INSTRUCTIONS FOR COMPLETING THE INITIAL APPLICATION

Please review the items below before you begin the initial application.

- Please ensure you have the **Request for LDH Support Form** signed by the appropriate LDH personnel. This document serves as a 'letter of support' for your project from LDH and is a required component of your LDH IRB submission. If you do not have this document, please see instructions below.
    1. Download the **Request for LDH Support Form** from website and complete the first page.
    2. If your project involves the use of LDH data, please complete a data request here and attach your **Request for LDH Support form** from Step 1.
    3. If your project does NOT involve the use of data, email the form from Step 1 to cphi@la.gov.

- **Use the checkboxes below to ensure all sections of the IRB application have been addressed and necessary attachments included.** Use the blank space to note the file names of associated documents. If a particular section does not apply for your project, state that clearly. You MUST respond to each prompt on the IRB application for it to be considered complete. Incomplete applications will cause delays.

☐ Section A: General Information
(attachments:_____)

☐ Section B.1: Abstract
(attachments:_____)

☐ Section B.2: Comprehensive Research Proposal
(attachments:_____)

☐ Section B.3: Potential Benefits
(attachments:_____)

☐ Section B.4: Potential Risks
(attachments:_____)

☐ Section B.5: Data
(attachments:_____)

☐ Section B.6: Data Management Plan
(attachments:_____)

☐ Section B.7: Informed Consent
(attachments:_____)

☐ Section B.8: Documented Decisions of Other IRBs
(attachments:_____)

☐ Section C: Approved Request for LDH Support
(attachments:_____)

☐ Section D: Researcher's Pledge (*PI must sign*)

☐ Section E: Faculty Sponsorship of Student PI (*required if PI is a student; faculty advisor must sign*)

☐ Section E does not apply (PI is not a student)

For any questions or concerns, please email ldh.irb@la.gov.

Institutional Review Board (IRB)

Initial Application

SECTION A: GENERAL INFORMATION

Title of Research Proposal: _____

Principal Investigator (PI) Name: _____

Street:	City, State, Zip Code:
Phone Number:	Email Address:
Affiliation(s): *(be specific)*	
Education/Qualifications (*attached curriculum vitae*)	

Co-Investigators: *List one investigator per line including name, affiliation, email address and contact number.* ***Attach curriculum vitae*** *for all co-investigators to show education/qualifications.*

Name	*Affiliation*	*Email*	*Contact Number*	*CV attached?*
				☐ yes
				☐ yes
				☐ yes
				☐ yes
				☐ yes
				☐ yes

University Faculty Sponsor: *If Principal Investigator is a student, please provide faculty sponsor information below and complete the* ***Faculty Sponsorship of Student PI*** *document (Section E).*

☐ Does not apply (PI is not a student)

Name	*Email*	*Phone*

Project Start and End Date: Start_____ End _____

Describe funding for the project. (*Attach documents as needed)*

☐ There is no funding specifically for this project.

Financial Conflict of Interest: *Select all that apply for any investigators or personnel* ***(when aggregated for their immediate family)*** *listed on this research:*

Ownership, business interest or financial interests of $10,000 or more associated with this study:

☐ Yes ☐ No ☐ Unsure

If yes, how will this conflict be managed?

Ownership, business interest or financial interests of less than $10,000 when the value of interest could be affected by the outcome of the research:

☐ Yes ☐ No ☐ Unsure

If yes, how will this conflict be managed?

Ownership, business interest or financial interests exceed 5% in any one single entity when aggregated for the immediate family:

☐ Yes ☐ No ☐ Unsure

If yes, how will this conflict be managed?

Compensation less than $10,000 when the value of the compensation could be affected by the outcome of the research:

☐ Yes ☐ No ☐ Unsure

If yes, how will this conflict be managed?

Physical location where research activities will be conducted:

SECTION B: PROJECT INFORMATION

SECTION B.1: Abstract

SECTION B.2: Comprehensive Research Proposal

Provide a full description of your research, including but not limited to:

- Your research question(s);
- How your study contributes to the literature;
- Type of research design; (e.g., randomized controlled trial; exploratory sequential design; descriptive; grounded theory; multiple baseline; correlational design; ethnography; reversal design)
- Recruiting (as applicable, attach scripts, written materials, location, who and how will they conduct recruiting)
- How you will select participants or data elements (e.g.: inclusion/exclusion criteria; convenience sampling method; random sampling method; etc.)
- Plans for actively monitoring participants during intervention, and how you will monitor ongoing data collection and assessments to ensure safety of individuals & fidelity of protocol (if applicable)
- Instrumentation (including any surveys, questionnaires, standardized tests, descriptions of technology-based data collection such as smart phone or smart watch apps, or other equipment used as part of the study)
- Incentives or items of monetary value (including gift cards and method for delivering; conditions necessary to receive incentives; measures in place to reduce possibility of coercion)
- Data storage/management/security; and
- Planned method of analysis (including software; statistical methods; etc.)

SECTION B.3: Potential Benefits

SECTION B.4: Potential Risks (address physical, psychological, or social harm, including breach of information, data, or biospecimens)

SECTION B.5: Data

Check all data elements below that you will be accessing (e.g.: from LDH database) or recording (e.g.: through survey or by observation) for your project.

☐ I will not be accessing or recording any of the items listed in 1-18 below for this research project.

Protected Health Information (PHI; as per 45 CFR 164.514(b)(2)(i))		Accessing	Recording
1.	Patient or Subject Names of Initials	☐	☐
2.	Street address	☐	☐
	Town or City	☐	☐

	Parish or County	☐	☐
	Complete ZIP code	☐	☐
3.	All elements of dates (except year) related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89	☐	☐
4.	Telephone numbers	☐	☐
5.	Facsimile (fax) numbers	☐	☐
6.	Electronic mail (email) addresses	☐	☐
7.	Social security numbers	☐	☐
8.	Medical record numbers	☐	☐
9.	Health plan beneficiary numbers	☐	☐
10.	Account numbers	☐	☐
11.	Certificate/license numbers	☐	☐
12.	Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
13.	Device identifiers and serial numbers	☐	☐
14.	Web universal resource locations (URLs)	☐	☐
15.	Internet protocol (IP) address numbers	☐	☐
16.	Biometric identifiers, including fingerprints and voiceprints	☐	☐
17.	Full-face photographic images and any comparable images	☐	☐
18.	Other unique identifying number, characteristic or code	☐	☐

Please respond to following questions in detail.

- List of all data elements/categories/variables captured, recorded or retrieved as part of the study
- Indicate whether and state how you already have access to the data as part of your employment, internship, or contract work.
- Identify who will have even temporary access to any data or study documents, not limited to research team members.
- Explain how you plan to use any private information ***(e.g.: incentive disbursement; matching records; contacting participants for recruitment or ongoing participation; an essential variable in your analysis)***
- Justify use of any private information in your research, explaining the alternatives you considered and why they failed to address your research questions.
- Address any other pertinent information that informs an IRB perspective.
- Describe your plan to protect any private information from improper use and disclosure;
- Describe your plan to destroy your data including any private information at the earliest opportunity consistent with conduct of the research justification for retaining them or a legal requirement to do so;
- If applicable, provide your assurance that any data you collect will not be reused or shared with any other person or entity, except as required by law.
- If you plan to maintain the information for other research projects, identify where you inform participants and/or describe the circumstances/regulations/code permitting you to retain that information for reuse.

SECTION B.6: Data Management Plan

- Describe your procedures to protect privacy and maintain confidentiality for all data and records accessed, collected, stored or otherwise managed, whether considered PII, PHI or not. If you refer to your home institution/agency's standards for transmitting or storing data, please ensure appropriate permissions are in place so IRB personnel can view/download the documentation.
- Does your proposal include any draft or fully signed memo of understanding, data sharing agreement, data use agreement, or any other contractual relationship with LDH? If so, please include; if not, state so.

SECTION B.7: Informed Consent

Check the appropriate selection and include attachment(s) as noted:

☐ Informed consent ***does not*** apply. Attach justification.

☐ If you think informed consent/assent ***does*** apply to your project, but it ***does not*** require ***written*** consent, provide your rationale. Include information about:

- level of risk;
- how this might impact the rights and welfare of individuals; and
- written materials or letters prepared for participants who do not provide written consent ***(if applicable).***

☐ ***Written*** informed consent ***does*** apply. Attach informed consent/assent, HIPAA authorization forms, and all documents related to individuals' informed decision-making. Describe in detail your process for obtaining consent/assent (e.g., who conducts consent/assent; in-person, virtual email, trainings they undergo prior to interaction with potential participants).

SECTION B.8: Documented Decisions from all other IRBs

NOTE: If your home institution has their own IRB or uses an independent IRB to review protocols, you ***MUST*** submit an application there as well. While applications may be submitted concurrently to multiple IRBs, as the IRB of Record, LDH requires decision letters from all other IRBs prior to issuing a decision.

Check the appropriate selection and include attachment(s) as noted:

☐ There are no other IRBs involved

☐ There is at least one other IRB involved. Their decisions are attached.

☐ There is at least one other IRB involved. Their decision is pending.

List all IRBs with jurisdiction over the project:

SECTION C. Request for LDH Support form

Please attach the completed and signed LDH Request for Support form.

SECTION D. Researcher's Pledge

I am applying to conduct the research project entitled above at the indicated LDH facilities/programs. I agree to conduct this research in an ethical and responsible manner and as stipulated by the proposal and this application. I agree to secure the approval of the LDH IRB for any modifications to the research protocol. I understand that I have an ethical and legal responsibility not to divulge the identity of any clients or any information about them as identifiable individuals, nor will the final compilation of results of this project contain any client identification information. As soon as the project is complete, all client-identifying information collected will be destroyed. I agree to keep the LDH IRB informed periodically of the progress of the project, and I will submit a report of the final results to the IRB and facilities/programs involved.

Signature: _____ Date: _____

Printed Name: _____

SECTION E. Faculty Sponsorship of Student PI (*complete only if PI is a student)*

I have reviewed this research application and proposal and find that the research design and planned data analyses are appropriate to the research objectives and that there are safeguards to protect the rights and welfare of the research participants. I hereby assume responsibility for supervision of this/these students' research activities during the course of the project.

Signature: _____ Date: _____

Printed Name: _____

PIs are encouraged to submit applications to LDH IRB concurrently with other institutions' IRBs. Please note, however, that as the IRB of Record, LDH IRB will require decision letters from all other institutions before it can issue a decision.