Institutional Review Board

Human Subjects Protection Training

Alysia Kwon, ScM
Director
Office of the IRB
December 16, 2025

Version: Updated September 3, 2025

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
- DPH/DPH learners must complete training post-test to receive a certificate of completion
  - Complete by 3pm on December 19th
  - Certificates available in TalentWorks 3-4 days after passing post-test
- Stay tuned for an 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. Visit the Library website for more information

For a full list of available books visit our website: Resources

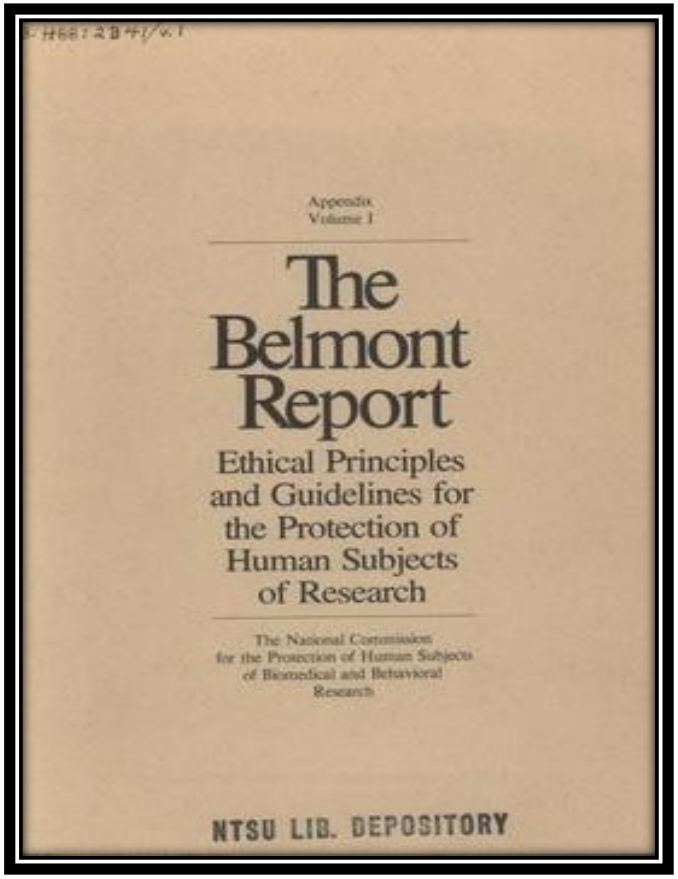
Basis for the IRB

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



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 Under the Federal Regulations

- Pregnant Women, Human Fetuses and Neonates (Subpart B)
- Prisoners (Subpart C)
- Children (Subpart D)
- Additional protections by our IRB:
  - Individuals with Impaired Decision-Making Capacity

Other Vulnerable Populations

- 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

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

Who Does Our/LAC DPH IRB Serve?

- DPH
- Department of Health Services (DHS)
  - Ambulatory Care Network (ACN)
  - Health Services Administration (HSA)
  - Correctional Health Services (CHS)
- Department 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

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, and shared?
  - Promotion of health equity/community engagement and reduction of disparities
- Ethical review required not only for research, but other related activities

DPH IRB Standard of Practice posted on SharePoint for internal use

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 and "related activities involving human subjects"
  - Certain needs assessments, quality improvements, and evaluations
- For research ***all federal regulations apply***
- For related activities projects, all **ethical principles and <u>spirit</u> 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 who are currently or formerly incarcerated persons, parolees or probationers 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

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 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.”

Chief Science Office (CSO)
IRB Standards of Practice (SOPs)

- Health equity, diversity and inclusion in research or related activities 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
  - DPH SOP CSO-011

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 (SOGI), and Disability Status per CSO SOPs (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)**

"Related Activities Involving Human Subjects" Requiring IRB Oversight

- Any process that involves collecting, accessing or analyzing data from or about individuals:
  - minors
  - currently or formerly incarcerated persons, parolees or probationers
  - pregnant persons
  - individuals with impaired decision-making capacity

- Projects involving artificial intelligence (AI)

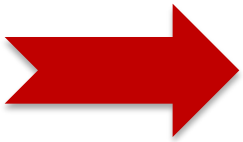
"Related Activities Involving Human Subjects" Requiring IRB Oversight, cont.

- Quality assurance, quality improvement projects
- Non-legally mandated surveillance
  - Public health surveillance and practice specific criteria and examples
- Needs assessments and program evaluations
- Full list of exceptions posted on IRB website
  - Best practices handout

Levels of IRB Review

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

Levels of IRB Review

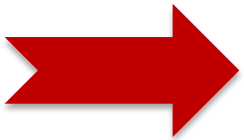


- **Related Activities Involving Human Subjects**
- **Exempt**
- **Expedited**
- **Full Board**

Related Activities Involving Human Subjects

- Formerly known as "Exempt as Non-research"
- Does not require written informed consent but “effective” consent required

Levels of IRB Review



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

Exempt Review

- Formerly known as "Research of an Exempt Type"
- Interview-based research **that does not deal with sensitive topics, e.g., substance abuse, HIV status**
- Observation of public behavior
- A study of previously collected data or records
- Requires either **documentation of informed consent or application for a waiver**, and cannot claim it is not research
- Falls into specific categories under the federal regulations (see reference slide)

Levels of IRB Review

- Related Activities Involving Human Subjects
- Exempt
- 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 (see reference slide)
  - 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, cont.

- "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

Levels of IRB Review

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

Full Board review

- Full board review covers studies that pose **"more than minimal risk"** and do not fall into any Exempt or Expedited review categories
- 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
  - AI projects
  - Projects involving participants who are currently or formerly incarcerated persons, parolees or probationers
    - ➢ A prisoner advocate is required

Exercise: What level of review?

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

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. 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 assess the efficacy of the education with the hopes of publication in a peer-reviewed journal. Exempt

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

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. Related activities review
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.

   IRB review not needed
7. Adults and children aged 16-17 will be asked to respond to weekly text message-based study to assess respiratory symptoms. Related activities review
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. Related activities review

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 (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 assign a priority category
- Once you receive review 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 Does your project involve external contractors/organizations who will 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

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? 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 review
- Principal investigator(PI)/project lead, Co-PI (if any, can only be 1 Co-PI), and Division Chief/Program Director signature
- DPH/DHS/DYD liaison signature (if applicable)
- 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
- Professional qualifications, e.g., Curriculum Vitae/resume or other supporting information
- 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)

Items You Will Need to Submit a New IRB Application

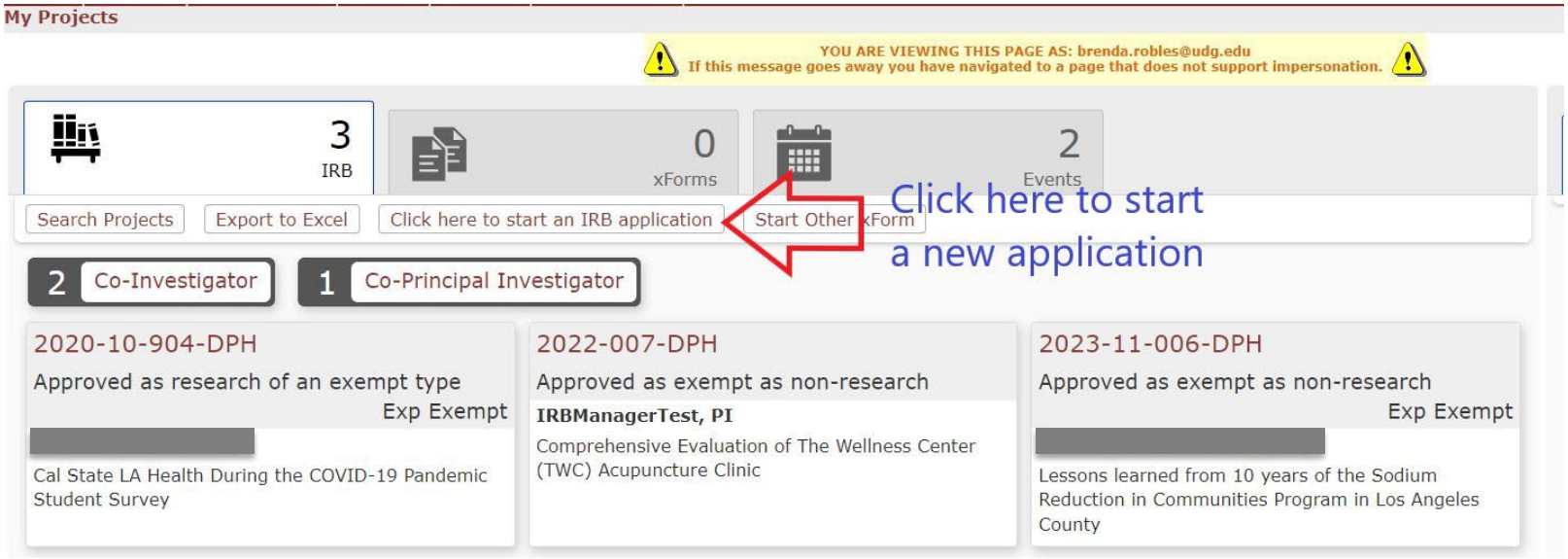
- Cybersecurity and Privacy Awareness Training Certificates (DPH badgeholders only)
- Budget (if applicable)
- Research Protocol (must follow the templated posted on the IRB website, written in prose)
- Lay summary (300 words max, include methodology; written in prose and not bullet points or list style)
- Data collection instruments, including surveys, focus groups, and interview questions and scripts
- Recruitment materials including flyers, posters, social media posts, text/phone scripts, etc.
- Documentation of PHIS ISO approval for software (if applicable)
- Laboratory Review Form (if applicable)

When you are ready to submit your IRB application

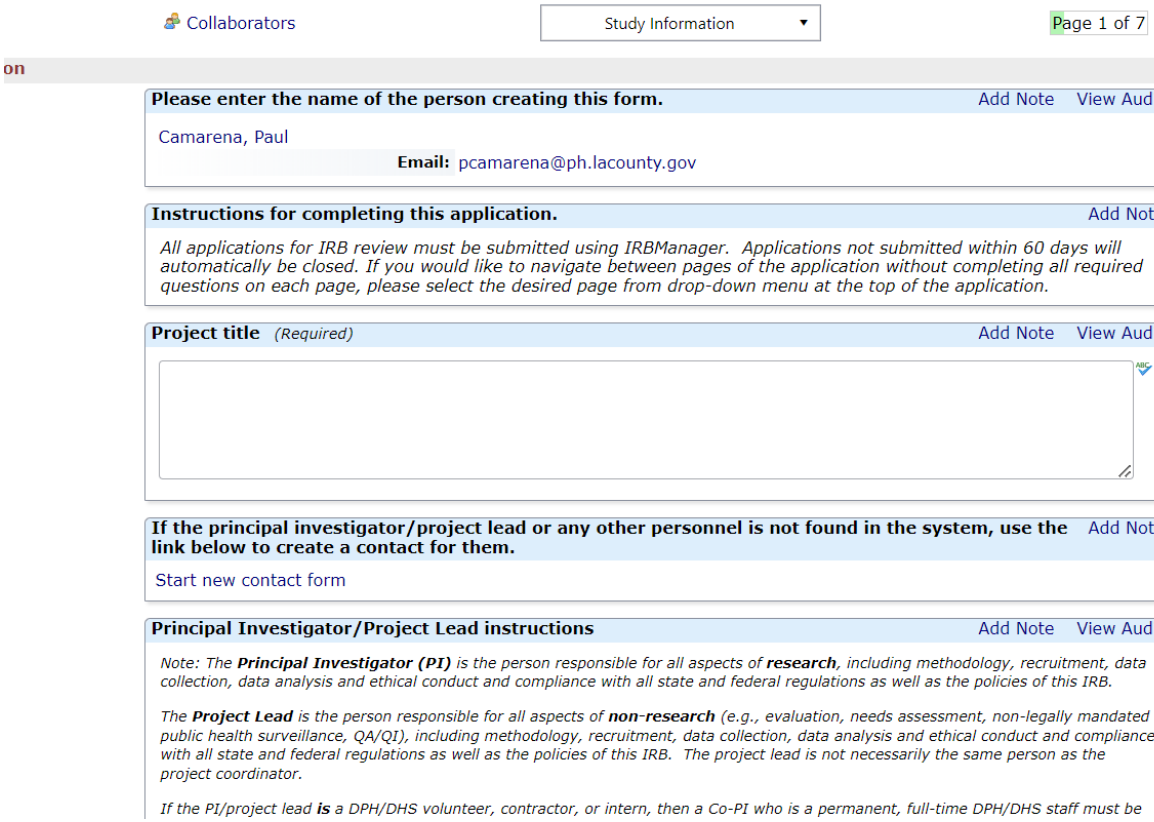
- Go to https://lacdph.my.irbmanager.com/Login.aspx and log in to IRBManager where you can submit:
  - New applications for IRB review
  - Amendment requests
  - Annual progress reports
  - Requests for continuing review
  - Reportable events reports
- County users can log in using your County email 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) 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/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 …

- 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/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 1 Co-PI), and Program Director/Division Chief will need to "sign" the electronic application using a unique link
- If the PI/Project lead or Co-PI for a research study 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

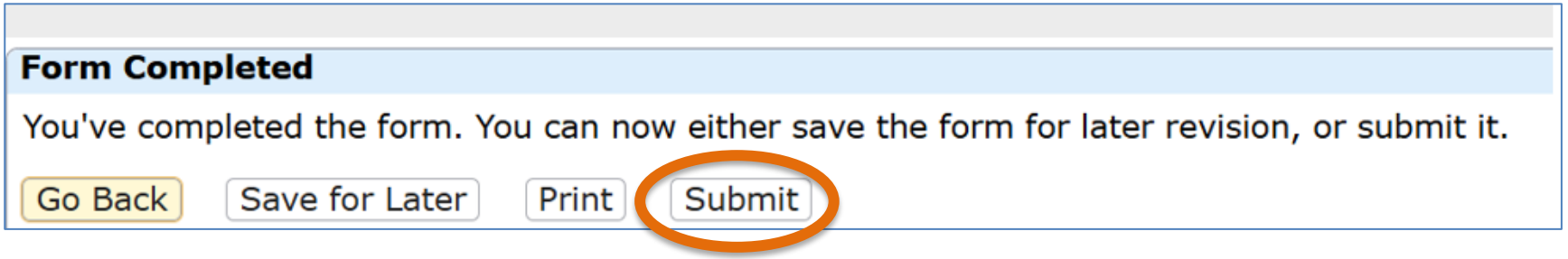
Signing and submitting an IRB application

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, 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:
  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

For fastest response time, please send all IRB inquiries to the IRB inbox at IRB@ph.lacounty.gov

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 or PI/Co-PI
- Submit annual progress report or continuing review request (as applicable) or risk automatic closure – submit progress report 2 weeks before due date and continuing review 4 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

Basic Elements of Informed Consent

- Purpose, duration, and procedures to be followed, identification of any procedures that are experimental
- 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

When obtaining informed consent:

- Must include all the basic elements
- If obtaining documentation of 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

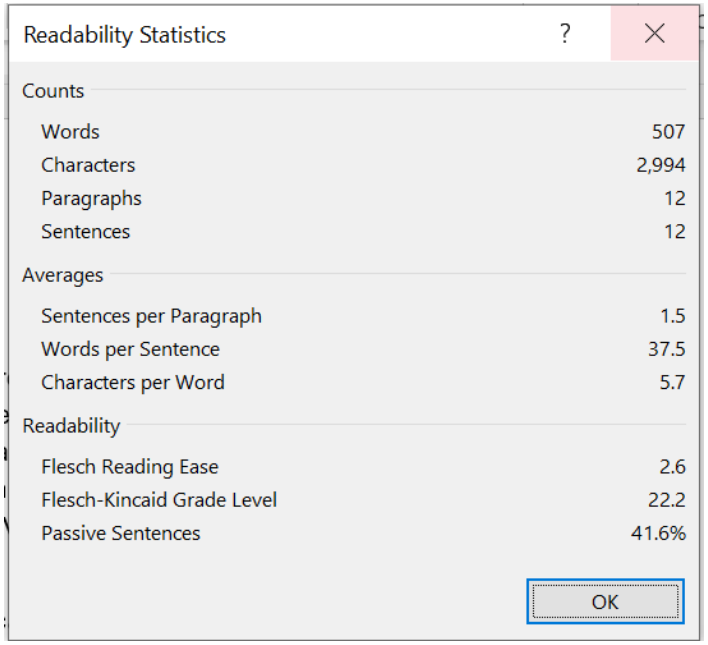
How to obtain reading level in Microsoft Word

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.



Informed Consent Documentation

- Documentation that the 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 IRB website
    - Must contain key information and detailed information sections unless waiver (including short form)

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

Informed Consent Waiver

- Requirement for documentation of informed consent can be waived under certain circumstances
  - Effective consent
  - Verbal, study information sheet
  - Short form
- 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 including 3 elements of voluntariness is required:

  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.

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

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)

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

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

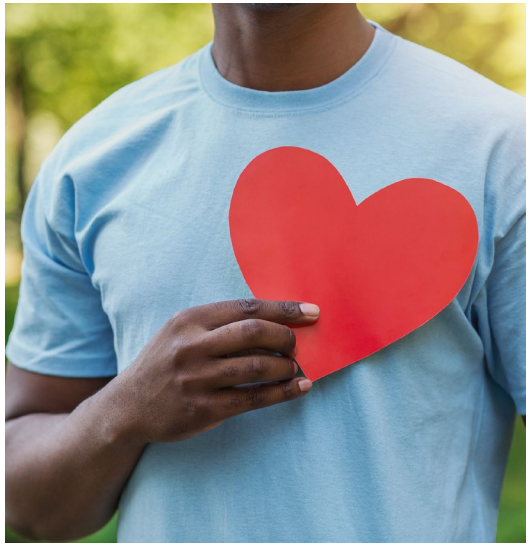
HIPAA Waiver Request in IRBManager

- 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: 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

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 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

- 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
- 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

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
- **HRP training video for CBOs:** IRB staff are working on developing an HRP training video in English for our community-based partners

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 Friday, December 19th
- 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

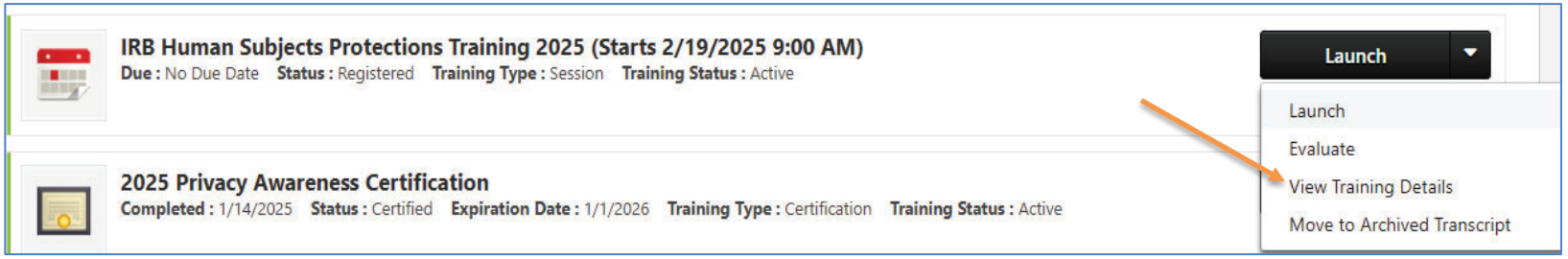
Accessing the IRB Human Subject Protection Training Post-Test

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

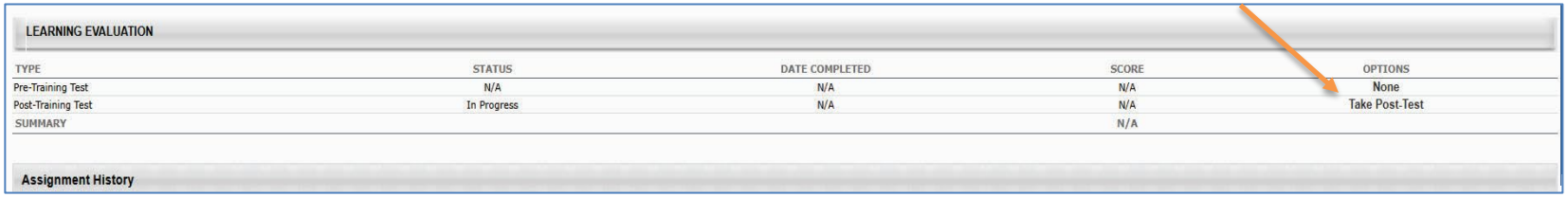
2. Click on **"View Transcript"** under My Inbox

Accessing the IRB Human Subject Protection Training Post-Test

3. Click on **"View Training Details"**



4. Click on **" Take Post-Test"**



Thank you!

Evaluation survey:

https://www.surveymonkey.com/r/RSPS226