Institutional Review Board

Human Subjects Protection Training

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Director
Office of the IRB
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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

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

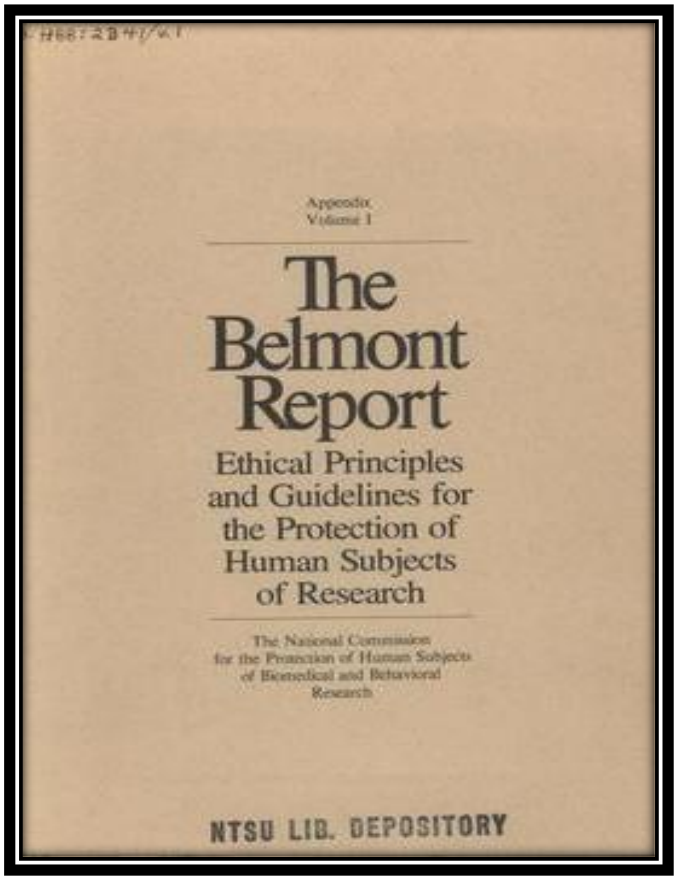
- Presentation slides will be available on the IRB website
- Evaluation survey will be available after training
- Must complete training post-test to receive a certificate of completion
  - Complete by 3pm on March 02, 2026
  - Certificates available in TalentWorks 3-4 days after passing post-test
- Stay tuned for an optional IRBManager demo after the end of today's training

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. DPH/DHS learners can visit the DPH Library website for more information.

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
  - Vulnerable Populations
- **Beneficence**
  - Minimize harm, maximize benefits
- **Justice**
  - Equity of risks and benefits

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…*"

Vulnerable Populations Receiving Additional Protections

- Pregnant Women, Human Fetuses and Neonates (Subpart B)
  - We refer to as pregnant persons
- Prisoners (Subpart C)
  - Formerly and/or currently incarcerated persons, parolees and/or probationers
- Children (Subpart D)

Other Vulnerable Populations

- Persons experiencing homelessness
- Persons with terminal illnesses
- Persons with medical vulnerabilities (life-impacting disorders/illnesses)
- Non-English-speaking participants
- Wards of the State
- Elderly
- Institutionalized persons

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

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 the DPH IRB?

- Oversight entity housed in DPH
- Required board make up for all IRBs:
  - Minimum 5 members
  - Diverse across race, gender, cultural background
  - Scientist, non-scientist
  - Not affiliated with institution (community members)
  - Prisoner advocates
- Here at LACDPH IRB, board made up of **15 people**
  - Meets once a month, every fourth Thursday

How Are We Different from Other IRBs?

- Expansion of purview as permitted by HHS Office for Human Research Protections (OHRP)
- We consider:
  - "Group harms" not just risks to the individual
  - Community engagement and accountability
  - Utility: How will results be used, applied, and shared?
  - Promotion of health equity/community engagement and reduction of disparities
- Ethical review required not only for research, but related activities involving human subjects

Who Does Our IRB Serve?

- DPH
- Dept. of Health Services (DHS)
  - Ambulatory Care Network (ACN)
  - Correctional Health Services (CHS)
  - Health Services Administration (HSA)
- Dept. of Youth Development (DYD)
- IRB of record for select community-based organizations

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

Health Services
LOS ANGELES COUNTY

los angeles county department of Youth Development

BIENESTAR

LOS ANGELES LGBT CENTER

Center for HealthJustice

RISING COMMUNITIES

DPH Policy 211

- Policy 211: Research and Related Activities Involving Human Subjects Reviewed by the Institutional Review Board
  - Sets forth the procedures for obtaining Institutional Review Board (IRB) oversight of research and related activities involving human subjects to ensure ethical treatment of human subjects as required by federal regulations 45 CFR 46
  - Policy includes pertinent definitions as well descriptions of both “research” and “related activities involving human subjects”

Chief Science Office (CSO)
IRB Standards of Practice (SOPs) For Your Reference

- Health equity, diversity and inclusion in research or related activities involving human subjects reviewed by the IRB
  - DPH SOP CSO-008
- Adverse/reportable events that must be reported to the IRB
  - DPH SOP CSO-009
- Auditing and quality improvement activities conducted by the IRB
  - DPH SOP CSO-010
- Conflicts of interest that must be reported to the IRB
  - DPH SOP CSO-011
- These SOPs have been adapted for non-DPH entities: policies

DPH IRB Policy on IRB Oversight

<u>Projects</u> involving collection or analysis of data from or about individuals:

- A project involves staff, facilities, clients, patients, funding, databases from DPH, DHS, DYD, etc.
- There are exceptions to projects requiring IRB oversight

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

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
- "Related activities involving human subjects"
  - Projects that collect, access or analyze data from or about individuals
  - Certain quality improvement projects
  - Needs assessments
  - Evaluation projects
- All ethical principles and spirit of federal regulations apply
  - Flexibility in how they are concretely applied

Projects Requiring IRB Oversight

- All projects that meet the federal definition of research
- Related activities involving human subjects
- Projects involving artificial intelligence (AI)

Exceptions:
Projects Where IRB Oversight is Not Required

- Collection of data in the course of providing clinical care
- Conducting legally mandated local, state or federal public health surveillance and environmental investigations
- Customer satisfaction surveys that do not collect/access:
  - Data about persons belonging to vulnerable populations
  - Data related to sensitive topics such as substance use/disorder
  - Personally identifiable information (PII), or protected health information (PHI)

Exceptions:
Projects Where IRB Oversight is Not Required, cont.

- Criminal investigation of activities in support of national security measures
- Anonymous meeting evaluations
- Staff assessments or other internal queries that pertain to core job duties and skills
- Program evaluation activities for internal use which do not collect/access:
  - Data about persons belonging to vulnerable populations
  - Data that involve sensitive topics, PII, and/or PHI

Exceptions:
Projects Where IRB Oversight is Not Required, cont.

- Training evaluations or internal use that are linked to receiving continuing educations units or certificates of completion or that do not collect or access:
  - Data that involve vulnerable populations
  - Data related to sensitive topics, PII, and/or PHI
  - Data where the IRB determines that informed consent is not required for participation in the trainings
- Projects that involve secondary analysis of de-identified data
  - Biomarkers such as retinal scans, etc., are not considered de-identified data

Exceptions:
Projects Where IRB Oversight is Not Required, cont.

- Listening sessions that do not collect/access:
  - Data about persons belonging to vulnerable populations
  - Data related to sensitive topics or PII and/or PHI

Applies to All Projects Where IRB Oversight Is Required

- Please follow CSO data collection SOPs (available upon request)
  - Race/Ethnicity
  - Sexual Orientation and Gender Identity (SOGI)
  - Disability Status
- Sound study design
- Equitable selection of subjects

Sound Study Design and Equitable Subject Selection

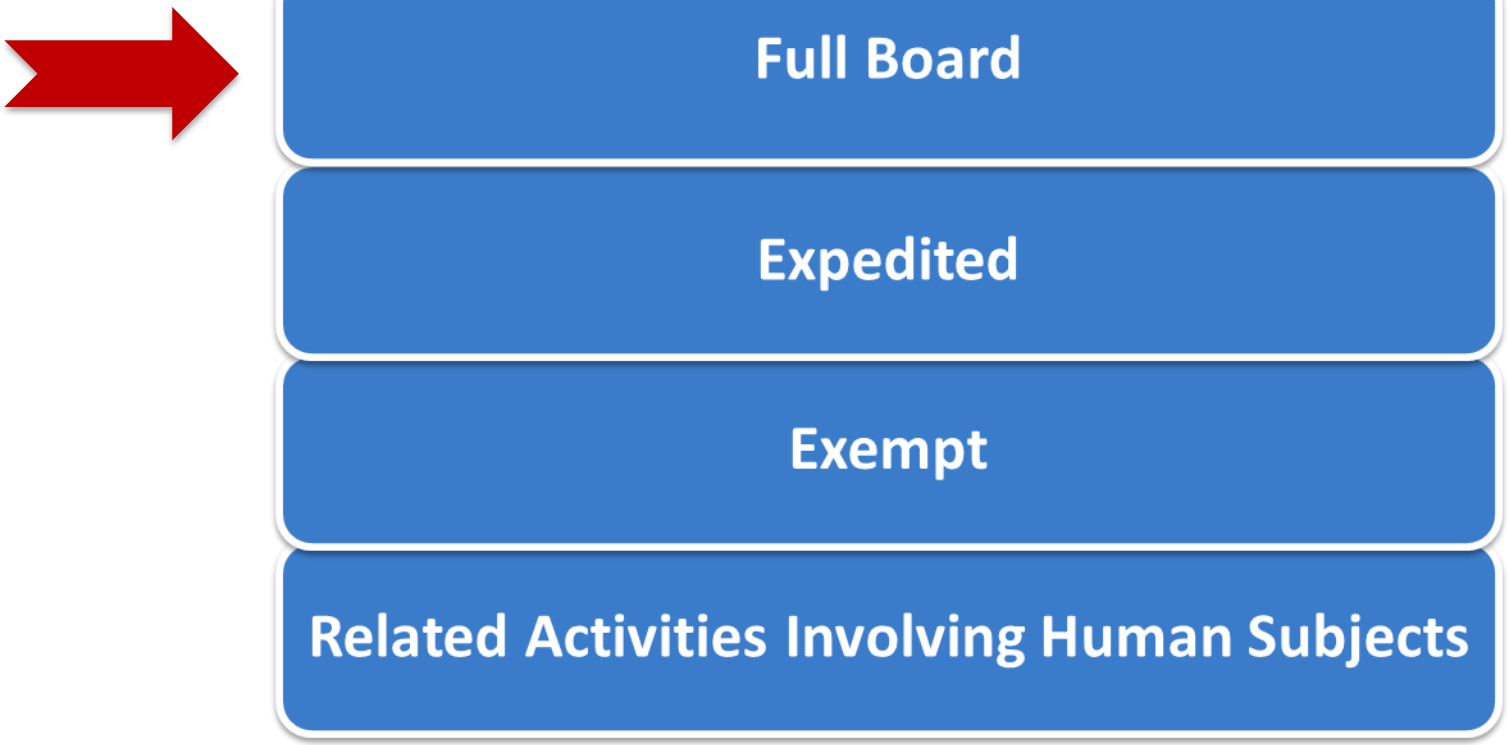
- *"Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk."* **§46.111(a)(1)(i)**

- *"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

- Full Board
- Expedited
- Exempt
- Related Activities Involving Human Subjects

Levels of IRB Review



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."*

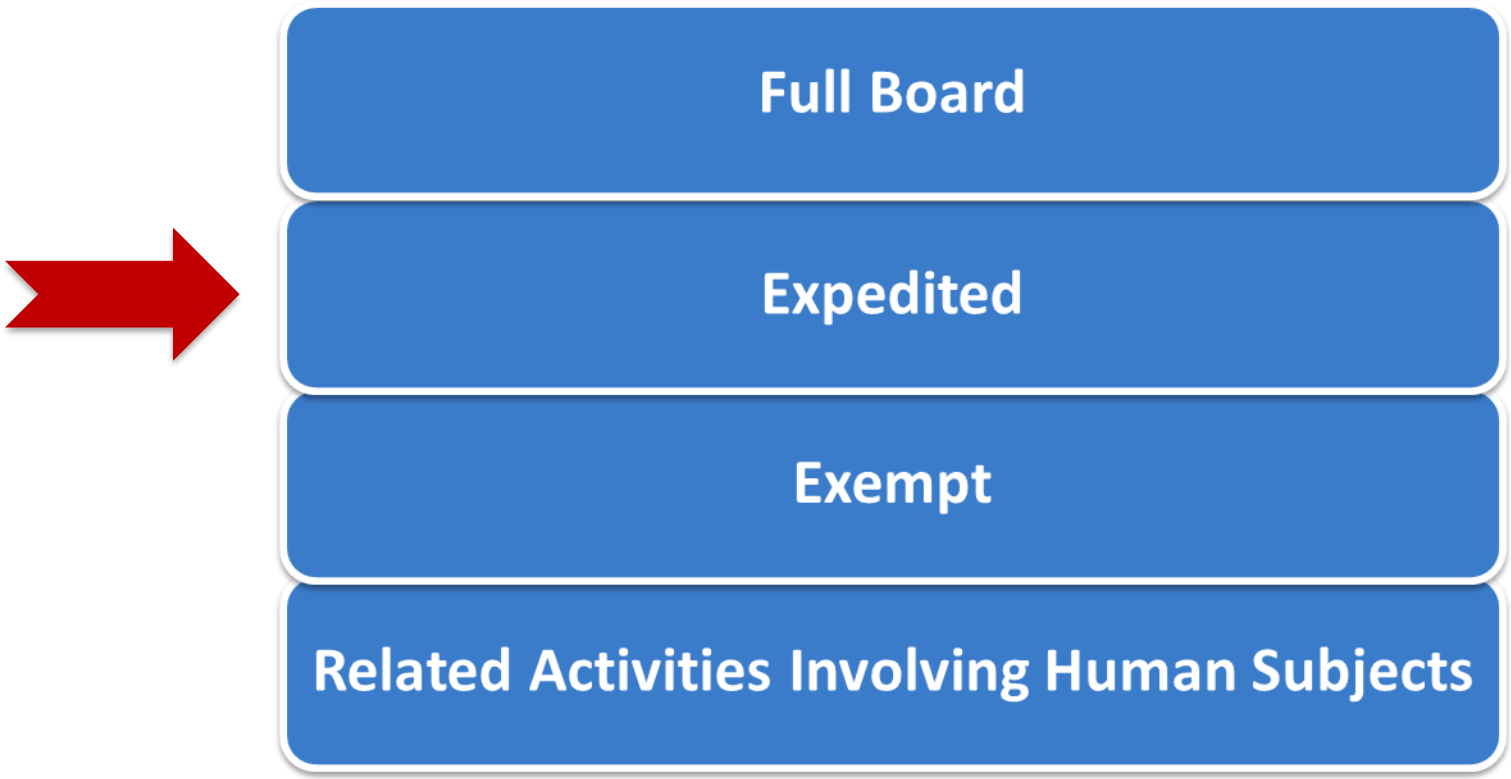
Full Board Review

- Highest level of scrutiny
  - ➢ Projects that pose more than minimal risk
  - ➢ Projects involving artificial intelligence (AI)
  - ➢ Projects involving currently or formerly incarcerated persons, parolees and/or probationers
    - ❖ Prisoner advocate is required
- Quorum of committee members must be present to vote
- Full board review projects will be discussed at the IRB meeting

Full Board Review, cont.

- Continuing review required
- Application must be received 6 weeks before the monthly IRB meeting

Levels of IRB Review



Expedited Review

- Refers to the way that federal regulations are applied when reviewing a research study
- Project poses no more than minimal risk
- The term “Expedited” means that review and approval can be given by Chair or IRB analyst without waiting for monthly IRB meeting
- Continuing review required for certain expedited projects
  - Stated in approval letter with the justification

Expedited Review, cont.

- One of the specific expedited categories per §46.110 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

Levels of IRB Review

Exempt Review

- Considered "research" and falls into specific categories per §46.104, for example:
  - Interview/survey/focus group-based research **that does not deal with sensitive topics**, e.g., substance abuse, HIV status
  - A study of previously collected data or records (except involving currently or formerly incarcerated persons, parolees, or probationers)
  - Projects involving blood draws of certain volume

Levels of IRB Review

Related Activities Involving Human Subjects

- Formerly known as "Exempt as Non-research“
- Not considered research but falls under IRB’s purview
- Does not require written informed consent but “effective” consent language is required

Effective Consent

- Can include at beginning of survey
- Include 3 elements of voluntariness:
    1. *Your participation in this project is entirely voluntary.*
    2. *You can choose to participate and withdraw at any time without penalty.*
    3. *You can refuse to answer any questions.*
- If the project involves minors:
    1. *It is up to you if you want to be in this project.*
    2. *You will not get in trouble if you choose not to be in the project. You can change your mind and stop at any time.*
    3. *You do not have to answer any questions you do not want to.*

Types of IRB Action

- Approval
- Full approval for one year (or completion of study as determined by IRB)
- Full approval for shorter period
- Approval with stipulations
- Tabled until revised or substantial questions answered
- Rejected

Exercise: What Level Of Review?

1. Full board
2. Expedited
3. Exempt
4. Related activities involving human subjects
5. Does not need IRB review

Exercises: What Level of Review?

Scenario #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. Survey results will be used to inform program planning.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic?is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #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 research journal.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic?is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #3

Adult 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. Self-reported STI diagnoses will be collected. Data will be used to assess usage rates and improve STI testing services in the clinic.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #4

On-line surveys will be administered to a general LAC population exposed to a mass educational campaign (posters, billboards, television messages) on the dangers of second-hand smoke to evaluate the intervention.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #5

Adults who may be exposed to silica such as those who work in construction, mining, masonry, sandblasting, and stone countertop fabrications will be invited to participate in listening sessions to assess their risks to being exposed to silica.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #6

Licensed firearms businesses will be surveyed about their practices related to persons subject to gun-violence restraining orders (GVRO) and weapons relinquishment. Data will be used to create a resource guide for persons subject to GVRO.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #7

Adults and minors aged 16-17 will be asked to respond to weekly text messages assessing respiratory symptoms. The data will used for programming planning.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Exercise: What Level of Review?, cont.

Scenario #8

Minors aged 13-15 will be asked to complete confidential pre- and post-test surveys to assess improvement in understanding the risks of fentanyl, and the use of naloxone to prevent fentanyl overdoses after watching an educational video campaign.

a) Is this research?
b) Data collection method?
c) Population?
d) Topic/is it sensitive?
e) What will data be used for?

Overview of the Application Process

- **Step 1**: Review IRB website and application checklist

- **Step 2**: Is DHS involved, even if DPH project?
  - If YES – Obtain DHS Research Oversight Board (ROB) review

- **Step 3**: Submit IRB application using IRBManager

External Process: ROB Review (Projects Involving DHS Sites)

Projects involving DHS staff or patients (such as DPH projects that include a DHS walk-in clinic or hospital) need to be reviewed and assigned a priority category by DHS' Research Oversight Board (ROB) to ensure feasibility and alignment with DHS' mission.

How to comply:

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

- Once you receive the priority category by email from the ROB, please print a PDF of the email and upload it your IRB application
- This can be a parallel process to the IRB review

External Process:
PHIS Information Security Office (ISO) approval

1. Will external contractors/organizations be collecting/using PII or PHI?
2. Does your project involve non-County approved/installed software?

If **YES** to 1 and/or 2 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
- PHIS ISO will follow up with project coordinator by email
- Parallel process to IRB application

External Process:
PHIS Information Security Office (ISO) approval, cont.

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 it be installed?
- Where will data be stored?
  - Physical
  - Electronic
- How long will the data be retained?
- Will data be transmitted? If so, where?
- Who will have access to the data
- 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 review
- Principal investigator(PI)/project lead, Co-PI (if any, can only be 1 Co-PI), and Division Chief/Program Director signature
- Professional qualifications, e.g., Curriculum Vitae/resume or other supporting information
- DPH/DHS/DYD liaison signature (if applicable)
- Budget (if applicable)
- Lay summary (300 words max, include methodology; written in prose and not bullet points or list style)
- Research Protocol (must follow the template posted on the IRB website, written in prose)
- Data collection instruments, including surveys, focus groups, and interview questions and scripts

Items You Will Need to Submit a New IRB Application

- Informed Consent forms, parental/guardian permission and/or child assent (including any scripts for verbal or effective consent)
- HIPAA individual authorization or a strong justification for a waiver of HIPAA authorization
- Recruitment materials including flyers, posters, social media posts, text/phone/email invitation scripts
- Laboratory Review Form (if applicable)
- Documentation of PHIS ISO approval for software (if applicable). DHS/DYD must obtain approval from their Departmental Information Security Officer (DISO)
- 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)

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
  - Amendment applications
  - Annual progress reports
  - Continuing review applications
  - Reportable events forms

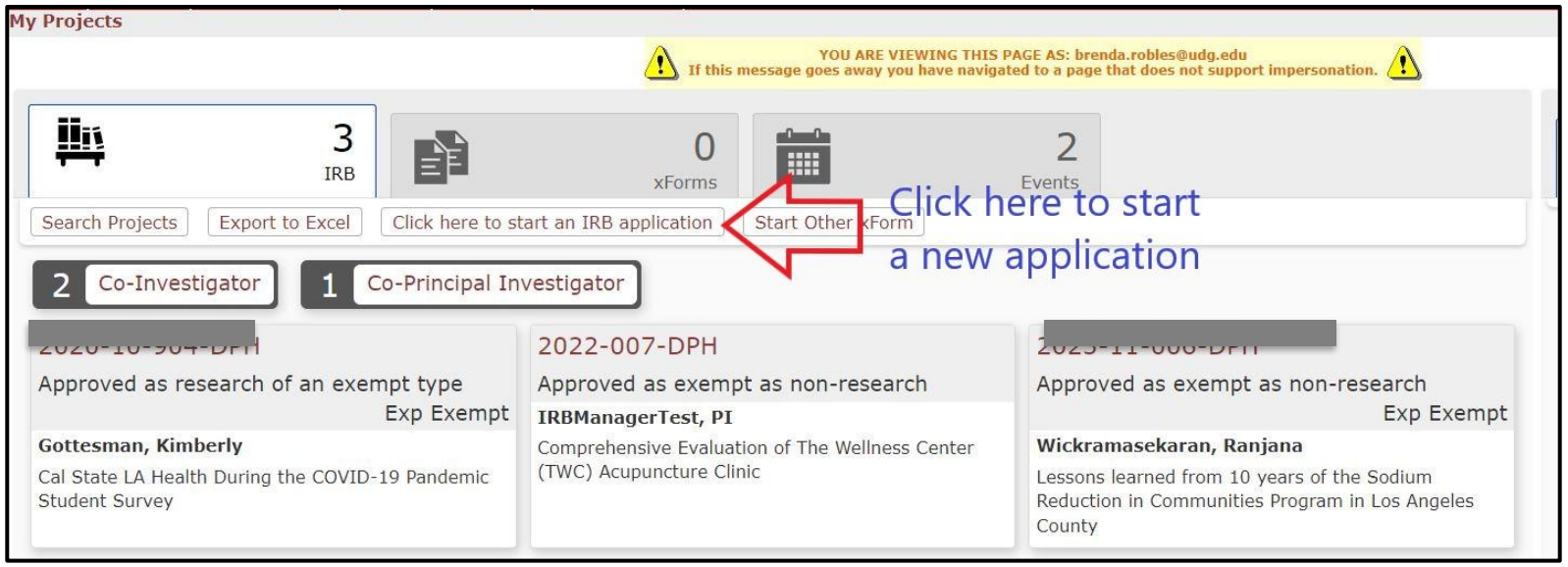
When You Are Ready to Submit Your IRB Application, cont.

- 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

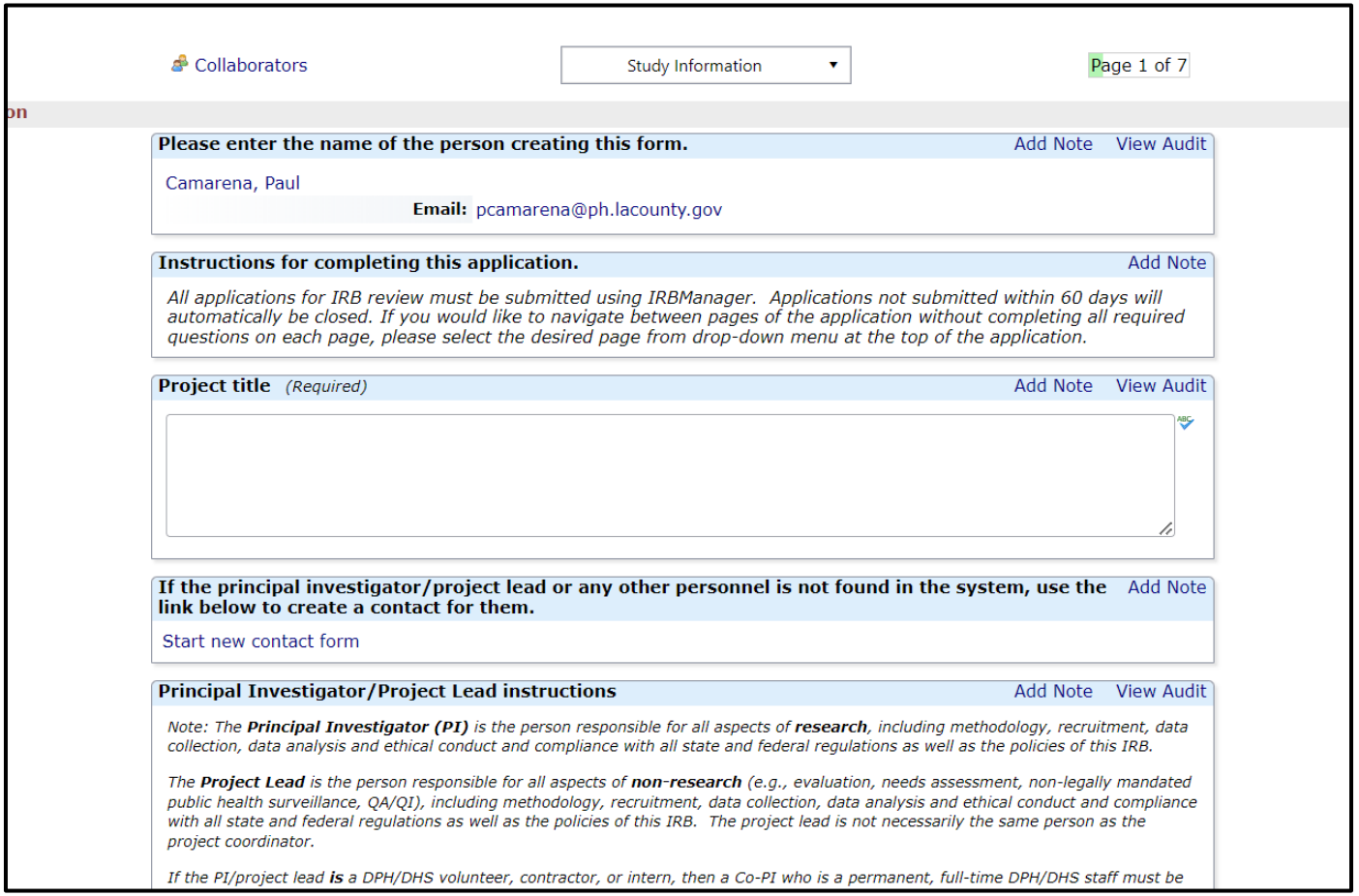
Home Page or “Dashboard”

From the dashboard you can:

- Access approved projects for which you are listed as a key personnel (from the “IRB” tab)
- Start new applications (also called “xForms”)
- Access applications in progress (from the “xForms” tab)



IRB Application



Collaborators | Study Information | Page 1 of 7

Please enter the name of the person creating this form. Add Note View Audit

Camarena, Paul

Email: pcamarena@ph.lacounty.gov

Instructions for completing this application. Add Note

All applications for IRB review must be submitted using IRBManager. Applications not submitted within 60 days will automatically be closed. If you would like to navigate between pages of the application without completing all required questions on each page, please select the desired page from drop-down menu at the top of the application.

Project title *(Required)* Add Note View Audit

If the principal investigator/project lead or any other personnel is not found in the system, use the link below to create a contact for them. Add Note

Start new contact form

Principal Investigator/Project Lead instructions Add Note View Audit

*Note: The **Principal Investigator (PI)** is the person responsible for all aspects of **research**, including methodology, recruitment, data collection, data analysis and ethical conduct and compliance with all state and federal regulations as well as the policies of this IRB.*

*The **Project Lead** is the person responsible for all aspects of **non-research** (e.g., evaluation, needs assessment, non-legally mandated public health surveillance, QA/QI), including methodology, recruitment, data collection, data analysis and ethical conduct and compliance with all state and federal regulations as well as the policies of this IRB. The project lead is not necessarily the same person as the project coordinator.*

*If the PI/project lead **is** a DPH/DHS volunteer, contractor, or intern, then a Co-PI who is a permanent, full-time DPH/DHS staff must be*

Application Screening vs. IRB Review

Screening:

- Administrative check to make sure the application is complete, including required approvals, training certificates, and correct files
- Time frame dependent on applicant response time

IRB Review:

- Once a complete application is submitted, the application undergoes an ethical and regulatory review to ensure the project meets the federal regulations (45 CFR 46) and complies with DPH IRB Standards of Practice/policies

For Your Project, the IRB Reviewer will ask, cont.…

- 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/assent/parental guardian permission 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, cont.…

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, e.g., to the community?

Is the project addressing health equity/community engagement? Is it measuring/collecting data on health equity and, if so, what data?

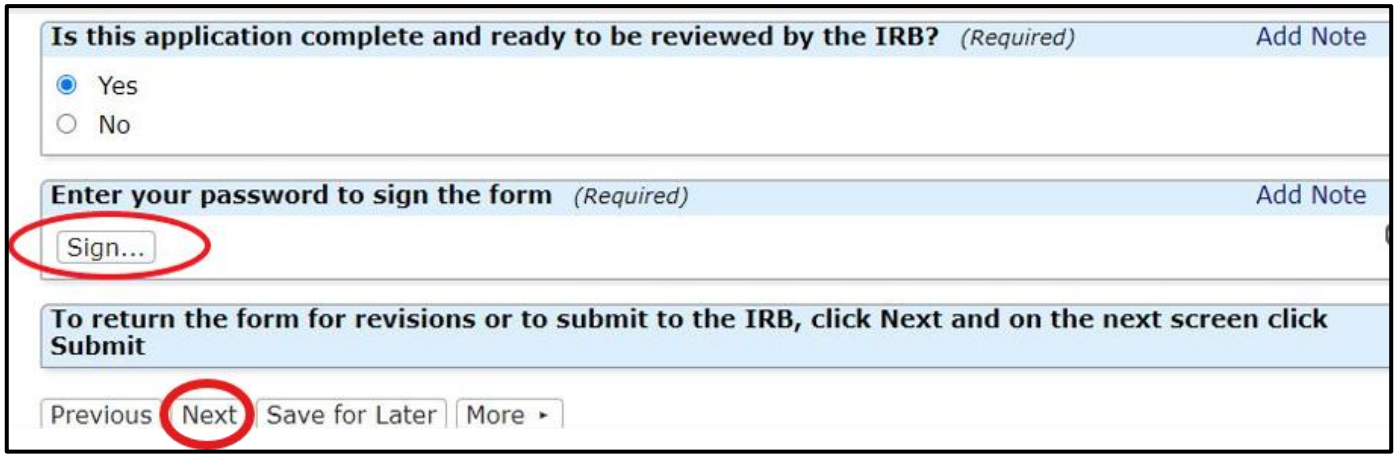
Required Signatures

- PI/project lead, Co-PI (if any, can only be one Co-PI), and Program Director/Division Chief will need to "sign" the electronic application using a unique link
- If the PI/Project lead (and Co-PI if applicable) is external, a DPH/DHS/DYD staff member will need to be designated as DPH/DHS/DYD liaison on your application
- Point of contact/person submitting the application will receive notification email as well

Signing and Submitting an IRB Application

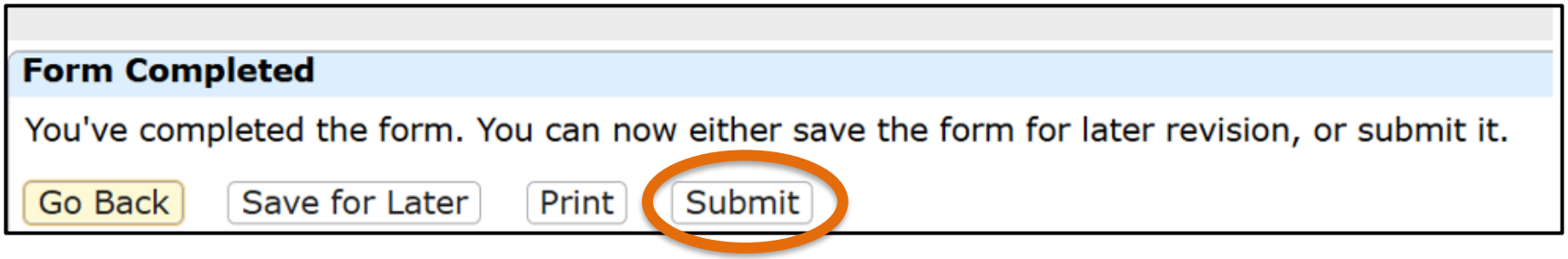
When signing an application:

- Click the "**Sign**" button
- Enter your login password when prompted
- Click the "**Next**" button at the bottom of the page



Signing and Submitting an IRB Application, cont.

- On the following screen, you must click "**Submit**" to complete the signature process



Helpful Tips for Submitting an Application

The best way to ensure a smooth screening/review process is to:

- Make sure that your application is **complete** and includes**:**
  - All correct documents
  - All consent forms/scripts and HIPAA authorizations
  - Recruitment materials (including social media posts, etc.)
  - Data-collection instruments
  - Training certificates
  - Documentation of required approvals
- Respond to emails from IRB staff or automated notification emails from the IRBManager system as promptly as possible

What Happens After Approval?

- Project activities may not begin until formal approval letter received through the IRBManager system
- IRB conducts project monitoring until completion via routine audits

What Happens After Approval? cont.,

- Submit an amendment application in IRBManager **before** you implement any changes – including changes to key personnel or PI/Co-PI
  - Must change the PI before the original PI leaves the institution
- Submit continuing review request if full board or noted in the approval letter, or risk automatic closure
  - 6 weeks before the monthly IRB meeting
- All other projects must submit the annual progress report or risk automatic closure
  - 2 weeks before due date

What Happens After Approval? cont.,

- 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
  - ➢ Include any manuscripts or reports
- Project teams must maintain up-to-date training certifications

Informed Consent
What Do the Regulations Say?

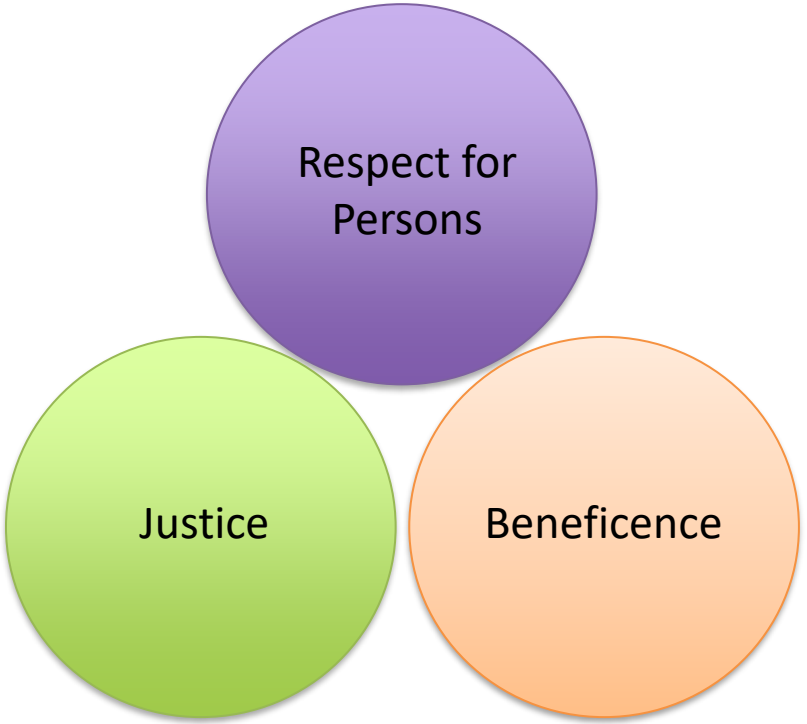
Federal regulations require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR), unless:

- Project is exempt under **§46.104**
- 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



Basic Elements of Informed Consent

- Purpose, duration, and procedures to be followed, identification of any experimental procedures
- Individual risks/discomforts
- Individual 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

Source: §46.116(b)

The Informed Consent Process

Active process

- Sharing information between the research team and the prospective participant in the language the participant can understand
  - The person obtaining consent should speak the language the participant can understand
- 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

Obtaining Informed Consent

- Must include all the basic elements
- Use clear, accurate and understandable language
- Avoid medical and scientific jargon - use common, everyday language
- General LAC population - 8th-grade reading level or lower

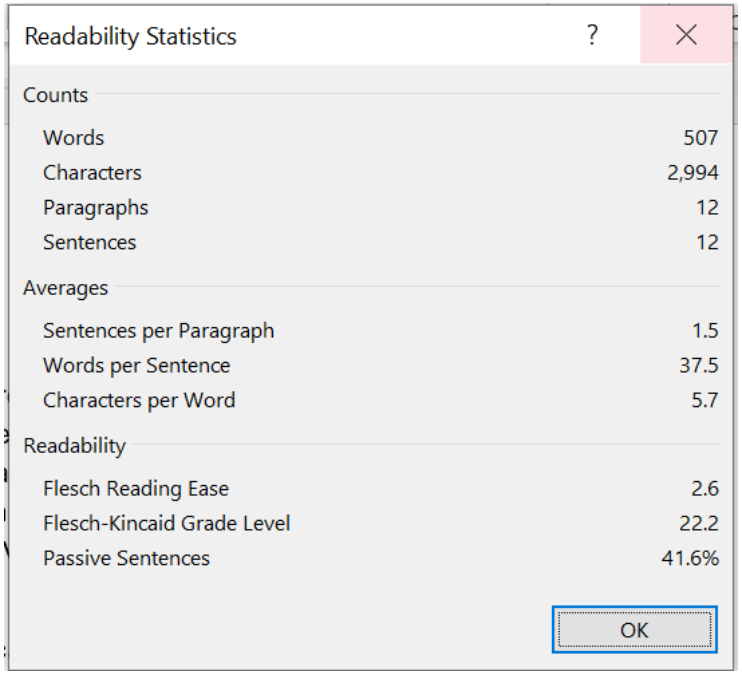
How to Obtain Reading Level in Microsoft Word for Your Reference

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.



Informed Consent Documentation

- Documentation that the process took place
  - Written 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
  - Must contain key information and detailed information sections
    - Template available on IRB website

Projects Involving Minors

- Both parental/guardian permission and teen/child assent required
- Ensure appropriate reading levels for forms/scripts
  - **Parental/guardian permission - 8th grade** or lower
  - **Teen assent** (ages 13-17) - 6th grade or lower
  - **Child assent** (for ages 7 to 12) - 2nd-grade or lower
  - If age groups are smaller, e.g., ages 10 to 12, reading level may be higher than above requirements

Informed Consent Waiver

- Documentation of informed consent can be waived under certain circumstances
  - Effective consent (related activities involving human subjects)
  - Verbal (must document collection of verbal consent)
  - Study information sheet
  - Short form
- Templates available on IRB website
- 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

Reminder: Effective Consent

- Include at beginning of survey
- Include 3 elements of voluntariness:
    1. *Your participation in this project is entirely voluntary.*
    2. *You can choose to participate and withdraw at any time without penalty.*
    3. *You can refuse to answer any questions.*
- If the project involves minors:
    1. *It is up to you if you want to be in this project.*
    2. *You will not get in trouble if you choose not to be in the project. You can change your mind and stop at any time.*
    3. *You do not have to answer any questions you do not want to.*

Additional Informed Consent Tips for Your Reference

- Explain terms in lay language the first time they are used
- Spell out abbreviations or acronyms the first time they are used
- Use short sentences and short paragraphs
- Use active voice rather than passive voice whenever possible; e.g., “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

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 of HIPAA individual authorization

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)

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

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:
  - PHI to be collected
  - 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

HIPAA Waiver Request in IRBManager, cont.

- 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

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?

§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."

§46.111[3]

"Selection of subjects is equitable."

What do the Federal Regulations Say? (cont.)

§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."

IRB Health Equity SOP/Policy

- 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
- 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

- Evaluation
- 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

Announcements

- **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
- **Trainings**
  - Evaluation and study design basics
  - For CBOs only: on-demand Spanish and English human subjects research protection training now available!

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 and pass training post-test to receive a certificate of completion
  - Complete by **3pm** on **Monday, March 2, 2026**
- Please allow **3-4 days after passing post-test** before checking for certificate
- Instructions for locating post-test and/or certificate available here: http://www.publichealth.lacounty.gov/IRB/Training.htm

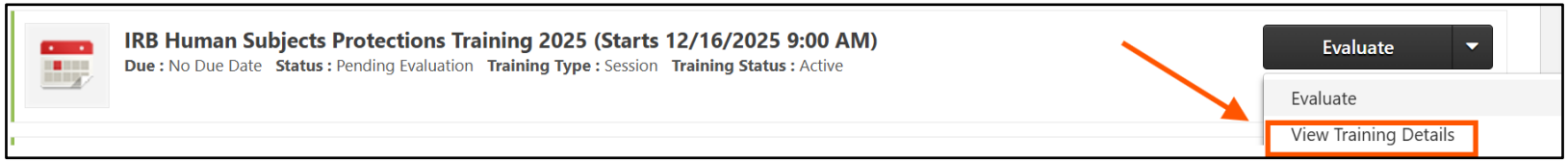
Accessing the IRB Human Subjects Protection Training Post-Test

1. Log into the TalentWorks portal at: https://lacounty.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=-1

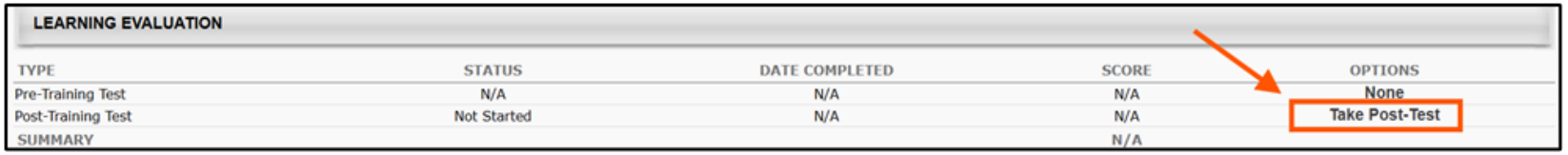
2. Click on **"View Transcript"** under My Inbox

Accessing the IRB Human Subject Protection Training Post-Test, cont.

3. Scroll down to find the training titled, "**IRB Human Subjects Protections Training 2025**". Click the drop-down arrow to find the option "**View Training Details**". Click on the "**View Training Details**".



4. Scroll down until you find the "**LEARNING EVALUATION**" section, and to the right you should see an option to click on to take the post-test. Click the "Take Post-Test" link.



Thank You!

Evaluation survey:

https://www.surveymonkey.com/r/HDWQ3FX