**VASSAR COLLEGE**

Institutional Review Board (IRB)

Instructions & Application

**Part I. General Instructions for Application for Research Proposal Review**

1. Your submission to the IRB must include the cover sheet and the application form, which is given in Part II below. Please label your cover sheet and application documents using the following format: JonesL.IRBcover.1Feb2021.docx, JonesL.IRBapp.1Feb2021.docx.

2. All applications must be typed. If your application contains several measures or appendices, please cut and paste files into one continuous document. **Email your application to irb@vassar.edu**. Please do NOT submit IRB applications directly to members of the IRB committee; doing so will result in lengthy processing delays.

3. Before completing the application, applicants may want to review pertinent materials on the IRB website concerning **harm, risk, minimal risk,** and **informed consent**. Also, if your research involves minors, pregnant women, prisoners, or the mentally disabled, check the relevant section of the Department of Health and Human Services Protection of Human Subjects website (e.g., for minors, check [here](https://www.ecfr.gov/cgi-bin/text-idx?SID=1aa3409cdfc033ec1e1b1ee1da2f4dba&mc=true&node=sp45.1.46.d&rgn=div6)) for additional regulations.

4. In order to provide adequate time for review, proposals must be submitted to the IRB at least thirty days before implementation.

5. While applications can be submitted to the IRB at any time, responding to your application may take longer if it is received right before or during the winter or summer breaks. Please plan accordingly.

6. Proposals involving off-campus subject populations in area schools should be based on consultation with the Education Outreach Coordinator (contact the Education Department at extension 7360). For research involving other kinds of community institutions, consultation with the Office of Community-Engaged Learning may be helpful.

7. Faculty members supervising students engaged in research should be attentive to the sensitive nature of certain topics of research (e.g., death and dying, sexuality, etc.) and use discretion in advising students interested in conducting empirical research in these areas.

8. For proposals undergoing full review, approval is limited to one year after the date the project was last approved by the Institutional Review Board (IRB). For projects continuing or being initiated beyond that period of time, investigators must resubmit the application for review. Continuing projects must meet any new federal and state guidelines.

9. If you change your research project materials or procedures in any substantive way after receiving IRB approval, you must send an email to **irb@vassar.edu** requesting approval of the modifications.

10. If you have any questions about the status of your project in this regard, please contact **irb@vassar.edu**.

**Part II. Application for Research Proposal Review** (12 PARTS)

1. Title of the proposal and date of submission:

2. Name and address of the primary investigator (must be a faculty member or administrator):

3. Department of origin of the proposal:

4. Name(s) of student research assistant(s) or student investigator(s):

5. Design Overview (Answer “Yes” or “No”. You will have the opportunity to address these issues in other parts of the application):

A. Is your research free of deception?

B. Are the risks to participants minimal (see 8C, 8D)?

C. Will the subjects be 18 years of age or older?

D. Will you be obtaining genuine informed consent (see 11C)?

E. Are participants’ responses anonymous?

6. Research proposal summary (100 words or less):

7. Theoretical justification for the research:

8. Detailed Research Proposal: Provide a detailed description of your research proposal. Describe the nature of the tasks and the role of the participants and investigator. Be sure to address the following components in your description.

A. Who will be the participants and how will they be recruited? How many participants do you expect to use?

B. Describe the psychological and/or physiological stimuli, manipulations, or interventions and the means used to administer them. Indicate the steps that will be taken to ensure the proper operation of the equipment used to administer stimuli and interventions. Give particular attention to prevention of accidental harm or injury to the subjects.

C. Describe the level of risk to which the participants will be exposed by participating in this study. Why are the risks necessary? Why is the research important enough to justify the risks?

Even in the case of minimal risk, participants should be informed of the nature of the potential risk. Federal and state guidelines define minimal risk as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

D. Is there any deception of the participants who will be involved? If so, what is its rationale? Why is deception necessary? Why is the research so important to justify the use of deception? Are there modifications to this research that would allow for genuine informed consent?

E. Describe the expected behavior of the participants and the behavior of the investigator during the research. This must include a written statement of what is to be read or said to the participant concerning the research.

F. Describe how the participants are to be debriefed and the mechanism for alleviation of stress or psychological harm that may derive from participation in this study. Provide a written statement of what will be said to, read to, or read by the subjects during the debriefing.

G. State what the information/data from this research are to be used for (e.g., class assignment, thesis, etc.). Who will have access to the data? What will be done with the data at the end of the study. Consider whether waiting until the end of the study may allow subjects to make a more informed choice about permitting archiving of their data.

H. If the current project is being conducted by students, please describe the level of involvement of the faculty advisor. How will students be trained?

9. Describe how the privacy and anonymity of participants are to be protected.

10. Include a copy of any questionnaires or interview questions that will be used. In order to ensure informed consent, participants should be informed of the nature of questions they will be asked and of the possible risks involved in consenting to the interview or study. For example, some questions may be personal or emotional in nature and may cause distress, embarrassment, or emotional reactions.

11. All IRB-approved research must include the appropriate consent form(s). For participants younger than 18 years old, the researcher must obtain consent of the parent/guardian and assent of the child prior to participation. All persons 18 and older must provide informed consent prior to participation in the project. Consent must be documented in writing unless a waiver permitting modifications is obtained from the IRB.
Please see the guidelines (11 C) for legally informed consent and make sure that your procedures and consent forms meet the requirements.

1. Submit a copy of each kind of consent form you propose using in your project.

Consent/assent form prototypes are attached to the application document. You should edit the relevant one(s) to fit your project and include only those with your application submission.
	* Adult Consent Form is to be used for participants 18 years and older.
	* Parent/Guardian Consent Form is to be used for parents/guardians of participants who are younger than 18.
	* Minor Assent Form is to be used with participants 7-17 years old.

Participants should sign two copies of each form. One copy is for the participant’s own records, and one copy should be stored by the investigator. This copy should not be stored with the participant’s answers/data.

1. **Children as participants.**
Researchers using children as participants must provide the parents/guardians with full information concerning the study, usually in the form of a letter. The consent form must provide detailed information about the project. Two copies of the Parent/Guardian consent form should be signed by the parent. One is to be retained by the parent and the other returned to the Primary Investigator. A copy of the letter to the parents providing the essentials of the proposed study must accompany the proposal to the IRB. The child should sign an assent form or be asked to assent to the research, depending on age, as explained below.

For those under 7 years of age, participation may go forward if the parent or guardian of the subject signs the Informed Consent on behalf of the subject, and the child verbally assents to the research. The participant must be allowed to withdraw from the research.

For those 7 to 17 years old, participation may go forward if the parent or legal guardian of the subject signs the Informed Consent on behalf of the subject, and the child affirms his or her intention to voluntarily participate in the research by signing an assent form. This form to be signed by the child should give an explanation of the procedures to be used, their potential to cause discomfort and inconveniences to the child, and the general purpose of the research. The participant must be allowed to withdraw from the research. The level of written and/or verbal instruction and information given to the child should be appropriate for the age, maturity, and condition of the child. The psychological development and emotional state of each child must be sufficient to enable meaningful assent.

For participants 14 to 18 years old, the parent or legal guardian must sign the Informed Consent. The same consent form as used in comparable adult research may be employed and this form must also be presented, under appropriate conditions, for obtaining the consent of the child before the research begins. Psychological development and emotional state of each child must be sufficient to enable meaningful consent. The child must assent to the research and must be allowed to withdraw from the research.

C. Guidelines for Legally Effective Informed Consent. Federal and State law require that LEGALLY EFFECTIVE INFORMED CONSENT be obtained from all human subjects who are participating in a research project or activity sponsored by or at Vassar College.

Informed consent means knowing consent. The person giving consent must be able to exercise free power of choice without undue inducement, coercion, or any element of force, fraud, or deceit.

The basic information necessary in seeking such consent includes:

1. An explanation of the purposes of the project, the expected duration of the subject’s participation, and procedures to be followed including identification of any procedures which are experimental. Participants should understand the procedures they will undergo, tasks they will complete, or types of questions they will be asked to answer. There should be a clear statement that the project involves research. Words such as "research," "investigation," "experiment," "clinical trial" or "investigation" should be included.

2. A description of any foreseeable harm, discomfort, and risk. Even in the case of minimal risk, participants should be informed of the nature of the potential risk.

According to federal guidelines: Minimal risk is defined as: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

3. A description of any benefits to the subject or others to be derived from the research (payment or course credit is not a benefit);

4. In the case of treatments, a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

5. A statement describing the extent to which confidentiality of records identifying the subject are to be maintained. Investigators are obligated to protect the privacy of study participants. All reasonable measures must be taken for maintaining the confidentiality of subjects’ records. However, absolute confidentiality cannot be promised. For example, a small subject pool may make individual participants recognizable. Some kinds of data must be made available to federal and regulatory agencies.

6. A statement of whom to contact for answers to pertinent questions about the research. This must be the PI.

7. A statement that the person is free to discontinue participation at any time without

penalty or prejudice.

Federal law requires that the actual procedure utilized in obtaining “legally effective informed consent” be fully documented. A written consent document embodying all of the basic elements of information given above must be read by or to the subject. In either case, the consent form must contain the required elements and must be signed by the subject or a legally authorized representative. In rare cases, where the risk to the subject is minimal and where these procedures will surely invalidate important objectives of the project, Board approval of modified procedures may be sought.

12. Is the project being conducted off campus? If so, please follow these additional guidelines:

1. Has the research been approved at another institution? Please provide a copy of the proposal, the date of the approval, and the approval code, if applicable.
2. Proposals involving off-campus subject populations in area schools should be based on consultation with the Education Outreach Coordinator (contact the Education Department at extension 7360). For research involving other kinds of community institutions, consultation with the Office of Community-Engaged Learning may be helpful.

**Consent forms: All information indicated must be included.**

**VASSAR COLLEGE**

Department of [Insert name]

Adult Consent Form

Primary Investigator: [Insert the name of the professor/supervisor]

Student Researcher(s):

Title of Project:

I acknowledge that on \_\_\_\_\_\_\_\_\_\_, I was informed by [Insert the name of the professor or administrator] of Vassar College of a research project having to do with the following:

[In this section, please:

1) overview the nature of the research project;

2) overview the basic procedures/types of questions and the participant’s role;

3) explain how confidentiality will be maintained;

4) describe the approximate duration of participation;

5) provide contact information (e.g., e-mail and phone number of the primary investigator) and state that participants may contact the PI with questions or concerns.]

**Potential Risks:**[Describe any potential risks and the level of risk, which cannot be less than minimal, i.e., comparable to that posed by normal daily activities.]

**Potential Benefits:** [Describe any potential benefits. In most cases, the participant will not benefit in any direct way from participation. Course credit, compensation, and contributions to knowledge/science are not included in this section.]

I am aware, to the extent specified above, of the nature of my participation in this project and the possible risks involved or arising from it. I understand that I may withdraw my participation in this project at any time without prejudice or penalty of any kind. I hereby agree to participate in the project. (You must be at least 18 years of age to give your consent.)

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

Date

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

 (Printed name of Participant)

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

 (Place: City and State)

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

 (Signature of Participant)

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

(Address: e.g., Residence Hall & Room #)

**VASSAR COLLEGE**

Department of [Insert name]

Parent/Guardian Consent Form

Primary Investigator: [Insert the name of the professor/supervisor]

Student Researcher(s):

Title of Project:

I acknowledge that on \_\_\_\_\_\_\_\_\_\_, I was informed by [Insert the name of the professor or administrator] of Vassar College of a research project having to do with the following:

[In this section, please:

1) overview the nature of the research project;

2) overview the basic procedures/types of questions and the participant’s role;

3) explain how confidentiality will be maintained;

4) describe the approximate duration of participation;

5) provide contact information (e.g., e-mail and phone number of the primary investigator) and state that participants may contact the PI with questions or concerns.]

**Potential Risks:**[Describe any potential risks and the level of risk, which cannot be less than minimal, i.e., comparable to that posed by normal daily activities.]

**Potential Benefits:** [Describe any potential benefits. In most cases, the participant will not benefit in any direct way from participation. Course credit, compensation, and contributions to knowledge/science are not included in this section.]

I am aware, to the extent specified above, of the nature of my child’s participation in this project and the possible risks involved or arising from it. I understand that I may withdraw my child’s participation in this project at any time without prejudice or penalty of any kind. I hereby agree to allow my child to participate in the project. (You must be at least 18 years of age to give your consent.)

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

Date

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

 (Printed name of Legal Guardian)

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

Home Address

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

 (Signature of Parent/Legal Guardian

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

 (Printed name of Child Participant)

**VASSAR COLLEGE**

Department of [Insert name]

Minor Assent Form

Primary Investigator: [Insert the name of the professor/supervisor]

Student Researcher(s):

Title of Project:

I was told by [Insert the name the person asking the questions/conducting the study] of Vassar College about a study:

[In this section, please:

1) overview the nature of the research project;

2) overview the basic procedures/types of questions and the participant’s role;

3) explain how confidentiality will be maintained;

4) describe the approximate duration of participation;

5) provide contact information (e.g., e-mail and phone number of the primary investigator) and state that participants may contact the PI with questions or concerns.

6) describe any potential risks and the level of risk;

7) describe any potential benefits]

If you want to stop participating in this project, you are free to do so at any time. You can also choose not to answer questions that you don't want to answer.

If you have any questions or concerns you can always ask me or call [name of PI] \_\_\_\_\_\_\_\_\_\_ at this number: \_\_\_\_\_\_\_.

I understand the project described above. My questions have been answered and I agree to participate in this project. I have received a copy of this form.

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

Date

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

 (Printed name of Participant)

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

 (Signature of Participant)