2019 IRB Training Update and Study Design Checklist

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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
- 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;**
  - Anonymous 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 public health surveillance?
- Is it internal program evaluation or needs assessment intended only for program monitoring, improvement, 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:

- Application for Exempt Review, including the signature page
- Request for Exempt Review
- 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 authorization or waiver 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 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)

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.

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, Vice Chair or full board)
3. Full approval for shorter period (by Chair, Vice Chair or full board)
4. Approval with stipulations (by Chair, Vice 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?

- Exempt review not required but “effective” consent required
- Waived/altered written consent in favor of:
  - Oral/verbal consent, e.g., phone survey
  - 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 waiver is granted

Waiver of Written Consent

- 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)

Waiver of Written Consent (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)

Other Conditions for Waiver of Written Consent

- Other conditions
- Principal risks are those associated with a breach of confidentiality
    - E.g., Research on women who have left abusive partners
- 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
- When requirement for documentation is waived, the IRB may require the researcher to offer the subjects information about the study in writing

Some FAQs and Problem Areas

- Whose signature do I need on the application?
- What's the "DPH/DHS Liaison"?
- What about student, volunteer, intern, contractor 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

Study Design Checklist

What the IRB Looks For: Study Design

- Public health importance of the study
- Methodology
  - Sound
  - Feasible – financial resources, infrastructure, buy-in from organization/program/facility?
  - Study design appropriate to the question(s)
- Subject selection, inclusion and exclusion criteria
  - Justified and equitable

Review: Terms

- Aim/Hypothesis – could be to:
  - Describe a population
  - Quantify relationship between factors
  - What association to you expect or want to find?
- Outcome
  - Dependent variable, disease, mortality/morbidity, e.g., whether a subject has experienced a complication)
- Predictor
  - Independent variable, exposure, treatment (surgery, drug, behavioral intervention), therapy, intervention, risk factor
- Relationship – implies causality, temporal relationship, dose-response (increased “dose” equals increased “response” or level/magnitude of outcome
- Association – implies correlation, temporal and causal relationship unknown
- Confounders
  - Factors outside of exposure of interest that may effect outcome

Experiments

- Uncontrolled trials
  - No comparison or “control” group that does not receive treatment
- Controlled Trials
  - Two or more groups including one “control” group
- Non-randomized – Results can be due to systematic bias
- Randomized control trial – true experiment
  - Considered “gold standard” of research methodologies
  - Minimizes bias
  - Unbiased distributions of confounders

A Note on Sampling

- Probability sampling
  - Subjects are randomly assigned to either group
  - Can use random number generator (simple random sampling) or every *nth* individual (systematic sampling)
  - Stratified sampling – define groups and randomize within those groups
- Non-probability sampling
  - Convenience sampling
    - Subjects easy to access
  - Snowball sampling
    - A few potential respondents are contacted and asked to refer to others with inclusion criteria
  - Purposive sampling
    - Sample is chosen by the researcher – specific characteristics in mind

Experiments

- Used for clinical trials, usually for short-term efficacy and safety
  - Vaccine trials, nutritional supplements
- Researcher manipulates exposure (treatment, drug)
  - Subjects randomly assigned to conditions
- Controlled clinical environment
- Blinded – Subjects do not know they are receiving treatment (e.g., placebos are administered to one group and treatment is administered to other group)
- Double-blinded – Subjects and investigators do now know who are receiving treatment

Experiments Cons/Obstacles

- Cons/Obstacles
  - Ethics – Sometimes unethical to give treatment OR to withhold treatment if treatment has been shown to be efficacious during study or prior to study
  - Contamination
  - Scale of treatment – e.g., surgeries have many steps, unable to measure all of them due to cost and time
  - External validity low - Unable to generalize to general population, adherence to regimen may be different in real world conditions

Observational

- Subjects not randomly assigned to conditions (exposure)
  - Outcomes can be due to systematic bias
- Subjects selected based on the values of the independent variable (exposure), rather than having the investigator assign values of the independent variable to the subject
  - E.g., independent variable/conditions not manipulated by researcher
  - Unable to assign conditions
    - Ethical considerations
    - Feasibility

Some Types of Observational Studies

- Exploratory – Formative, explore potential issues or notable aspects of a population or problem
- Descriptive – Describe a population or phenomena/problem
- Analytic – Test a hypothesis, ask a research question
  - Cohort
  - Case-Control
  - Cross-Sectional

Cohort Studies

- Longitudinal observational study
  - Two cohorts from same source population, only subjects at risk for developing the outcome
  - Prospective, retrospective (historical; subjects still chosen based on exposure)
  - Surveys, interview or written records
- Subjects chosen based on exposure status
  - Can study common or rare exposures (not diseases), e.g., exposure to toxic chemicals, rare adverse effects of drugs
- Can study multiple outcomes simultaneously
- Cons:
  - Need large sample size
  - Can be costly
  - Time-consuming – long durations
  - Loss to follow-up (attrition)
    - Differential loss to follow-up can be source of selection bias
  - Recall or information bias
  - Less control over variables/data collection

Case-Control Studies

- Two groups differing in outcome
  - Matched (if possible) on selected characteristics, usually race, gender, age
  - Compare presence or absence of exposure in both groups
- Can study rare outcomes or outcomes with long latency
- Quick, inexpensive to implement
- Can require fewer subjects
- Multiple exposures or risk factors can be assessed
- Data collected retrospectively: Interview/survey, medical record abstraction
- Cons:
  - Recall bias, interview bias
  - Difficult to validate information
  - Cannot control confounders easily
  - Must select appropriate comparison group

Cross-Sectional Studies

- Cross-Sectional
  - Often times descriptive study
  - Measures predictor and outcome at the same time – “snapshot”
  - Can measure prevalence – proportion of subjects with given exposure at one point in time

Differences

Experiment

- Subjects may receive care that differs from common clinical care
- Generally high cost (time and money) per patient
- Strict inclusion and exclusion criteria (based on ethics and feasibility)
- Can only measure one or two interventions at a time - cannot assess interactions, e.g,. comorbidities, effects of two drugs at the same time
- Can measure compliance
- Blinding is possible
- Cost is too high for rare outcomes

Observational

- Subjects may receive usual clinical practice
- Research does not manipulate intervention, which limits ethical concerns (mainly to privacy issues)
- Can be low cost per participant
- Can include a broad range of patients or specific inclusion or exclusion criteria
- Can measure multiple interventions or comparisons
- More difficult to quantify directly; isolate correlations
- No blinding
- Much more feasible for rare outcomes

Differences (cont.)

Experiment

- Products that lack commercial interest may never get evaluated
- Small effects, use surrogate markers
- Disadvantaged groups tend to be underrepresented (e.g, those with comorbidities, women, older patients)
- Patients tend to be younger, healthier, socioeconomically advantaged, better educated, more likely to adhere to new treatment, thus excluding those who may be most in need of treatment
- Nonadherence more likely due to strict treatment regimen

Observational

- Therapy may be tailored to needs of patient
  - Exposure may vary by patient
- Survivor bias: difficult to assess new or prevalent users of treatment (prevalent users may have survived early period of therapy and are healthier

Confounding

- Observational: Known factors, if measured, can be controlled, but very difficult to control adequately for unmeasured factors
  - Confounding by indication: when treatment interventions are assigned by patient-physician decision making related to disease severity, underlying health of patient, expertise and experience of physician, interaction
    - "Healthy users effect": Physicians more likely to prescribe a treatment based on likelihood of positive outcome
- Experiment: Randomization addresses known and unknown confounding

Theoretical Basis and Review of Existing Research

- Used to explain, predict, and understand phenomena
- Challenge and extend existing knowledge
  - Critical evaluation
- If explicit, it connects researcher to existing knowledge
- Literature Review
  - Systematic review of existing research
  - Identify - what existing research (if any) is out there that might inform your study/project?
  - Appraise - what are the strengths and limitations of previous research? What is missing that needs to be addressed or further studied?
  - Synthesize research – Not just listing out each study's findings one by one

Using Existing Databases

- Ready-made large-scale population-based investigations
- Can study rare exposures, diseases/outcomes inexpensively and rapidly
- Outcomes may be more likely to reflect daily clinical practice if data sources comprise complete target population data
- Because these existing databases collect data for administrative or other purposes unrelated to research objectives, certain biases are reduced or eliminated:
  - Nonresponse - data already collected
  - “Hawthorne” effect - reactivity where individuals change their behavior due to awareness of being observed
  - Recall- not asking subjects to remember or recall past behaviors or events
  - Loss to follow-up – no need to follow a group of people across time
- Can measure long-term/delayed health effects

Evaluation Research

- Common projects that come to our IRB
- Can use experimental or observational research design
  - Should be cognizant of types of bias that can occur
- Assess an intervention or program during and/or after implementation
  - Systematic process
  - Performance measurement
  - Used to maintain or improve program quality
  - Ensure future planning more evidence-based
    - "Information bearing on whether a belief or proposition is true or false, valid or invalid, warranted or unsupported" may not be the same as scientific findings or causal efficacy (Schwandt, 2009)

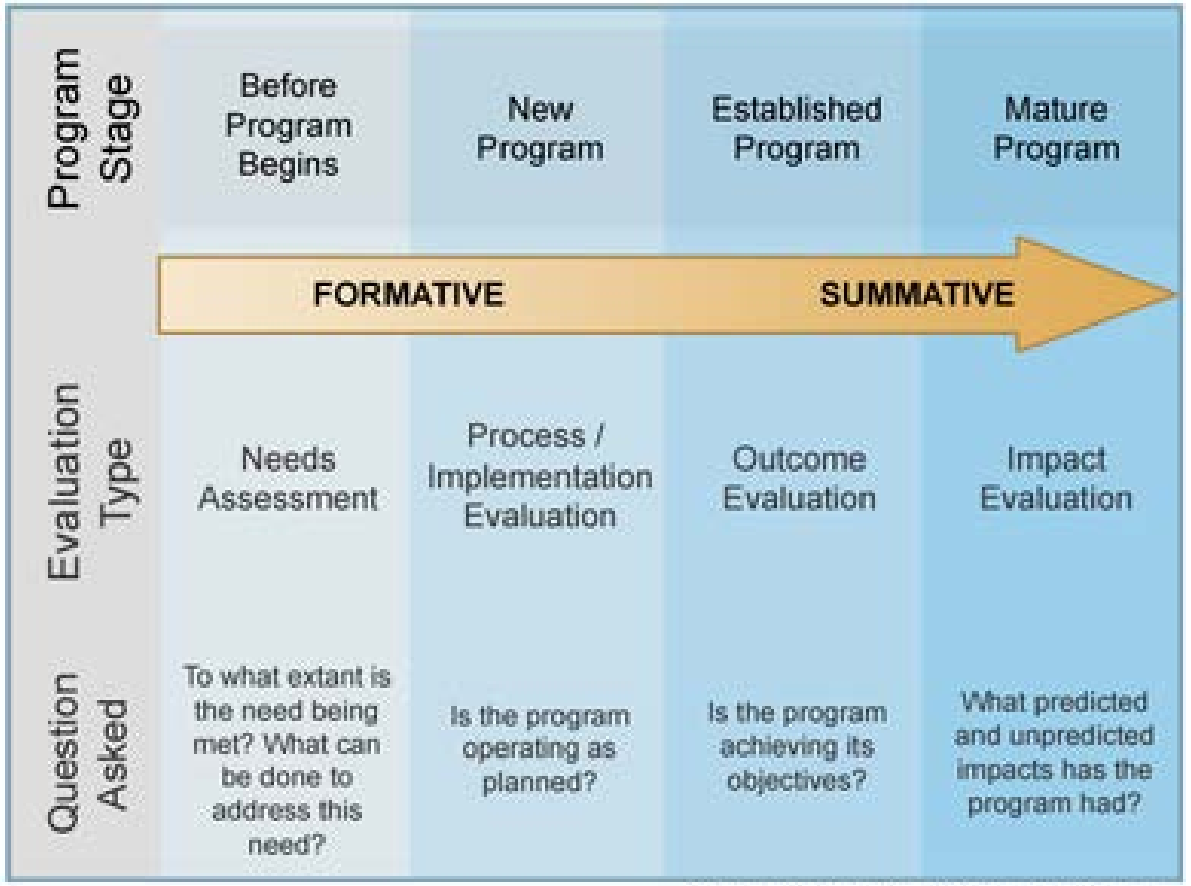
What We Consider Evaluation Research

- Not just traditional sense of evaluation or what is termed “evaluation research”
  - Pilot projects
  - Demonstration projects
  - Implementation research
  - More systematic implementations that are regarded as best practice or have already been demonstrated in research trials
    - If we want to see if real world efficacy or feasibility is same we see in controlled environment.

Evaluation Research, (cont.)

- Formative
  - Needs Assessment: Who needs the program, how great is the need, how best to meet the need(s)?
  - Process Evaluation: Measures effort and direct outputs, how much was accomplished? Whether program operating as planned
    - Can be measured continuously or at one time
- Summative
  - Outcome: Effect and changes that result from program/intervention
    - Short-term effects
  - Impact: Community-level change or longer-term results
    - Net Results, typically on entire school, organization

Evaluation Research



These summative evaluations build on data collected in the earlier stages.

Adapted from:

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Steps for Evaluation Research

- Engage Stakeholders
  - Who, how? Both internal and external
- Identify program elements to monitor
  - Which ones and justification?
  - Products and services delivered
  - Resources that contribute to implementation
  - Adherence to time line
- Select key evaluation questions
  - What do you want to learn?
  - Indicators, how to measure changes/effects of intervention
- Determine how information will be gathered
  - What data sources, research design?

Steps for Evaluation Research, (cont.)

- Develop a data analysis plan and reporting plan
  - How will monitoring and evaluation questions be coded, summarized and analyzed?
  - What are timelines and budgets? How will costs and evaluation be presented?
- Share lessons learned, ensure findings will be applied
  - How will conclusions be justified?
  - What is the evaluation implementation summary? Who will create?
  - How can the information be used to revise intervention/programs?
  - Final summary – how will it be disseminated?

A Note on Surveys, Interviews and Mixed Methods

- Qualitative - Focus groups, key informant interviews, observations/site visits, etc.
- Data collection instruments (final draft) required
- Survey courses offered by Dr. Lisa Smith, DPH OHAE: lismith@ph.lacounty.gov
- Survey resources listed in References and Additional Resources slide (with asterisk)

Group Exercise

Your program is about to implement a media intervention to increase knowledge about opioid misuse. How would you go about designing an evaluation for this program?

1. When would you begin your evaluation plan and what steps would you take?
2. How would you go about finding out the specific needs of the population?
3. When would you perform an impact evaluation and what types of indicators would you use?
4. At what point(s) would you disseminate the findings to stakeholders and how would you do so?

Review: What the IRB Looks For: Study Design

- Public health importance of the study
- Methodology
  - Sound
  - Feasible
  - Appropriate to the question(s)
- Subject selection, inclusion and exclusion criteria
  - Justified and equitable

Review: Additional Items the IRB Looks For

- Risk assessment: Does the project pose “no more than minimal risk” to participants?
  - Are the risks reasonable in relation to anticipated benefits?
  - Has the project taken all reasonable steps to minimize risk?
- Consent form (if included):
  - Is it appropriate in length and language to the study and the population?
  - Does it include the basic required elements?
  - Is the waiver/alteration of informed consent form adequately justified?
- Vulnerable populations?
  - Fully informed consent
  - Voluntariness of participation
  - Other special protections?
- Are provisions to ensure privacy and confidentiality of data collected adequate?
- Budget?
- Community Engagement
- Potential controversy?

References and Additional Resources

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We Like to Help!

- Forms and instructions on the web: http://publichealth.lacounty.gov/irb/
- Call the office: (213) 288-8675
- Write us with questions: irb@ph.lacounty.gov
- Can be available for in-person or telephone consultations

Thank you!