Institutional Review Board

Human Subjects Protection Training

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Director
Office of the IRB

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

Ground Rules

- Please keep your microphones on mute
- Please enter your questions in the chat box or raise your hand using the reaction buttons
- Please remember this is a safe space and be respectful of others and their opinions

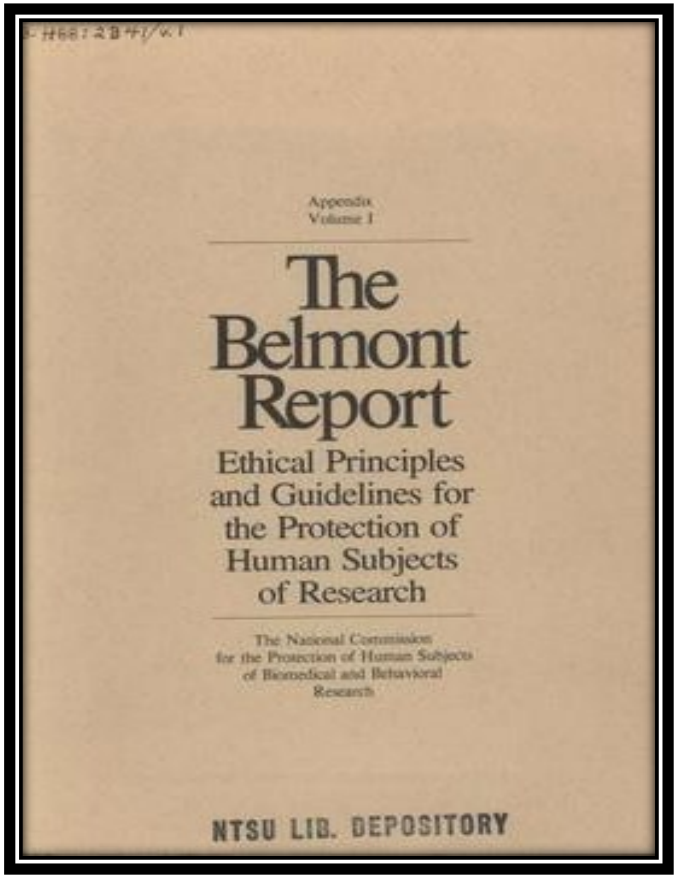
Administrative Items

- Presentation slides available on the **IRB website**
- Evaluation survey will be available after training
- **NEW!** Training post-test
  - Required to receive a certificate of completion
  - Have until 4pm on **Monday, May 19th** to complete
- Certificates of completion will be available in TalentWorks after passing post-test

Brief History of Ethics in Research

- USPHS Untreated Syphilis Study at Tuskegee, 1932-1972
- Willowbrook Hepatitis Experiments, 1955-1970
- Milgram's experiments on obedience, 1960s

Books such as *Acres of Skin, The Immortal Life of Henrietta Lacks*, and other resources on ethics in research are available through the DPH Library: Instructions for accessing e-books
For a full list of available books visit our website: Resources



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

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

Our IRB

- **We consider**:
  - "Group harms" not just risks to the individual
  - 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

By law, the IRB functions to ensure:

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

What is a Vulnerable Population?

- "The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are ***vulnerable to coercion or undue influence***, [emphasis added] such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons." **§46.111(a)(3)**
- **Coercion/undue influence** "The *Belmont Report* states that coercion involves "…an overt threat of harm…to obtain compliance, and offer of excessive, unwarranted, inappropriate reward…"
- **Persons with impaired decision-making**
- **Economically or educationally disadvantaged persons**

What is a Vulnerable Population, cont.?

- Other examples:
  - Persons experiencing homelessness
  - Persons with terminal illness or medical vulnerability (life-impacting disorders/illnesses)
  - Non-English-speaking participants
  - Wards of the State
  - Elderly
  - Institutionalized persons
  - Probationers and parolees
    - We apply same protections as prisoners

What is "Research?"

- **Federal regulatory definition <u>§46.102(l)</u>:** "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 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:

- A project is anything involving staff, facilities, clients, patients, funding, databases from DPH, DHS, etc.
- Projects involving participants with past or current involvement with the criminal justice system must be reviewed by the Full Board including secondary data analysis

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 for external use and/or publication
- Program evaluation for internal program use with intention to publish and/or that collect/access data that involve sensitive topics such as substance use/disorder or that collect/access data about persons belonging to vulnerable populations
- Certain quality assurance and quality 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
- Environmental investigation

Exceptions to DPH IRB Submission Policy, cont.

No submission required if:

- Authorized operational activities in support of criminal justice or criminal investigative activities or defense/national security
- Staff assessments or other internal queries that pertain to core job duties and skills
- Customer satisfaction surveys that do not collect/access data from vulnerable populations or involve sensitive topics (such as substance use), OR that do not collect/access personally identifiable information (PII) or protected health information (PHI)

Exceptions to DPH IRB Submission Policy, cont.

No submission required if:

- Evaluations for internal use for trainings that are linked to receiving CE units or certificates of completion or that do not involve vulnerable populations and/or where the IRB determines that informed consent is not required for participation in the trainings
- Program evaluation for internal use with no intention to publish and that do not collect/access data that involve sensitive topics such as substance use/disorder or that do not collect/access data about persons belonging to vulnerable populations

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)
- Sound study design
- Equitable selection of subjects

Sound Study Design and Equitable Subject Selection

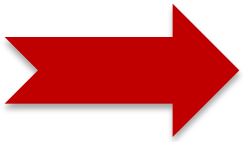
- "Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk." **§46.111(a)(1)(i)**

- "Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted." **§46.111(a)(3)**

Levels of IRB Review

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

Levels of IRB Review

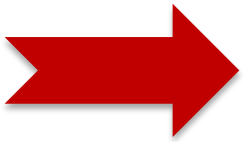


- Exempt as Non-Research
- Research of an Exempt type
- Expedited
- Full Board

Exempt as non-research

- Most standard Quality Assurance/Quality Improvement activity
- Most program evaluations
- Needs assessments
- 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
- Requires either **written consent or application for a waiver**, and cannot claim it is not research

Exempt Categories

Exemption #1: EDUCATIONAL EXEMPTION [45 CFR 46.104(d)(1)]
Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption #2: SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR [45 CFR 46.104(d)(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)

Exemption #2 only may apply to research subject to subpart D - Additional Protections for Children Involved as Subjects in Research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

Exempt Categories, cont.

Exemption #3: BENIGN BEHAVIORAL INTERVENTION [45 CFR 46.104(d)(3)(i)]

A "benign intervention" is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact.

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:

(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).

Exempt Categories, cont.

Exemption #4: SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS) [45 CFR 46.104(d)(4)]

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 HIPAA 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).

Exempt Categories, cont.

Exemption #4: SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS) [45 CFR 46.104(d)(4)], cont.

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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.

Note: Collection and analysis of protected health information (PHI) and personally identifiable information (PII). If you intend to collect both PHI and PII, the research could not be reviewed under an Exempt category. This study would likely fall under an Expedited Category #5.

Since HIPAA does not apply to biospecimens, Exempt #4(iii) applies only to the secondary use of PHI (which can include information obtained from biospecimens), not the biospecimens themselves.

Exempt Categories, cont.

Exemption #5: PUBLIC BENEFIT / SERVICE PROGRAM RESEARCH [45 CFR 46.104(d)(5)] (rarely used at DPH)

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.

Exemption #6: TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE [45 CFR 46.104(d)(6)] (rarely used at DPH)

Levels of IRB Review

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

What is Minimal Risk?

According to the federal regulations at **§46.102(j)**, *minimal risk* means that "the probability **and** [emphasis added] 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

- 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)
  - Recordings of minors

Expedited Review

- "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 or IRB analyst, without waiting for monthly IRB meeting

Expedited Categories

Category 1

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required; or

(b) Research on medical devices for which (i) an investigational device exemption application (21CFR812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

*NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Expedited Categories, cont.

Category 3

Prospective collection of biological specimens for research purposes by noninvasive means.

[Examples:

(a) hair and nail clippings in a non-disfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.]

Expedited Categories, cont.

Category 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. Where medical devices are employed, they must be cleared/approved for marketing.

*NOTE: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.

[Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.]

Expedited Categories, cont.

Category 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 research participants. 45 CFR 46.101(b)(4). This refers only to research that is not exempt.

Category 6

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

Category 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 research participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Expedited Categories, cont.

Category 8

Continuing review of research previously approved by the convened IRB as follows:

(a) where:

(i) the research is permanently closed to the enrollment of new participants;

(ii) all participants have completed all research-related interventions; and

(iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants have been enrolled and no additional risks have been identified; or

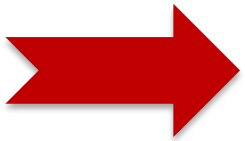
(c) where the remaining research activities are limited to data analysis.

Category 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 a 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
  - Majority of committee members must be present to vote on study approval
  - Projects involving participants with past or current involvement with the criminal justice system must be reviewed by the Full Board

Exercise : What level of review?

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.
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 assess 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.

Exercise: What level of review?

5. Persons who work with silicosis will be invited to participate in listening sessions to assess their experiences working with silicosis.
6. Licensed firearms businesses will be asked questions about their general business practices related to relinquishing weapons for persons subject to gun-violence restraining order.
7. Adults and children aged 16-17 will be asked to respond to weekly text message-based study to assess respiratory symptoms.
8. Children aged 13-15 will be asked to complete confidential pre- and post-test surveys to assess improvement and understanding of fentanyl and the use of naloxone after an educational video campaign.

Overview of the application process

- **Step 1**: Review IRB website and application checklist
- **Step 2**: Is DHS involved?
  - If YES – Obtain DHS ROB approval
- **Step 3**: Submit IRB application using IRBManager

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 staff submit final drafts of protocol, budget, and other relevant project materials to the IRB via email at IRB@ph.lacounty.gov

- IRB staff will forward your email to the ROB who will then review the proposal and will assign a priority category
- Once you receive approval from the ROB, please print a PDF of the approval email confirmation and upload it your IRB application

External process:
PHIS Information Security Office (ISO) Approval

1 Is your project collecting/using personally identifiable information (PII) or protected health information (PHI) accessing PHI?
2 Does your project involve external contractors/organizations?
3 Does your project involve non-County approved/installed software?

If **YES** to 1 and 2 or **YES** to 3, your project needs PHIS ISO approval.

How to comply:

- An IT ticket will be created automatically if criteria are met when your IRBManager application is submitted
- Your online application will include questions needed for PHIS ISO

Ensure that:

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

What will PHIS ISO 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

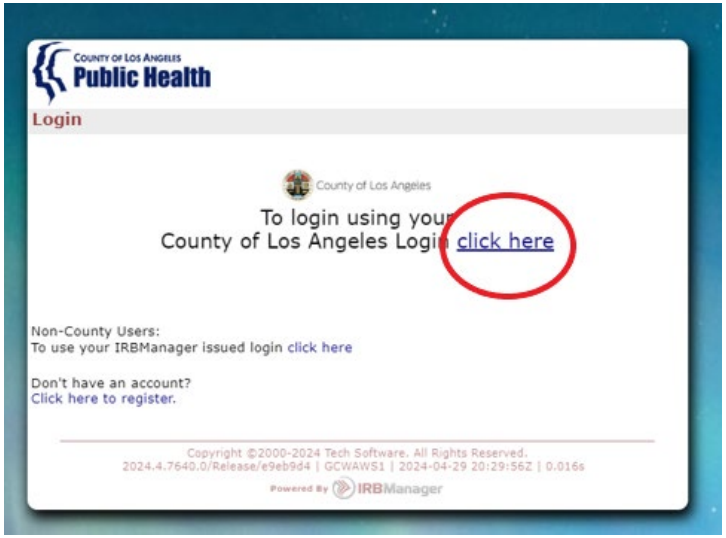
- **Before you begin an IRB application:** DHS projects must obtain ROB approval
- Principal investigator(PI)/project lead, Co-PI (if any), and Division Chief/Program Director signature
- DPH/DHS liaison signature (if applicable)
- Informed Consent forms (including any scripts for verbal or effective 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
- Recruitment materials including flyers, posters, social media posts, text/phone scripts, etc.

Items You Will Need to Submit a New IRB Application

- Research Protocol (must follow the template posted on the IRB website)
- Lay summary (300 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 (CITI or this training)
- HIPAA Training Certificate for all study personnel (TalentWorks for DPH badgeholders; CITI for others
- Cybersecurity and Privacy Awareness Training Certificates (DPH badgeholders only)
- Data collection instruments, including surveys, focus group and interview questions and scripts
- Documentation of PHIS ISO approval for software (if applicable)
- Laboratory Review Form (if applicable)

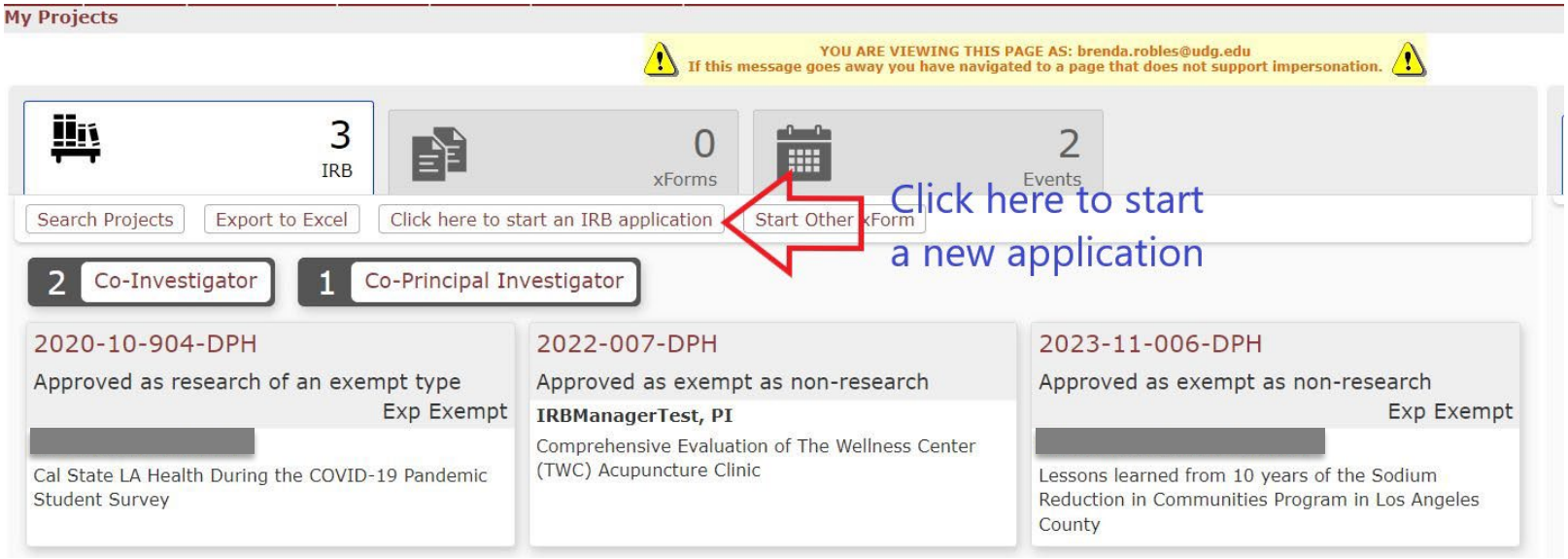
When you are ready to submit your IRB application

- 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 and video tutorials with steps for navigating IRBManager is available on the IRB website

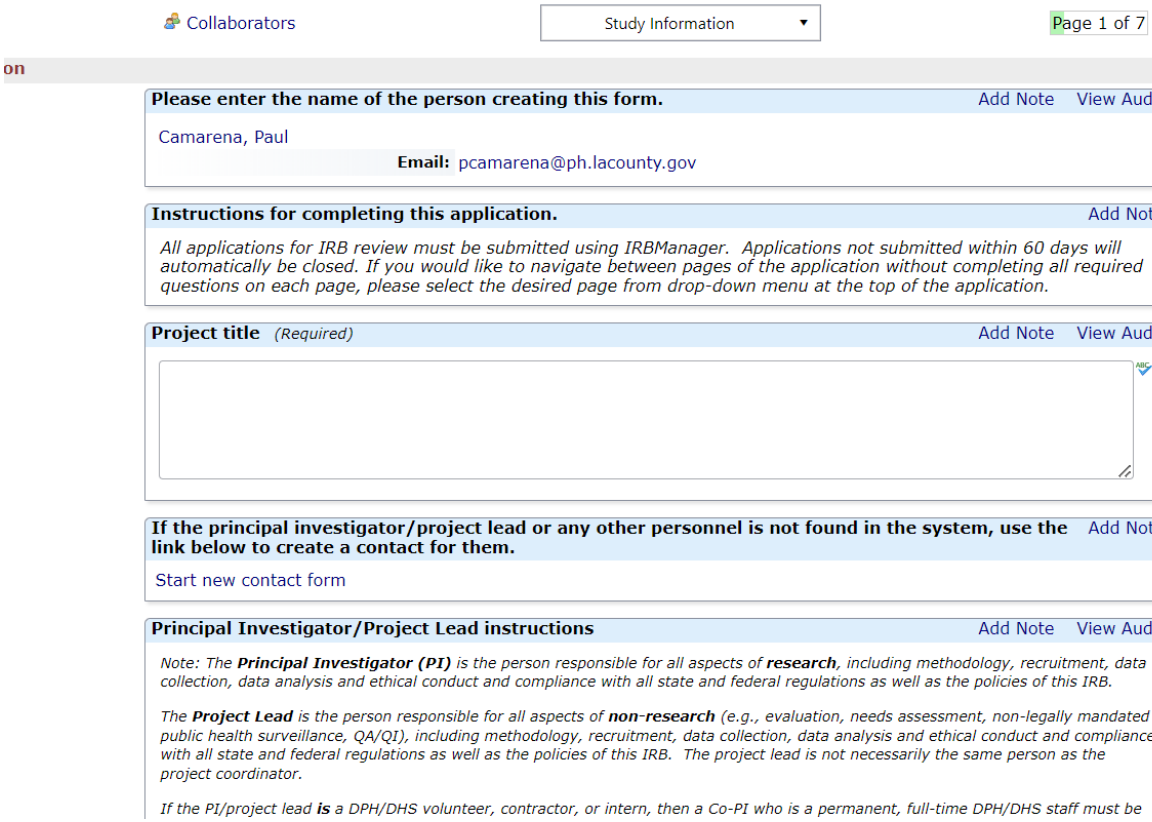


Home page or “Dashboard”

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



Application Screening vs. IRB review

Screening:

- Administrative check to make sure the application is complete, including required approvals and training certificates

IRB Review:

- Once complete, application are reviewed to ensure the project meets the ethical and quality standards outlined in the code of federal regulations (45 CFR 46, known as "the Common Rule") as well as DPH IRB Standards of Practice/policies

For your project, the IRB reviewer 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?
- Is personally identifying information (PII or PHI) minimized and is each item necessary and justifiable?

For your project, the IRB reviewer will ask …

- 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 the community be involved in the project?
- How will the data be analyzed? How will the results be disseminated?
- Is the project addressing health equity? Is it measuring/collecting data on health equity and, if so, what data?

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
- On the following screen, click "**Submit**" to complete the submission process

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 within 7 days of research team awareness
- 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 **§46.104**
- 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

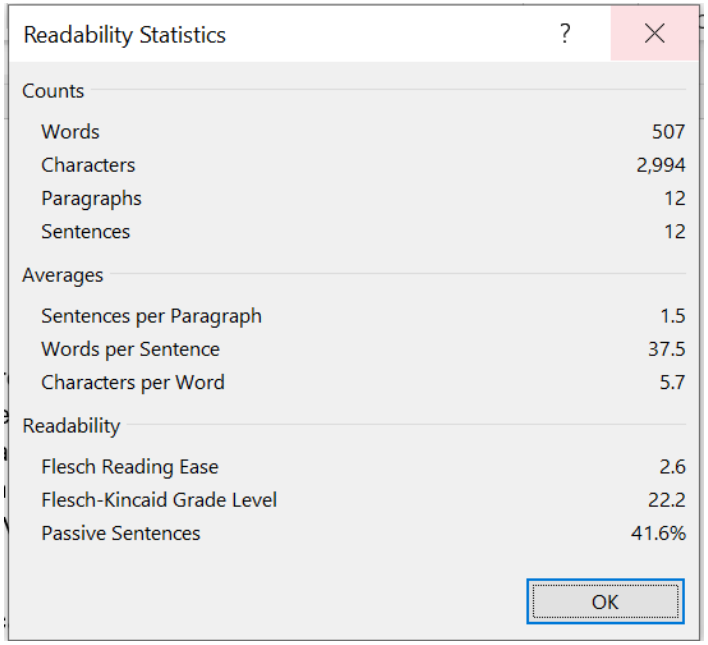
How to obtain reading level in Microsoft Word

Step 1: Open your Informed Consent document in Word.

Step 2: From the toolbar at the top, click “Review” to bring up more options and then click on “Editor.”

Step 3: The Editor function will check your document for spelling, grammar and readability. Results are displayed on the right-hand side. Select “Document stats” from the results.

Step 4: A window with document stats will pop up**.** “Flesh-Kincaid Grade Level” is the number that lets you know the reading level of the text in your document.



Research and related activities involving minors

- If minors will be involved in the project, the following are required:
  - Parent/guardian permission forms
  - Teen and/or child assent forms
- All applicable forms must be at appropriate reading levels:
  - **Parent/guardian permission forms** should be at no greater than an **8th-grade** reading level
  - **Teen assent** forms (for **ages 13-17**) should be at no greater than a **6th-grade** reading level
  - **Child assent** forms (for **ages 7 to 12**) should be at no greater than a **2nd-grade** reading level

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 of PI and IRB
- Voluntary participation, refusal or withdrawal

Informed Consent Documentation

- Documentation that process took place
  - Record of the participant's agreement to take part in the project
  - May be electronic, audio or video recording, as approved by the IRB
  - Copy given to subject
  - Template available on website
    - Must contain key information and detailed information sections
- Parental/guardian permission and child assent required when involving minors

Informed Consent Waiver

- Requirement for Documentation of Informed Consent can be waived under certain circumstances
  - Effective consent
  - Alteration (verbal, study information sheet)
- 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

Effective Consent

- For projects using an effective consent, language about voluntariness is required, such as:

  Your participation in this project is entirely voluntary. You can choose to participate and withdraw at any time without penalty. You can refuse to answer any questions.

- Or (if the project involves minors):

  It is up to you if you want to be in this project. You will not get in trouble if you choose not to be in the project. If you choose to be in the project, you can change your mind and stop at any time. You do not have to answer any questions you do not want to.

Key Terms to Remember for Your Reference

- **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, e.g., a medical record
  - 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
- **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

- If a technical term is used, define or explain it in lay language the first time
- 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 project
- Use active voice rather than passive voice whenever possible; for example, use “We will draw a blood sample” instead of “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

Helpful Tips for Submitting an Application

- The best way to ensure a smooth screening/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.), training certificates, and required approval documentation
  2) respond to emails from IRB staff or automated notification emails from the IRBManager system as promptly as possible

Please send IRB inquiries to the IRB inbox at IRB@ph.lacounty.gov

HIPAA Authorization

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 (must use form on IRB website)
- Waiver (HIPAA Counsel will make determination)

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

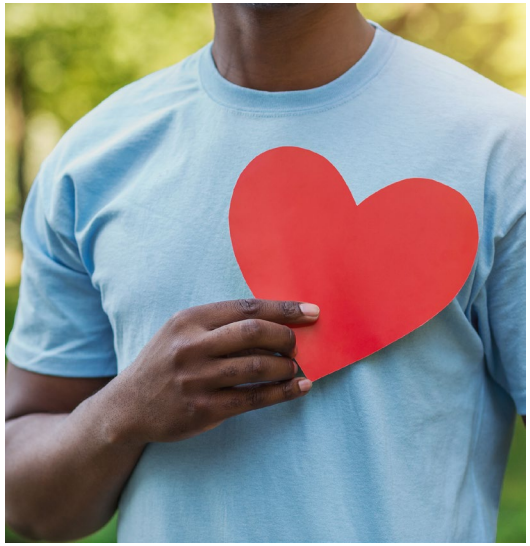
18 Personal Identifiers Under HIPAA

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

What is Health Equity?

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.



What do the federal regulations say?

- **45 CFR 46.116[a](3)**

  "The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative."

- **45 CFR 46.111[3]**

  "Selection of subjects is equitable."

Source: *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1*

What do the federal regulations say? (cont.)

- **45 CFR 46.107(a)**

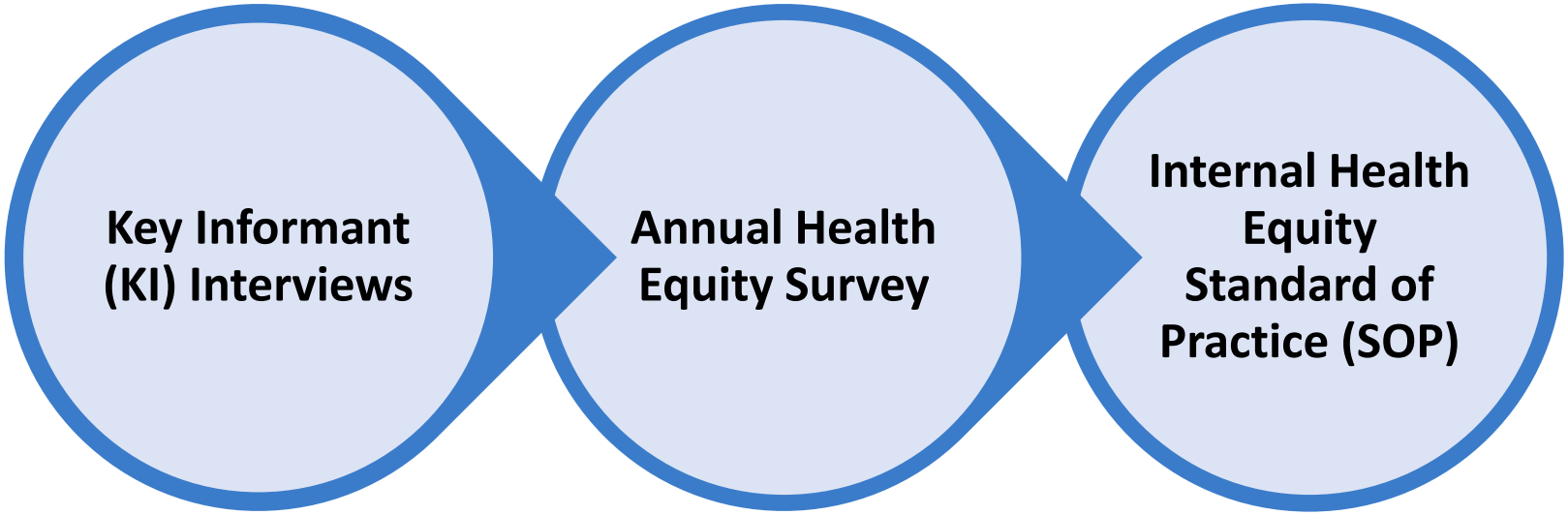
> "The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. "

Source: *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1*

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

Phases of the Health Equity Initiative



- Reports summarizing results from the interviews and survey is available on the IRB website

- Applies to all 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 SOP

- 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 the 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: Next Steps

- 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
- PI/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

Coming soon!

- **IRB Office Hours:** IRB staff will be hosting office hours weekly or biweekly (TBD) so that staff can ask questions about their projects and/or applications without having to schedule a consultation
- **Artificial Intelligence training:** we are adding a training module about AI in research to our web-based CITI training
- **HRP training video:** IRB staff are working on developing an HRP training video in English for our community-based partners as an alternative to our web-based CITI training

An email blast will be sent out with updates as we have more information – please stay tuned and check our website regularly!

Any Questions??

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

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

Reminders

- Must complete training post-test to receive a certificate of completion
    - Have until 4pm on Monday, May 19th to complete
- Please allow 1-2 days after completing post-test before checking for certificate
- Instructions for locating post-test and/or certificate available here: http://www.publichealth.lacounty.gov/IRB/Training.htm

Thank you!

Evaluation survey:

https://www.surveymonkey.com/r/6BT3C8C