

WYOMING DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
PROTOCOL SUBMISSION REQUIREMENTS

Research which involves the participation of **human subjects** requires approval or exemption from the Institutional Review Board (IRB) prior to the initiation of the project. The Code of Federal Regulations defines **research** as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The regulations define **human subject** as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." These regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

The Code of Federal Regulations, Title 45 CFR § 46.101, enumerates several categories of research that the IRB *may* find to qualify for **expedited** review or be **exempt** from IRB review.

Exempt categories are: 1) research involving normal educational practices; 2) research using data from educational tests; 3) research involving survey or interview procedures; 4) research involving observation of public behavior; 5) research involving collection of publicly available data; and 6) research involving the study or evaluation of the Social Security Act or other public benefit programs. This is only an overview of each category and specific requirements for each category must be met before an exemption from IRB review is appropriate. Designated reviewers of the IRB will make the determination as to whether or not a project is exempt based on the information provided in the proposal.

Expedited review categories are: 1) clinical studies of drugs and medical devices only when certain conditions are met; 2) collection of blood samples by finger stick, heel stick, ear stick, venipuncture when certain conditions are met; 3) prospective collection of biological specimens for research purposes by noninvasive means; 4) collection of data through noninvasive procedures employed in clinical practice (excluding x-rays or microwaves); 5) research involving data, documents, records, or specimens that have been collected for nonresearch purposes; 6) collection of data from voice, video, digital, or image records made for research purposes; 7) research on individual or group characteristics or behavior; 8) continuing review of research previously approved by the IRB for long-term follow-up of subjects and data analysis; 9) continuing review of research previously approved by the IRB where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified.

- Again, designated reviewers of the IRB will make the determination as to whether or not a project qualifies and can be approved through the expedited review procedure based on the information provided in the proposal.
- All projects involving human subjects that do not qualify as exempt or for expedited review will be reviewed by the full Board.
- All projects that propose to involve minors as research subjects (ages 18 and under), whether or not the research might otherwise meet the requirements for exemption or expedited review, will be reviewed by the full Board.
- Investigators proposing research projects that require full board review will be invited to attend

the IRB meeting at which the proposal will be reviewed

Proposals may be submitted at any time, but must be received by the 15th of the month for review at the end of the month, regular meetings. Researchers are encouraged to submit proposals electronically as attachments to e-mails to Karl Musgrave at karl.musgrave@health.wyo.gov or Richard Harris at richard.harris@health.wyo.gov. Alternately, proposals may be submitted in hard copy typed on letter size white paper (c/o Karl Musgrave, Preventive Health and Safety Division, 6101 Yellowstone Road, Suite 510, Cheyenne, WY 82002). Supporting materials (letters, survey instruments, etc.) not available in an electronic format may be provided in hard copy format to accompany an electronic proposal submission.

Wyoming Public Health Department Institutional Review Board requires that submissions of all protocols meet the Code of Federal Regulation Title 45 CFR. The following items must be submitted to meet those regulations:

1. Protocol

The protocol should address the elements listed below. If a protocol from another agency or institution is used the protocol can include an addendum for missing elements.

2. Protocol summary

Please submit a brief summary for each of the requested items as it applies to your protocol. Limit the protocol summary to a total of three pages and use the protocol summary template if desired.

3. Consent form

4. Instruments

Any data collection surveys, questionnaires or instruments must be submitted.

5. HIPAA Compliance Form (if protocol involves protected health information)