Human Subjects and Public Health Practice
Guidelines for Ethical Data Collection

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Background
Why should I be concerned about this? I'm not doing research.
What are the ethical issues involved in gathering data from people?
How do I make sure that my project meets these ethical principles?
How do I know whether my assessment project requires IRB review?
If I think my assessment project may be research, what happens then?
If my assessment project is NOT research, what happens then?
What can local public health staff do to ensure ethical assessment practice?

Background

Have you ever…

…conducted a client satisfaction survey?

…interviewed community members about their top health concerns?

…held focus groups to test prevention and health promotion messages?

…performed chart audits to measure prevalence of a health condition in a school?

…surveyed participants about health behaviors to evaluate whether a program worked?

If so, you need to understand your responsibilities for protecting human subjects.

Community health assessment and program evaluation involve gathering data from people through surveys, interviews, focus groups, and other methods. Whenever we are collecting or using data[1] from individuals, we need to consider several issues related to ***human subjects***. We need to identify whether our work falls in the category of research, requiring formal review by an Institutional Review Board (IRB), or whether it is public health practice. Regardless of whether it is research or practice, we also must consider how we will protect the autonomy and privacy of participants, avoid exploitation of vulnerable populations, maximize benefits, and minimize risk.

The purpose of these guidelines is to assist public health staff in (1) designing assessments and evaluations that meet ethical principles for use of human subjects, and (2) obtaining review by an IRB when appropriate.

[1] Includes personal information and client records

Why should I be concerned about this? I'm not doing research.

Consider the following hypothetical scenario:

> *Janet comes to the health department for WIC services. The receptionist hands her a survey on family planning and asks her to fill it out while she's waiting. Janet takes a seat and looks over the survey – it looks long and she's not sure she can finish it before her name is called. She starts in on the questions about sexual activity and birth control use, growing uncomfortable – why do they need to know about this to give her WIC coupons? In spite of her unease, she hurries to finish – she doesn't want to risk not getting her coupons because she needs them to buy milk for her baby.*
>
> *Terry, the WIC program manager, looks over the survey responses from her clients. Though she got a good response, she realizes that several of the questions didn't capture what she needed to know. Disappointed, she files the surveys away. A few months later, a friend calls asking whether she can use the data from the surveys for a school project. Glad that the survey data will be of some use, Terry gives the surveys to her. Later, she wonders whether her friend will know any of the clients who responded to the survey.*

What ethical issues are raised in this hypothetical scenario?

- Was Janet told the purpose of the survey and how her responses would be used?
- Was she told about the risks and burdens involved in participating in the survey – including an estimate of how long it would take to respond?
- Did she know that responding to the survey was voluntary and that choosing not to respond or not responding to certain questions would not affect the services she was seeking from the health department?
- Was the privacy of the survey respondents protected? Was Janet told who would see her responses, how her survey responses would be protected from disclosure to unauthorized persons, and that her survey responses would be given to other parties, for other purposes?
- Was Janet told who would benefit from the survey and what risks, such as threat to confidentiality, there might be to her?

This scenario is designed to show how, without intending to, we can encounter ethical issues in carrying out our work. This possibility exists across programs and public health activities; the use of WIC in this example is just an illustration. It's in our interest to implement our assessment and evaluation projects in an ethical manner to protect the participants. Doing so helps to foster community trust in public health and maintain credibility for our agencies.

What are the ethical issues involved in gathering data from people?

In 1974, the National Commission for the Protection of Human Subjects produced a guiding framework for ethical human research (see the Belmont Report). **This framework is also relevant for public health assessment and evaluation activities that involve gathering data from people.** The framework is organized around three ethical principles:

1. Respect for persons: This principle speaks to the need to respect people's autonomy, particularly their ability to make independent decisions and act on those decisions. In the context of assessment (and research), this principle is implemented through ***informed consent*** (i.e., giving people the

information they need to make an informed and independent decision about whether to participate in the project/study).

2. Beneficence: This principle addresses the need for projects/studies to maximize benefits and minimize risks. In assessment (and research), this principle is implemented by a ***risk/benefit analysis*** that fully considers the physical, psychological, emotional, and other risks to participants and weighs these against the benefits that will accrue to the participants, the population group, and/or society.
3. Justice: This principle refers to selecting participants for the project/study in such a way that there is ***fair opportunity for inclusion*** and vulnerable populations are not exploited. For instance, it would be unethical to take advantage of populations that are readily accessible for studies simply because they are incarcerated or institutionalized. This principle also addresses the need for studies to include diverse populations (e.g., women, people of color) so that these groups can benefit from the knowledge gained. Individuals and groups that *benefit* from the research should **also** bear the risks and burden.

How do I make sure that my project meets these ethical principles?

To ensure ethical treatment of participants in your assessment or evaluation project, start by thinking about the ***purpose***. What are you trying to learn and how will the information be used for public health practice? Remember that asking people to participate in data collection is always an imposition on their time. Using information about program clients may also pose risks to their privacy. We should only do so when we can demonstrate a clear and compelling need for collecting the information.

It is also important to think carefully about the ***methods*** you will use to ensure they are sound and appropriate for your project. Issues to consider include sample size, response rate, sources of bias, procedures to protect confidentiality, the data collection instrument (are the questions valid and reliable?), etc. Keep in mind: a poorly designed assessment or evaluation may yield data that can't be used, achieving none of the intended benefits and representing a waste of time - and possibly intrusion into personal matters - for the participants.

Consider what ***population group*** you will seek to participate in your project. Think about the principle of justice and ask yourself: why am I collecting/using data from **this** group? Health department clients can offer us valuable information, but don't use them as your study population simply because they are readily accessible.

To address the principle of beneficence, consider the ***risks and benefits*** of the project. Potential risks to participants include time, stress, intrusion into personal or sensitive issues, emotional discomfort, breach of confidentiality, etc. Potential benefits may include a chance to talk with others experiencing a similar health issue, improved services, information that could lead to new grants in the community, etc. Do the benefits clearly outweigh the risks to participants?

Confidentiality is another important consideration. Think about how records or information will be handled, stored, and accessed. Will participation be anonymous, confidential, or neither? Will data collection be conducted in a group setting, in which it may be difficult to assure confidentiality? Are personal identifiers needed? When will they be removed from the data and destroyed?

Finally, decide how you will obtain ***informed consent*** from participants in a manner that respects their autonomy. Consent forms typically describe the project purpose, identify the sponsoring organization; explain the procedures, duration, risks and benefits of the project; identify the confidentiality protections and limits to confidentiality (e.g., reporting of abuse or communicable disease); and state

that participation is voluntary. Be sure that the reading level of the consent forms is appropriate for the intended subjects. Develop assent forms or scripts at appropriate reading levels for child participants, individuals with low literacy, or cognitive difficulties. If the project participants are clients of your agency, be sure to inform them that refusal to participate will not change their access to services.

A set of questions was developed to assist public health staff in designing quality assessments and evaluations that meet the principles for ethical data collection with human participants. See "Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation." Sample responses are found in Examples A, B and C.

How do I know whether my assessment project requires IRB review?

Sometimes, assessment and evaluation projects fall into the category of research, requiring review by an Institutional Review Board (or IRB, for short). An IRB is a committee appointed by and often affiliated with an institution (e.g., an agency, university or hospital) that assures the protection of human subjects in the research conducted under the auspices of that institution. The review process is intended to protect the rights of people participating in research and to ensure that the research is sound and is likely to produce benefits that outweigh risks to participants.

One way to distinguish between research and public health practice is in the intended uses of the work:

- If the main purpose of the project is to produce ***generalizable knowledge*** (applies to people other than the ones studied) to improve public health practice and the benefits extend beyond the study participants *from whom the information was collected*, it is considered research. See research examples.
- If the main purpose is to prevent disease or injury, or improve a current, ***on-going*** public health program or services AND the knowledge gained will primarily benefit the participants, the project may be considered non-research (i.e., public health practice). See non-research examples.

IRB review of your project may be required if it involves the collection/use of data from people and:

- It is funded or sponsored by the federal or state government
- It will produce information that is applicable beyond the immediate population from whom it was collected
- It's an evaluation of a new, modified, or previously untested intervention, service, or program
- It involves the collection of sensitive or personal information
- It involves vulnerable populations (e.g., children, pregnant women, etc.)

When in doubt, consult with an IRB.

The requirement for IRB review is also linked to funding: all federally-funded research requires IRB review and approval, as does all research sponsored or conducted by the Washington State Department of Health (DOH).

In practice, distinguishing research from non-research is not straightforward. Both research and non-research assessment activities may use established scientific methods for gathering data. Both research and non-research involve gathering information on health issues. And both research and non-research can be conducted by public health practitioners. *It is best to consult with an IRB.* **The Washington State Institutional Review Board (WSIRB) will assist local health jurisdictions (LHJs) and other entities in making this determination: (360) 902-8075 or wsirb@dshs.wa.gov. IRB staff will provide a written assessment of**

whether your activity is research that requires IRB review and approval. It is better to have IRB find that the project is not research, or is research exempt from human subjects requirements (exempt), than to find out later that the project must be stopped or the data should not be used because it comprises research that was conducted without IRB review and approval.

The WSIRB does not consider publication, in and of itself, to be a deciding factor for whether a given activity comprises research that requires IRB review.

A decision tree for distinguishing research from non-research is included on page 9. The Centers for Disease Control and Prevention (CDC) also has Guidelines for Defining Health Research and Public Health Non-Research on their website.[2]

If I think my assessment project may be research, what happens then?

If your project appears to be research, the next step is to contact an IRB to make that determination. The WSIRB can help you determine whether IRB review is necessary. To actually have your project reviewed, your agency must designate an IRB through the federal Office of Human Research Protection's Federal Wide Assurance process. Your agency may designate the WSIRB or an IRB affiliated with a local university – a list of registered IRBs in Washington State can be found on the WSIRB Links page. If the research is funded by DOH or uses DOH, DSHS or L&I records or clients as subjects, the WSIRB would conduct human subjects review.

IRB review of research involves a written application in which you must describe the purpose, methods, significance, and budget of the project, including detailed information on recruitment and data collection procedures, informed consent, risks/benefits to participants, and confidentiality. The principle investigator(s) also must complete approved human subjects protection training. The review process takes time – often several months depending on the complexity of the study and completeness of the proposal – so plan well in advance of when you need to begin data collection. For information on the WSIRB review process, see: https://www.dshs.wa.gov/SESA/research-and-data-analysis/human-research-review-section.

If my assessment project is NOT research, what happens then?

Even if your project does not require IRB review and approval, you may wish to ask for informal consultation with professional staff of an IRB and to submit an Exempt Determination Request if you believe your project does not require IRB review. If the project is very sensitive or involves a vulnerable population (such as children or people with a serious disease), you may wish to request advice from IRB staff on the ethical conduct of your assessment or evaluation. If the activity does not require IRB review and approval, WSIRB staff can document this in writing as part of their consideration of the request for exemption. Such documentation may be necessary if you later propose to publish findings from public health assessments or evaluations.

Even if you do not obtain formal review and approval from an IRB, you still should conduct your assessment in a manner which is consistent with the principals for ethical research with human subjects described above and complete the "Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation."

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[2] See also: http://www.cdc.gov/od/science/integrity/hrpo/

What can local public health staff do to ensure ethical assessment practice?

- **Establish policies/protocols** for your agency regarding the collection and use of data from people. Establish an internal review team for non-research assessment and evaluation activities. Look at an example of a policy from Clark County Public Health.
- **Complete the "Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation"** for each project involving data collection from human participants or analysis of client records.
- **Ask for advice** on your project early in the planning process. Consult with colleagues in public health. If your project involves sensitive topics, vulnerable populations, or potentially falls in the category of research, consult with staff at the WSIRB.
- **Designate an IRB** for your agency. It's best to do this **before** seeking a grant that requires it.
- **Get trained** in the protection of human subjects. The WSIRB web site contains links to free in-person and web-based learning opportunities: WSIRB Training.

Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation

1. What is the **purpose** of the project? Does the purpose justify the use of human subjects? What question(s) are you trying to answer? How will the information be used? Who is the audience for the results?

2. What **methods** will you use to gather data? Are these methods appropriate for the question(s) you're trying to answer? Are you using a validated data collection instrument? If not, how will you pre-test your questions? What sample size and response rate is needed to make good inferences from the data?

3. What **population group** are you seeking for the project? How will you access/locate people to participate? Consider the principle of justice: why are you collecting/using data from this group?

4. What are the potential **risks** and burdens of the project to participants? Consider time, stress, possible intrusion into personal or sensitive issues, emotional discomfort, breach of confidentiality, etc.

5. What are the potential **benefits** of the project? To participants? To the health department? To the community? Do the benefits outweigh the risks to participants?

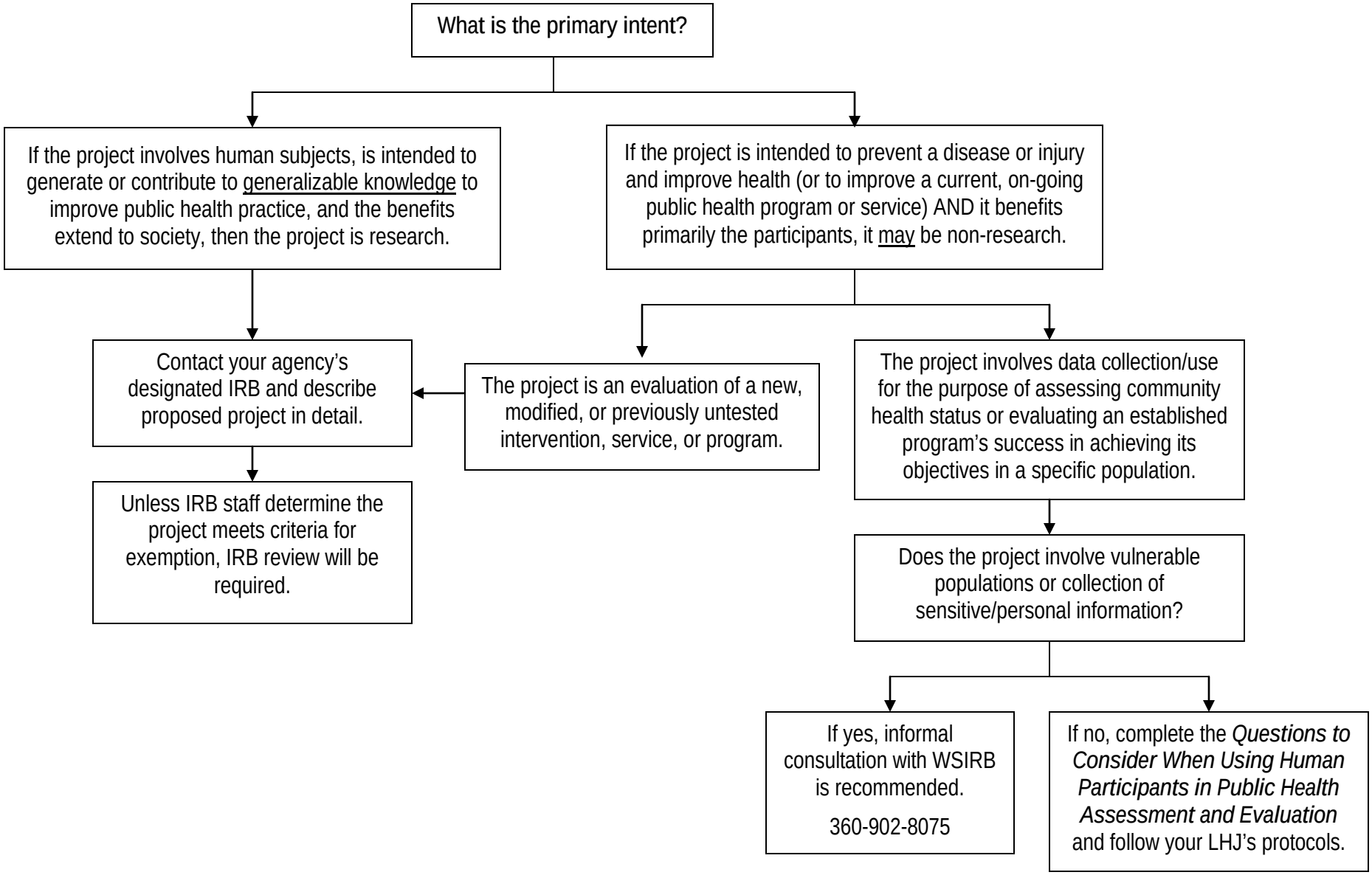
6. How will you handle **confidentiality** of personal or sensitive information? Will participation be anonymous, confidential, or neither? How will data be stored? Who will have access to data and for how long? Are personal identifiers needed? For what purpose? When will they be removed from assessment information and destroyed?

7. How will you obtain **informed consent** from people to participate in the project? A consent form should be simply worded (at a reading level appropriate to the audience) and cover the following elements:
   - The purpose of the project and what participants would be asked to do
   - Person(s) and group(s) conducting the project
   - Expected duration of participation
   - Benefits that can be expected from participation, if any
   - Potential risks or harms that may occur
   - How confidentiality of information will be maintained and any limits to confidentiality
   - Statement that participation is voluntary, that refusal to participate will not result in a loss of services or benefits, and that participation can be stopped at any point during the project without penalty
   - Information on who to contact for answers to questions about the project

Assessment and Evaluation Projects Considered Research

- Meningococcal Disease Case-Control Study of High School Students (study of high school students with meningococcal disease and several unaffected classmates to identify associated risk factors)
- First Smiles: Use of Chlorhexidine and Xylitol Gum for Caries Prevention in Public Health Clinics (study to identify which method is best adhered to among public health clinic clients)
- If It Happens, It Happens: Qualitative Assessment of Unintended Pregnancy (interviews with Medicaid-eligible women regarding pregnancy attitudes, beliefs and experiences)
- Behavioral Risk Factor Surveillance System (BRFSS), including local modifications of BRFSS (random digit dial survey of Washington State adults)
- Healthy Youth Survey (school-based survey of students in grades 6, 8, 10, and 12)
- PRAMS: Pregnancy Risk Assessment Monitoring System (mail/telephone survey of new mothers)

Assessment and Evaluation Projects Considered Non-Research

- Childhood Immunization Studies (birth certificate follow-back or cluster studies used to determine immunization status in community to direct program planning and education)
- Client Satisfaction Surveys for public health programs (examples include family planning clinics, HIV counseling and testing, WIC, etc. which are used to identify specific program performance and improvement areas to better serve clients' needs)
- Needs Assessment for HIV Prioritized Population (may take different data collection formats -- survey, key informant interviews, focus groups -- to help determine the status and service needs of a specific targeted population)
- Program Evaluation of Immunization Program (chart audit of client records to determine if vaccinations have been appropriately signed for and documented in order to document program performance and make changes where necessary)

Is It Research or Public Health Practice?