**Clarion University Application for IRB Review**

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Complete Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department/ School/ College\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student Advisor (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address:

Department/ School/ College

Principal Investigator: (Please check one):

\_\_\_Faculty

\_\_\_Administration/Staff

\_\_\_Undergraduate student

\_\_\_Graduate student

Affiliation other than Clarion University

**Date Submitted**:

**Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Proposed Dates: Beginning Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ Completion Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (including data analysis)

Funding Agencies Supporting This Research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator**

Name of Investigator:

Please check one:

\_\_\_Faculty

\_\_\_Administration/Staff

\_\_\_Undergraduate student

\_\_\_Graduate student

Affiliation other than Clarion University

Department/Program/Affiliation:

E-mail:

Phone:

Fax:

Mailing Address

**Co-Investigators** (if applicable)

Name:

Department/Program/Affiliation:

E-mail:

Phone:

Mailing Address

|  |
| --- |
| **REVIEW LEVEL** |

Please check one:

**\_\_\_Exempt**

*Exempt projects involve no risks to the participants. Examples include: anonymous questionnaires or surveys that do not involve a sensitive topic or utilize minors, research being conducted in educational settings involving normal curriculum, and research on archival data. Exemptions do not apply to research involving: Pregnant Women, Fetuses, Prisoners, children < 18 years old, and/or Persons with Cognitive Disabilities. Exempt conditions include:*

* *Conducted in commonly accepted educational settings, involving normal educational practices.*
* *Use of educational tests, survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside of the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Exception to anonymity if the human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.*
* *Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to subjects.*
* *Conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.*
* *Taste and food quality evaluation and consumer acceptance studies.*

**\_\_\_Expedited**

*Expedited projects usually pose no more than minimal risks to the participants and other vulnerable participants. Examples include: questionnaires, surveys, and interviews that are not anonymous but do not involve sensitive topics or participants with cognitive impairment. Expedited projects involve no more than minimal risk to human participants and the following conditions (using standard methods):*

* *Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth and permanent teeth if patient care indicates a need for extraction.*
* *Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.*
* *Recording of data for subjects 18 or older using noninvasive procedures routinely employed in clinical practice.*
* *Collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week from subjects 18 or older who are in good health and not pregnant.*
* *Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accompanied in accordance with accepted prophylactic techniques.*
* *Voice recordings made for research purposes, such as investigations of speech defects.*
* *Moderate exercise by healthy volunteers.*
* *The study of existing data, documents, records, pathological specimens or diagnostic specimens.*
* *Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory or test development, in which the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.*
* *Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption are not required.*

**\_\_\_Full Board**

*Full review protocols involve more than just minimal risks, vulnerable participants or questionnaires/ surveys on a sensitive topic. Full review protocols will always require an informed consent document and require high standards to provide the participants with anonymity and/or confidentiality.*

|  |
| --- |
| **PROJECT DESCRIPTION** |

You must give the IRB enough information to enable them to make judgments regarding the status, approval or disapproval of your research. It is very important that you answer each question and section carefully and completely. If a section or subpart does not apply to your research, please indicate this by putting “N/A” in that space. Use as much space as you need. If the IRB doesn’t have enough information to make an adequate judgment, it will table your submission and request additional information. This can cause significant delays in the process.

Please use language and terminology that is understandable by people who are unfamiliar with your area of research.

**II. Project Overview:** Please provide a brief explanation (limit 200 words or less). Include the following in the explanation:

1. Research question and a brief statement of the problem to be investigated
2. Rationale of the study:
3. Justification for use of human subjects

Protocol Description:

II**. Participants in this Study**

**A. Subject selection**

* Will extra credit or grade be given to students who participate in the

project? Yes No

* Will subjects include anyone other than Clarion University students? Yes No
* Will subjects include minors (children under 18), people with special

needs, prisoners, or pregnant? If yes, circle group or groups. Yes No

* Will subjects be video/audio taped? Yes No
* Will subjects be identifiable to anyone other than the researchers?

through records, responses, or identifiers linked to the subjects? Yes No

* Does research deal with sensitive aspects of subjects' behavior, such

as illegal conduct, drug use, sexual behavior, or use of alcohol? If yes,

circle from above or otherwise list aspect(s) addressed: Yes No

* Are subjects free to withdraw at any time without penalty? Yes No
* Are there any deceptive elements to the study? Yes No
* Will subjects be exposed to any psychological stress (assault on

values, self-esteem, fatigue) or physical stress (electric shock, cold, etc.)? Yes No

1. Anticipated number of participants \_\_\_\_\_\_\_\_
2. Inclusion and exclusion criteria with justification.

**B. Identification and Recruitment of Potential Participants**

Attach copies of ALL materials that will be used to recruit participants (e.g. letters, advertisements, flyers, posters, email scripts)

1. Describe how you will gain access to potential participants, how participants will be contacted, and what information will be given during the recruitment process.
2. If participants will receive compensation in any way for their participation (e.g. money, course credit), indicate the type and the amount, the method of distribution of compensation and identify the source(s) of funds used for the compensation.
3. Will participants and/or data be accessed from a cooperating institution (e.g., school, university, business, agency)? If yes, a permission letter signed by an appropriate official (on the cooperating institution’s letterhead) granting access to participants and/or data must be provided to the IRB committee. The letter must be dated and signed within six months of the study.

**C. Interventions, Assessment Procedures and Other Sources of Data**

Attach copies of everything that is being used for the purposes of this study (e.g. tests, surveys, observation recording sheets, interview questions, laboratory reporting sheets, debriefing materials).

1. Describe your method/procedure, including all testing, observations, interviewing, interventions, educational programs or laboratory procedures. Describe how data will be recorded (e.g. video or audiotape, notes). Give approximate amount of time needed from participants.
2. If deception is involved or if information will be withheld from participants, describe the type of deception or the information being withheld and explain why this is necessary. Describe your procedures for debriefing participants. Include a copy of the debriefing statement with this application.
3. Discuss any physical, psychological, financial, social/economic or legal risks, or harm from breaches of confidentiality that might result from participation in this study and assess the likelihood and seriousness of these risks. Explain why it is necessary to expose participants to potential risks. For each risk identified, describe actions that will be taken to minimize the risk. If benefits do not outweigh risks, explain why this project is justified.
4. Explain how data will be recorded (describe any coding procedure). Will anyone besides the principal investigator and co-investigators have access to the raw data or any other form of data (please describe)? How will data be reported if presented or published (particularly important – will identifying information be masked)?
5. How will data be stored during the study? What will happen to data at the conclusion of the study? (Please refer to the IRB website for policy and procedure on record retention.)
6. If audio recording or video recording is conducted, describe how the recordings will be stored and what will happen to them at the conclusion of the study?
7. Describe how records (e.g. consents, survey, tapes, notes) will be destroyed. If records will not be destroyed, please explain why not. The principal investigator shall keep the informed consent for a period of three years after the study is complete. Until records are destroyed, they must be kept in a secure place, accessed only by the investigator, co-investigators or sponsor/advisor.
8. Expected length of time for study to be completed (data collection and analysis)?

**D. Informed consent** - **Attach consent and assent forms and/or script for oral explanation**

**E. Attach the following:**

a.Include one copy of the questionnaire, survey, test, etc. to be used in the research in its modified form for this study, including the informed consent statement at the

beginning, if applicable.

b. If applicable, include permission letter from survey author to use and/or modify the survey.

c. Proof of Completion of CITI modules.

|  |
| --- |
| **SIGNATURES** |

**The principal investigator, co-investigators and the advisor/sponsor must sign the application. By signing and submitting the application to the IRB, all parties listed agree that they have read and agree to the following statements.**

* I understand that I have responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research project.
* I agree to comply with all Clarion University policies and procedures, applicable federal, state and local laws, and the ethical principles of my profession.
* I understand that if any revisions/changes are made in the project I must obtain IRB review and approval prior to implementation of changes.
* I will immediately report any adverse events or unanticipated problems to the IRB.
* I understand that no part of the proposed research described in this application may be carried out until I have received final approval from the IRB.
* Additional statement for advisors/sponsors - I understand that I am the primary responsible party for legal and ethical performance of this project. I certify that I have read and approved this protocol and I agree to meet with the principal investigator(s) on a regular basis to review project progress and help resolve any problems which arise. I also certify that I will provide written approval of all revisions and additions to this protocol.

**Principal investigator:**

Name (please print)

Signature Date

**Co-investigators (if applicable) (copy and paste additional signatures lines as needed):**

Name (please print)

Signature Date

**Advisor / Sponsor (if applicable):**

Name (please print)

Signature Date

**SAMPLE CONSENT FORM (Required for Expedited and Full Board Review)**

**University Affiliation**: Clarion University of PA Administrative Office

108 Carrier Administration Building

Clarion, PA 16214

814-393-2337

**Project Title:**

**Principal Investigator:** Name with address, telephone number, and e-mail address

You are invited to participate in a research study being conducted through Clarion University*.* We ask that you read this form and ask any questions you may have before you decide whether or not you want to participate in the study. The University requires that you give your signed agreement if you choose to participate.

**Purpose of the Study:**

The purpose of this study is… *[Explain research question and purpose in lay language]*

**Procedures:**

If you agree to participate in this study, we would ask you to do the following things… *[Explain tasks and procedures and include the duration of the subject’s participation]*

**Risks and Benefits of Being in the Study:**

The study has the following risks… *[Risk must be explained, including the likelihood of the risk. If there are no risks, then state there are no risks.]*

The benefits to participation are… *[If no benefit, state that fact here. Compensation, including credit, is not considered a benefit.]*

**Compensation:**

*[Explain compensation, if any. If extra credit is offered, please elaborate. Also, if extra credit is offered, an alternative project must be identified, which requires a comparable amount of effort and extra credit. The alternative extra credit project must be offered for students who do not want to participate in the study.]*

**Confidentiality:**

All information will be handled in a confidential manner to the extent provided by law, so that no one will be able to identify you when results are recorded. The records of this study will be kept \_\_\_\_\_\_\_\_\_\_\_\_\_

**Right to Refuse or End Participation:**

I understand that I may refuse to participate in this study or withdraw any time. I also understand that I may be withdrawn from the study any time by the investigator(s).

Complaints or Concerns: Please contact the advisor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and/ or The Institutional Review Board at Clarion University of Pennsylvania.

Clarion University of PA Administrative Office

108 Carrier Administration Building

Clarion, PA 16214

814-393-2337

**Statement of Consent:**

I have read the information described above and have received a copy of this information. I have asked questions I had regarding the research study and have received answers to my satisfaction. I am 18 years of age or older and voluntarily consentto participate in this study.

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

Signature of Research Participant Date

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

Signature of Investigator

IRB Research Approval #:

***Thank you for your participation.***

**SAMPLE PARENTAL CONSENT WITH YOUTH ASSENT FORM**

**University Affiliation**: Clarion University of PA Administrative Office

108 Carrier Administration Building

Clarion, PA 16214

814-393-2337

**Project Title:**

**Principal Investigator:** Name with address, telephone number, and e-mail address

Your child (or ward) is invited to participate in a research study being conducted through Clarion University*.* We ask that you read this form and ask any questions you may have before you decide whether or not you want your child (or ward) to participate in the study. The University requires that you give your signed agreement if you choose to have your child (or ward) participate.

**Purpose of the Study:**

The purpose of this study is… *[Explain research question and purpose in lay language]*

**Procedures:**

If you agree to have your child (or ward) participate in this study, we would ask your child (or ward) to do the following things… *[Explain tasks and procedures and include the duration of the subject’s participation]*

**Risks and Benefits of Being in the Study:**

The study has the following risks… *[Risk must be explained, including the likelihood of the risk. If there are no risks, then state there are no risks.]*

The benefits to participation are… *[If no benefit, state that fact here. Compensation, including credit, is not considered a benefit.]*

**Compensation:**

*[Explain compensation, if any. If extra credit is offered, please elaborate. Also, if extra credit is offered, an alternative project must be identified, which requires a comparable amount of effort and extra credit. The alternative extra credit project must be offered for students who do not want to participate in the study.]*

**Confidentiality:**

All information will be handled in a confidential manner to the extent provided by law, so that no one will be able to identify your child (or ward) when results are recorded. The records of this study will be kept private. In any report or presentation, we will not include anyinformation that will make it possible to identify a research study participant.

**Right to Refuse or End Participation:**

I understand that I may refuse to participate in this study or withdraw any time. I also understand that I may be withdrawn from the study any time by the investigator(s).

**Statement of Consent:**

I have read the information described above and have received a copy of this information. I have asked questions I had regarding the research study and have received answers to my satisfaction. I am 18 years of age or older and voluntarily consentto allow my child (or ward) to participate in this study.

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

Signature of Parent/Guardian Date

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

Relationship of Parent/Guardian to Participant

*[If the minor is between the ages of 13 – 17, the researcher can add a youth assent paragraph to the bottom of the parental consent. Once the parent has signed the consent, the youth is given the form to read and the researcher explains the study.]*

I have read the information described above and I have received permission from my parent(s) to participate in the study. I understand the procedures, what will happen to me in the study and have had my questions answered to my satisfaction. I know that I can quit the study at any time. I agree to participate in the study.

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

Signature of Minor for Assent Date

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

Signature of Investigator

IRB Research Approval #:

***Thank you for your participation.***

Same as the individual consent.