**IRB Protocol Template**

**GENERAL INFORMATION**

Project title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Select appropriate design methodologies (select all that apply):

\_\_\_ Survey/Interviews/Focus Groups

\_\_\_ Naturalistic Observations

\_\_\_ Experimental design with between-subjects conditions and/or control group

\_\_\_ Experimental within-subjects design

\_\_\_ Qualitative

\_\_\_ Archival Analysis

Describe the purpose of the research. State the benefits to the participant and society. Write so someone outside your field can understand what you desire to investigate.

Describe the research design (survey, naturalistic observation, archival analysis, etc). Include if your sample will be random, systematic, cluster, convenience sample, etc.

Describe the subject / participant population including age ranges and explain how participants will be recruited.

Describe the procedures in detail from start to finish. Be concrete and specific. Your description should be written so that someone outside of your field can understand it. For example, in the case of research with human participants make it clear what participants will experience and do.

**EXEMPT CHECKLIST**

To determine whether your project is exempt or not, read the following six statements and indicate if any of them are relevant to your project. If you do not check any of these boxes, continue to fill out the exempt form below. If you do check any then proceed to the Non-Exempt form further down.

Exempt Checklist:

\_\_\_ My project does not fit within any of the categories below and does not meet criteria for exempt status *(If this box is checked, you will not fill out the remainder of the Exempt section)*

\_\_\_ Children / minors will be observed by adults who are also participating in the observed activities

\_\_\_ Identifiable information will be collected that could impact participants’ financial standing, employability, reputation, or put them at risk for criminal or civil liability

\_\_\_ Participants are under 18 years of age (other than in an established educational setting and involving minimal risk)

\_\_\_ Pregnancy will be a prerequisite for serving as a participant

\_\_\_ Fetuses in utero are subjects in this research

\_\_\_ Participants are presumed to not be legally competent

\_\_\_ Participants will be asked sensitive questions about personal feelings, behavior, interactions or sexual experiences, AND will have responses linked to their identity

\_\_\_ Alcohol, drugs, or other substances will be ingested, injected, or inhaled

\_\_\_ Blood and / or body fluids will be drawn

**EXEMPT CATEGORIES *(Exempt protocol application)***

Indicate the exemption categories that are applicable to the project. See a more detailed description below.

\_\_\_ Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices

\_\_\_ Category 2: Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior…

\_\_\_ Category 3: Research involving public officials or confidentiality maintained…

\_\_\_ Category 4: Research involving publicly available, or unidentifiable existing data…

\_\_\_ Category 5: Research involving public benefit or service programs…

\_\_\_ Category 6: Research involves taste and food quality evaluation, using wholesome foods or foods with approved / safe additives…

Provide a brief explanation of how your project fits in the exemption categories you have selected:

***RESEARCH QUALIFYING FOR EXEMPTION FROM FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS*** *(Quoted from the Code of Federal Regulations, Title 45, Part 46.101)*

1. *Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or on the comparison among instructional techniques, curricula, or classroom management methods. (For example: Testing the effectiveness of two different approaches to teaching a mathematical concept in a classroom setting would qualify for exemption under this category or, evaluating a departmental program).*
2. *Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior,****UNLESS****(i) information obtained is recorded in such a manner that the human subjects can be identified, directly or indirectly, through identifiers linked to the subjects;****AND****(ii) any disclosure of the subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation*
3. *Research involving the use of educational tests (cognitive, diagnostic, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section,****IF****(i) the human subjects are elected or appointed public officials or candidates for public office;****OR****(ii) federal statute(s) require(s) without exception that confidentiality of personally identifiable information be maintained throughout the research and thereafter.*
4. *Research involving the 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 through identifiers linked to the subjects.*
5. *Research and demonstration projects which are conducted by, or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise example:*
	* *(i) public benefit or service programs;*
	* *(ii) procedures for obtaining benefits or services 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.*
6. *Taste and food quality evaluation and consumer acceptance studies, if,*
	* *(i) if wholesome foods without additives are consumed or,*
	* *(ii) if a food is consumed that contains a food ingredient at or below the level of and for a use 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.)*

**EXEMPT INFORMATION**

Will data collected be anonymous and / or confidential? Please select all that apply:

\_\_\_ Anonymous means no one (not even the researcher) will be able to link to the subject’s identity with his / her responses

\_\_\_ Confidential means that the researcher will be able to link the subject’s identity with his / her responses, but that this link will be maintained in a confidential manner.

\_\_\_ Other – please describe below:

Please describe how you will maintain anonymity and / or confidentiality, or why this is not applicable to your project:

Please indicate the data collection method(s) to be used

\_\_\_ Self-Administered Survey

\_\_\_ Phone Survey

\_\_\_ Personal Interview

\_\_\_ Observational

\_\_\_ Public Record

\_\_\_Taste Evaluation

\_\_\_ Pathological or Diagnostic Specimens

If none of the above describe the data collection methods used, please describe them in detail.

Please describe the experimental methods to be used, if applicable

Will compensation or extra credit be provided to the subjects for participation in your research project? If yes, indicate how much, when they will receive the incentive, and what form of compensation will be offered. Must they complete the project to be paid?

You will also need to include documents including recruiting materials (flyers/advertisements), surveys and/or interview questions, consent forms, and approval documents.

**Personnel**

|  |  |
| --- | --- |
| **Name of Investigator and Role on Project** | **Human Subjects Training date and #** |
|  |  |
|  |  |
|  |  |
|  |  |

**Non-Exempt form**

This section is not required if your protocol qualifies for exempt status.

**PARTICIPANTS**

Anticipated maximum number of participants

Age ranges of participants; please select all that apply

\_\_\_ 0-7 years

\_\_\_ 8-17 years

\_\_\_ 18 years or older

\_\_\_ 65+ years

Please specify and explain the age range of your participants if they do not match the above categories (i.e. ages 6-12).

Source / Type of participants and location where studies will take place

How will participants be recruited?

\_\_\_ Phone

\_\_\_ Selected using confidential records to screen (medical, school)

\_\_\_ Email

\_\_\_ Postal Mail

\_\_\_ Newspaper / magazine advertisement

\_\_\_ Flyers / notices

\_\_\_ Handouts to be distributed

\_\_\_ Convenience sample drawn from existing groups

\_\_\_ Convenience sample drawn from an established participant pool (e.g. psychology participant pool)

If you are utilizing recruitment methods other than the options above, please explain

If flyers are posted, please indicate where they will be posted

If convenience sample will be drawn from an existing group, please provide information about the group

Are there participants who will be excluded? If yes, please explain why

Will compensation or extra credit be provided to the subjects for participation in your research project? If yes, indicate how much, when they will receive the incentive, and what form of compensation will be offered. Must they complete the project to be paid?

Informed Consent / Assent. Please check all that apply

\_\_\_ Written informed consent for individuals 18 and older

\_\_\_ Verbal informed consent for individuals 18 years and older

\_\_\_ Child assent process for children 0-7

\_\_\_ Written assent for children 8-17

\_\_\_ Verbal assent for children 8-17

\_\_\_ Written parent / guardian consent for minors or impaired individuals

\_\_\_ Partial consent / assent: this study involves deception

\_\_\_ Requesting a waiver for consent / assent

If requesting waiver of documentation, indicate which of the following apply

\_\_\_ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (These criteria cannot be used for FDA-regulate studies), OR;

\_\_\_ The research presents no more than minimal risk of harm to subjects and involves no procedures for which consent is normally required outside of the research context. This paragraph only applies to FDA-regulate studies per 21 CFR 56.109(c)(1).

If requesting alteration of consent / assent, indicate which of the following apply

\_\_\_ The research involves no more than minimal risk;

\_\_\_ The waiver or alteration will not adversely affect the rights and welfare of the participants;

\_\_\_ The research could not be practicably carried out without the waiver or alteration, AND;

\_\_\_ Whenever appropriate, the subjects will be provided with the additional pertinent information after participation

If you are utilizing other methods for consent / assent other than those described in the previous options, please describe them here

If any of the participants are not competent to give consent (e.g. minors, prisoners, institutionalized) then explain in detail how you will obtain parental / guardian consent and the participant assent / consent

If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary. Please upload a debriefing statement when prompted.

If you are asking for a waiver of consent / assent, justify why consent / assent will not be obtained

**RISKS AND BENEFITS**

Potential risks or inconvenience from research to participants. Please check all that apply

\_\_\_ Will interfere with participant’s normal routine (e.g. school attendance, medical treatment)

\_\_\_ Use of private records

\_\_\_ Use of medical records – you will need to upload HIPAA form when requested

\_\_\_ Use of educational records or academic work

\_\_\_ Presentation of materials that participants might consider offensive or upsetting

\_\_\_ Social or economic risk (reputation, culture, employability, etc.)

\_\_\_ Breach of confidentiality

\_\_\_ Identification of illegal activity

\_\_\_ Risk of injury or bodily harm

\_\_\_ Change in diet or exercise

\_\_\_ Psychological

\_\_\_ Legal

\_\_\_ Discomfort

\_\_\_ Embarrassment

Please elaborate on any risks checked above or additional risks that are not listed

Explain the steps that will be taken to minimize risks or inconveniences to participants. **(Be detailed and complete, even if above you indicated “no greater than minimal risk”, please answer this item.)**

In the event that any potential risks occur, they will be handled by (Check all that apply and provide a description of how you will handle risks)

\_\_\_ Compensation

\_\_\_ Counseling

\_\_\_ Other

Describe the benefits of the research to the individual participants

Describe the benefits of the research to society, academic knowledge, or both

**DATA**

Confidentiality of data – data gathered will include the following (please check all that apply)

\_\_\_ Name

\_\_\_ Date of birth

\_\_\_ Mailing address

\_\_\_ Email address

\_\_\_ Phone or fax number

\_\_\_ Social Security Number

\_\_\_ Medical records

\_\_\_ License, certificate or vehicle ID

\_\_\_ IP address

\_\_\_ Biometric identifiers

\_\_\_ Photos / images recordings

\_\_\_ Audio-only recordings

\_\_\_ Audio / video recordings

\_\_\_ Signatures, or handwriting samples

\_\_\_ Participants and their responses cannot be identified

If data gathered is not categorizable into the above options, please provide additional details

Methods of data collection (please check all that apply)

\_\_\_ Questionnaire or survey

\_\_\_ Interview

\_\_\_ Observation

\_\_\_ Educational tests (e.g. cognitive, aptitude, or achievement)

\_\_\_ Recording video

\_\_\_ Recording audio

\_\_\_ Pictures

\_\_\_ Computer collected task data

\_\_\_ Existing databases, archival data, or documents

\_\_\_ Focus groups

\_\_\_ Physical tasks

\_\_\_ Physiological measurements

\_\_\_ Blood will be drawn (provide additional details in field below)

\_\_\_ Web or internet (provide additional details in the field below)

\_\_\_ Record of public record (describe in field below)

If you are using other methods for data collection not described in the options above, please explains

Provisions used to maintain confidentiality (please check all that apply)

\_\_\_ Data will only be made available to Principal Investigator and immediate study personnel

\_\_\_ Data collection will be anonymous (no identifiers that can link to specific subject)

\_\_\_ Data collection will be confidential and de-identified (collected with identifiers, but identifiers removed)

\_\_\_ Data collection will be intentionally identified (linked to subject by personal identifiers)

\_\_\_ Data will be rendered anonymous for reporting

\_\_\_ Data will be stored in a locked office

\_\_\_ Data will be stored in a locked cabinet

\_\_\_ Data will be coded to a master list

\_\_\_ Data will be stored on a restricted computer

\_\_\_ Data will be password protected

\_\_\_ Data will be stored in a locked private office

\_\_\_ Data will be encrypted

\_\_\_ Data will be stored behind a firewall system

If you are using other methods to maintain confidentiality, please describe

Disposition of data at completion (please check all that apply)

\_\_\_ Data will be de-identified and kept for future PI analysis

\_\_\_ Audio / video tapes will be destroyed and files deleted after transcription

\_\_\_ Data will be retained indefinitely after de-identification for meta-analytic purposes, as a requirement for publication, and / or for longitudinal comparisons with future datasets

\_\_\_ Data will be de-identified and the made available as a public data set for secondary analysis. (This use must be specified in the consent document)

If the disposition of data at completion of study does not match any of the above options, please explain

Additional considerations (please check all that apply)

\_\_\_ An investigational device (IDE) will be used

\_\_\_ The Idaho Research Foundation will be, or has been notified

\_\_\_ Ethyl alcohol will be ingested by the participants

\_\_\_ An investigational new drug (IND) will be used

\_\_\_ Other drugs will be used

\_\_\_ None of the above

International research (see guidelines at [U.S. DHHS](http://www.hhs.gov/ohrp/international)\*)

\_\_\_ This research will be conducted outside the U.S.

\_\_\_ I have reviewed all international requirements\* and will follow those requirements

\_\_\_ No information was available for the country where I will be conducting my research. I have made a reasonable effort to seek information about IRB equivalents in that location

Health Insurance Portability and Accountability Act

\_\_\_ I will be using individuals’ personal health information

\_\_\_ HIPAA applies to this project

Please explain how HIPAA does not apply to this project

Family Education Rights and Privacy Act ([FERPA](http://www.uidaho.edu/registrar/faculty/ferpa))

\_\_\_ I will be using individuals’ student records

\_\_\_ FERPA applies to this project

If either above apply, please explain how you will comply with FERPA regulation

You will also need to include documents including recruiting materials (flyers/advertisements), surveys and/or interview questions, consent forms, and approval documents.

**Personnel**

|  |  |
| --- | --- |
| **Name of Investigator and Role on Project** | **Human Subjects Training date and #** |
|  |  |
|  |  |
|  |  |
|  |  |