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Institutional Review Board Human Subjects Protection Training

May 8, 2024

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Training Objectives

After completing this training, you will have a better understanding of:

-the principles underlying ethical research

-the role of the IRB and the types of IRB review

-how to submit an IRB application

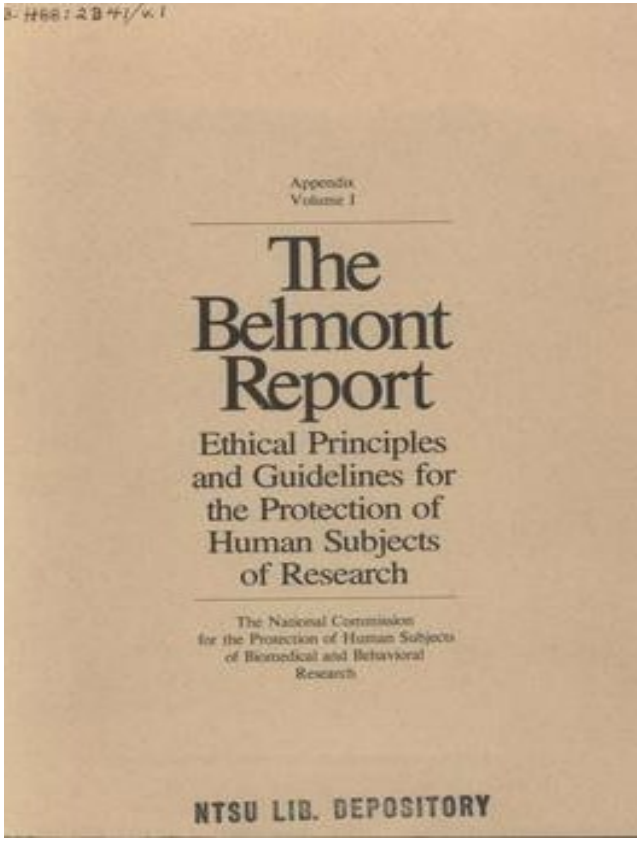
-the IRB's Health Equity Initiative

Administrative Items

- Presentation slides will be available on the **IRB website**
- Evaluation survey will be available after training
- **NEW!** Training knowledge check
  - Required to receive a certificate of completion
  - Have until 4pm on **Friday, May 10th** to complete
- Certificates of completion will be available in TalentWorks

Brief History of Ethics in Research

- Tuskegee Syphilis Experiment, 1932-1972
- Willowbrook Hepatitis Experiments, 1955-1970
- Milgram's experiments on obedience, 1960s



An Ethical Framework

- Belmont Report, 1979
  - National Research Act, 1974 - National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research
  - Provided the foundation for the federal human subjects research regulations known as “the Common Rule” (45 CFR 46)

Principles Outlined in The Belmont Report

- Basic Principles of Biomedical Research Ethics
  - **Respect for Persons**
    - **Autonomy**
  - **Beneficence**
    - **Minimize harm, maximize benefits**
  - **Justice**
    - **Equity of risks and benefits**

Legal Basis for the IRB

The "Common Rule" (45 CFR 46)

- Published in 1991, revised in 2017-2018
- Outlines basic requirements for IRBs

LAC Board of Supervisors, 1999

- HIVNet
- Lack of community sensitivity and engagement
- Creation of LAC DPH IRB

What is the DPH IRB?

- Oversight entity housed in DPH
- Board made up of **15 people**
  - Minimum 5 members
  - Diverse across race, gender, cultural background
  - Scientist, non-scientist
  - Not affiliated with institution (community members)
  - Prisoner advocates
- Meets once a month, every fourth Thursday

By law, the IRB works to ensure:

- Risks are minimized
- Selection of subjects is equitable
- Appropriateness of design and methods
- Informed consent is properly obtained and documented
- Privacy of participants is protected, and confidentiality of data is maintained
- Additional protections are in place if vulnerable groups involved
- Language equity
- Compliance with applicable regulations

Our IRB

- **We consider**:
  - Community not just individual rights
  - Community engagement and accountability
  - Utility: How will results be used, applied, shared?
  - Promotion of health equity/reduction of disparities
- Ethical review required not only of research, but other related activities

DPH IRB Standard of Practice posted on SharePoint for internal use

Who Does DPH IRB Serve?

- Covers DPH, Ambulatory Care Network (ACN), Health Services Administration (HSA), and Correctional Health Services (CHS)

- IRB of record for community-based organizations and other health departments

Ambulatory Care Network
HEALTH SERVICES • LOS ANGELES COUNTY
Quality • Compassion • Responsibility

Health Services
LOS ANGELES COUNTY

BIENESTAR

LOS ANGELES LGBT CENTER®

RISING COMMUNITIES

Center for HealthJustice

What is "Research?"

- **Federal regulatory definition §46.102(l):** "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- Difficulties may arise when applying this definition in practice

Does it matter if it's research or not?

- Yes, but only in **how** regulations apply
- Exempt categories for research and "non-research"
- For research (including generalizable program evaluation) ***all federal regulations apply***
- For exempt as non-research projects all **ethical principles and spirit of federal regulations apply, but more flexibility in how they are concretely applied**

DPH IRB Policy on IRB Submission

<u>Any project</u> involving collection or analysis of data from or about individuals, whether "research" or not:

- Needs IRB consultation for determination of whether IRB review is needed
- A project is anything involving staff, facilities, clients, patients, funding, databases from DPH, DHS, etc.

The best policy is to **ask** via e-mail if you are not sure... **AND never assume** that a past determination by the IRB will automatically apply to a new project

Related activities requiring review

- "Related activities" means any process that involves collecting, accessing or analyzing data from or about individuals other than research, including but not limited to:
  - program evaluation, including evaluation for internal program use;
  - certain quality assurance and improvement projects;
  - certain non-legally mandated surveillance;
  - needs assessments;
  - projects using surveys that collect data from the respondent but not necessarily about the respondent.

Exceptions to DPH IRB Submission Policy

No submission required if:

- Does not involve humans (e.g., animals only, some lab studies)
- Legally mandated reporting/surveillance
- Information collected/charted as part of clinical care
- Anonymous meeting evaluations
- Authorized operational activities in support of criminal justice or criminal investigative activities or defense/national security
- Customer satisfaction surveys that do not collect/access data from vulnerable populations such as minors or persons experiencing homelessness or involve sensitive topics such as substance use/disorder
- Customer satisfaction surveys that do not collect/access personally identifiable information (PII) or protected health information (PHI)
- Environmental investigation

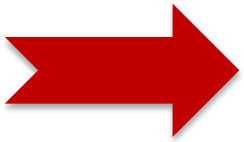
Applies to all projects

- Project activities or changes may not begin until approval letter has been received
- Please follow data collection guidelines on Race/Ethnicity, Sexual Orientation, Gender Identity, and Disability Status per Chief Science Office Standards of Practice (available upon request)

Levels of IRB Review

- Exempt as Non Research
- Research of an Exempt type
- Expedited
- Full Board

Levels of IRB Review

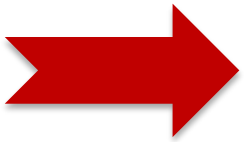


- Exempt as Non Research
- Research of an Exempt type
- Expedited
- Full Board

Exempt as non-research

- Most standard Quality Assurance/Quality Improvement activity
- Most internal program evaluations or needs assessment intended only for program monitoring, improvement, etc.
- Does not require written informed consent but “effective” consent required

Levels of IRB Review



- Exempt as Non Research
- Research of an Exempt type
- Expedited
- Full Board

Research of an Exempt Type

- Interview-based research **that does not deal with sensitive topics**
- Observation of public behavior
- A study of previously collected data or records (if publicly available or recorded in de-identified manner)
- Requires either **written consent or application for a waiver**, and cannot claim it is not research

Levels of IRB Review

- Exempt as Non Research
- Research of an Exempt type
- Expedited
- Full Board

Expedited Review

- Project poses no more than minimal risk
- One of the expedited categories, for example
  - Survey/interview-type methods that include sensitive topics
  - Previously collected data or records that are not totally de-identified (e.g. you might need addresses for geo-coding or names/SSNs for cross referencing)
  - Recording of minors

What is Minimal Risk?

According to the federal regulations at §46.102(j), *minimal risk* means that 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 or during the performance of routine physical or psychological examinations or tests.

Expedited Review

- The classification Expedited Review refers to the way that federal regulations are applied when reviewing a research study.
- "**Expedited**" **DOES NOT** refer to the timing or speed of review – the DPH IRB reviews all applications in the order that they are received.
- Expedited review and approval can be given by Chair, Vice Chair, or IRB analyst, without waiting for monthly IRB meeting

Expedited Review Categories for Your Reference (from the federal regulations 45 CFR 46)

1 Clinical studies of drugs and medical devices only when certain conditions are met

2 Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts

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

Expedited Review Categories, (cont.)

5 Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes

6 Collection of data from voice, video, digital, or image recordings made for research purposes

7 Research on individual or group characteristics/behaviors, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Expedited Review: Continuing Research

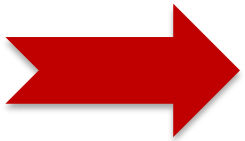
8 Continuing review of research previously approved by the convened IRB when certain conditions are met, for example:

- Remaining research activities are limited to data analysis

9 Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

Levels of IRB Review

- Exempt as Non Research
- Research of an Exempt type
- Expedited
- Full Board



Full Board review

- Full board review covers studies that pose **"more than minimal risk"** and do not meet the criteria for Exempt or Expedited review
- Projects deemed full board review will be discussed at the following IRB meeting
    - Quorum of committee members must be present to vote on study approval

Exercise : What level of review?

For each example shown, what type of review would the project be categorized as? Exempt as non-research, research of an exempt type, expedited or full board? What are the reasons for your choice?

1. An in-person survey will be conducted among minors in juvenile detention centers about their social service and healthcare needs when they leave the detention centers. Full Board
2. Focus groups will be conducted among men who received education regarding HIV prevention and management on internet dating sites. The data will be used to evaluate the efficacy of the education with the hopes of publication in a peer-reviewed journal.

Exercise: What level of review?

3. Patients in a public health clinic will be surveyed in waiting rooms to find out what their experiences were with rapid STI testing services in the clinic. Data will be used to assess usage rates and improve STI testing services in the clinic.
4. On-line surveys will be administered to a population exposed to a mass educational campaign (posters, billboards, television messages) on the dangers of second-hand smoke to evaluate the intervention with potential for publication. Participants will be recruited through advertisements on social media.

Answers to Exercise

- Example 1: Full Board review
- Example 2: Expedited review
- Example 3: Expedited review
- Example 4: Exempt review

Overview of the application process

- **Step 1**: Review IRB website and application checklist
- **Step 2**: Is DPH or DHS involved?
    - Yes, DPH – Will project use surveys?
        - Yes – Obtain DPH RATE review
        - No – Proceed with Step 3
    - Yes, DHS – Obtain DHS ROB approval
- **Step 3**: Submit IRB application using IRBManager

External process: RATE Review (DPH projects)

Per **DPH Policy 117**, surveys used by DPH projects (including projects funded by DPH) must be reviewed by the Office of Health Assessment and Epidemiology (OHAE) Rapid Assessment, Training and Evaluation (RATE) Unit

How to comply:

Project team submits final drafts of survey(s) and protocol to IRB via email at IRB@ph.lacounty.gov

Ensure that:

- Any survey questions asking about Race/Ethnicity, Sexual Orientation/Gender Identity, and Disability Status follow DPH SOPs (available upon request)
- Protocol follows the template posted on the IRB website
- Documents do not contain any internal comments or tracked changes

External process: ROB Review (DHS projects)

Projects involving DHS (including DPH projects that involve DHS) need to be reviewed and assigned a priority category by DHS' Research Oversight Board (ROB) to ensure the proposed activities are feasible and align with DHS' mission

How to comply:

Project team submits final drafts of protocol, budget, and other project materials to IRB via email at IRB@ph.lacounty.gov

Ensure that:

- Include the project protocol, budget and relevant study documents as attachments.
- The IRB will forward your email to the ROB who will then review the proposal and will assign the priority category.

External process: PHIS Software Approval

- Is your project collecting/using personally identifiable information (PII) or protected health information (PHI) accessing PHI?
- Does your project involve external contractors/organizations?

If **YES** to both questions, your project needs PHIS approval.

How to comply:

- An IT ticket will be created automatically when your IRBManager application is submitted
- Your online application will include questions for PHIS

Ensure that:

- Your responses are complete or risk delay of your approval.
- Once you receive approval from PHIS, please printout a PDF of the approval email and upload it your IRB application

Some of the questions PHIS will ask?

- What is the software (including version) that you will use in your project?
    - How will it be used? Where will the software be installed?
- Where data will be stored (physical and electronic) and how long will the data be retained?
- Will data be transmitted, and, if so, where?
- Who will have access to the data and who is the “data owner” (must be one person)?

Items You Will Need to Submit a New IRB Application

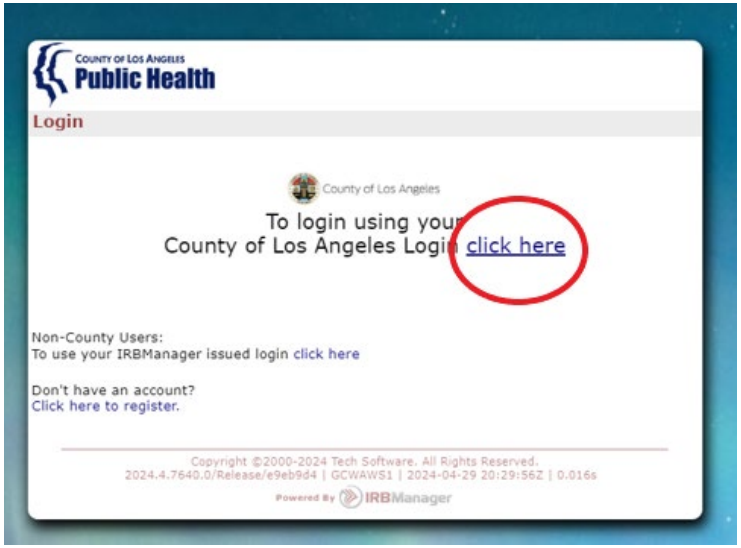
- **Before you begin an IRB application:**
  DPH projects must obtain RATE review. DHS projects must obtain ROB review
- Principal investigator(PI)/project lead, Co-PI (if any), and Division Chief/Program Director signature
- DPH/DHS liaison signature (if applicable)
- Informed Consent forms (including any scripts for verbal or effective consent)
- HIPAA individual authorization or a strong justification for a waiver of HIPAA authorization
- Professional qualifications, e.g., Curriculum Vitae/resume or other supporting information

Items You Will Need to Submit a New IRB Application

- Research Protocol (must follow the template posted on the IRB website)
- Lay summary (500 words max, written in prose and not bullet points or list style)
- Materials used for recruitment including fliers, scripts for social media posts, etc.
- Budget (if applicable)
- Certificates of Human Subjects Protection Training for all study personnel
- HIPAA Training Certificate for all study personnel
- Data collection instruments, including surveys, focus group and interview questions and scripts
- Documentation of PHIS IT approval for software (if applicable)
- Laboratory Review Form (if applicable)

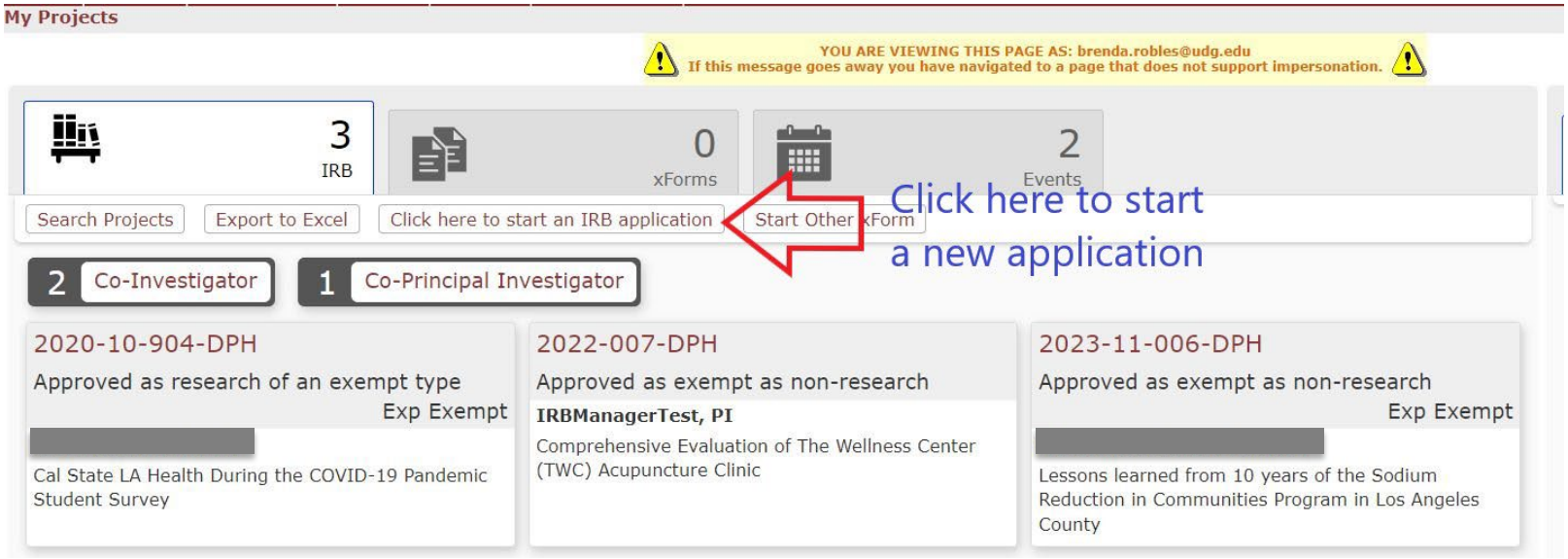
When you are ready to submit your IRB application

- Go to https://lacdph.my.irbmanager.com/Login.aspx and log in to IRBManager where you can submit:
  - New applications for IRB review
  - Amendment requests
  - Annual progress reports
  - Requests for continuing review
  - Adverse events reports
- County users can log in using your County email and password
  - Try logging in with County credentials before registering for a new account
  - A user guide with basic steps for navigating IRBManager is available on the IRB website

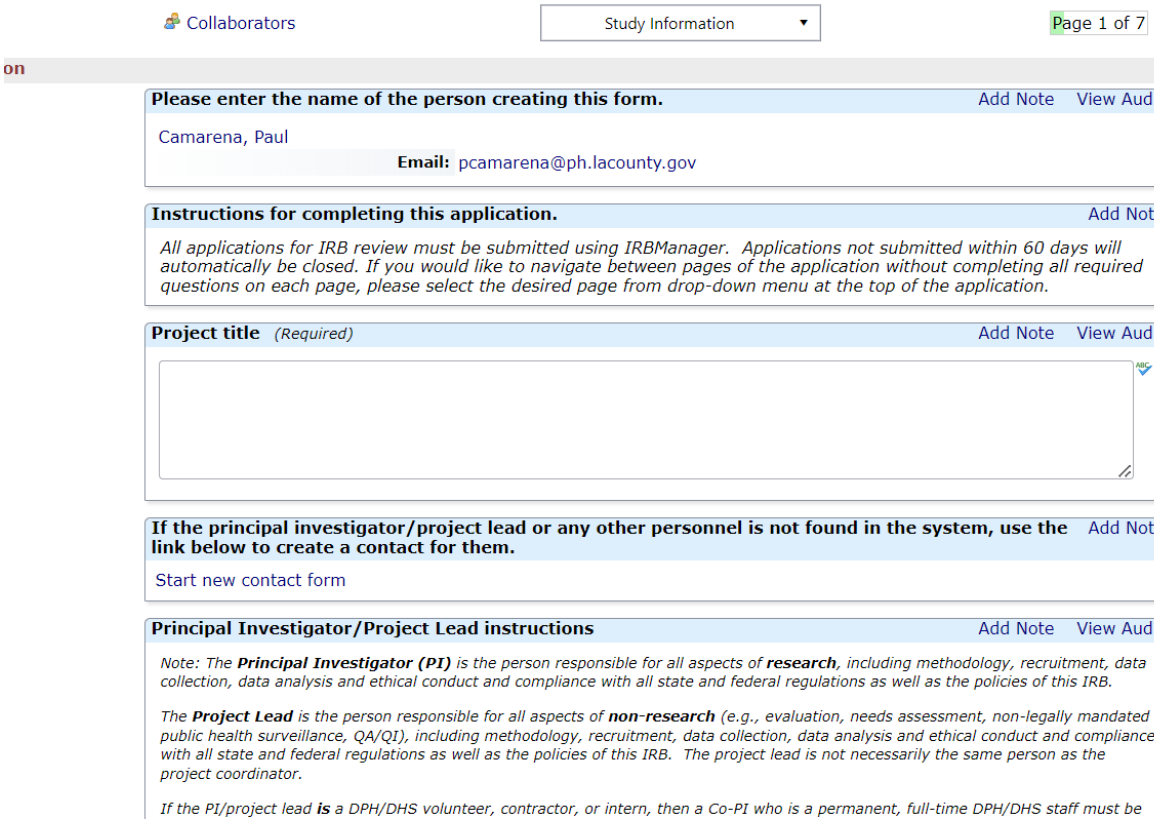


Home page or “Dashboard”

From the dashboard, you can access approved projects for which you are listed as a key personnel (from the “IRB” tab), you can start new applications (also called “xForms”), and you can access applications in progress (from the “xForms” tab)



IRB application



For your project, the IRB will ask …

- Why is the project and the question(s) it poses important to public health?
- Are the methods clearly described and appropriate to the question and is the study team capable of carrying them out?
- Who will be recruited and how? Are consent procedures clear and adequate?
- Are forms and instruments, including recruitment materials, clear, intelligent, sensitive and at appropriate literacy levels?

For your project, the IRB will ask …

Is personally identifying information minimized and is each item necessary and justifiable?

Are individual privacy and data confidentiality protections adequate?

Have potential risks been thought through and minimized, including group harms and risks to vulnerable populations?

How will community be involved in the project?

How will the data be analyzed? How will the results be disseminated?

Required Signatures

- PI/project lead, Co-PI (if any), and Program Director/Division Chief will need to “sign” the electronic application
- If the Principal Investigator/Project lead or Co-PI for a research study is not a permanent DPH/DHS employee, a DPH/DHS staff member will need to be designated as DPH/DHS liaison on your application

Signing and submitting an IRB application

When signing an application:

- click on the “sign” button,
- enter your login password to sign the application,
- click on the “Next” button at the bottom of the page to submit the application.

Types of IRB Action

- Approval (with category of exemption or expedited review specified)
- Full approval for one year (or completion of study for exempt/expedited projects)
- Full approval for shorter period
- Approval with stipulations
- Tabled until revised or substantial questions answered
- Rejected

What happens after approval?

- IRB conducts project monitoring until completion via routine audits
- Submit an amendment application in IRBManager **before** you implement any changes – including changes to key personnel.
- Submit annual progress report or continuing review request (as applicable) or risk automatic closure – submit 2 weeks before due date
- Report any adverse or unexpected events or protocol deviations to IRB
- Submit a final report when project is complete
- Project teams must maintain up-to-date training certifications for key personnel

Informed Consent
What do the federal regulations say?

Federal regulations require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR), unless:

- the project is exempt under 45 CFR 46.101(b)
- the IRB determines that certain conditions have been met such that informed consent can be waived

Informed Consent
Ethical Framework

Founded on the principle of respect for persons:

- Individuals should be treated as autonomous agents
- Rights and welfare of persons with diminished autonomy must be appropriately protected

The Informed Consent Process

Active process

- Sharing information between the investigator and the prospective participant
- Time for questions
- Clarification

Participants should be able to freely decide whether to initially enroll in the research, or later, to withdraw or continue participating in the research

When obtaining informed consent:

- Must include all the basic elements
- If obtaining written informed consent, must include key information section plus a detailed section
- Use the preferred language of the prospective participant
- Use clear, accurate and understandable language
    - Avoid medical and scientific jargon; instead, use common, everyday language
    - General population - 8th-grade reading level or lower

Basic Elements of Informed Consent

- Statement that it is research, purpose, duration, procedures to be followed, identification of any procedures that are experimental
- Risks/Discomforts
- Benefits
- Alternative procedures or treatments, if any
- Confidentiality of records
- If more than minimal risk, explanation of any compensation and medical treatments if injured
- Contact information
- Voluntary participation, refusal or withdrawal

Additional Elements of Informed Consent (if relevant to project)

- Statement that the procedure may involve unforeseeable risks to subject
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR's consent
- Any additional costs to the subject that may result from participation in the research
- Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
  - How compensation will be affected if they choose not to complete an interview
  - Discussion of what happens to data already collected

Additional Elements of Informed Consent (if relevant to project, cont.)

- That significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects in the study
- **New in 2019:** That the subject's biospecimens, even if identifiers removed, may be used for commercial profit and whether the subject will share in this profit
- Whether clinically relevant results, including individual research results, will be disclosed to subjects, and under what conditions
- Whether the research will or might include whole genome sequencing

Informed Consent Waiver

- Requirement for Documentation of Informed Consent can be waived under certain circumstances
- IRB determines whether conditions have been met for eligibility of waiver
- Inconvenience is **not** a justifiable reason
- To request waiver, you will be required to answer questions on the IRB application

Key Terms to Remember

- **Identifiable private information:** Information that an individual can reasonably expect will not be made public through which the identity of the subject may readily be ascertained
  - Also known as sensitive personal information (SPI), personally identifiable information (PII)
- **Protected health information (PHI):** Identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral, e.g., a medical record
- **Anonymous:** No identifiable private information or PHI is collected, thus cannot be re-identified
- **Confidential:** Identifiable private information is collected but kept private from public view, stored away from public view, can be de-identified and re-identified
  - Public: Anyone not associated with the data collection for the study
- **Vulnerable populations:** Subjects in research studies vulnerable to the possibility of coercion or undue influence (Pregnant women, prisoners, children, economically disadvantaged populations)

Additional Informed Consent Tips for Your Reference

- Spell out abbreviations or acronyms the first time they are used
- Use short sentences and short paragraphs
- Avoid details that do not help participants make a decision about being in the study
- Use active voice rather than passive voice whenever possible; for example, use “We will draw a blood sample”, not “A sample of blood will be drawn”
- Use bullets for long lists of procedures or risks
- Use subheadings to break up large amounts of text
- If text messaging will be used for project activities, the consent form should state that standard messaging rates will apply

HIPAA Privacy Rule

What is HIPAA?

- Health Insurance Portability and Accountability Act of 1996

When does HIPAA apply?

- PHI: protected health information
- Any of 18 types of demographic identifiers or health care delivery information, including ZIP code.
- Any PHI collected or transmitted in any form by a “covered entity”
- Applies to all data collection activities

Two ways to comply

- HIPAA Individual Authorization
- Waiver

HIPAA Waiver Request in IRBManager

- Strong justification for a waiver needed
  - Describe how the study could not practicably be conducted without access to and use of the PHI
  - Inconvenience is not a **JUSTIFIABLE** reason
- Include a detailed list: 1) PHI to be collected 2) list of the source(s) used/accessed for the PHI.
- Describe how the uses and disclosures of PHI will be limited to the "**minimum necessary**" to achieve the purpose(s) of the investigation.
- Describe the plan to destroy the identifiers at the earliest opportunity.
  - This must be done unless there is a health or clinical justification for retaining the identifiers or such retention is otherwise required by law.
- Describe the plan to protect identifiers from improper use and disclosure. Indicate where PHI will be stored and who will have access
    - List all entities that might have access to the study's PHI such as sponsors, FDA data safety monitoring boards

Helpful Tips for Submitting an Application

- Update your contact information in IRBManager to include your degree(s)
- The best way to ensure a smooth review process is to:
  1) make sure that your application is **complete** including all consent/HIPAA documents, recruitment materials (including social media posts, etc.), data-collection instruments (including phone or email scripts for recruitment, interviews/focus groups, etc.), and PHIS approval
  2) respond to emails from IRB staff or automated notification emails from the IRBManager system as promptly as possible
- When you submit an application, IRB office receive an automated notification from IRBManager so there is no need to inform the IRB with a separate email
- Please send IRB inquiries to IRB inbox at IRB@ph.lacounty.gov

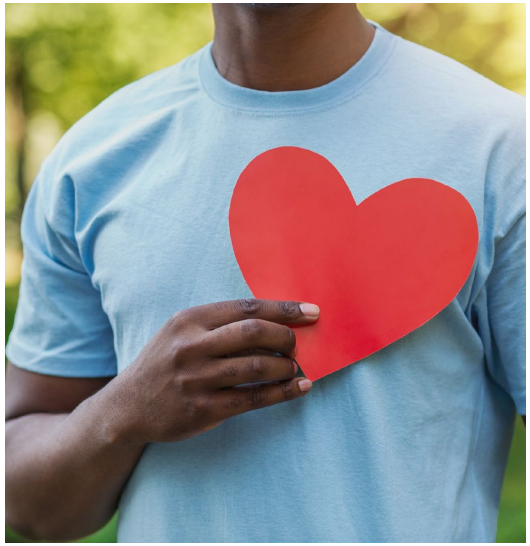
Additional Protected Health Information, for your reference

- All geographical subdivisions smaller than a State, including zip code
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- Phone numbers
- Fax numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Biometric identifiers, including finger and voice prints
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

IRB Health Equity Initiative

LAC DPH defines health equity as ***"when everyone has a fair and just opportunity to attain their optimal health and well-being."***

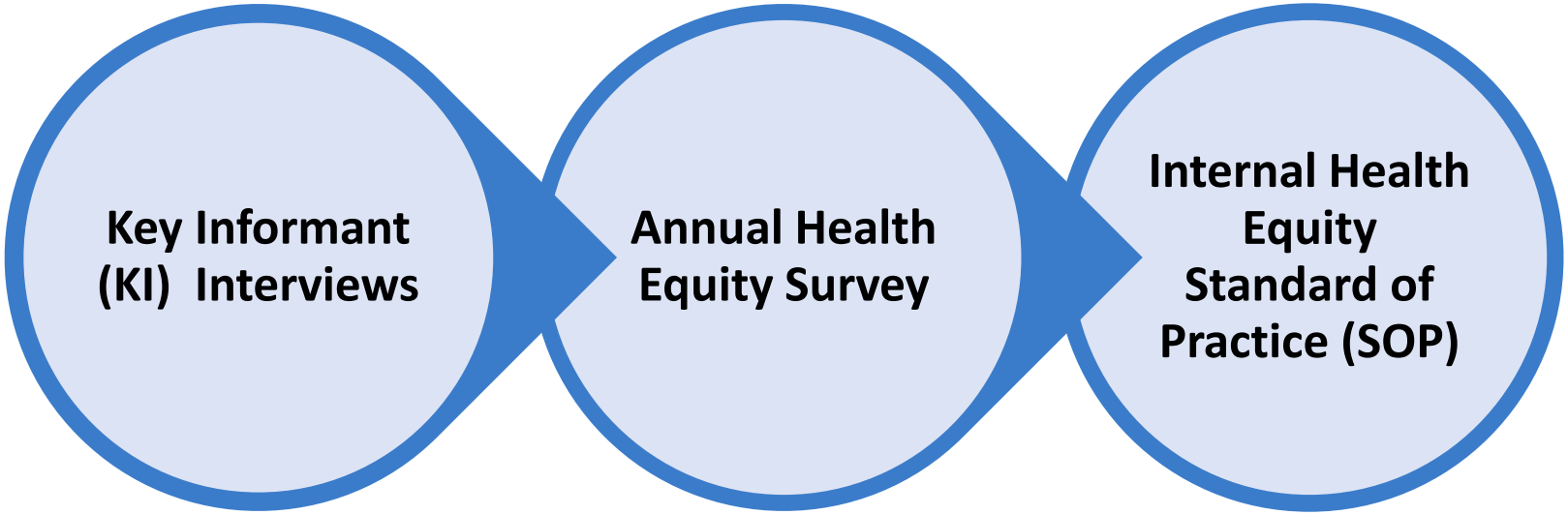
- striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on certain social conditions.



IRB Health Equity Initiative

- Addressing health equity in research is a matter of justice and is necessary to ensure that research and related activities produce quality (robust and generalizable) data that can better inform action at all levels.
- As a research goal, health equity is a lens through which all research activities should be viewed.
    - From study design all the way to dissemination of results

IRB Health Equity Initiative



- A Health Equity Report summarizing results from the interviews is available on the IRB website

- Apply to DPH projects and will provide guidance for reporting progress toward meeting health equity objectives, including the methods used to measure health equity

IRB Health Equity Initiative

- **New:** Health Equity SOP regarding health equity, diversity and inclusion in research and related activities reviewed by the DPH IRB
    - Internal version available on IRB intranet
    - External version available on IRB website
- SOP informed by key informant interviews and health equity survey completed as part of IRB's Health Equity Initiative (HEI).
- Please refer to our Health Equity Initiative page for more information about the HEI and our efforts to develop this SOP.

IRB Health Equity Initiative

- IRB will collect data and report on health equity to ensure research and related activities are addressing the following:
    - community engagement
    - recruitment and sampling equity
    - language and cultural equity
- Project leads should be prepared to answer questions about health equity in their projects when they submit new applications and annual progress reports to the IRB

Any Questions??

Visit our website:
http://publichealth.lacounty.gov/irb/

Write us with questions:
irb@ph.lacounty.gov

Frequently Asked Questions

- Do all projects require an annual progress report?
  - All projects, even if approved through completion of study, must submit an annual progress report unless directed to submit a Continuing Review application (in approval letter) or risk automatic closure.
- What about student, volunteer, intern projects?
  - For such projects, an experienced researcher who is a full-time DPH staff member will need to be named as Co-Principal Investigator.
- Study expiration dates are serious!
  - Submit continuing review applications at least 1 month prior to study expiration or risk automatic closure of your project.
- Should I obtain IRB approval for amendments (changes) to a project even if exempt?
  - All projects must obtain IRB approval prior to implementing any changes to a project (including changes in personnel), even if it is exempt.

More Frequently Asked Questions

- Does “exempt” mean IRB review is not needed?
  - Studies that are designated as exempt must still undergo an initial IRB review, but they may not require annual renewal (i.e., continuing review).
- What happens if we disagree with the IRB’s decision or conditions?
  - If you have questions or concerns about our decision or stipulations, please contact us.
- Who should be included on the application?
  - Anyone listed on the protocol as a member of the research team should be included on the application as key personnel.
- How long will it take to get IRB approval?
  - Time to approval is impacted by level of review, thoroughness of the application, and speed with which applicants respond to IRB stipulations and/or requests for more information.
  - Exempt and Expedited studies typically take the same amount of time to review. A complete application (after receiving PHIS approval and/or RATE/ROB review) will take approximately 2 to 5 weeks.

Thank you!

Evaluation survey:

https://www.surveymonkey.com/r/6TN2936

Knowledge Check:

https://www.surveymonkey.com/r/R5N8GQW