APPLICATION TO INVOLVE HUMAN SUBJECTS IN RESEARCH

Expedited and Full IRB Review

SUBMISSION CHECKLIST

[ ]  Application to Involve Human Subjects in Research Form

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

[ ]  Informed Consent Forms

[ ]  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 13 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 TO INVOLVE HUMAN SUBJECTS IN RESEARCH

1. **Title of Study:** Click here to enter title.
2. **Campus:** Choose LACCD Campus:
3. **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:** \_\_\_\_\_\_\_\_\_\_\_\_\_

**5. Contact Person/Study Coordinator** (if applicable)**:**

|  |  |
| --- | --- |
| **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** (if applicable)**:**

|  |  |
| --- | --- |
| **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;
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* 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** (if applicable)**:**

|  |  |
| --- | --- |
| **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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| **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). |

SECTION II | PROJECT/RESEARCH SUMMARY

**Briefly describe the proposed project or study by answering the questions below. Please use lay language and avoid jargon.**

*Attach a copy of the Informed Consent (or Assent) Form and/or the measures (e.g., surveys) to be used in the project.*

* **What is the purpose of the study?**

Click here to enter text.

* **What is the research question(s)?**

Click here to enter text.

* **Please describe the study population** (e.g., who will participate in the study)

Click here to enter text.

* **Please describe the research methods** (e.g., the type of study you are conducting, data sources, survey instruments, interview or focus group protocols, data collection process)

Click here to enter text.

* **What are the expected results of the study?** (Briefly describe study aims, anticipated findings, and contributions)

Click here to enter text.

* **How will the research procedures protect human subjects & maintain confidentiality?**

Click here to enter text.

* **What is the expected duration of the study?**

Click here to enter text.

* **Briefly describe any assistance you may need from the Office of Institutional Effectiveness, if any.**

Click here to enter text.

* **Is this research for a thesis or dissertation project?**

 [ ]  Yes [ ]  No

 If Yes, for which institution? Click here to enter text.

SECTION III | SUMMARY INFORMATION

**Research involving human subjects is reviewed by the LACCD’ Institutional Review Board (IRB). Additional/Specific information is oftentimes needed based upon the nature of research being conducted to satisfy regulatory and local requirements. To aid the IRB staff in routing this application for the most appropriate review, please check all appropriate boxes in this section.**

**QUESTION 8 IS REQUIRED. IF REQUESTING AN EXPEDITED REVIEW, PLEASE REFER TO APPENDIX FOR ELIGIBLE CATEGORIES AND PROVIDE AN EXPLANATION.**

1. **REVIEW REQUEST:** Please review this research following:

[ ]  Expedited Review - Under Category: Select a Category.

 *(Please see the appendix for the categories eligible for expedited review 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.

[ ]  Full Committee Review

1. **LENGTH OF PARTICIPATION.** Please describe the length of subject participation in this research.
* **The length of each subject’s participation in this research is anticipated to be:**

Click here to enter text.

* **Subjects will be followed after participation in this research every**  Click here to enter text. **(length of interval) for**  Click here to enter text. **(length of time).**
1. **MEDICAL / SOCIOBEHAVIORAL.**  Will medical procedures be performed as a part of this research?

[ ]  Yes [ ]  No

1. **SPONSORSHIP.** Is this activity sponsored?

[ ]  Yes [ ]  No

1. **SUBJECT POPULATION:** *(check all appropriate boxes)*

[ ]  Minors [ ]  Cognitively or psychologically impaired

[ ]  Elderly [ ]  Exclusion of minorities

[ ]  Students [ ]  Non-English speaking

[ ]  Staff/Faculty [ ]  Other:

**If Other, Please Specify:** Click here to enter text.

1. **NATURE OF RESEARCH:** *(check all appropriate boxes)*

[ ]  Interviews [ ]  HIPPA Waiver

[ ]  Surveys [ ]  Medical Records Review

[ ]  Study of existing data [ ]  Behavioral observation

[ ]  Waiver of consent [ ]  Investigational devices

[ ]  Deception [ ]  Use of Protected Health Information

1. **LOCATION(S) OF RESEARCH TO BE CONDUCTED AT:**

[ ]  City [ ]  Mission [ ]  Trade-Tech

[ ]  East [ ]  Pierce [ ]  Valley

[ ]  Harbor [ ]  Southwest [ ]  West

[ ]  Other locations; **Please Specify**:Click here to enter text.

1. **LACCD DEPARTMENTS AFFECTED BY THE RESEARCH:** (Indicate all the departments you plan to utilize for in the study.)

[ ]  Health Wellness Center

[ ]  Laboratory

**Please specify department, course number, and section number:**

 Click here to enter text.

[ ]  Classroom

**Please specify department, course number, and section number:**

Click here to enter text.

[ ]  No LACCD Departments will be utilized

1. **ADDITIONAL EXPENDITURES:**
2. **Does this research require any capital/equipment expenditures?**

[ ]  Yes [ ]  No

**If yes, please specify the item/equipment:** Click here to enter text.

1. **What is the cost?** Click to enter cost.
2. **Will this research study require any additional LACCD staff time?**

[ ]  Yes [ ]  No

**If yes, please explain:** Click here to enter text.

1. **List all non-standard of care LACCD serves in *specific detail* (blood tests, X-rays, pathology specimens, medical record reviews, investigational drug/device, pharmacy, etc.)**

Click here to enter text.

SECTION IV | PROTOCOL SUMMARY

**INSTRUCTIONS: Please respond to each of the following questions and state “Not Applicable” for topics that are not applicable to your application. Address each topic independently in the sequence listed without reliance on information covered under other subparts. Referring to sections of related grant application is not an acceptable substitute as these materials are not written with the aim of addressing human subject protection questions. Provide complete to permit review by all members of the IRB. Definitions should be provided for terms unlikely to be understood by lay and out of specialty reviewers.**

1. **Recruitment Incentives.** Is the study sponsor offering any incentive connected with subject enrollment or completion of the research study (i.e., finder’s fees, recruitment bonus) that will be paid directly to the research staff?

[ ]  Yes [ ]  No

**If yes, please detail the nature of the compensation so that the IRB may consider its appropriateness and whether disclosure is necessary in consent materials.**

Click here to enter text.

1. **Survey/Questionnaire Administration.**
2. **This research will involve collection of data using the following technique(s):**

[ ]  Telephone call [ ]  Survey Instrument [ ]  Interview [ ]  Focus Group

[ ]  N/A [ ]  Other; **Please Specify**:Click here to enter text.

1. **Does this research involve presentation of sensitive information to subjects?**

[ ]  Yes [ ]  No

**If yes, how do you propose to ensure that subjects are aware of the nature of the information to be provided to them before they are presented with the sensitive information?**

Click here to enter text.

1. Does this research propose to collect sensitive information from subjects?

[ ]  Yes [ ]  No

1. **Data Collection, Storage, and Confidentiality.**

**Does this research propose to collect information from subjects that may be considered to be sensitive?**

[ ]  Yes

[ ]  No

* 1. **How will data be collected and recorded during the course of this research?**

Click here to enter text.

* 1. **Will data collected during this study be associated with personal identifiers or coded to protect personal privacy?**

Click here to enter text.

* 1. **Where will the data be stored and how will it be secured during the study?**

Click here to enter text.

* 1. **Please identify the individual(s) who will have access to the data and/or to the codes? If data with subject identifiers will be released, specify the person(s) or agency to whom this information will be released.**

Click here to enter text.

* 1. **What will happen to the data when the research has been completed?**

Click here to enter text.

1. **Potential Risks and Discomforts:** Please describe the nature, probability, and magnitude of potential risks and/or discomforts that may be associated with this research. If data are available, estimate the probability that a given harm may occur, and its potential reversibility.

Click here to enter text.

1. **Risk Classification:** What is the overall risk classification of the research: minimal, greater than minimal, significant, or unknown?

[ ]  Minimal

[ ]  Greater than Minimal Risk

[ ]  Unknown

 **If Unknown, please explain why the risks are unknown?**

Click here to enter text.

*Note: Regulations define “minimal risk” as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life during the performance of routine physical or psychological examinations or tests.”*

1. **Justifying Risks. Please provide a justification for exposing subjects to the potential risks described in this application.**

Click here to enter text.

1. **Minimizing Risks. What steps will be taken to prevent and/or minimize any potential risks or discomforts associated with this research?**

Click here to enter text.

1. **Potential Benefits:**
2. **What potential benefits may subjects receive as a result of their participation in the research?**

Click here to enter text.

1. **What potential benefits to society may be expected from this research?**

Click here to enter text.

1. **Risk/Benefit Ratio. What is the risk/benefit ratio of the research, compared with that of the available alternatives?**

[ ]  Favorable *(proceed to question 26)*

[ ]  Unfavorable *(please contact the IRB Administrator for additional guidance)*

1. **Payment for Participation. Will subjects be paid for their participation in this research?**

[ ]  Yes *(If Yes, please complete the rest of this section)*

[ ]  No *(If No, please go to question 27)*

* 1. **Please describe the nature (amount and frequency) of subject payment during participation in this research:**

Click here to enter text.

* 1. **Is payment during participation in research intended to be an inducement for participation?**

[ ]  Yes

[ ]  No

1. **Please describe the conditions subjects must fulfill to receive payment for participation in this research.**

Click here to enter text.

*Note: The IRB does not believe that payment for participation in research should be an inducement to participate or so large as to compel a subject to participate in research who otherwise would not do so. Rather, payment for participation should be a reimbursement for costs, time, effort, etc. related to participation in the research. As such partial payment should be offered to subjects who are not able (or are not willing) to finish participation in research.*

1. **Financial Obligations for Subjects.** Will subjects incur a financial obligation as a result of participation in this research?

[ ]  No

[ ]  Yes

**If Yes, please describe and specify whether costs are related to “standard of care” procedures performed ancillary to research.**

Click here to enter text.

1. **Emergency Care and Compensation for Research-Related Injury:**
	1. **Please describe the procedures that will be followed in the event of a research-related or emergency (including first aid, emergency treatment and follow-up care).**

Click here to enter text.

* 1. **Please describe the resources available at the study site to manage a research related injury or emergency.**

Click here to enter text.

* 1. **Who will be responsible for the cost associated with managing a research-related injury or emergency?**

Click here to enter text.

*Note: The IRB does not believe that subjects should be responsible for the costs associated with managing a research related injury. If this application proposes to have subjects be responsible for costs associated with managing a research related injury, please provide justification for this position.*

1. **Consent Process.** **Please describe the consent process to be followed for this research and steps that will be taken to minimize the possibility that subjects are coerced or unduly influenced.**

Click here to enter text.

1. **Subject Comprehension.** **How will the study team ensure that subjects are able to understand the information provided during the consent process?**

Click here to enter text.

1. **Consent / Assent Forms. Specify the form(s) that will be used among the following:**

[ ]  Adult consent form

[ ]  Parental consent form

[ ]  Proxy consent form

[ ]  Youth assent form (age 13-18)

[ ]  Child assent form (age 7-12)

*Note: A copy of the forms marked above should be attached to this application.*

APPENDIX – CATEGORIES OF RESEARCH ACTIVITIES ELIGIBLE FOR EXPEDITED REVIEW

## Human subject research activities involving no more than minimal risk to the subjects may be eligible for expedited review by Los Angeles Community College District’s Institutional Review Board Co-Chairs. The principal investigator/project director is authorized to make the first determination of eligibility for expedited review; however, the District bears the responsibility for concurring in that determination based on information provided by the principal investigator.

**Research activities eligible for expedited review:**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to [45 CFR 46.101(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research. Questions about whether a research activity may be appropriate for expedited review can be directed to the Institutional Research Office.