**Albion College Institutional Review Board**

**Cover Sheet: Self-Report of Review**

**Status Form C – 3**

**STUDENTS, FACULTY AND COMMUNITY MEMBERS ARE ELIGIBLE TO SUBMIT THIS TYPE OF PROPOSAL FOR A PROPOSAL NEEDING FULL REVIEW.**

**Proposal type (please check one):**

 NEW [ ] Suggested Revisions [ ] Renewal [ ] Addendum [ ]

 (Pending approval) (Up to 12 months) (Changes to previously approved proposals)

Principal Investigator (PI):

(Principal Investigator name – **PLEASE PRINT**)

E-Mail address: Phone number:

\_\_\_\_\_In my judgment, the above named research project qualifies as a FULL IRB review. **C-3 form see below**

**Is this study receiving any external funding?** No \_\_\_\_

IF YES \_\_\_\_ **please provide the name of the funding agency and, the proposal title (if different from above)**

**For STUDENTS:** Is this proposal connected to a FURSCA project? No \_\_\_\_

IF YES \_\_\_\_ **please note the FURSCA committee requires IRB approval prior to the project start date.**

**For FACULTY:** Are you asking for FDC funding for this project? No \_\_\_\_

IF YES \_\_\_\_ **please note you must obtain IRB approval before funds can be relinquished from the college.**

\*\*\* Note to faculty: the committee encourages you to obtain a peer-review of your proposal.

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**PLEASE PROVIDE A BRIEF ABSTRACT/ SUMMARY OF YOUR PROPOSAL**

Project Title:

**EXACT** dates for Data Collection: Start: \_\_\_\_\_\_\_\_\_\_\_\_ End: \_\_\_\_\_\_\_\_\_\_\_\_

Summarize your proposal, to include what, when, how, and where:

**Albion College Institutional Review Board**

**Signature Page**

Signature Page for:

(Principal Investigator name – **PLEASE PRINT**)

Project Title:

I certify that the statements herein are accurate and complete. I agree to protect the rights and welfare of the human participants taking part in my research, to abide by College guidelines for securing informed consent, to safeguard the confidentiality of my research data, and to inform the chair of the IRB should any changes in the research protocol or human participant issues arise during the course of this research.

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**   (Principal Investigator)

Principal Investigator **Email:**  **Phone:**

Principal Investigator Status: Faculty/Staff Student Community Member

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Sponsor Name:

(Sponsor name – **PLEASE PRINT**)

I have reviewed this proposal and my signature indicates that the proposed project meets previously established standards for and I will oversee this research in its entirety. Failure to give proper oversight may cause a delay in the approval process.

**Signature:**   **Date:**

(Sponsor)

Sponsor **Email:**  **Phone:**

COMMITTEE USE ONLY BELOW THIS LINE

Approval Signature of IRB Chair:

Date approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval of IRB Member:

Via email on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval of IRB Member:

Via email on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB Form C-3**

**Checklist for Research Qualifying for Full Review**

Directions: Submit this form and the research proposal to the IRB committee at IRB@albion.edu if you believe your project requires full IRB review. Please check all applicable items in Part I, include a full research proposal that explicitly provides all relevant information as requested in Part II, and check all applicable items in Part III.

**Part I:** (Check all items that apply to your research project.)

|  |  |
| --- | --- |
|  | The research involves minors, prisoners, fetuses, pregnant women, or mentally or cognitively disabled individuals as participants. [NB: The accompanying proposal must indicate clearly why the use of participants in any of these categories is scientifically necessary.] |
|  | The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability, be stigmatizing, or be damaging to the participant’s financial standing, employability, insurability, or reputation. [NB: The accompanying proposal must indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve participants’ anonymity/protect participants’ confidentiality.] |
|  | The research involves the collection of information regarding sensitive aspects of the participants’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior). [NB: The accompanying proposal must indicate clearly why the collection of such information is scientifically necessary and what steps will be taken to preserve participant’s anonymity/protect participant’s confidentiality.] |
|  | The procedures of this research involve more than minimal risk to the participant (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests). [NB: The accompanying proposal must identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures, indicate clearly how such risks to participants are reasonable in relation to anticipated benefits, describe procedures designed to protect against or minimize such risks, and assess their likely effectiveness.] |
|  | This research does not fall into any of the categories explicitly identified as qualifying for Monitored or Expedited status |

**Part II:**

Please provide a copy of the full research proposal. In the spaces below, indicate where in the proposal (give page, line numbers) relevant information can be found. If any of the following are not explicitly covered in the proposal, address them in a supplementary statement.

**Part III:** (At least one item should apply.)

|  |  |
| --- | --- |
|  | Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. [NB: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio- or videotapes, names will be recorded, even if they are not directly associated with the data).]  |
|  | Collection of data through use of the following procedures:a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.  |
|  | Collection of data from voice, video, digital or image recordings made for research purposes where identification of the participants and/or their responses would not reasonably place them at risk of criminal or civil liability, be stigmatizing, or be damaging to the participants' financial standing, employability, insurability, or reputation. |

**All proposals must provide the following information:**

1. What is the purpose of the proposed study? Please cite references to other research studies that relate to your hypothesis or research question, state why this research is important, and how it adds to general knowledge in your field. Please answer in approximately in 200-300 words. Please be concise.

2. Describe the proposed participant sample and number (a reasonable maximum number must be included). Please give the sample’s expected age range and gender. If participants are under the age of 18 the parents or guardian will need to give permission first.

3. How will participants be recruited and selected? How did your research hypothesis guide this sample?

4. Briefly describe all research procedures that will apply to human participants. Be sure to indicate:

a) approximately how much time each participant is expected to devote to the research.

 b) how data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio- or videotapes be employed in data collection?). Attach copies of

 all written instruments and/or describe any apparatus with which participants will be in direct contact.

c) methods for obtaining informed consent or assent in the case of minors. For minors, indicate how the consent of parents or legal guardians will also be obtained. Attach copies of all materials used to obtain informed consent or assent. See Informed Consent or Parental Permission templates.

d) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research). Normally data should be stored for seven years upon completion of the data collection in a locked cabinet in a faculty member’s office or lab. If your unencrypted laptop computer used for data storage is lost, you must report it immediately to IRB@albion.edu.

e) if deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. **[NB: If the research is such that debriefing cannot be carried out, the project must be submitted for full IRB review.]**

5. Indicate any benefits that are expected to accrue to participants as a result of their involvement in the research. In the event that participants will be paid, describe all payment arrangements, including how much participants will be paid should they choose to withdraw from the study prior to completion of the research.

6. Describe any relationship between researcher and participants, such as: teacher/student; superintendent/principal/teacher; employer/employee. If such a relationship exists, how will it affect the participant's ability to take part voluntarily and how will the principal investigator handle it? If your research involves data gathering at a school, please include a letter or email from the teacher of the class involved and principal of the school.

**All proposals must provide the following information:**

***Failure to meet these requirements will result in your application being delayed.***

**FINAL CHECKLIST**

Is there an EXACT beginning and ending date for the proposed data collection? Yes \_\_\_\_

Have you included a good description of your proposal, including citations of other related research? Yes \_\_\_\_

Is the participant sample described? Yes \_\_\_\_

Is the number of participants stated clearly? Yes \_\_\_\_

Is the issue of using minors as participants included? Yes \_\_\_\_

How and where will collected data be stored? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for how long? \_\_\_\_ (Seven years is typical)

Is deception being used? Yes \_\_\_\_

Is a copy of the debriefing sheet included (required if deception is used)? Yes \_\_\_\_\_

Does the debriefing statement adequately address sensitive information and remind subjects of contact information? Yes\_\_\_\_\_

Is a copy of the research survey included with this proposal? Yes \_\_\_\_\_

Is a copy of the informed consent form included with this proposal? Yes \_\_\_\_

Will the participants experience any discomfort that is greater than in everyday life? Yes\_\_\_\_ No\_\_\_\_\_

Please explain, if yes\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What safeguards are in place? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**INFORMED CONSENT CHECKLIST**

Does the informed consent have a statement in the beginning that the study involves research? Yes \_\_\_\_

Is the consent form written at an appropriate reading level for the participants? Yes \_\_\_\_

Is there an explanation of the purpose of the research? Yes \_\_\_\_

Is the expected duration of participation stated? Yes \_\_\_\_

Is it stated that participation is voluntary, and refusal to participate or discontinue involves no penalty? Yes \_\_\_\_

Is a description of the procedures to be followed included? Yes \_\_\_\_

Are any foreseeable risks or discomforts to subjects described? Yes \_\_\_\_ No\_\_\_\_\_\_

Are any benefits to the subjects or others described? Yes \_\_\_\_ No\_\_\_\_\_\_

If compensation is to be given, is it described? Yes \_\_\_\_ No\_\_\_\_\_\_

Is there a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained? Yes \_\_\_\_

Did you include contact information for answers to questions about research and participant rights? Yes \_\_\_\_

Does it include a signature line, and a line for the printed written name of the participants, and the date? Yes\_\_\_\_

In addition to PI’s contact information, you must include the following statement:

“If you have any question about your rights as a participant in this research project you can contact the chair of Albion College’s Institutional Review Board at: IRB@albion.edu.”

**PROTOCOL FOR RE-SUBMITTING, if the committee has questions:**

If the IRB committee has questions about your proposal, you will need to answer the questions via email. Once reviewed and agreement that no further changes are needed, conditional approval will be given. Then you need to re-submit the entire proposal with the new information. Once Schara has a clean copy of your re-submitted proposal, the email approval from the chair will be sent and the data collection can begin. This process can take several weeks, so plan ahead.

Revised February 2017