**Hobart and William Smith Colleges**



**Institutional Review Board**

**Form B**

**Application for Exemption from IRB Review**

**for Research with Human Subjects**

**Directions**: This application is to be submitted to and approved in writing by the IRB ***prior*** to the initiation of any investigation involving human subjects. **Note that research activities will only be considered for exemption from further review when all items in Section One and at least one item in Section Two apply.** Please submit a signed, paper copy and an electronic version of your application with copies of all consent forms, surveys, questionnaires and/or interview protocols you plan to use to the Office of Academic and Faculty Affairs.

**PRINCIPAL INVESTIGATOR** *Name*: Click here to enter text.

*HWS Department Affiliation*: Click here to enter text.

*Campus Address*: Click here to enter text.

*Email Address*: Click here to enter text.

*Phone Number*: Click here to enter text.

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| **If the Principal Investigator is a student, a faculty/staff supervisor must be identified to oversee the project. The Supervisor’s signature is required at the end of this form.**  *Name of Faculty/Staff Supervisor*: Click here to enter text.  *Supervisor’s Campus Address*: Click here to enter text.  *Supervisor’s Email Address*: Click here to enter text.  *Supervisor’s Phone Number*: Click here to enter text. |

**PROJECT** *Title*: Click here to enter text.

*Project Involves*:  Faculty/Staff research

Independently conducted student research

Other: Click here to enter text.

*Anticipated* *Starting Date*: Click here to enter text.

*End Date*: Click here to enter text.

*Project Collaborators:* Click here to enter text.

*(Indicate institutional affiliation if non-HWS)* Click here to enter text.

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| *For IRB use only*: **Application #** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Submission Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_ Approved \_\_\_ Not approved **Revision Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Chair’s Name Chair’s Signature Date |

**SECTION ONE:** Please answer Yes or No for each statement as it applies to the project:

Yes  No 1. ***No*** participating human subjects fall under a protected category (non-HWS students under 18 years of age; pregnant women, fetuses, or neonates; institutionalized persons; persons with psychiatric, cognitive, or develop-mental disorders; or persons under the influence of alcohol or drugs).

Yes  No 2. The research is conducted anonymously or the research ***does*** ***not*** involve the collection or recording of behavior that, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

Yes  No 3. The research ***does not*** involve deception.

Yes  No 4. The research involves ***minimal to******no*** foreseeable risk (physical, psychological, social, legal, reputational, or financial) to human subjects.

Yes  No 5. The research ***does not*** require a waiver from informed consent procedures.

Yes  No 6. The research is conducted anonymously (i.e., ***does not*** link participant name or other identifier with results) and preserves confidentiality (i.e., **does not disclose** any identifying information about participants when reporting the research).

**If you answered Yes to every statement in Section One, please proceed to Section Two. If you cannot answer Yes to every statement in Section One, you are not eligible for exemption from IRB review and must fill out *Form A: Application to Conduct Research with Human Subjects*.**

**SECTION TWO:** Please check all categories that apply to your research project:

1. Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or (b) any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. The research also does not involve deceiving the subjects regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (a) the identifiable private information or identifiable biospecimens are publicly available; (b) information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (c) the research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under the health care operations of 45 CFR 160 and 164; or (d) the research is conducted by, or on behalf of, a federal department or agency using government-generated or government-controlled information obtained for non-research activities.

5. Research and demonstration projects that are conducted or supported by a federal department or agency, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**SECTION THREE:** Please provide all of the information requested below.

1. Purpose of the investigation: *Provide a brief overview of the proposed research to be conducted and list the overall objectives of the study.*

Click here to enter text.

2. Description of methodology – *Clearly describe the research procedures you plan to use to meet the objective(s) of this project. Specifically, explain how the project will be conducted, data collected, and participants identified in line with the objective(s). Include copies of all scripts, surveys, questionnaires, interview protocols, and other relevant documentation you plan to use as appendices.*

Click here to enter text.

3. Plan of data analysis –*Once collected, how will the data be analyzed and used? What statistical/analytical methods will be used for the data to meet the objectives of this project?*

Click here to enter text.

4. Dissemination of findings – *How do you intend to disseminate the findings of this research project? Please check all applicable venues that may be used in disseminating the findings to others.*

Publication in an academic, scholarly, or other public domain

Publication in a public campus domain (ie, Honors thesis)

Publication in an internal program/department campus project

Presentation at an academic conference

Presentation at a campus conference/forum (does not include classroom presentations)

Presentation at an off-campus conference, community event, or other public forum

Distribution/sharing of data from the research with others

Contribution to another larger/related research project

Other – please explain: Click here to enter text.

None – please explain: Click here to enter text.

Click here to enter text.

5. Estimated number of total participants (including those to be solicited and recruited): Enter text.

Estimated number to be studied: Enter text.

6. Demographics of participants: *Describe your subject population in broad demographic terms.* *Describe the criteria used in the selection process. Indicate if there are any special inclusion or exclusion criteria.*

Click here to enter text.

7. Participant incentives/costs: *Will any inducements (e.g. money, course credits, gift cards, or other compensations) be offered in exchange for participation in this research project? Will participants incur any costs from participation? If so, describe the nature of the inducements or costs, and how they will be distributed. Include a copy of any material you will use to recruit participants (e.g., advertisements, flyers, telephone scripts, verbal recruitment, or cover letters)*

Click here to enter text.

8. Confidentiality: *Describe the steps that will be taken to ensure confidentiality of all personal data collected. Be specific. How will you ensure that research personnel (including students) understand their responsibilities in maintaining confidentiality? How will confidentiality be preserved as data are collected, stored, analyzed, and published? When will data identifying individual participants be destroyed*?

Click here to enter text.

**ASSURANCE STATEMENT**

I confirm that the procedures described above are accurate and will be followed in the course of the research project. I have completed the online Human Participant Protections Education Training Course and am including a copy of my certificate to that effect. I will notify the IRB of any changes to procedures and if unanticipated problems arise during the research process.

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Signature of the Principal Investigator Date

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| **For Faculty/Staff Supervisors of Student Research:**  Federal guidelines mandate that research be of sufficient merit to justify the participation of human subjects. In the case of student research, the responsibility for determining merit is shared with the student’s supervisor. By signing below, I acknowledge that I have reviewed the proposed project with the student researcher named above and find the research to be of sufficient merit to justify the use of human participants. I acknowledge my responsibility for protecting the rights and welfare of human research participants, ensuring compliance with IRB protocols and expectations, and assisting the student researcher in the effective administration and conduct of this project. I also acknowledge that I have completed the online Human Participant Protections Education Training Course within the last ten years.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Faculty/Staff Supervisor Date |