Overview of Human Subjects Research and the VDH Institutional Review Board (IRB) Process

"Understanding and Getting Through the Process"

VDH VIRGINIA DEPARTMENT OF HEALTH
Protecting You and Your Environment

Why Do We Have IRBs?

Nazi Military Experiments

To protect the rights and welfare of human subjects involved in research.

To educate the larger community about ethical issues in human subjects research.

To oversee compliance with federal and state regulatory requirements for human subjects research.

Nuremberg Doctor's Trial

What Needs to be Reviewed by the VDH IRB?

In general, any human subjects research that is conducted:

- by VDH
- by outside investigators in collaboration with VDH
- by outside investigators using VDH data

- However, not all studies require IRB review.

How Do I Decide What Needs to be Reviewed and What Type of Review?

There are five key decision steps:

- Is the project considered research?
- Does the project involve human subjects?
- Does the project qualify for exemption review?
- Does the project qualify for expedited review?
- May informed consent and/or its documentation be waived or altered?

Is the Project Considered Research?

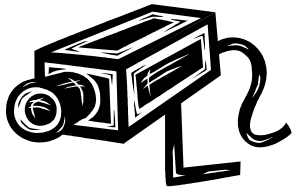
A systematic investigation designed to develop or contribute to generalizable knowledge

Is the Project Considered Research?

- Is the project surveillance involving only the usual data collection systems for public health?
- Is the project an evaluation to assess the success of a specific ongoing public health program?
- Is the project an investigation both to determine the cause and/or extent of a community health problem and to develop a control plan?

If you respond in the affirmative to ANY ONE of the above three questions, then the project is NOT considered research!

Is the Project Considered Research?



Surveillance

- Regular ongoing collection & analysis of health-related data solely to monitor the frequency of occurrence & distribution of disease or health condition in the population pursuant to the Code of Virginia is not considered research.

- Surveillance activity conducted in whole or in part to gather data & obtain knowledge from which to generalize to other populations and/or settings is considered research (e.g., determining why certain groups are at higher risk of disease)

Is the Project Considered Research?

Program Evaluation

- Assessing the success of a specific program in achieving its objectives as part of normal public health program operations in order to improve quality, effectiveness, and cost-effectiveness is not considered research.

- Assessing the success of a specific program in order to develop or contribute to generalized knowledge is considered research.

Is the Project Considered Research?

Investigation

- If the primary purpose is to investigate and respond to public health emergencies and/or to determine the cause and/or extent of community health problems (preventable diseases and epidemics pursuant to the Code of Virginia) and develop plans for its control, it is not considered research.

Is the Project Considered Research?

Fuzzy Gray Area

- Although consensus has not yet been reached on this issue, the following report on public health practice vs. research by the Council of State and Territorial Epidemiologists (CSTE) is a good source for guidance:

Council of State and Territorial Epidemiologists
Leaders in Applied Public Health Epidemiology

Public Health Practice vs. Research

A Report for Public Health Practitioners
Including Cases and Guidance for Making Distinctions

Is the Project Considered Research?

The Rule of Thumb

- Err on the side of caution! It can't hurt you to have a study reviewed. It can come back to bite you if you don't! An IRB may NOT retroactively review a study.

Does the Project Involve Human Subjects?

- Does the project involve obtaining private information about living individuals?
- Is the private information individually identifiable?
- Does the project involve intervention or interaction with living individuals for the purpose of obtaining data?

If you respond in the affirmative to ANY ONE of the above three questions, then the project DOES involve human subjects!

Does the Project Involve Human Subjects?

Private Information

- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

Does the Project Involve Human Subjects?

Individually Identifiable

- Private information is recorded in such a way that the identity of the subject may be ascertained by the investigator or may readily be inferred from the information obtained.

Does the Project Involve Human Subjects?

Intervention

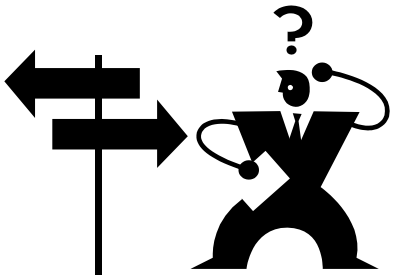
- Physical procedures by which data are collected, such as venipuncture, and manipulations of the subject or the subject's environment.

Interaction

- Communication or interpersonal contact with the subject, the subject's next of kin, or the subject's physician or hospital.

Determining the Type of IRB Review

If your project is considered human subjects research, then it must undergo either exemption, expedited or full board review.

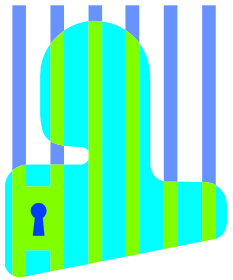


Does the Project Qualify for Exemption Review?

Some categories of human subjects research are considered exempt from review. However, the determination of exemption must be made by the IRB; not by the investigator or members of the research team.

Does the Project Qualify for Exemption Review?

- Does the project involve vulnerable populations?
  - Pregnant women
  - Children (persons who have not attained the legal age for consent to treatments or procedures involved in the research)
  - Prisoners
  - Mentally disabled persons



If you respond in the affirmative to ANY ONE of the above populations, then the project does NOT qualify for exemption review.

Does the Project Qualify for Exemption Review?

- Do ALL activities fit into one or more of the following?
  - Normal educational practices in established settings.
  - Educational tests, surveys, interviews, or observation of public behavior (unless identified AND sensitive).
  - Uses existing publicly available data OR existing data recorded without identifiers.

Continued…

Does the Project Qualify for Exemption Review?

- Is research on elected or appointed public officials or candidates for public office.
- Evaluates a public benefit service program.
- Assesses taste & food quality or consumer acceptance

If you responded in the affirmative to the above, then the project qualifies for exemption review.

Does the Project Qualify for Expedited Review?

- Has the project already been approved by another institution's or agency's IRB or does it involve only minor modifications to previously approved research?

If you responded in the affirmative to the above, then the project qualifies for expedited review.

Does the Project Qualify for Expedited Review?

- Do all activities involve no more than minimal risk?

Minimal risk: risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

If you responded in the affirmative to the above, then the project may qualify for expedited review.

Does the Project Qualify for Expedited Review?

- Do all activities fit into one or more of the following?
  - Collection of hair & nail clippings, deciduous teeth, or permanent teeth if care indicates a need for extraction.
  - Collection of excreta & external secretions.
  - Recording of data using noninvasive routine procedures.
  - Collection of blood samples by venipuncture.
  - Collection of both supra- and subgingival dental plaque & calculus.

Continued…

Does the Project Qualify for Expedited Review?

- Voice recordings made for research purposes.
- Moderate exercise by healthy volunteers.
- The study of existing data, documents, records, or pathological or diagnostic specimens
- Research on individual or group behavior or characteristics of individuals where the investigator does not manipulate the subjects' behavior & research does not involve stress to subjects.
- Research on drugs or devices for which an investigational new drug/device exemption is not required.

If you responded in the affirmative to the above, then the project qualifies for expedited review. If not, then it must undergo full board review!

The Review Criteria

- Adequacy of the description of the potential benefits and risks involved
  - The degree of risk and whether subjects are unnecessarily exposed to risks.
  - The necessity and utility of the research and whether the benefits outweigh the potential risks
- Adequacy of the research design/ methodology

Continued…

The Review Criteria

- Equity in criteria for selection of subjects
- Adequacy of protection of rights and welfare of participants:
  - Voluntary Participation
  - Informed Consent (written):
    - must be legally effective (assent should be sought for those not legally capable of providing consent)
    - involves full disclosure of nature of research and participation
    - involves adequate comprehension on the part of the subjects

Continued…

The Review Criteria

- Competence and qualifications of researcher
- Adequate provisions for monitoring data
- Adequate provisions for protecting privacy of subjects and maintaining confidentiality of data
- Additional safeguards for protecting vulnerable populations from coercion

Basic Elements of Informed Consent

- Statement of research
- Purpose
- Duration of participation
- Procedures (including anything experimental)
- Risks, benefits, and alternatives
- Confidentiality of records
- Availability and nature of compensation

Continued…

Basic Elements of Informed Consent

- Voluntary nature of participation
  - right to refuse or halt participation at any time and without penalty
- Whom to contact with questions about
  - the research
  - the research subjects' rights
  - in the event of a research related injury

Waivers of Informed Consent

- An IRB may approve procedures which do not include all elements of informed consent or waive informed consent if:
  - The research involves no greater than minimal risk.
  - The alteration or waiver does not adversely affect rights and welfare of subjects.
  - The research could not practicably be carried out without the alteration or waiver
  - When appropriate, subjects will be "debriefed" after participation

Waivers of Documentation of Informed Consent

- An IRB may waive the requirement for written documentation of informed consent if:
  - The principle risks are those associated with a breach of confidentiality concerning the subject's participation in the research; and the consent document is the only record linking the subject with the research OR
  - The research presents no more than minimal risk; and involves no procedures for which written consent is required when performed outside of a research setting.

How To Succeed?

Follow the directions!
Follow the directions!
Follow the directions!
Follow the directions!

Where do I find directions and forms?

http://www.vdh.virginia.gov/OFHS/irb.htm

The Exemption Review Process

- The Principal Investigator must submit:
  - Exemption review request form
  - Cover letter with explanation as to why the project should be regarded as exempt.
  - Study protocol and any materials (letters to subjects, questionnaires, etc.)
  - CV or resume

- Materials are reviewed by the Chair of the IRB and one additional IRB member.

The Exemption Review Process

- The Principal Investigator will be notified of a decision within 15 business days.

- If the IRB determines a project to be exempt, it does not need to undergo continuing review…all other human subjects research projects must undergo continuing review at an interval appropriate to the degree of risk, but not less than once per year.

The Expedited Review Process

- The Principal Investigator must submit:
  - Request for review form
  - Study protocol and any materials (letters to subjects, questionnaires, etc.) that will be supplied to study subjects
  - CV or resume
  - IRB approval documents (if study has been approved by another IRB)

- Materials are reviewed by the Chair of the IRB and one additional IRB member.

The Expedited Review Process

- The Principal Investigator will be notified of a decision within 15 business days.
- If approved, the study must undergo continuing review on an annual basis.

The Full Board Review Process

- The Principal Investigator must submit:
  - Request for review form
  - Study protocol and any materials (letters to subjects, questionnaires, etc.) that will be supplied to study subjects
  - CV or resume

- Materials are reviewed by the Chair of the IRB and all members of the IRB

The Full Board Review Process

- The Principal Investigator must attend an IRB meeting and present the research protocol and answer any questions.
  - VDH IRB meetings are held quarterly (January, April, July and October) – and will be held more frequently if needed (all requests must be reviewed within 45 days)
  - A quorum (majority of members) must be present at the meeting
  - Decisions will be made within 7 days of the meeting

The Full Board Review Process

- If approved, the study must undergo continuing review at an interval appropriate to the degree of risk, but not less than once per year.

Investigator Responsibilities

- Obtain legally effective informed consent unless waiver is approved by the IRB
- Obtain IRB approval prior to initiating research or making changes to approved research
- Comply with IRB findings and oversight
- Ensure research is conducted within period of IRB approval

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Investigator Responsibilities

- Report unanticipated problems (adverse events) to the IRB
- Be available to answer research related questions
- Retain all research related records for a period of at least three years after completion of the study.

For More Information about the VDH IRB

- Visit the VDH website at http://www.vdh.virginia.gov/OFHS/irb.htm

- Contact:

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