2019 IRB Training Update Workshop and New Informed Consent Rules

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Review: Principles and Basis

- Belmont Report (1979), Common Rule (1990)
- LAC Board of Supervisors, 1999
- Basic Principles of Biomedical Research Ethics
  - –Respect for Persons (Autonomy) – 2 aspects
  - –Beneficence (minimize harm, maximize benefit)
  - –Justice (fairness in distribution of benefit and risk)

By law, the IRB functions to ensure:

- Risks to subjects are minimized by having sound design, methods, procedures with 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, perspective
  - Community engagement and accountability
  - Utility. How will results be used, applied, shared ?
  - Appropriateness of design and methods, e.g. 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**
- **We offer help**

The IRB will ask …

- Why is the project and its question(s) important to public health? How will the results be communicated and used?
- Are the methods clearly described and appropriate to the question and is the study team capable of carrying them out?
- Are consent procedures clear and adequate?
- Are forms and instruments clear, intelligent, sensitive and at appropriate literacy level?
- Is personally identifying information minimized and is each item necessary and justifiable?
- Are data confidentiality protections adequate?
- Have potential risks been thought through and minimized, including to vulnerable populations?
- How have and will community be involved in the project?

DPH Policy on IRB Submission

- ***Any project involving collection or analysis of data from or about individuals, whether "research" or not***
- Needs IRB review and at least determination of exemption from full IRB review
- A project = anything involving staff, facilities, clients, patients, funding, databases from DPH, DHS, et al.

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 internal or client satisfaction surveys;
  - Meeting evaluations;
  - (other categories may be added over time)
- **The best policy is to ask via e-mail or phone call if you are not sure. …. AND never assume that a past determination by the IRB will automatically apply to a new project**

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**

Step 1: Is it exempt as non-research?

- Is it routine, standard-practice public health activity, i.e. no innovations or new twists?
- Is it standard QA/QI activity?
- Is it internal program evaluation or needs assessment intended only for program monitoring, improvement, etc.?
- Is it:
  - Journalism, oral history
  - Public health surveillance
  - Criminal justice or criminal investigative activities and activities in support of defense/national security, etc.

Step 1: Is it exempt as non-research? (cont.)

- **If YES to any of the previous categories,**

  -AND-

- **if NO to** "Is the project intended in whole or in part to generate new, generalizable knowledge?" … go to **Step 2**
- **Otherwise,** go to **Step 3**, or call/write IRB

Step 2: Exempt as Non-Research

- Requires a short-form application and requires IRB approval letter before you begin
- Does not require written informed consent document; does not require annual renewal (but does require you to notify us of any changes, and send a short annual or final report)
- May have easier time gaining cooperation from outside partners/sources of data
- Does require some kind of *effective* informed consent

Step 2: Exempt as Non-Research (cont.)

- Must have starred items on IRB Checklist:
- Application/signature page
- Exemption/Expedited Checklist
- Short protocol: Why doing it? How doing it (data to be collected or analyzed and method)? How will you obtain effective informed consent? How results will be used/shared?
- Instrument or survey (if there is one)
- HIPAA if applicable
- IRB certificate(s)
- Does not require annual renewal (aka “continuing review”), but does require annual report and notification of any changes

Step 3: Research of an Exempt Type

- Okay, it does not qualify as non-research, but:
  - Is it interview-based research **that does not deal with sensitive subjects that would pose risk for respondents if it became known ?**
  - Is it observation of public behavior?
  - 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,** stay on Step 3.
- **If no to all,** go to Step 4.

Step 3: Research of an Exempt Type (cont.)

- Similar to "exempt as non-research" except requires other items on IRB checklist (unless N/A), requires either written consent or application for a waiver (see waiver form), and cannot claim it is not research
- Does not require annual renewal (aka "continuing review"), but does require annual report and notification of any changes

Make sure that even an exempt application contains:

- How will the results be used and shared?
- Who will be recruited, invited, selected to participate? (Or whose records, etc.)
- Clear explanation of the methods, to get data and to analyze/summarize it
- Appropriate consent (may be verbal, embedded, etc.) or request for waiver
- Protection of privacy, confidentiality
- Equitable selection or participation

Optional inclusions if relevant

- MOUs or agreements/permissions with partners
- Budget
- Scripts, recruitment materials
- Anything that would help us understand the project and why you believe it is exempt

HIPAA Privacy Rule

- When does HIPAA apply?
  - Any of 18 types of demographic identifiers or health care delivery information, including, e.g., ZIP code. Does not have to have a name! Called PHI – personal or protected health information
  - Any PHI collected or transmitted in any form by a "covered entity" (hint: all DPH is such an entity)
  - Applies to data collection activities that are exempt as non-research or are exempt research

Two Ways to Comply with HIPAA

- Individual Authorization for Disclosure of PHI (see form and instructions on website)
- Waiver or Alteration of HIPAA Individual Authorization (see form and instructions)
- Usually preferable to get authorization together with or as part of informed consent for "major" research studies
- Waiver is usually granted otherwise

Step 4: Expedited Review

- Does your project involve survey/interview-type methods that include sensitive topics?
- Does the project involve previously collected data or records, but is not totally de-identified (e.g. you might need addresses for geo-coding or names/SSNs for cross referencing)?
- Is it minimal-risk research in another category?
- **If Yes,** submit expedited review application
- **If No,** submit full board review application (Step 5)

Step 4: Expedited Review (cont.)

- Application is the same for either one: all items on the IRB checklist unless not applicable; written informed consent or waiver if eligible.
- Difference is that for expedited, it must be “minimal risk” and fit into one of the categories; full-board is not so limited
- Expedited review and approval can be given by Chair or designated experienced member, without waiting for next IRB meeting

Step 5: Full Board review applications

- Does it fit into steps 1-4?
- Application is the same for either one: all items on the IRB checklist unless not applicable; written informed consent or waiver if eligible.
- Difference is that for expedited, it must be “minimal risk” and fit into one of the categories; full board is not so limited
- Expedited review and approval can be given by Chair or designated experienced member, without waiting for next IRB meeting

Types of IRB Action

1. Approval and Classification as Exempt (with type of exemption specified)
2. Full approval for one year (by Chair or full board)
3. Full approval for shorter period (by Chair or board)
4. Approval with stipulations (by Chair or full board)
5. Tabled until revised or substantial questions answered
6. Rejected

After Approval

- Not over with approval: IRB has responsibility to monitor projects until finally completed
- Must submit any changes for approval before implementing them (even if exempt!)
- Must submit annual progress report and, unless exempt or expedited, request for continuing approval
- Must report any adverse or unexpected events or protocol deviations
- Notify IRB, with final report, when all done

Informed Consent

Let's Review

- Tuskegee Syphilis Experiment (1932-1972)
- Willowbrook Hepatitis Experiments (1955-1970)
- What do these have in common?
  - Subjects were unable to consent, unknowingly submitted to disease and treatment

Informed Consent, Key Terms to Remember

- **Legally authorized representative (LAR)** is an individual or judicial or other body:
  - Authorized by law to consent on behalf of a prospective subject to the subject's participation in the research
- **New in 2019: Broad Consent:** Prospective consent for unspecified future research using identifiable private information or identifiable biospecimens
- **Vulnerable populations**
  - Subjects in research studies vulnerable to the possibility of coercion or undue influence
    - Pregnant women, prisoners, children

Informed Consent, Process vs. Documentation

- What is the difference between process and documentation?
- **Process:**
  - Provide information to prospective subject
  - Engage with subject
- **Documentation:**
  - Documentation that process took place
  - Record of the subject's agreement to take part in the study

Informed Consent, Process (cont.)

- **NEW in 2019:**
  - **Key information - concise and focused presentation of essential information most likely to:**
    - Assist a subject in understanding the research
    - What is expected of them
    - Potential risks of harm and benefits
  - **Followed by detailed consent (if necessary)**

Informed Consent, Process (cont.)

- Must be:
  - Clear, accurate and understandable
  - In preferred language of subject
  - Contain all the basic elements plus the CA Human Rights in Medical Studies
- Obtain the voluntary agreement of subjects to take part in the study
  - The agreement is only to enter the study – subjects may at any time
    - Withdraw
    - Decline to answer specific questions
    - Decline to complete specific tasks during the research

Basic Elements of Informed Consent

- 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

Basic Elements of Informed Consent (cont.)

- Statement about confidentiality of records
- If more than minimal risk, explanation of any compensation and medical treatments if injured
- Contact person and phone for questions about the research or rights or injury (PI & IRB)
- Statement that participation is entirely voluntary, refusal or withdrawal will not involve penalty or loss of benefits

Basic Elements of Informed Consent (cont.)

- **New in 2019** - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens should be included:
  - That private information may have identifiable information removed and **could be used** for future research studies without additional informed consent or
  - That the subject's information or biospecimens collected as part of the research, even if identifiers are removed, **will not be used** or distributed for future research studies

Additional Elements of Informed Consent

- 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 (cont.)

- That significant new findings developed during the course of the research 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

Other Issues Around Consent

- Payment or gifts offered as reimbursements for participation
  - Must not be coercive, unduly influence subjects
  - Must be described during consent process
    - Conditions under which subjects will receive partial or no payment
- Exculpatory language – subjects may not be asked to:
  - Waive or appear to waive any legal rights or
  - Release a researcher, sponsor or institution from liability for negligence

Other Issues Around Consent (cont.)

- Setting and Time
  - Subjects must feel entirely free to choose whether to take part in a research study
    - Adolescents whose parents are in the room
    - Athletes recruited by coach
    - Employees asked to take part by their employer
  - Subjects must be given adequate time to consider when study:
    - Involves more than minimal risk
    - Involves sensitive information

Informed Consent Documentation

- Documentation of consent provides a record that the consent took place
  - Consent form signed by the subject or the subject'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
- Explicit if research and in spirit if exempt

When is Written Consent Not Necessary?

- Waived/altered written consent in favor of:
  - Oral/verbal consent
    - E.g., Phone surveys
  - Brief, embedded consent at top of survey form
    - E.g., street intercept
  - Study information sheet sometimes required
- Screening, recruitment – **New in 2019:** federal regulations do not require it but we ask for a waiver request of written consent

When is Written Consent Not Necessary? (cont.)

- Conditions (must meet all four):
  1. Research involves no more than minimal risk
  2. Research involving or not involving identifiable private information or identifiable biospecimens, could not be practicably be carried out without the requested waiver or alteration
     - Does not mean time consuming, expensive or inconvenient
     - Means it would not be possible to answer the research question
       - Disclosing purpose of the research may influence how subjects respond (deception must be approved by IRB and previously agreed upon by subject)

When is Written Consent Not Necessary? (cont.)

3. Waiver or alteration will not adversely affect the rights and welfare of the subjects
4. When appropriate, the subjects or LAR will be provided with additional pertinent information after participation (debriefing)

When is Written Consent Not Necessary? (cont.)

- Other conditions:

  -Principal risks are those associated with a breach of confidentiality

    - E.g., Research on women who have left abusive partners

  -When requirement for documentation is waived, the IRB may require the researcher to offer the subjects information about the study in writing

  - Subjects are members of a cultural group in which signing forms is not the norm, and the study presents no more than minimal risk of harm

Templates or Examples

- Some templates in your packet:
  - Written Consent to Participate in Research (full written)
  - Oral Consent Script / Sample Template
- General Guidance:
  - Q & A format
  - 8th grade reading level (*USA Today*)

Okay, what does it mean for our work here?

- Exercises (with a partner or two):
  - Exercise 1:
    - What elements are most important to be included in a short verbal or oral consent process?
  - Exercise 2:
    - Choose one or more of the following studies and decide what type of consent (if any) that the studies would require.

Exercise 2: What type of consent is needed?

1. An in-person survey will be conducted with staff members at a hospital about experiences with a program that links potential human trafficking victims with advocates who are survivors of human trafficking.
2. In-person baseline and follow-up surveys will be conducted with participants in a program that assists low income women while pregnant and until 8 weeks postpartum.

Exercise 2: What type of consent is needed? (cont.)

3. A follow-up phone survey will be conducted among participants who received 6 weeks of acupuncture treatment in an intervention study
4. Urine samples to test if participants are current smokers will be taken periodically during an intervention to embed smoking cessation education in DHS clinics.
5. Focus groups of medical cannabis users will be conducted among participants who receive prescriptions from a doctor for cannabis.

Some FAQs and Problem Areas

- Whose signature do I need on the application?
- What's the "DPH/DHS Liaison" ?
- What about student, volunteer, intern projects?
- Modifications and changes, even for exempt?
- **Expiration dates are drop-dead serious!**
- Budgets … Why? How much detail?
- What happens if we disagree with the IRB's decision or conditions?

More FAQs

- Do project materials need to be in some languages in addition to English?
- Can an application be submitted online or electronically?
- If we're not collecting names, does it still need IRB oversight?
- HIPAA compliance, including exempt projects
- Who needs to be IRB-certified, and why?
- Single IRB – we are already in transition

We Like to Help!

- Forms on web: http://publichealth.lacounty.gov/irb/
- Call the office: 213-250-8675
- Write us with questions: jsenterfitt@ph.lacounty.gov, ocoronado@ph.lacounty.gov or akwon@ph.lacounty.gov
- Can be available for in-person or telephone consultations

Thank you!