Researcher Name:



**INSTITUTIONAL REVIEW BOARD (IRB)**

**REVIEW FORM**

**FOR PROJECTS USING HUMAN SUBJECTS**

Investigators are responsible for ensuring that the rights and welfare of human subjects participating in research activities are protected, and that methods used and information provided to gain subject consent are appropriate to the research. **The IRB will review only those assignments, activities, or investigations that are defined as research.** “Research” as defined by federal administrative bodies is “a systemic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102). Course projects whose primary intent and design are pedagogical, and are intended to contribute to the general body of knowledge, are subject to IRB review.

All the research activities involving the use of human beings as research subjects (participants) must be reviewed and approved by the Pawling High School’s Science Research Program’s IRB Institutional Review Board (IRB).

Investigators may not solicit subject participation or begin data collection until they have received approval or written concurrence that research has been determined to be exempt from the Institutional Review Board.

This form may be downloaded and completed but must be submitted in both electronic and hard copy due to signature requirements. If you have questions about the IRB application form or about the review process, contact:

Gillian Rinaldo

Pawling High School

Science Research Program Director

IRB Committee Chair

Work Phone: 845-855-4620

Cell Phone: 914-414-6688

E-mail: Rinaldog@pcsdny.org

The Institutional Review Board generally meets on an ad hoc basis as proposals are submitted for review. Applicants must allow a minimum of 2 weeks for the review process. Allow for extra time if proposal is submitted during the summer or winter. Proposals describing research that involves more than minimal risk to participants or the school district (any harm anticipated in the proposed research that is more probable or of greater magnitude than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, or those researchers using PCSD students as subjects/participants, or investigations utilizing the PCSD as the premise for their research) will require a full review. This will require initial approval from the Pawling High School IRB Committee, followed by Central Administrative IRB approval.

A notice of the IRB’s action will be sent to and communicated with the researcher(s). It is the responsibility of the researcher(s) to see that the form is given to any agency which may require it.

**INSTRUCTIONS:**

Your responses to the 24 questions in the IRB summary proposal sheets that follow are basic to the Institutional Review Board’s determination about the protection of the rights and welfare of human subjects in your research. Your responses should be clear, complete, and easy to understand.

Place your typewritten response immediately under each question (not on a separate sheet). It is important that you answer every question. If you believe that a question does not apply to your research, enter a response such as “N/A” or “does not apply” and ***please explain how and why this does not apply to your research.***

**Copies of the following must be included with this form:**

1. The letter/script that will be used to inform participants of the nature of the research.

2. The informed consent the subject(s) will sign.

3. Copies of surveys, instruments or measures, questionnaires, interview schedules, focus group questions and/or other materials used to collect data.

Submit one complete hard copy and one digital copy (as a .docx or .pdf file, via e-­‐mail or usb) to:

Gillian Rinaldo

Pawling High School

IRB Committee Chair

Room A-37

E-‐mail: Rinaldog@pcsdny.org

**IRB Review Form for Projects Involving Human Subjects**

**Pawling High School**

|  |  |
| --- | --- |
| **Research Project Title** |  |
| **Category** |  |
| **Topic Area** |  |
| **Principal Investigator(s)**  (First Name, Middle Initial, Last Name) |  |
| **Cell Phone** |  |
| **Email** |  |
| **Signature** |  |

**Application Questions**

**Please type your responses.**

INTRODUCTION TO THE PROPOSED RESEARCH

1. Provide the date when you propose to begin research and the date when you anticipate that research will be completed.

|  |  |
| --- | --- |
| Proposed start date: |  |
| Anticipated completion date: |  |
| Data Destruction date: |  |

2. Indicate any source(s) of funding for the proposed research i.e., fundraisers or grants.

DESCRIPTION OF THE PROPOSED RESEARCH

3. Provide a brief (1 page or less) description of the purpose of your research.

4. Indicate the setting or location(s) where research will be conducted. Attach letters of support or agreement, as necessary, showing that you have permission to conduct research at that location.

\*If you are interacting with human subjects outside of the United States, describe what procedures are required to adhere to the human subjects mandates for the country where data collection will take place.

Fieldwork will be conducted in New York: No formal permission is required for such fieldwork, nor is such permission relevant so long as the research is being conducted digitally or on property that you own. In NY, individuals choose to participate or not based on their own interests and incentives offered by the Principal Investigator.

5. Does the proposed research require that you deceive participants in any way?

\_\_\_\_ Yes

\_\_ \_\_No

6. If your response is “yes”, describe the type of deception you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script.

7. Describe in detail what will happen to or be required of subjects in your investigation.

RISKS AND BENEFITS

8. Describe any potential physical or psychological risks or problems that a research participant may encounter by participating in this investigation. Also describe how you plan to minimize these risks. Examples of risks and problems include but are not limited to physical injury, painful simulation, deception, coercion, embarrassment, lack of confidentiality, lack of full disclosure, and lack of feedback for subjects. If appropriate, include a description of any special qualification or training by investigators that will be used to minimize risk for the subject (e.g. CPR certification).

9. Describe the potential benefits of conducting this research. List the benefits to the participants themselves, contributions to the field of knowledge, and benefits to society as a whole. If the research participants will not receive any direct benefits from participating in this study, indicate this in your response.

PARTICIPANTS

10. Indicate the total number of participants you require, and your sampling procedure.

11. Do you plan to use vulnerable subjects in your investigation? Examples of vulnerable subjects include students, children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons.

\_\_\_\_ Yes

\_\_ \_\_No

12. Describe the type and source of subjects required (i.e., single parents in NY, psychology class students from Dutchess County, patients at Putnam County Medical Center Hospital, sixth graders at Pawling Middle School, etc.).

13. Explain why this particular type, source and age of participant is important to this particular research study.

14. Provide an estimate of the amount of time that will be requested from each person who participates in this research study (number of sessions, amount of time per session, and duration of period of time over which the research will take place).

15. Describe the relationship between the participants and the researcher. How does the researcher know or how will you identify these participants. Please identify any potential biases that may occur due to this relationship.

INFORMED CONSENT PROCEDURES

16. Describe what you have done to make sure your subjects are fully informed about their role in the research, that their confidentiality will be maintained, and that their participation is voluntary, and that they can withdraw at any time without penalty. Include a description of how and by whom consent will be sought from subjects.

17. Describe any incentives, inducements, or reimbursements (e.g. extra credit, research credit, cash payment, volunteer hours, raffle, and gift) that will be offered to the participants. Indicate whether participants will receive the incentives if they withdraw before the study has been completed.

18. Describe all methods of participant recruitment (e.g. where and how you will identify and recruit participants).

CONFIDENTIALITY OF THE DATA

19. Indicate the intended use of your data. Check all that apply.

\_\_\_\_\_ Requirement for SUNY Albany’s Science Research Program

\_\_\_\_\_ Science Research Competitions

\_\_\_\_\_ Publication/journal article

\_\_\_\_\_ AP Science Research I

\_\_\_\_\_ AP Science Research II

\_\_\_\_\_ Results released to participants/parents

\_\_\_\_\_ Undergraduate project

\_\_\_\_\_ Results released to mentor

\_\_\_\_\_ Results released to employer or school

\_\_\_\_\_ Conferences/presentations

\_\_\_\_\_ Results released to agency or organization

\_\_\_\_\_ Other

Describe below:

20. Describe the steps you will take to insure the confidentiality of the data. Indicate how you will safeguard data that includes identifying or potentially identifying information (e.g. coding). Indicate when identifiers will be separated or removed from the data.

21. Indicate where and how you will store the data and how long you plan to retain it. (Research proposals that involve any type of use of human subjects must be retained for 1 year minimum.) Describe how you will dispose of it (e.g. erasure of tapes, shredding of data).

22. Will results of this research be made available to the subjects involved?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

23. If so, how and when?

24. Who is guiding you in this research endeavor?

Mentor(s)

|  |  |
| --- | --- |
| Name: |  |
| Affiliation: |  |
| Phone: |  |
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| Email: |  |
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**Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects. See especially sections 46.102 Definitions, 46.116 General Requirements for Informed Consent, and 46.117 Documentation of Informed Consent. The document is available at**

**http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm. See references throughout this application to 45 CFR 46.**