2019 IRB Training Update and Community Engagement Workshop

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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?

Who Does Our IRB Serve?

- Covers DPH, ACN, HSA and Correctional Health Services
  - DHS hospitals have separate IRBs, mostly for biomedical research. We primarily see applications for social and behavioral research
- All DPH, ACN and HSA projects require DHS/HSA liaison in addition to the PI and Co-PIs
- ACN may require additional steps
  - Please contact Laura Sklaroff for guidance: Lsklaroff@dhs.lacounty.gov
- IRB of record for community-based organizations and smaller health departments (MOU)
  - Bienestar
  - LALGBT Center
  - Pasadena Public Health Department (MOU)

What is "Research?"

- **Federal regulatory definition:** "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- Many problems in practice with applying this definition, e.g.
  - Who decides if research or not?
  - Shouldn't ethical standards/review apply even if a project is **not** technically research?
  - Can projects be partly research and partly not?

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**

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; “exempt exempt”):
  - Does not involve humans (e.g. animals only, some lab studies);
  - Legally mandated reporting/surveillance;
  - Information collected/charted as part of **clinical care;**
  - 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**

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

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.)

- All items on the IRB checklist required unless not applicable; written informed consent or waiver if eligible
- Must be “minimal risk” and fit into one of the expedited categories
- 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 as for expedited
  - All items on the IRB checklist unless not applicable
  - Written informed consent or waiver if eligible.
- Full board covers studies that pose “more than minimal risk”

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
- HIPAA (and IRB/CITI) training required every 3 years for key research personnel who work with identifiable data

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 full 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

- **Key information (new)**- concise and focused presentation of essential information at beginning of form most likely to:
  - Assist a subject in understanding the research
  - What is expected of them
  - Potential risks of harm and benefits
  - Less than one page
  - Followed by detailed consent (if necessary)

Terms

- **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) or personal information (CA Senate Bill 1386)
- **Identifiable biospecimen:** A biospecimen for which the identity may be readily ascertained
- **Protected health information:** 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

Informed Consent

- Must be:
  - Clear, accurate and understandable
    - 8th grade reading level
    - Q & A format
  - 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.)

- 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

Informed Consent Documentation

- Documentation of consent provides a record that the consent took place
  - Consent form signed by the subject or the subject's legally authorized representative (LAR)
  - 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
  - May be electronic, audio or video recording, as approved by IRB
- Screening, recruitment – 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

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

Community-Engaged Research

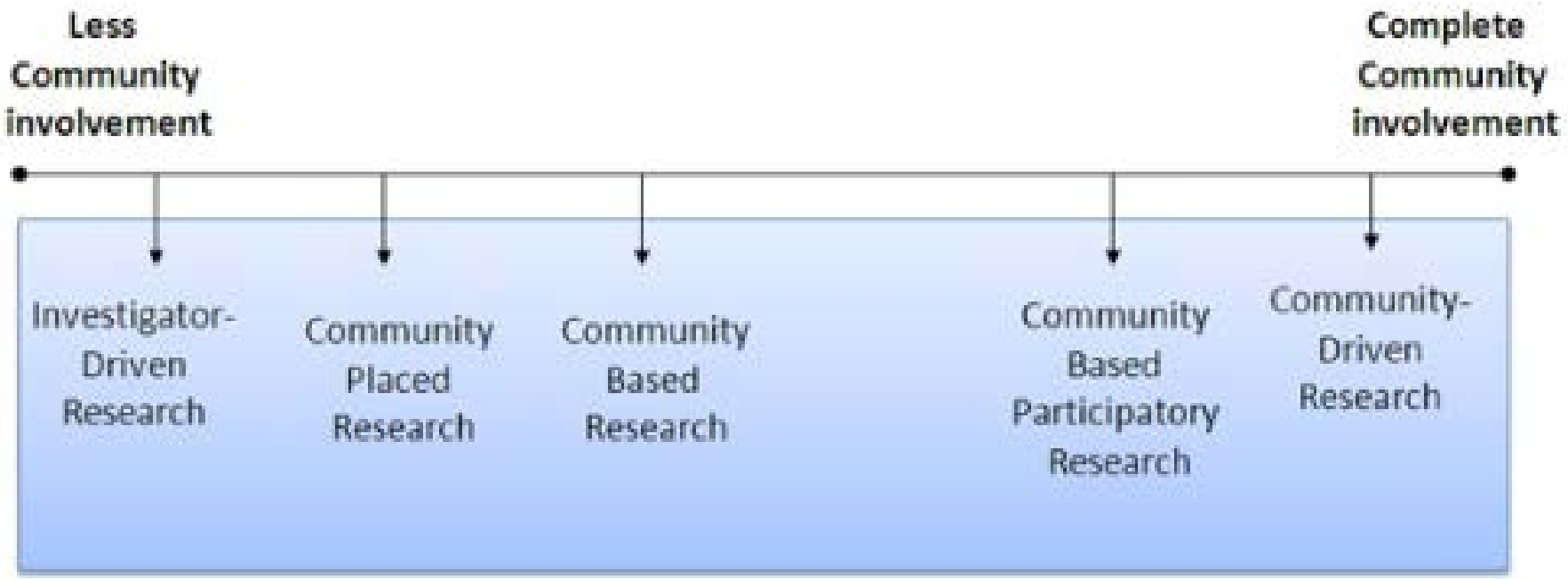
What is Community?

- "A group of people who are linked by social ties, share common perspectives or interests, and may or may not also share a geographic location" (MacQueen et al., 2001)
- Shared language, occupation, ethnic group, faith, age, activities, goals, sexual orientation
- Organizational membership
- Public, non-profit, or private
- Church, school, club, community-based organization
- Not homogeneous with one voice

Community-Engaged Research (CEnR)

- Framework/approach, principles, not methodology
- "The process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being" (CDC 1997)
- Quantitative or qualitative data collection and analysis
- Broad term
  - High community engagement: Collaboration
    - Community Advisory Board
    - Researcher/community partnership
  - Moderate community engagement: Consultation/Coordination
    - Community-based organization assists in implementing a study design
    - Church provides site for research activities
  - Minimal/Lack of community engagement: No
    - Information and education campaigns, outreach,
    - Random phone sampling, street intercept

CEnR Continuum



Winkler 2011

History and Theoretical Basis

- Theories from Anthropology, Psychology, Education, Sociology, Public Health, Social Work
- "Action research" to overcome social inequality (Kurt Lewin, 1940s)
- Co-learning (Wallerstein and Duran, 2003)
- Empowerment education and community organization (Paulo Freire and Myles Horton)
  - Participatory action research
  - Empowering poor and oppressed groups
  - Solutions coming from communities themselves
  - Adult education: learners are not empty vessels; learning is not one way
  - Socio-political action

Integration into Research and Funding Mechanisms

- Mid-1980s: CDC recommended community involvement in research and demonstration projects
- 1997: Institute of Medicine formally integrated community involvement into the prevention research framework
- Early 2000s
  - National Institute of Environmental Health Sciences program to encourage use of community involvement to address health disparities
  - W.K. Kellogg Foundation funded community-based public health initiative for 10 year long projects and academic fellowships
- 2006: NIH initiated Clinical and Translational Science Award (CTSA)
  - Mandated community engagement at biomedical institutions

Benefits of CEnR

- Research done IN and WITH communities
- Subject has become participant (NEJM, AJPH)
- Addresses limitations to “traditional” research
- Addresses needs of community
- Recognizes unique strengths of each party
- Uses knowledge to bring about action
  - Directly influence health outcomes
  - Tailor interventions to specific communities
  - Effect social change and eliminate/mitigate disparities in health outcomes

Benefits of CEnR, cont.

- Participants can understand purpose of the research and how the results may affect them
  - Informed consent
  - Response rates
- Improve reliability and validity of data collection instruments
- Produce culturally sensitive questions and design
- Yields important and culturally sensitive explanations, local interpretation of findings
- Is an intervention in and of itself
- Results likely to be translatable to similar communities

Collaboration

- Contributions may vary for depending on community context, experience and background of researchers
  - Infrastructure and capacity of community organization
- Partnerships with organizations
  - Address issues local health issues, important to community
  - The people affected by the issue
  - Development of a solution
  - Way to “give back” to the community

Collaboration (cont.)

- Respect, cooperation, time, build on strengths of participants
  - Community advisory board
- Co-learning
- Process: long-term commitment to sustainability

Terms of Engagement

- Mutually agreed upon
  - Memorandum of Understanding (MOU)
  - Financial support
  - Research activities, roles and responsibilities, outcomes
  - Data ownership and sharing
    - Developing research tools
    - Data collection methods and interpretation
  - Methods for disseminating research results to both academic and community audiences
    - Products may be collaboratively owned

Research Phases

- Question identification: What is/are the problem(s)?
- Design: What methods will be used that will engage community members, be interesting and inspire participation?
- Tool development: Iterative process with community input and tests for reliability and validity
- Subject recruitment: Criteria, consent, and training
- Data collection: Roles for community members and researchers
- Data cleaning, analysis and interpretation: Contextual information, incorporate community interpretation ideas
- Capacity building
- Work to build mutual trust

Dissemination

- Multiple dissemination strategies
- Community informed strategies more likely to lead to action, more time urgent
  - Community members:
    - Local newspapers, magazines, radio programs
    - Joint community meetings
  - Researchers:
    - Peer-reviewed journals
    - Program implementation, evidence in legal or legislative campaigns, grant applications
    - Some journals may not publish articles whose findings have previously been published in the newspaper, TV or other media

Potential Challenges

- Can equal partnership be achieved?
- Unequal distribution of power
  - Research institutions often have control of finances
  - Community-based organizations do not have infrastructure that supports research; have minor share of research funds
  - Vocabulary, scientific jargon used to control access to knowledge
  - Mistrust of researchers – history of feeling used, perceptions of whose opinions considered valid

Potential Challenges (cont.)

- Time
  - Foster and maintain partnerships
  - Participatory methods
  - Community members may need time to build infrastructure and capacity to work as research collaborators
  - Researchers may need time to understand community processes, gain trust and initiate/maintain relationships

Putting it Into Practice

- Research plus capacity-building: to assess and develop effective strategies for important issues
  - Vulnerable populations
  - Communities with lack of resources, high risk for health outcomes
  - Equality in some or all phases of research and decision-making
  - Identify problems and work together to build mutual skills and develop solutions
- Not just:
  - For qualitative research
  - After the proposal is written

Where Does the IRB Fit?

- Revised Common Rule does not specifically address CEnR
  - Lack of IRB experience with CEnR
  - IRB Policies and Procedures do not specifically address community risks

Ethical Challenges

- Community risk vs. individual risk - is associating participants with research harmful to community or individuals?
- Reinforcing negative stereotypes?
- Disrupting community cohesion?
- Privacy and confidentiality when community members are part of research team
  - Community members of research team may know the individuals they are recruiting

Ethical Challenges, cont.

- Community consent – how is it to be obtained?
- Compensation for participation (in addition to funding for organizations)
- Conflicts of interest
- How are community leaders involved in decision-making?
- Avoiding exploitation

Some Solutions

- Minimize possibility of community members interacting with study participants who are friends or neighbors
  - Hire data collectors who are not part of community if needed
- Work with community partners to help discuss stereotypes of the community and advise on how best to approach groups
  - Informed consent about potential of stigma
- Train community members about data storage and access
- Use non-technical language in informed consent, or translating appropriately

What the IRB Requires

- How is the IRB going to apply this to evaluate/approve projects?
- What should “minimum criteria” of level of engagement be?
  - Demonstrated consciousness or frank acknowledgement of the importance of CEnR
  - Outline of the steps that were taken to achieve adequate CEnR
  - Consultation with the community on ways to disseminate findings

Does This Apply to My Project?

- We intend this requirement to apply not just full-blown research but other activities that come to IRB
  - Program evaluation
  - Needs assessment
  - Studies that qualify for exemption
  - Studies not otherwise not considered classical research

Group Exercise

- Scenario: A group of researchers wants to work on obesity prevention in a local neighborhood where high rates of obesity have been found.
  - **Question 1:** What would you do before actually designing the project? What would you do before putting together the IRB application?
  - **Question 2:** The project is funded. What would do you to make sure there is maximum community engagement in the operationalization of it?

Group Exercise

- **Question 3:** The project is underway but participants are not finishing the surveys. What should you do to solve this problem and be able to collect complete data?
- **Question 4:** How would the project members plan to disseminate the results? What would you do if you found some results that were counter-intuitive and/or stigmatizing?

References and Additional Resources

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We Like to Help!

- Forms on web: http://publichealth.lacounty.gov/irb/
- Call the office: 213-288-8675
- 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!