulnerable human subjects:** Click here to enter text.

**B. METHODS AND PROCEDURES**

B1. **Method of Subject Selection** - Describe the study’s method(s) of identification and recruitment of prospective subjects. Describe the selection criteria in terms of equitable and fair distribution of burdens, risks and benefits of research. Provide a copy of any planned advertisements.

Click here to enter text.

B2. **Study Site** - State the location(s) where the study will be conducted. The IRB may require a letter of support to conduct the study at a non-Ursinus site. Consult the IRB with any questions. Please review the procedures for research occurring offsite and outside the USA in our [Standard Operating Procedures](https://www.ursinus.edu/live/files/4294-sop-2021-update).

 Click here to enter text.

B3. **Full Description of the Study Design, Methods, and Procedures** - Describe the research study in detail.

Discuss the study design; study procedures; sequential description or timeline of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures.

Click here to enter text.

**Attach copies of any and all research instruments to be used, such as surveys, rating scales, demographic forms, or questionnaires. All study instruments must be approved by the IRB.**

**C. INFORMED CONSENT**

C1. **Potential Risks** - Identify the potential risks of the study. Specify the types and levels of risk. Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury.

Click here to enter text.

C2. **Protection Against Risks** - Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of psychological or medical referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality or privacy (e.g., for existing data), state this.

Click here to enter text.

C3. **Potential Benefits** - Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

Click here to enter text.

C4. **Compensation for Participation** - Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

Click here to enter text.

C5. **Alternatives to Participation** - Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

Click here to enter text.

C6. **Information Withheld** - Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

Click here to enter text.

C7. **Confidentiality** - Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

**Will you collect or receive any of the following identifiers?**

|  |  |
| --- | --- |
|  | Telephone numbers  |
|  | Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death.  |
|  | Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of a zip code. |
|  | E-mail addresses |
|  | Social security numbers  |
|  | Medical record numbers |
|  | Health plan beneficiary numbers |
|  | Account numbers  |
|  | Certificate/license numbers  |
|  | Vehicle identifiers and serial numbers (VIN), including license plate numbers  |
|  | Web universal resource locators (URLs)  |
|  | Internet protocol (IP) address numbers  |
|  | Full face photographic images and any comparable images |
|  | Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher. |

 **Identifiers in research data**.

Are the identifiers above linked or maintained with the research data? [ ]  Yes [ ]  No

**Data sharing.** With whom will *identifiable* (contains any of the 16 identifiers listed in question above) data be shared outside the immediate research team? For each, explain confidentiality measures. Attach data use agreements, if any. This could include other researchers, registries, journals, sponsors, and so on.

Click or tap here to enter text.

**Data security for storage and transmission**. Please check all that apply.

***For electronic data stored on a computer:***

[ ]  Secure network [ ]  Password access [ ]  Data encryption

[ ]  Password protected file(s) [ ]  Other comparable safeguard (describe):

***For******portable computing devices/external storage devices:***

[ ]  Power-on password [ ]  Automatic log-off [ ]  Data encryption

[ ]  Password protected file(s) [ ]  Other comparable safeguard (describe):

***For hardcopy data:***

[ ]  Locked suite or office [ ]  Locked cabinet

[ ]  Data de-identified by research team (data stripped of any identifiers)

[ ]  Data coded by research team with a master list secured and kept separately

[ ]  Other (describe):

**Post-study disposition of identifiable data or human biological materials**. Describe your plans for disposition of data that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

 Click here to enter text.

**D. SUBJECT RECRUITMENT AND INFORMED CONSENT PROCESS.** *Remember, informed consent is a process, not just a signed document, and informed consent means the subject must be informed about the study in a language they understand***.**

The standard consent process is for all subjects to sign a document containing all the elements of informed consent as specified in the federal regulations. If you will obtain consent in any manner, complete **sections D1**-**D4**.

In addition, if you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete **section E**.

If you are requesting a waiver of any or all of the elements of consent, complete **section F**.

D1. Describe the plans for subject recruitment and the informed consent process that will be followed. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If cognitively impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation.

Click here to enter text.

D2. Describe who will seek informed consent from the prospective subject. NOTE: Research Informed Consent must be obtained by someone qualified to answer the questions that the subject or their representative may ask regarding the research.

Click here to enter text.

D3. Describe the method of documenting the informed consent process.

Click here to enter text.

D4. Describe how the continuing informed consent process will be conducted.

 Click here to enter text.

**E. Justification for a waiver of *written* (signed) consent**. *The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true.

*Chose E1 or E2:*

E1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., sensitive topic and public knowledge of participation could be damaging).

[ ]  Yes [ ]  No

Explain: Click here to enter text.

E2. 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 (e.g., phone survey).

[ ]  Yes [ ]  No

Explain: Click here to enter text.

*NOTE: A consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document****.* *All informed consent documents must be approved by the IRB.***

**F.** **Justification for a full or partial waiver of consent.** *The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biologicalspecimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived.

[ ]  Requesting **waiver of some elements** (specify): Click here to enter text.

[ ]  Requesting **waiver of consent entirely** Please justify.

To justify a full waiver of the requirement for informed consent, you must be able to answer “yes” or “not applicable” to items F1-F4. *Insert brief explanations that support your answers***.**

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| --- |
| F1. Will the research involve no greater than minimal risk to subjects or to their privacy?  [ ]  Yes [ ]  NoExplain:Click here to enter text. |
| F2. Is it true that the waiver will *not* adversely affect the rights and welfare of subjects? *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)*[ ]  Yes [ ]  NoExplain:Click here to enter text. |
| F3. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? *(e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)*[ ]  Yes [ ]  Not applicableExplain: Click here to enter text. |
| F4. Would the research be impracticable without the waiver? *(If you checked “yes,” explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* [ ]  Yes [ ]  NoExplain:Click here to enter text.  |

**G. LISTING OF ACRONYMS AND/OR TERMS.** Please provide a listing of acronyms and/or terms. Include definitions for those used in the Protocol and Informed Consent Document(s) (e.g., Complete Responses (CR), Adolescents in Healthy Contexts (AHC), etc.). This additional information is needed to facilitate the review process since the IRB members may not be familiar with the specific area of research submitted, although they are familiar with clinical research design principles and may be experts in their own fields.

Click here to enter text.

I, as the individual responsible for the conduct of the study and study team, agree to provide whatever oversight is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any research with human subjects before I have received approval/or complied with all contingencies made in connection with the approval. I understand that as the principal investigator, I am ultimately responsible for the welfare and protection of human subjects and will carry out the project as approved.

**Signature of Principal Investigator**:

Date: Click here to enter text.

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by Ursinus College policy and federal law.

**Signature of Principal Investigator:**

Date: Click here to enter text.

*Additions to, or changes in procedures involving human subjects, as well as any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the IRB.*

*The IRB will not review applications with incomplete protocols.*