Institutional Review Board Human Subjects Protection Training

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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

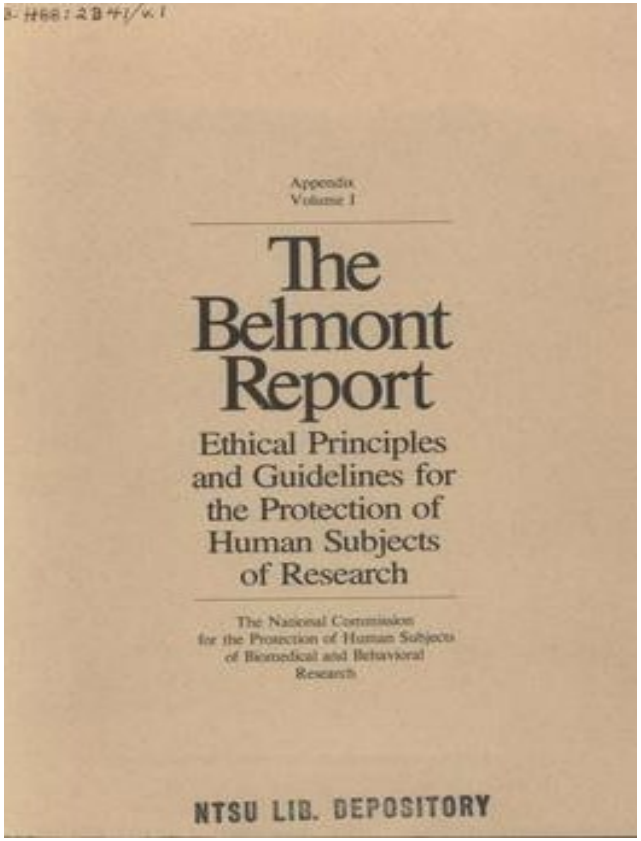
Please enter your questions in the chat box or raise your hand using the reaction buttons

Presentation slides are available on the IRB website

Certificates of completion will be available on TalentWorks after the training

Brief History of Ethics in Research

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



An Ethical Framework

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

Principles Outlined in The Belmont Report

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

Legal Basis for the IRB

- Common Rule, 1991, revised 2017-2018
- LAC Board of Supervisors, 1999
  - HIVNet
  - Lack of community sensitivity and engagement
  - Institutional Review Board (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)
  - Prison advocate
- Meets once a month, every fourth Thursday

By law, the IRB functions to ensure:

- Risks to subjects are minimized by having procedures posing no unnecessary risk
- Risks, if any, are reasonable re: benefits/importance
- Selection of subjects is equitable
- Informed consent will be obtained and documented
  - (Or waived/altered by IRB if criteria are met)
- Privacy of subjects protected, and confidentiality of data maintained
- Appropriate additional safeguards to protect rights and welfare of subjects from vulnerable groups
- Assure compliance with regulations

Our IRB Goes Beyond the Minimum

- **We broaden ethical principles to include**:
  - Community not just individual rights, community engagement and accountability
  - Utility: How will results be used, applied, shared?
  - Appropriateness of design and methods
    - Is the question important?
    - Do methods match the question?
    - Is recruitment/selection representative of our populations?
  - Promotion of health equity/reduction of disparities

- Ethical review required not only of research, but other related activities
- **LAC-DPH IRB Standard of Practice posted on SharePoint for internal use**

Who Does DPH IRB Serve?

- Covers DPH, Ambulatory Care Network (ACN), Health Services Administration (HSA), and Correctional Health Services
- IRB of record for community-based organizations and other health departments

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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?

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

DPH IRB Policy on IRB Submission

- ***Any project involving collection or analysis of data from or about individuals, whether "research" or not***
- Needs IRB review and <u>at least</u> determination that full IRB review is not needed
    - Consultation with the IRB office is required for determination
- A project = anything involving staff, facilities, clients, patients, funding, databases from DPH, DHS, etc.

Submission Policy, cont.

- **Exceptions** (no submission required at all):
  - Does not involve humans (e.g. animals only, some lab studies);
  - Legally mandated reporting/surveillance;
  - Information collected/charted as part of **clinical care;**
  - Anonymous meeting evaluations;
  - Authorized operational activities in support of criminal justice or criminal investigative activities
  - Activities in support of defense/national security
- **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**

The IRB will ask …

Why is the project and the question(s) it poses important to public health?

Are the methods clearly described and appropriate to the question and is the study team capable of carrying them out?

Who will be recruited and how? Are consent procedures clear and adequate?

Are forms and instruments, including recruitment materials, clear, intelligent, sensitive and at appropriate literacy levels?

The IRB will ask …

- **Is personally identifying information minimized and is each item necessary and justifiable?**
- **Are individual privacy and data confidentiality protections adequate?**
- **Have potential risks been thought through and minimized, including group harms and risks to vulnerable populations?**
- **How will community be involved in the project?**
- **How will the data be analyzed? How will the results be disseminated?**

Exempt as non-research

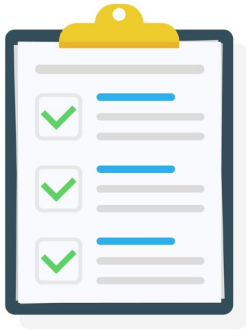
1. Is it standard QA/QI activity?
2. Is it internal program evaluation or needs assessment intended only for program monitoring, improvement, etc.?

If YES to any of above questions

Your project can be considered "Exempt as non-research"

Exempt as Non-Research Application

- Does not require written informed consent document but does require an “effective” consent
- Does not require annual renewal (aka “continuing review”) unless stated and justified in approval letter
- Does require an annual progress report and amendment applications
  - Failure to submit an annual report will result in automatic closure of project
- 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)
- Project activities or changes may not begin until approval letter has been received



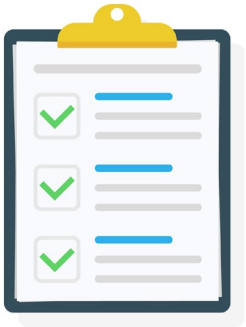
Research of an Exempt Type

1. Is it interview-based research **that does not deal with sensitive topics?**
2. Is it observation of public behavior?
3. Is it a study of previously collected data or records (if publicly available or recorded in de-identified manner)?

If YES to any of above, your project can be reviewed as Exempt

Research of an Exempt Type Application

- Similar to "exempt as non-research" except requires either **written consent or application for a waiver**, and cannot claim it is not research
- Does not require annual renewal (aka "continuing review"), but does require annual progress report and amendment applications
    - Failure to submit an annual report will result in automatic closure of project
- 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)
- Project activities or changes may not begin until approval letter has been received



Expedited Review

1. Does your project pose no more than minimal risk?
2. Does your project involve survey/interview-type methods that include sensitive topics?
3. Does the project involve 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)?
4. Does it involve recording of minors?

If Yes, your project can undergo Expedited review

What is Minimal Risk?

- According to the federal regulations at **§46.102(j)**, *minimal risk* means that the probability **and** magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Expedited Review Categories for Your Reference

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

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

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

4 Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

Expedited Review Categories, (cont.)

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

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

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

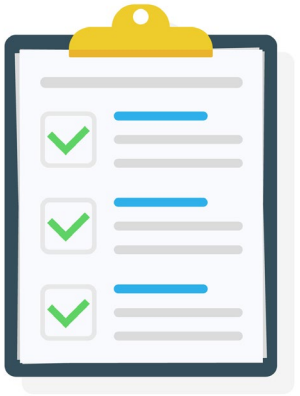
Expedited Review: Continuing Research

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

- Remaining research activities are limited to data analysis

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

Expedited Review Application



- Must be “minimal risk”
  - One of the expedited categories or
    - On-going data analysis only
    - Minor revisions
- Does not require annual renewal (aka “continuing review”), but does require annual progress report and amendment applications
    - Failure to submit an annual report will result in automatic closure of project

Expedited Review Application, (cont.)

- Expedited review and approval can be given by

  Chair, Vice Chair, or IRB analyst, without waiting for monthly IRB meeting
- Please follow data collection guidelines on Race/Ethnicity, Sexual orientation/Gender Identity, and Disability Status per Chief Science Office Standards of Practice (please inquire for these SOPs)
- Project activities or changes may not begin until approval letter has been received

Full Board review applications

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

Exercise : What level of review?

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

Exercise: What level of review?

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

Items You Will Need to Submit a New IRB Application

1. Before you begin an IRB application:
   - Projects originating in/funded by DPH, or involving DPH staff/clients, need documentation that surveys have undergone review by the Office of Health Assessment and Epidemiology (OHAE) Rapid Assessment, Evaluation and Training (RATE) unit
   - Projects originating in DHS or using DHS data/facilities/patients need documentation that the project has undergone Research Oversight Board (ROB) review and has been assigned an ROB category
2. Principal investigator(PI)/project lead, Co-PI (if any), and Division Chief/Program Director signature
3. DPH/DHS liaison signature (if applicable)
4. Informed Consent forms (including any scripts for verbal or effective consent)
5. HIPAA individual authorization or a strong justification for a waiver of HIPAA authorization
6. Professional qualifications, e.g., Curriculum Vitae/resume or other supporting information

Items You Will Need to Submit a New IRB Application, (cont.)

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

RATE Review (DPH projects)

- Per DPH Policy 117, surveys (including projects funded by DPH) must be reviewed by Office of Health Assessment and Epidemiology (OHAE) Rapid Assessment, Training and Evaluation Unit (RATE). This should be completed prior to submitting an IRB application.

1. Program submits final drafts of survey and protocol to IRB, ensure that
   - Any survey questions regarding Race/Ethnicity, Sexual Orientation/Gender Identity, and Disability Status follow DPH SOPs (available upon request)
   - The study protocol follows the format in the template posted on the IRB website
   - Documents do not contain any internal comments or tracked changes

RATE Review (cont.)

2. IRB forwards materials to OHAE-RATE
3. OHAE-RATE reviews and compiles the edits and emails to program
4. Program attaches finalized clean documents to IRBManager application along with documentation that RATE review took place (pdf of email thread suffices)
   - Documents should not contain any internal comments or tracked changes

ROB Review (DHS projects)

For any projects that either originate out of DHS, or will collect data about/from DHS staff:

- DHS requires that your project be reviewed and assigned a priority category by DHS' Research Oversight Board (ROB) in order to ensure that your project and intended activities are feasible and align with DHS' mission.
- Please send an email to IRB@ph.lacounty.gov requesting ROB review before the IRB application is submitted
  - Include the project protocol, budget and relevant study documents as attachments.
  - The IRB will forward your email to the ROB who will then review the proposal and will assign the priority category.
- A pdf of the email response (with the priority category) from the ROB should be attached to the IRBManager application.

Required Signatures

- PI/project lead, Co-PI (if any), and Program Director/Division Chief will need to "sign" the electronic application
  - Will receive automated emails from the IRBManager system with instructions for providing their required signature as needed during the review process
  - May need to provide their signature multiple times if any changes are made to the application after it is submitted initially
- 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
  - Will also receive automated emails from IRBManager with instructions for providing their signature as needed during the review process

The protocol should answer the following:

- Who is doing the research and what are their affiliations?
- 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? What are your eligibility and exclusion criteria?
- Are consent procedures clear and adequate? Are forms and instruments, including recruitment materials, clear, intelligent, sensitive and at appropriate literacy levels?

The protocol should answer the following:

- Is personally identifying information/protected health information minimized and is each item necessary and justifiable?
- What are your data source(s), including primary and secondary sources?
- Are individual privacy and data confidentiality protections adequate?
- Have potential risks been thought through and minimized, including group harms and risks to vulnerable populations?
- How will community be involved in the project?
- How will the data be analyzed? How will the results be disseminated?

Types of IRB Action

1. Approval (with category of exemption or expedited review specified)
2. Full approval for one year (or completion of study for exempt/expedited projects)
3. Full approval for shorter period
4. Approval with stipulations
5. Tabled until revised or substantial questions answered
6. Rejected

After Approval

- IRB has responsibility to monitor projects until completion
  - the IRB will conduct routine **audits** of projects to ensure compliance
- Must submit amendment application for any changes before implementing them (even if exempt!)
- Must submit annual progress report or continuing review request (as applicable)
    - Failure to submit will result in automatic closure of project
- Must report any adverse or unexpected events or protocol deviations
- Must submit a final report upon completion
- Research personnel must make sure that their training certifications for Human Subjects Research Protection and HIPAA are up-to-date

Informed Consent – What do the federal regulations say?

- Federal regulations require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR), unless:
  - the project is exempt under 45 CFR 46.101(b); or
  - 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

Key Terms to Remember

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

The Informed Consent Process

- Should be an active process of sharing information between the investigator and the prospective participant
    - Provide ample opportunity to ask questions and seek 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 (required)

- Statement that it is research, for what purpose, expected duration, description of the procedures to be followed, identification of any procedures that are experimental
- Description of foreseeable risks/discomforts
- Description of benefits to subject and others
- Disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject
- Statement about confidentiality of records
- If more than minimal risk, explanation of any compensation and medical treatments if injured
- Contact person and phone number for questions about the research, rights or injury (PI & IRB)
- Statement that participation is entirely voluntary, refusal or withdrawal will not involve penalty or loss of benefits

When obtaining informed consent, you must:

- Include all the basic elements
  - CA Experimental Research Subject's Bill of Rights may also be required
- Use clear, accurate and understandable language
  - Avoid medical and scientific jargon; instead, use common, everyday language that is appropriate for the target population
  - For the general population we recommend an 8th-grade reading level or lower
- Use the preferred language of the prospective participant
- Must include key information section plus a detailed section

Additional Elements of Informed Consent (if relevant to project)

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

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

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

Informed Consent Documentation

Documentation that process took place

- Record of the participant's agreement to take part in the study
  - Signed by the participant or the participant's LAR
- May be electronic, audio or video recording, as approved by IRB
- Copy given to subject

- Must contain basic elements and relevant additional elements
- Requirement for Documentation of Informed Consent can be waived under certain circumstances
  - IRB determines whether conditions have been met for eligibility of waiver
  - Inconvenience is not a justifiable reason

Additional Informed Consent Tips for Your Reference

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

HIPAA Privacy Rule

- What is HIPAA?
  - Health Insurance Portability and Accountability Act of 1996
- When does HIPAA apply?
  - PHI: protected health information
  - Any of 18 types of demographic identifiers or health care delivery information, including ZIP code.
  - Any PHI collected or transmitted in any form by a "covered entity"
  - Applies to all data collection activities (exempt as non-research or research of an exempt type)
- Two ways to comply
  - HIPAA Individual Authorization
  - Waiver

HIPAA Waiver Request in IRBManager

- Strong justification for a waiver needed
    - Describe how the study could not practicably be conducted without access to and use of the PHI
    - Inconvenience is not a justifiable reason
- Include a detailed list of the PHI to be collected and a 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

Additional Protected Health Information, for your reference

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

PHIS Software Approval

- All software used for data collection, data entry, or data analysis needs to be approved by PHIS IT Security Team before use
    - Includes software from Microsoft Office Suite and Survey Monkey
- An IT ticket will be created automatically when your IRBManager application is submitted
    - Your online application will include questions for PHIS
    - Incomplete or insufficient responses will delay your application
- Once you receive approval from PHIS, please printout a PDF of the approval and attach it to your application
- Need to ensure access to data is restricted to project staff conducting data collection, entry and analysis (Need-to-Know)
- DHS applicants should contact Vahe Haratounian at vharatounian@dhs.lacounty.gov

What does PHIS want to know?

- What is the software (including version) that you will use in your project?
    - How will it be used? Where will the software be installed?
- What are the specific data elements that will be used/accessed with the software?
- Will personally identifiable information (PII) or protected health information (PHI) be used with the software?
- 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)?
- Do project personnel have current Cybersecurity and Privacy Awareness training certifications?

When you are ready to submit your IRB application

- Go to https://lacdph.my.irbmanager.com/Login.aspx and login to access the portal where you can submit:
  - new applications for IRB review
  - amendment requests
  - progress reports
  - requests for continuing review
  - adverse events reports
- County users can log in using your County SSO credentials
  - Non-County users will have to create a login if one has not already been created for them
- A user manual containing basic steps for navigating **IRBManager** is available on the IRB website

Improving the IRBManager Experience

- Next time you log in to IRBManager, please update your contact information to include your degree(s) and verify that your email address is correct (that is where all system notifications will be delivered).
  - Steps for updating contact information can be found in the user manual posted on the IRB website
- PIs/project leads, Co-PIs, Study Contact Persons, Form Creators, DPH/DHS liaisons, Program Director/Division Chief (DPH) for a given project will receive automated email notifications at some stage in the review process.
  - **Please make sure that they are aware of this and are checking their email inbox!**
- When you submit an application using IRBManager, IRB staff receive an automated notification so there is no need to send a separate email to the IRB that you have submitted an application.

Improving the IRBManager Experience, continued

- The classification Expedited Review refers to the way that federal regulations are applied when reviewing a research study. “Expedited” does not refer to the timing or speed of review – the DPH IRB reviews all applications in the order that they are received.
- The best way to ensure a smooth review process is to:
  1) make sure that your application is complete including all consent/HIPAA documents, recruitment materials (including social media posts, etc.), data-collection instruments (including phone or email scripts for recruitment, interviews/focus groups, etc.), and PHIS approval
  2) respond to emails from IRB staff or automated notification emails from the IRBManager system as promptly as possible.
- Projects that do not submit annual progress reports 2 weeks before the due date risk automatic closure.
  - This applies to all projects including Exempt and Expedited projects

IRB Health Equity Initiative

- LAC DPH defines health equity as ***"when everyone has access to the goods, services, resources, and power they need for optimal health and well-being."***
    - striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on certain social conditions.

IRB Health Equity Initiative

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

IRB Health Equity Initiative

- Completed Key Informant Interviews and a Health Equity survey.
    - A Health Equity Report summarizing results from the interviews is available on the IRB website
- Based on interview and survey data, the IRB is developing a Health Equity Standard of Practice that will explain the IRB's role in advancing and measuring health equity in research and related activities.
    - This SOP will apply to DPH projects
    - Will provide guidance for reporting progress toward meeting health equity objectives, including the methods used to measure health equity

IRB Health Equity Initiative

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

Frequently Asked Questions

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

More Frequently Asked Questions

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

Any Questions??

We Like to Help!

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

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

Thank you!

Evaluation link:

https://www.surveymonkey.com/r/M9S3GDW