IRB Review, HIPAA and Oral Health Surveys
Guidance and Resources for State and Territorial Dental Programs[1]
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Is your state or territory planning on conducting an oral health survey?

If yes, then you need to be aware that certain federal policies may impact both your planning and data collection processes; namely Protection of Human Subjects and the Health Insurance Portability and Accountability Act. These are complex policies that can be daunting; therefore, ASTDD developed this short synopsis that gives you general guidance and resources on IRB review and HIPAA in terms of oral health surveys. We hope that you find this information useful.

What is an IRB?

An IRB, Institutional Review Board, is the group or committee that is given the responsibility by an institution to review that institution's research projects involving human subjects. The primary purpose of an IRB review is to assure the protection of the safety, rights and welfare of the human subjects. Another commonly used name for an IRB is "Human Subjects Review Committee."

Federal, state and local laws require IRB review and approval for non-exempt government funded research involving human subjects. One of these laws is the Federal Policy for the Protection of Human Subjects, known as the Common Rule. The Common Rule vests authority within IRBs to approve, disapprove, or require modifications of all federally-funded human subjects research and many institutions apply the Common Rule principles to all human subjects research regardless of funding sources. In addition there are a few state and local laws authorizing state or local IRBs to review research involving human subjects, including research conducted or funded by state or local public health agencies.

For More Information:
Federal Policy for the Protection of Human Subjects
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/

If an activity is deemed non-research by an entity outlined in the Federal Common Rule, such as the agency's director or an IRB, IRB review and other human subject protections are not required. For the most part, public health practice is not research; so if an activity is deemed to be public health practice, it does not require full IRB review. This does not mean that persons involved in public health practice are not obliged to act ethically. The responsibility to protect human participants in public health practice is addressed through federal, state, and local administrative and regulatory oversite and protections.

Making the distinction between research and public health practice can be difficult because, in many ways, they are alike. They both entail the collection and assessment of individually identifiable health information from living individuals, they both involve actual or potential risks to participants, and they both may be justified as laudable activities that further the public good.

[1] Excerpted from: Hodge JG, Gostin LO. Public health practice vs. research. A report for public health practitioners including cases and guidance for making distinctions. Council of State and Territorial Epidemiologists, May 2004.
Available at: http://www.cste2.org/webpdfs/CSTEPHResRptHodgeFinal.5.24.04.pdf

What is research?

The Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."
Some of the essential characteristics of human subjects research include:

- Involves living individuals
- Involves, in part, identifiable private health information
- Involves research subjects who are selected and voluntarily participate, absent a waiver of informed consent; and
- Supported by principles of bioethics that focus on the interests of individuals while balancing the communal value of research.

What is public health practice?

In general, public health practice involves the application of proven methods to monitor the health status of the community, investigate unusual occurrences of disease, implement preventive control measures based on current understanding within public health sciences, and evaluate programs.

As with research, there are several essential characteristics of public health practice.

- Specific legal authorization for conducting the activity as public health practice
- Corresponding governmental duty to perform the activity to protect the public's health
- Direct performance oversight by a governmental public health authority
- May legitimately involve persons who did not specifically volunteer to participate or provide informed consent, and
- Is supported by principles of public health ethics that focus on populations while respecting the dignity and rights of individuals.

The Council of State and Territorial Epidemiologists (CSTE) defines public health practice as:

> *The collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community.*

Oral health surveys – research or public health practice?

One of the essential questions for state and territorial dental programs considering an oral health survey is whether open-mouth oral health surveys are research or public health practice.

CSTE has developed a set of assumptions and questions that public health practitioners can use to determine if an activity is research or public health practice. Following are key questions with answers specific for oral health surveys.

1. Will the activity involve the collection and analysis of identifiable health data?
   If not, then neither the Common Rule nor HIPAA apply and IRB approval is not necessary. Therefore, if an oral health survey is not collecting identifiable information, it probably does not need IRB approval.

2. Does your agency have general legal authority for the activity?
   In other words, is there legislation that gives your agency authority to "acquire any health data needed to monitor health conditions in the population"? The existence of general legal authorization supports a finding of public health practice, but does not conclusively lead to this end.

3. Is there any intent underlying the activity to test a hypothesis?
   If the purpose of the oral health survey is to test a hypothesis then it is research. Most oral health surveys, however, do not test hypotheses.

4. Will the participants benefit from the activity?
   For an activity to be considered public health practice, it should provide some benefit to the participants. In the case of oral health surveys, it can be argued that the screening and referral letter is a benefit to each participant.

5. Are the participants in the activity selected randomly?
   If an activity has a control group or randomly selects its participants to eliminate bias, the activity is likely to be considered research not public health practice. Since oral health surveys do not have control groups, you don't need to worry about that issue. To address the issue of random selection; most oral health surveys randomly select schools not individual participants. As long as you do not randomly select participants, an oral health survey could be considered public health practice not research.

To summarize, in most cases, oral health surveys can be considered public health practice rather than research. But who in your agency is the person that can actually make that decision? In most states, legal authority allows the agency director to make this determination. Many agency directors, however, are uncomfortable making the decision and ask the IRB to make the final determination.

Guidance: Oral health programs planning an oral health survey should always review the agency's policies regarding IRB review. Prior to implementation of an oral health survey, dental programs should consider obtaining one of the following:

1. A waiver from the agency director.
2. A waiver from the IRB. Submit a letter to the agency's IRB outlining the survey as public health practice; reiterate the fact that public health practice is outside the scope of the IRB, and ask the IRB to consider waiving the survey.
3. Approval from the IRB.

What is HIPAA?

HIPAA stands for the Health Insurance Portability and Accountability Act of 1996. HIPAA provides protection for the privacy of certain individually identifiable health data, referred to as protected health information or PHI. When Congress passed this legislation, they limited the health-information privacy regulations to a defined set of covered entities that include health plans, health-care clearinghouses and health care providers.

For More Information:
Centers for Disease Control and Prevention
HIPAA Privacy Rule and Public Health
http://www.cdc.gov/privacyrule/Guidance/Content.htm

National Institutes of Health
http://privacyruleandresearch.nih.gov/

Department of Health and Human Services, Office for Civil Rights
http://www.hhs.gov/ocr/privacy/

Are you a HIPAA covered entity?

When considering the impact of HIPAA on oral health surveillance, first determine if your agency is a covered entity. If the agency does not provide direct health services or administer a health plan such as Medicaid, it is not a covered entity and HIPAA does not apply. Even if you are a covered entity, HIPAA expressly permits protected health information to be shared for specified public health purposes. In addition, a public health agency that is a covered entity may become a hybrid entity by carving out its non-covered functions so that the Privacy Rule provisions apply only to its health-care component.

My agency is a covered entity – how will this impact our oral health survey?

If you are a covered entity, HIPAA could potentially impact how you collect and transmit oral health survey data. If your agency requires that you comply with HIPAA, there are several options to consider. The first, and probably the easiest, is to collect non-identifiable data. The two primary identifiers are name and date of birth. This is not an issue for most oral health surveys because name is not necessary and age is an acceptable substitute for date of birth. If you must collect identifiable data, another option is to protect confidentiality through a variety of means including privacy envelopes.

Guidance: Dental programs planning an oral health survey should determine if their agency is a covered entity and if so review their agency's HIPAA policies. To assure compliance with privacy laws, dental programs should consider collecting only non-identifiable data.

Where can I get additional information?

ASTDD can provide additional information. Please contact us if you have any questions.

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Additional resources

- Otto JL, Holodniy M, DeFraites RF. Public health practice is not research. Am J Public Health 2014; 104:596–602. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025700/
- The Centers for Disease Control and Prevention Policy *Distinguishing Public Health Research and Public Health Nonresearch*. Available at: https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf
- Johns Hopkins School of Public Health. Guidance: Determining Public Health Practice from Public Health Research. Available at: http://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/guidance-on-practice-vs-research-2016-2-23.doc