APPLICATION FOR EXEMPTION FROM IRB REVIEW

Exempt from IRB Review

SUBMISSION CHECKLIST

[ ]  Application for Exemption from IRB Review Form

[ ]  Appropriate Appendices (e.g., project instruments, surveys, or interview protocols)

[ ]  Consent form and/or statement indicating that the study meets the requirements to obtain a waiver of consent

[ ]  Documentation of human subject protection training for all key research personnel

[ ]  Recruitment materials/advertisements (If Applicable)

[ ]  A full copy of the research proposal submitted for federal, state, or external funding (If Applicable)

[ ]  A completed Institutional Approval Form (page 12 of this document) (done by College Institutional Effectiveness Office or District Research Committee)

SUBMISSION INSTRUCTIONS

Submit the application and any other supporting documentation to the IRB office electronically (esc-irb@email.laccd.edu). This application must be typed; no handwritten applications will be accepted.

LACCD IRB

770 Wilshire Boulevard

Los Angeles, CA 90017

esc-irb@email.laccd.edu

APPLICATION FOR EXEMPTION FROM IRB REVIEW

1. **Title of Study:** Click here to enter title.
2. **Campus:** Choose LACCD Campus:
3. **Briefly describe the proposed project or study. Please include the hypothesis, purpose, research questions, methodologies, and background information. Please use non-technical language.**

Click here to enter text.

1. **Principal Investigator (PI):**

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Pager/Cell Phone:**  (XXX) XXX- XXXX |
| **City:** Click here to enter text. | **Fax Number:**  (XXX) XXX- XXXX |
| **State:** State | **Zip:** ZIP\_CODE | **Email:** Email Address |
| **Completion Date of Human Subject Protection Training:** Select Completion Date |

1. **Principal Investigator’s Assurance**

I understand that as Principal Investigator, I have the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulation imposed by the Los Angeles Community College District’s Review Board. I am responsible for the actions of co-investigators and must notify the IRB in writing of any addition or deletion of a co-investigator to/from the protocol.

I agree to comply with all IRB policies, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research including, but not limited to, the following:

* Performing the protocol by qualified personnel according to the approved protocol;
* Implementing NO changes in the approved protocol or consent form without prior IRB approval, (except in an emergency, if necessary to safeguard the well-being of human subjects);
* Obtaining the legally effective consent from human subjects or their legally responsible representative, and using ONLY the currently approved, stamped consent form;
* Assuring that each executed consent form includes the name of the person who explained the protocol, the subject’s signature, the signature of a witness, and the signature of the investigator;
* Reporting in writing all **fatal or life-threatening adverse events** to the IRB **within 72 hours (3 days) after discovery**;
* Promptly reporting in writing all **serious and/or unexpected adverse events** to the IRB **within 7 calendar days after discovery**;
* **Reporting all adverse events at continuing review** (including all deaths, regardless of cause).

**Signature of PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Contact Person/Study Coordinator:**

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Pager/Cell Phone:**  (XXX) XXX- XXXX |
| **City:** Click here to enter text. | **Fax Number:**  (XXX) XXX- XXXX |
| **State:** State | **Zip:** ZIP\_CODE | **Email:** Email Address |
| **Completion Date of Human Subject Protection Training:** Select Completion Date |

1. **Co-Investigator:**

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Pager/Cell Phone:**  (XXX) XXX- XXXX |
| **City:** Click here to enter text. | **Fax Number:**  (XXX) XXX- XXXX |
| **State:** State | **Zip:** ZIP\_CODE | **Email:** Email Address |
| **Completion Date of Human Subject Protection Training:** Select Completion Date |

I agree to comply with all IRB policies, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research including, but not limited to, the following:

* Performing the protocol according to the IRB-approved protocol;
* Implementing NO changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects);
* Obtaining the legally effective consent from human subjects or their legally responsible representative, and using ONLY the currently approved, stamped consent form;
* Assuring that each executed consent form includes the name of the person who explained the protocol, the subject’s signature, the signature of a witness and the signature of the investigator;
* Reporting in writing all **fatal or life-threatening adverse events** to the IRB **within 72 hours (3 days) after discovery**;
* Promptly reporting in writing all **serious and/or unexpected adverse events** to the IRB **within 7 calendar days after discovery**.

**Signature of Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Research Staff:**

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Email:** Email Address |
| **City:** Click here to enter text. | **Completion Date of Human Subject Protection Training:** 5/11/2018 |
| **State:** State | **Zip:** ZIP\_CODE |
| **Role within project (Duties to be performed):** Please provide a brief list of what the research personnel will be doing for the project (for example, collecting data, analyzing results, data entry). |

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Email:** Email Address |
| **City:** Click here to enter text. | **Completion Date of Human Subject Protection Training:** 5/11/2018 |
| **State:** State | **Zip:** ZIP\_CODE |
| **Role within project (Duties to be performed):** Please provide a brief list of what the research personnel will be doing for the project (for example, collecting data, analyzing results, data entry). |

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| **City:** Click here to enter text. | **Completion Date of Human Subject Protection Training:** 5/11/2018 |
| **State:** State | **Zip:** ZIP\_CODE |
| **Role within project (Duties to be performed):** Please provide a brief list of what the research personnel will be doing for the project (for example, collecting data, analyzing results, data entry). |

**QUESTION 9 IS REQUIRED. PLEASE REFER TO APPENDIX FOR CATEGORIES OF EXEMPTION AND PROVIDE AN EXPLANATION.**

1. **Exemption Category Claimed:** Choose a Category.

*(Please see the appendix for the categories of exemption at the end of this form)*

* 1. **Please provide an explanation as to how your research falls into this category.**

Click here to enter text.

1. **Estimated period of project or of human subject involvement:**

**Start Date:**  Select a Start Date. **End Date:** Select and End Date.

1. **Funding Source** *(if applicable)*:

*Check appropriate box and include funding source.*

[ ]  Industry Sponsored [ ]  Investigator Sponsored [ ]  Privately Sponsored [ ]  Grant [ ]  Other **Source:** Click here to enter source.

1. ***Conflict of interest.* Do any of the investigators listed on this study have a potential conflict of interest?**

 [ ]  Yes [ ]  No

 **If Yes, Please Explain:** Click here to enter text.

1. **Has the potential conflict of interest been disclosed and managed?**

 [ ]  Yes [ ]  No [ ]  Not Applicable

 **If Yes, Please Explain:** Click here to enter text.

1. ***Source of Subject Population.* Number of Subjects, projected records, data files, or specimens:**

Click here to enter text.

**IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORY # 4,**

**ANSWER ALL PARTS OF QUESTION 15 ONLY TO COMPLETE THE IRB APPLICATION.**

**-------------------------------------------------------------------------------------------------------------------------**

**IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORIES # 1 - 3 OR # 5 - 6,**

**SKIP QUESTION 15 AND COMPLETE QUESTIONS 16 – 22 TO FINISH IRB APPLICATION.**

1. **Will data, documents, records, biological specimens be used?**

 [ ]  Yes [ ]  No

1. **What are the types of data, documents, records, or specimens?**

Click here to enter text.

1. **Were the data/biological specimens to be used for your project originally collected solely for research purposes?**

[ ]  Yes [ ]  No

*If Yes, please include a copy of the IRB approved consent form used for the original collection of data/biological specimens.*

1. **Is the source of data/biological specimens publicly available (i.e., available to the general public)?**

[ ]  Yes [ ]  No

1. **Will the data/biological specimens you receive contain any identifiers?**

[ ]  Yes [ ]  No

**If Yes, Please Describe:**

Click here to enter text.

1. **Who will have access to the data/specimens?**

Click here to enter text.

1. **Describe provisions that will be taken to maintain confidentiality of data/specimens. Describe the security plan for the data/specimens including how and where stored and duration of storage (e.g., encrypted data, password protected, etc.)**

Click here to enter text.

**IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORIES # 1 - 3 OR # 5 - 6,**

**COMPLETE QUESTIONS 16 - 22:**

1. **Describe the recruitment procedures:**

*(Include any flyers, advertisements, informed consent forms, etc.)*

Click here to enter text.

1. **Describe the procedures in which subjects will participate. If data collection instruments will be used indicate the time necessary to complete them, the frequency of administration, and the setting in which they will be administered (such as telephone, mail, or in person interview).** Please note that exploration of sensitive or private topics is not an exempt activity.

*(Please submit a copy of all instruments for this study, including all questionnaires, surveys, protocols for interviews, etc.)*

Click here to enter text.

1. **Will data be recorded by audiotape or videotape?**

[ ]  Yes [ ]  No

**Please clarify how subjects will be identified in study records / taped responses:**

 Click here to enter text.

1. **Will the study subjects be identifiable either by name or through demographic data?**

[ ]  Yes [ ]  No

*If “Yes” is checked, please answer questions 20a and 20b. If “No” is checked, please go to questions 21.* *(Note: Aggregate grouping of demographic data will prevent subject identification through that data.)*

* 1. **Please describe how the confidentiality of subject’s identity will be maintained.**

Click here to enter text.

* 1. **Please describe how subject identifiers will be maintained or destroyed after the study is completed.**

Click here to enter text.

1. **Do you intend to collect protected health information (PHI) from subjects in the course of providing treatment / experimental care?**

[ ]  Yes [ ]  No

1. **Will you have access to PHI in the subject’s records?**

[ ]  Yes [ ]  No

**If you answered yes to either of questions #20 or #21 you must do one of the following:**

* 1. obtain the authorization of the patient, or
	2. obtain from the IRB a waiver of HIPAA authorization [see HIPPA Waiver form] and a waiver of research informed consent, or
	3. obtain from the IRB permission for the use of a limited data set (LDS)] and a waiver of research informed consent, or
	4. obtain from the IRB permission for the use of a de-identified data set and a waiver of research informed consent, or
1. ***Informed Consent.*** *Please attach an appropriate informed consent document to this application. If subject participation is anonymous, an Information Sheet is recommended. If subject participation is not anonymous, please attach a consent form to this application or provide a justification for a waiver of informed consent.*

**Waiver or alteration of the requirements for informed consent should be justified by addressing the items listed below:**

* 1. **Explain why the proposed study presents no more than minimal risk to the subjects.**

Click here to enter text.

* 1. **Describe why the proposed research could not practicably be performed without the waiver of informed consent.**

Click here to enter text.

* 1. **Explain why a waiver of informed consent will not adversely affect the rights and welfare of the subjects.**

Click here to enter text.

APPENDIX – CATEGORIES OF EXEMPTION

**Federal Regulations stipulate that a study can be exempt if the study meets one or more of the following conditions:**

**Categories (1-6)**

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 the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

 (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

**(3)**  (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

**(4)** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

**(5)** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or 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: (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 and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level 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.

**Federal regulations Stipulate that a study cannot be exempt if:**

1. **The study targets one or more of the following populations:**
	* + Prisoners
		+ Fetuses
		+ Pregnant Women
		+ Children / Minors
2. **The Study involves the following types of research:**
	1. Human in-vitro fertilization (i.e. and fertilization of human ova which occurs outside the body of the human);
	2. Review of records if the information gathered from these records is identified in such a way that is can be linked back to the individual (either directly or through the use of a code);
	3. Surveys or interviews given to minors;
	4. Any procedure that may cause a subject either physical of psychological discomfort or is perceived as harassment above and beyond what the person would experience in everyday life;
	5. Deception;
	6. Observation of minors if the investigator participates in the activities being observed unless there is a federal statute covering the activity; or
	7. If the sponsoring agency requires that the proposed research received full or expedited review even when the activities would otherwise qualify for exemption; or

Studies granted exemption by the IRB are exempted for the life of the research unless changes are made to the study procedures. Changes to exempted research must be reviewed by the IRB to ensure that the research continues to qualify for exemption. Even minor changes to research may necessitate IRB review under current regulations. Investigators are encouraged to contact the IRB office if changes to exempted research occur and there are questions regarding the need to submit research for continuing exemption determination.