



**NTWC**  
National Tribal Water Center



# Formative Assessment for Program Development: A User's Guide



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## Frequently Asked Questions

### What is a formative assessment?

Formative assessment is a type of evaluation conducted at the beginning of a health education or health behavior program. As the first part of the ongoing process of program development and evaluation, it identifies and describes a community's needs, resources, and capacity. While typically associated with the model of community-based participatory research, formative assessment can be conducted as part of any outreach effort.

### Why do we need to do formative assessments?

Formative assessments save environmental health practitioners time, money, and other valuable resources by allowing them to more accurately understand their target population and the baseline values of outcomes of interest. They are critical to preventing false assumptions and provide a more accurate picture of a population's current capacity and needs.

### When should I conduct a formative assessment?

Ideally, formative assessments are conducted before the beginning of any type of intervention or health behavior program. They provide information that is timely and specific to their target population.

### Who can conduct a formative assessment?

Any community, agency, organization, or individual can conduct a formative assessment. Assessments are designed to incorporate local perspectives into the design of health programs in a meaningful way, and target populations are a partner in this process.

### What can I expect to find in this guide?

This guide briefly overviews the basic steps of a formative assessment. It was written specifically for environmental health staff working for the Indian Health Service and other environmental health staff who also work with tribes or tribal organizations. Examples of materials are included throughout the guide.

### Where can I learn more?

At the end of this guide is a list of helpful materials. Readers who wish to learn more about conducting formative assessments can use these materials to expand their knowledge base or may contact the National Tribal Water Center ([ntwc@anthc.org](mailto:ntwc@anthc.org) or 907-729-3600) for more specific guidance.

## Conducting a Formative Assessment

Formative assessment is a user-driven method for creating effective public health programs. Before beginning a formative assessment, read through the entire guide to ensure you have an understanding of the overall process.

A formative assessment has five basic steps:

1. Describe purpose of assessment
2. Assess needs and identify gaps
3. Create a capacity inventory
4. Define assumptions
5. Summarize and implement

The first three steps are the basis of the formative assessment. The final two steps incorporate the findings into program development.

### Step 1: Describe purpose of assessment

#### *Why are we doing this? What do we hope to accomplish?*

It is important to identify the purpose of your formative assessment. This first step can seem so obvious that, paradoxically, it is often forgotten. Taking the time to think about and describe what you hope to learn will help focus your efforts and ensure that you obtain meaningful outputs.

You may consider the following questions:

- o Who are our stakeholders?
  - o **Stakeholders** are those with an interest in the program or proposed intervention
- o What are we hoping to accomplish?
- o What will our end product look like?
- o Are we developing a new program or refining one that has previously been developed?
- o If we are developing a new program, why?
- o Where will we be conducting our work?
- o How much time do we think it will take to conduct our assessment?

This step strengthens your formative assessment by identifying and describing its intent and purpose. All team members should be able to clearly identify and describe the purpose of a program—this creates unity and consistency. Programs can describe the purpose of their assessments formally or informally; these descriptions range from things like vision or mission statements to itemized lists of goals. These can serve as an evaluation tool throughout the formative assessment process.

## Step 2: Assess needs and identify gaps

### *What are the current conditions? What does the situation look like?*

The purpose of a needs assessment is to identify gaps in current services, describe current perceptions about the feasibility and acceptability of a potential intervention, and identify potential leverage points for public health action. To ensure that programs are effectively developed and implemented, your team must understand local perceptions about health outcomes and potential interventions. Successful interventions combine strong science and theory with specific tailoring based on the unique needs of the target population. The **target population** is the group that will be receiving your health program or intervention.

See [Attachment 1: Health Behavior Theories & Models](#) for descriptions of several theories of behavior that can be used when developing questions for a needs assessment.

Examples of questions to be answered through a needs assessment include:

- Do people believe that a particular health condition is a problem?
  - Why or why not?
  - Is there another health outcome that is more important to our target population?
- How do people want to address a particular health condition?
- What are some barriers to people adopting the desired behavior?
- Who is practicing the desired behavior?
  - What motivates them to do so?
- What services are currently available?
  - What percentage of the population is aware of these services?
  - What do people already know about these services?
  - How do people feel about these services?
  - How do people learn about these services?
- Where do people go or who do they ask for information about the topic?
- What do people think about our program?

Quantitative or qualitative methods can be used to conduct a needs assessment. Public health practitioners have access to a variety of data types and sources. **Quantitative data** is numerical in nature (e.g., percentages or frequency counts). **Qualitative data** describes a phenomenon, often through the perspective of the target population. **Primary data** is what you as a public health practitioner collect yourself, and the data is specific to your target population. **Secondary data** has been collected by someone else for some other purpose; secondary data may also not be specific to your unique population.

#### *Example: Primary and Secondary Data Sources*

You are conducting a health education program aimed at decreasing tobacco use among residents of a

specific tribal community. In order to understand if your program is working, you need to identify changes in the rate of tobacco use. This means that you want to compare the smoking rates at the end of your program with the baseline rates. The local IHS Area Office collects primary data on smoking rates among your target community or records of tobacco product sales at the local store. Secondary data comes from the CDC's Behavioral Risk Factor Surveillance System (BRFSS) on overall rates of tobacco use among American Indians and Alaska Natives nationwide. All of these datasets contain information helpful to the development of a smoking cessation program. The primary dataset is more specific since it is limited to the target community; the secondary dataset is very rigorous and has high statistical reliability since it was collected as part of a highly standardized survey.

Data specific to your target population may be the most helpful to your program; external (secondary) data sources may also contain relevant information. In the example above, primary data on local smoking rates identifies a baseline that can be measured over time to determine changes within a population (e.g., whether people smoke less after the program is implemented), while secondary data collected by the CDC on nationwide smoking rates also provides a meaningful comparison when trying to understand local smoking rates (e.g., whether they smoke more or less than other groups within the US).

A variety of strategies are available for assessing needs and identifying gaps, such as the following:

- Questionnaires
- Key informant interviews
- Focus group discussions
- Talking circles
- Field observations

When selecting the most appropriate tool for your assessment, be sure to select one that can be properly used and will provide adequate data. Quantitative and qualitative tools can be used to capture different aspects of the same phenomenon. Mixed-methods assessments (those that use both quantitative and qualitative methods) provide a more comprehensive picture than one method alone. Formative assessments can incorporate a variety of data to establish baselines and describe perceptions. Medical record reviews are considered to be the gold standard for epidemiological surveys, while focus group discussions provide unique insight into behaviors and practices that are unable to be captured through systematic questionnaires. Both methods provide unique data and they complement each other.

Defining the purpose of your assessment in Step 1 gives you a well developed idea of the data that would be most relevant and helps you choose the most appropriate tools and measures for your program in Step 2.

Field teams must be trained in the use of specific methodologies to ensure consistency, and different tools require appropriate skill sets. Depending upon the methods used and team members' individual

roles and responsibilities, staff may require training in survey administration, data collection procedures, data entry, and analysis. Focus group moderators must be able to engage participants in a meaningful dialogue without influencing their responses. Survey teams collecting information need to record responses correctly, clearly, and consistently. Individuals collecting qualitative data should be trained on how to capture key words and other data if conversations are not being recorded. When audio data is recorded, staff must be trained on transcription. For more information on specific qualitative research methods, see Guest, Namey & Mitchell (2012).

A formative assessment conducted to inform the development of a specific program or programmatic activity is not considered research by the U.S. Department of Health and Human Services. Please refer to the link provided in [Attachment 4: Helpful Websites](#) if you have any questions or for more information on the subject. For non-research programs, staff must still be trained appropriately on sensitive matters, such as how to invite participants or make referrals for services.

*Example: Tools and Data*

<b>Tool</b>	<b>Data Collection Options</b>	<b>Response Options</b>	<b>Examples</b>
<b>Questionnaire</b>	-Paper -Electronic: PDAs, laptops, tablet computers, smartphones -Online (need secure site)	-Yes/No -Numerical responses -Likert scale (ratings) -Multiple choice -Most frequently identified (“Top Three”) -Open-ended (typically with key words captured)	-Have you smoked a cigarette in the past 30 days? -How many glasses of water did you drink yesterday? -How confident are you in your health care provider? -Name the top three health concerns that you have for your children.
<b>Key informant interview</b>	-Interviewer’s notes -Audio recording -Visual recording	-Open-ended -Basic demographic information on participants	-What do you think are some things that make it difficult to come to the clinic for antenatal care? What are some of the things that make it easy?
<b>Focus group discussion</b>	-Note taker’s notes -Audio recording -Visual recording	-Open-ended -Basic demographic information on participants	-What do people in this neighborhood say about how the new coal mine has affected your community?
<b>Field observations</b>	-Observer’s field notes -Audio recording -Visual recording	-Data tool collecting relevant information like date, time, location of observation	-From 10:00-10:30, 7 children were observed riding bicycles without helmets in the park.

Nontraditional data sources may also provide useful information for your program. For example, a program interested in decreasing the amount of sugar-sweetened beverages people drink may obtain access to sales records at the local store for these products. In this example, sales records could be used as a baseline for how often people buy different beverages. These records could be followed over time to determine changes in sales of these items.

### Step 3: Create a capacity inventory

#### *What are the resources available to us? How can we capitalize on strengths?*

Far too often, the approach is taken that a community or target population is simply a consumer of a program rather than being an active participant. This approach can decrease participation and uptake if a program is perceived as being externally imposed (i.e., coming from the outside) in a negative way. Resources that are not recognized may be wasted.

Capacity inventories document in detail the unique resources currently available within a community. Resources can be anything from personnel to actual physical items; inventories can be kept using electronic spreadsheets or other methods of documentation. Capacity inventories should be updated on a regularly scheduled basis as new resources become available and existing resources are depleted.

#### *Example: Capacity Inventory*

<b>Resource</b>	<b>Description</b>	<b>Point of Contact</b>
<b>Community health clinic</b>	<ul style="list-style-type: none"> <li>- Staff includes 3 administrative, 2 nurses, 1 physician, 1 behavioral health aide</li> <li>- Conference room available after 5:00 PM for small meetings; whiteboards in conference room</li> <li>- Free wi-fi internet access available on site</li> </ul>	Dr. Jane Smith Primary Care Physician 907-555-XXXX
<b>Tribal council</b>	<ul style="list-style-type: none"> <li>- 7 local leaders within community elected every 2 years; current representatives have held positions for a range of 5-16 years; excellent source of local knowledge regarding preferences and practices</li> <li>- Highly invested in success of program: passed resolution in its support</li> <li>- Tribal council hall available for large community meetings (up to 300 people), which must be scheduled minimum of 10 days in advance; overhead projector available for use if a laptop is provided</li> </ul>	Mr. Michael Anders Senior Tribal Administrator 907-555-XXXX
<b>Local cable channel</b>	<ul style="list-style-type: none"> <li>- &gt;90% of homes in community report regularly watching the local cable channel 3-4 hours a week</li> <li>- Costs \$200 to air an advertisement on the local cable channel for a period of 4 weeks beginning on the first of each month</li> <li>- High school film club has offered to make a 90-second video</li> </ul>	Ms. Sherry Eby Station Manager 907-555-XXXX



clip advertising the program for free

By using local resources that people may already be familiar with, you increase the likelihood that a target population will embrace a program. In an increasingly strained financial climate, it is also essential to capitalize on resources that are already available.

## Incorporating Findings into Programs

At this point in the formative assessment process, you have collected data critical to the development of your program. The next two steps incorporate these findings into your program in a meaningful way.

### Step 4: Identify your assumptions

#### *What are our assumptions?*

Countless interventions have failed as a result of flawed assumptions. Assumptions can include things such as the willingness of community members to participate or the acceptability of an intervention that has not been piloted. Assumptions should be tested whenever possible. Formative assessments are integral in minimizing the number or effect of any assumptions.

*Example: Assumptions and Errors*

<b>Assumption</b>	<b>Error</b>	<b>Potential Solutions</b>
<b>Recruiting participants will be easy because we are offering free nicotine replacement products</b>	-Assumes all potential participants want to quit smoking -Assumes primary barrier to quitting smoking is cost of nicotine replacement products	-Assess baseline levels of willingness to participate in a smoking cessation program -Identify and describe barriers to quitting smoking
<b>People will want to participate in our program because of their home's poor indoor air quality</b>	-Assumes participants understand indoor air quality can affect their health -Assumes participants believe their indoor air quality is currently affecting their health	-Assess local perceptions of factors that can affect respiratory health -Describe perceived severity of health outcomes associated with poor indoor air quality

## Step 5: Summarize and implement findings

### *What do these results mean for our program?*

At this step in the formative assessment process, it is time to integrate findings into your program in a meaningful way. Data must be properly analyzed and results incorporated into specific objectives or activities.

*Example: Formative Assessment Questions and Program Development*

<b>Question</b>	<b>Program Development</b>
<b>Do people believe that a health condition is a problem?</b>	-Address health outcomes identified by target population as of significant concern to them -Educate population about risk factors, preventive behaviors
<b>How do people want to address a health condition?</b>	-Use methods acceptable to target population -Identify new ways to improve health
<b>What services are currently available?</b>	-Identify resources available to programs and community -Educate population about available resources
<b>What do people already know about these services?</b>	-Address gaps in knowledge about purpose of programs -Increase uptake of available services
<b>How do people feel about these services?</b>	-Ensure programs are acceptable -Address potential sensitivities related to programs
<b>How do people learn about these services?</b>	-Use preferred and effective methods for reaching target population
<b>What do people think about our program?</b>	-Create culturally acceptable and meaningful programs

An important component of a formative assessment is setting goals for your program. Setting clear and concise goals for your program focuses efforts, maximizes resources, and increases the likelihood of success. A commonly used set of criteria for effective goal-setting is the SMART criteria. These criteria help you set goals that are Specific, Measurable, Attainable, Relevant, and Time-bound.

**Specific:** While setting broad goals may seem to ensure success, goals that are too broad lack meaning to participants and programs. Goals that are not specific also cannot be measured; specificity allows you to define success.

**Measurable:** Outcome measures should be identified and established for each goal. The same measures used to establish baselines should be used to measure outcomes so you can accurately make comparisons and evaluate progress.

**Attainable:** Understanding perceptions about the benefits and barriers to engaging in health behaviors can help you set goals that are realistic and achievable. If a goal is not realistic, participants and program staff alike will become frustrated with failure. For example, it is unrealistic to expect all participants to

immediately quit smoking without any relapses, but it is possible to achieve more attainable goals, such as initially cutting down on the number of cigarettes smoked per day as the first step in the process of quitting smoking entirely.

**Relevant:** Relevance to participants can be established in several ways. Goals can be personally meaningful to participants, such as when they capitalize on personal values (e.g., setting a goal to improve oral health in children that is based on values of family). Goals can also be relevant by addressing perceived health concerns (e.g., setting a goal to reduce road dust after repeated complaints from community members about the effect of traffic on air quality).

**Time-bound:** Programs and goals both need to have clear start and end dates. Project timelines, such as Gantt charts, help team members and participants understand the steps of program development, implementation, execution, and evaluation. Timelines may also be required for grant applications or as a part of your organization’s regular internal procedures.

*Example: SMART Goals*

<b>SMART</b>	<b>During the six months of our program, 10 heads of household will attend six training sessions about how to improve their indoor air quality by opening the vents installed in their home. Participating households will learn and be able to name a minimum of three negative health effects caused by smoking indoors; they will be encouraged to participate in a tobacco cessation program available to them free of charge. Upon completion of the program, carbon monoxide (CO) levels in the 10 participating households will decrease to &lt;5 ppm; participants will open ventilation installed in their household a minimum of twice daily, and all participating households (100%) will no longer allow the use or have evidence of tobacco products indoors.</b>
<b>Specific</b> Who? What?	10 heads of household.
<b>Measurable</b> How?	Attendance at training sessions; CO levels <5 ppm within participating households; vents opened twice daily (recorded on activity log); no observed tobacco products (observation).
<b>Attainable</b> Reasonable?	The community has interest and is invested in the proposed program due to many recent respiratory illnesses among children and elders. It is believed that the stated goals are attainable within the context.
<b>Relevant</b> Meaningful to participants?	The goals are personally meaningful to the participants; they want to see improvements in their indoor air quality to improve the health of the residents.
<b>Time-bound</b> When?	Attendance during the six months of our program; CO levels and behavior changes to be observed upon completion of the program.

## Summary

By taking the time to conduct a formative assessment, providers increase the effectiveness of their programs in a variety of ways. Understanding local perceptions helps create programs that are

acceptable to participants. Resources are identified and able to be more effectively used. Gaps in services can be addressed through effective program development and implementation.

## Attachment 1: Health Behavior Theories & Models

**Diffusion of innovation theory (DOI):** This theory focuses on the process by which innovations (novel products or ideas) are disseminated and implemented within a population. Users are described based on how early they are to adopt an idea or behavior. **Innovators** are those members of a population that are the first to adopt; this is usually a very small percentage of a group. They are followed by **early adopters**, the **early majority**, and the **late majority**. **Laggards** are those who make the change late, if ever.

**Health belief model (HBM):** This model predicts behavior based on the perception of four factors: **vulnerability** to a health outcome, **severity** of a health outcome, **barriers** to engaging in a behavior, and **benefits** to engaging in a behavior. Think of this in terms of four questions: How likely is it that that a health condition will happen to me (vulnerability)? How bad will it be to have that health condition (severity)? How hard is it to prevent that health condition from happening (barriers)? How will I benefit by taking protective actions or changing my behaviors (benefits)? More recent inceptions of the health belief model also incorporate self-efficacy (the belief that one is able to engage in a behavior) as a component.

**PRECEDE/PROCEED:** This planning model consists of two main components. PRECEDE stands for Predisposing, Reinforcing, and Enabling Constructs in Educationally ecological Diagnosis and Evaluation. PROCEED stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development.

PRECEDE is comprised of four phases of assessments:

- 1) Social Assessment
- 2) Epidemiological Assessment
- 3) Educational and Ecological Assessment
- 4) Administrative and Policy Assessment and Intervention Alignment

These are followed by the four phases of PROCEED, including:

- 5) Implementation
- 6) Process Evaluation
- 7) Impact Evaluation
- 8) Outcome Evaluation

This model is based on describing your desired outcome, identifying the factors affecting it, and designing an intervention to reach your goal outcome.

**Social cognitive theory (SCT):** This theory describes learning as the result of the environment, cognitive processes, and behavior; human behavior is motivated and regulated by “self-influence.” Self-influence

is the process through which individuals internally monitor and regulate their behaviors. Other components of SCT often used when designing programs include expectations, locus of control, reinforcement, collective efficacy, and emotional-coping response.

***Theory of reasoned action (TRA)***: This predicts behavioral intention rather than actual behavior (although intention correlates strongly with actions). Intentions are a result of attitudes and subjective norms. Attitudes are an individual's beliefs about a behavior; subjective norms are a person's perceptions about others' opinions and how the individual values (weighs) those opinions.

***Theory of planned behavior (TPB)***: An expansion of TRA, this theory incorporates perceived behavioral control (similar to self-efficacy) into its algorithm for behavioral intentions.

***Transtheoretical model (TTM)***: Also referred to as "stages of change." According to TTM, individuals move through different stages of readiness and action with regards to engaging in behaviors based on their knowledge and understanding of behaviors and outcomes, as well as the pros and cons associated with each. The original conception of TTM includes a temporal component for each stage (e.g., "Individuals are more than 6 months away from making a change").

## Attachment 2: Special Considerations

### Cultural issues

As of 2013, there are more than 500 federally recognized tribes located across the United States. Tribes vary widely in size, and most individuals who identify as Alaska Native/American Indian live in the southwestern and southern United States. These groups represent a myriad of distinct cultures.

Because a formative assessment is conducted in partnership with the target population, it provides useful information that can be helpful in addressing issues related to cultural differences. Examples of these include:

- *Roles:* Men may be responsible for packing and hauling water (making them the most reliable source of information on how much water is used per week), while women may be responsible for taking care of ill family members (making them the most reliable source of information on how often people get sick). Knowing whom to ask about certain things helps to ensure that you will receive the most accurate and precise information.
- *Sensitivity:* Individuals may be unwilling to openly discuss an illness out of fear that doing so will invite the condition upon themselves or their family. Understanding sensitivities related to different topics is essential to helping participants feel comfortable, as well as providing you with an accurate picture of local perceptions.

The more knowledgeable you are about specific cultural preferences and practices, the more likely you are to select an approach that makes people feel comfortable. You are also more likely to select methods that provide useful data; questions must be appropriately worded in order for answers to be relevant and accurate.

### Ethical concerns regarding research

The U.S. Department of Health and Human Services (HHS) defines research as a systematic investigation designed to develop or contribute to generalizable knowledge. ***Formative assessments for the purpose of informing specific program design and evaluation of programs for the purpose of improving service delivery with a targeted population are not considered research.*** Human subject research involves obtaining information about living individuals through intervention or interaction with them. Human subject research must be reviewed by the appropriate Institutional Review Boards (IRBs) prior to beginning.

In addition to review by any applicable IRBs, programs may also need to be reviewed by local entities like a tribal council or health board. Know the specific procedures in the area where you will be working to ensure that all of the appropriate parties are involved accordingly. Programs that are determined to be exempt from IRB review must still consider local review prior to implementation.

Many minority populations have had negative experiences with members of the scientific community. Being sensitive to and openly addressing these concerns can help alleviate them and make programs more acceptable. By incorporating local input into the development and implementation of programs, you can avoid many of these issues entirely.

For more information on whether activities are deemed research, refer to the human subject regulations decision charts are available online at: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>. These charts are a helpful reference; they are not meant to be definitive guides and cannot replace review by an IRB. Specific policies are detailed through the HHS Office for Human Research Protections.

## **Recordkeeping**

Early establishment of a standardized, systematic recordkeeping system alleviates future stress. Specific policies for recordkeeping vary by organization, and it is important to be aware of applicable policies.

Specific laws are in place regarding health information, as are established policies for the maintenance of federal records. Individuals working with federal records should be knowledgeable about any applicable rules and regulations to ensure compliance.

Personally identifiable information (PII) such as names or addresses may also be subject to additional policies related to privacy and storage. Typically, PII is maintained separately from data with a unique identifier linking the two. De-identified data is used for analysis.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 set standards for individuals' rights to understand and control how their health information is used. Any program that involves the use of health information like health records may be subject to HIPAA. Online training is available for staff to ensure they are knowledgeable about policies and procedures; regular training is often required to ensure programs are compliant with applicable rules and regulations. Check with your specific agency or organization to learn how you can obtain and maintain HIPAA training.



## Attachment 3: Recommended Readings

Ariely, D. (2009). Predictably irrational, revised and expanded edition: the hidden forces that shape our Decisions. Harper.

Burger, J., Gochfeld, M., & Pletnikoff, K. (2009). Collaboration versus communication: The Department of Energy's Amchitka Island and the Aleut Community. *Environmental Research*, 109, 503-510.

Cottrell, R.R., Girvan, J.T., & McKenzie, J.F. (2012). Principles and foundations of health promotion and education (5th ed.). Pearson Education: USA.

Glanz, K., Rimer, B.K., & Viswanath, K. (2008). Health behavior and health education: theory, research and practice. Jossey-Bass.

Guest, G.S., Namey, E.E., & Mitchell, M.L. (2012). Collecting qualitative data: a field manual for applied research. SAGE Publications, Incorporated.

Nicol, D.J., & Macfarlane-Dick, D. (2006). Formative assessment and self-regulated learning: a model and seven principles of good feedback practice, *Studies in Higher Education*, 31(2), 199-218.

Public Health Leadership Society (2002). Principles of the ethical practice of public health version 2.2. Available online at: [http://nnphi.org/uploads/media\\_items/ph-code-of-ethicsbooklet.original.pdf](http://nnphi.org/uploads/media_items/ph-code-of-ethicsbooklet.original.pdf)

Teufel-Shone, N.I., Siyuja, T., Watahomigie, H.J., & Irwin, S. (2006). Community-based participatory research: Conducting a formative assessment of factors that influence youth wellness in the Hualapai community. *American Journal of Public Health*, 96, 1623-128.

## Attachment 4: Helpful Websites

American Public Health Association. <http://www.apha.org>

Centers for Disease Control and Prevention: Health Literacy. <http://www.cdc.gov/healthliteracy/>

National Commission for Health Education Credentialing, Inc. <http://www.nchec.org/>

National Environmental Health Association. <http://www.neha.org>

Plain Language Action and Information Network (PLAIN). *Plain language: Improving communication from the federal government to the public.* <http://www.plainlanguage.gov/index.cfm>

U.S. Department of Commerce National Institute of Standards and Technology.  
<http://www.nist.gov/index.html>

U.S. Department of Health and Human Services. *Human subject regulations decision charts.*  
<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

U.S. Department of Health and Human Services. *Health information privacy: training materials.*  
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/training/>



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