

Wyoming Department of Health

Institutional Review Board

Policy and Procedures

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POLICY AND PROCEDURES

I. Policy Scope

All research activities at the Wyoming Department of Health must have approval by the Investigational Review Board (IRB) prior to implementation. Specifically, all research will be conducted within the parameters of the Code of Federal Regulations and its sections 45 CFR 46 and 38 CFR 15, and, where applicable, 21 CFR 50 and 56.

1. Any project meeting one or more of the following criteria should be submitted to the IRB to determine if review is needed:
 - a. Studies involving human subjects research activities that originate from a program within the WDH or are funded using monies generated through WDH programs.
 - b. Involvement of agency employees or interns, or listing a WDH employee or intern as the Principle Investigator or as a collaborating investigator on the study.
 - c. Activities performed under the direction of or contract with a program or division of the Wyoming Department of Health, which involve any of the following:
 - i. the collection of information or biological material through direct contact with an individual
 - ii. use of existing WDH data on file or archived biological material from citizens of the state of Wyoming.
 - iii. use of surveys that involve the collection of protected health information or will solicit information from special groups (including but not limited to; children, pregnant women, prisoners).
2. Research protocols that require review by an institutional review board and have been reviewed and approved by another IRB still are required to be reviewed by WDH IRB and approval if:
 - a. WDH employees or interns are listed as collaborating investigators on the study
 - b. WDH data on file or archived biological material is to be accessed in the research
 - c. Data collected through the research will be used by a WDH program
 - d. Funding for the research was provided or facilitated by WDH
3. Research projects being performed by interns or employees of the agency to fulfill the requirements of educational activities, including university or college degrees or course of study projects, must be sponsored by the individual's immediate supervisor and the corresponding division administrator if the investigator represents themselves as an employee of the agency and the project will collect information either through direct contact of human subjects or use of existing WDH data on file or archived biological material.

II. Purpose

To ensure that research studies at Wyoming Department of Health are conducted in compliance with all Federal; State law, and agency regulations and ethical standards regarding human research. The IRB shall review all research projects for:

1. Scientific integrity
2. Risk/benefit analysis
3. Safety of human subjects
4. Ethical treatment of research participants

5. Consent and assent document quality
6. Justice and equity in selection of research subjects
7. Investigator and research staff training

III. Reporting Agencies

The Office of Human Research Protection (OHRP) under the direction of Health and Human Services (DHHS) oversees the activities of the WDH - IRB. DHHS - OHRP sets rules and guidelines, and approves all Investigational Review Board (IRB) registrations and Federal Wide Assurances for the protection of human subjects in research. The Wyoming Department of Health IRB reports to this agency as an oversight agency from DHHS.

IV. Definitions

- **Adverse Events (AE'S):** These include side effects to a subject that are both serious and unexpected and clearly related or possibly related to the research.
- **Amendments:** Amendments are considered to be any change to the currently approved protocol and consent process.
- **Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- **Business Associate Agreement:** A contract or Memorandum of Understanding that sets forth the terms and conditions pursuant to which WDH as the Covered Entity will allow the use and disclosure of a limited data set to the data recipient such as a contractor or co-investigator not affiliated with WDH.
- **Children:** Persons who have not reached the legal age for consent to treatments or procedures involved in the research. Emancipated minors may be included in a specific research project on a case-by-case approach as reviewed and approved by the IRB.
- **Code of Federal Regulations (CFR):** The Department of Health and Human Services National Institute of Health office for Protection from Research Risks set of common rules for research.
- **Consent Documents:** Documents presented to a subject or parent/guardian prior to the beginning of a study in order to obtain informed consent.
 - Adult Informed Consent: This is required when subjects are 18 years and older. This should be written to the subject using appropriate language ("You"). Adult Informed Consent may be signed by the research participant or by his/her guardian.
 - Parental Permission Document: This is required when subjects are 17 years and younger. This should be written to the parent/guardian using appropriate language ("Your child").
 - Assent Document: This is required for children enrolled in studies that are 7-17 years of age. If a parent signs consent but the child withholds assent for research procedures, the procedure may not be utilized.
- **Emancipated Minor:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities, such as self-support, marriage, or procreation. State statute § 35-4-131 specifically addresses consent of persons under 19 to treatment for sexually transmitted diseases.
- **Emergency use:** the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval (21 CFR 56.102(d)). The

emergency use provision is an exemption from prior review and approval by the IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR 56.102(d) exist, allows for one emergency use of a test article without prospective IRB review. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

- **Guardian:** An individual who is authorized by law to consent on behalf of a child or person adjudicated as lacking legal competence.
- **High Risk:** If, in the opinion of the Primary Reviewer, there is an appreciable increased likelihood of mortality or morbidity from the study and the offsetting benefits are benefits to others rather than to the individual(s) participating in the research. All board members will review the complete protocol of all high-risk studies.
- **Human Subjects 45CFR46.102(f):** A living individual about whom an investigator conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information: Name, SSN, Medical Record Number, Date of Birth, Zip Codes, Address, Telephone #, Cultural Beliefs (identification of a person may occur only in some combination of this information).
- **Individual Authorization:** According to the HIPAA Privacy Rule covered entities can use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself.
- **Informed Consent:** The voluntary choice of an individual to participate in research based on an accurate and complete disclosure of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.
- **Investigator:** An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject, or in the event of an investigation conducted by a team of individuals) is the responsible leader of the team.
- **Life-threatening:** disease or condition where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
- **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. These can include but are not limited to studies that involve survey, questionnaire, interview, medical records review, observation of behaviors, etc.
- **Moderate Risk:** Research involving greater risk of harm than those ordinarily encountered in daily life or during the performance of routine physical or psychological evaluations or tests but presenting the prospect of direct benefit to the individual subjects, or the research presents no prospect of benefit to the subject but is likely to yield knowledge about his/her disorder or condition.
- **New Study:** A new study is one that is being considered for initial review and approval.
- **Parent:** a biological or adoptive parent of a child.

- **Permission:** Agreement of parent(s) or guardian to the participation of their child or ward in research.
- **Protected Classes:** Categories of people for whom there are special regulations and protections. The protected classes are: Prisoners, Fetuses, Pregnant Women, and children. Special consideration is also shown for cognitively impaired persons, mentally ill, elderly, minorities, students, employees, and volunteers.
- **Protected Health Information (PHI):** Individually identifiable health information that is or has been collected or maintained by WDH or an agent acting under contract or on behalf of WDH, including information that is collected for research purposes only, and can be linked back to the individual participant. Once this has occurred, use or disclosure of such information must follow federal privacy guidelines.
- **Protocol:** This is the study plan provided by the Principle Investigator (PI).
- **Protocol Summary:** This document is completed by the PI and includes a summary of the protocol or can be the study plan for the entire study. Protocol summaries are required for all studies submitted to the IRB.
- **Research:** An activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.
- **Risk:** The probability and magnitude of harm or discomfort anticipated in the research.
- **Severely debilitating:** disease or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand, or foot, loss of hearing, paralysis, or stroke.
- **Social/Behavioral Research 63 FR 606304 (Relevant Categories for Expedited IRB Review):**
 1. Research on individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identify (such as can be associated with social behavior), language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus groups, program evaluation, human actors evaluation, or quality assurance methodologies.
 2. Studies Involving Deception: These are practices where the investigator cannot inform the research subject of all the details of the research protocol without compromising the outcomes of the research.
- **Sponsor:** a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than the individual (e.g. a corporation or agency) who uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor.
- **Waiver of Authorization:** Approval from the IRB to collect and disclose protected health information associated with a research study without authorization from the linked individual. To approve a waiver of authorization under the HIPAA Privacy Rule the investigators must demonstrate that the study particulars meet the following criteria:
 1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - (a) an adequate plan to protect the identifiers from improper use and disclosure;

- (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and,
 - (c) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.
2. The research could not practicably be conducted without the waiver or alteration;
 3. The research could not practicably be conducted without access to and use of the protected health information.

V. Committee Policies

A. Committee Formation

1. The IRB is a committee of the Wyoming Department of Health. New IRB members are appointed by majority vote of the existing board membership to ensure a board composition that meets regulatory mandates. All members are registered with the Office of Human Research Protections as official members of the IRB.
2. The IRB shall be registered with the Office of Human Research Protections Division of Health and Human Services with an official IRB number. Appropriate Federal Wide Assurances shall be current and in good standing.
3. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
4. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas and shall not consist entirely of members of one profession.
5. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. This non-scientific member may be a representative with legal expertise.
6. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

7. The IRB may not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
8. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.
9. A quorum is at least a majority of the members of the IRB, including at least one member whose primary concerns are in nonscientific areas. In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting.
10. The Wyoming Department of Health shall prepare and maintain adequate documentation of IRB activities, including the following:
 - a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
 - b. Minutes of IRB meetings which shall be sufficient to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
 - c. Records of continuing review activities.
 - d. Copies of all correspondence between the IRB and investigators.
 - e. A list of IRB members in the same detail as described in CFR46.103(b)(3),
 - f. Written procedures for the IRB in the same detail as described in CFR 46.103(b)(4) and 46.103(b)(5).
 - g. Statements of significant new findings provided to subjects, as required by CFR 46.116(b)(5).
 - h. The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research.

B. Protocol Review Processes-Submission of Protocols for Review

1. All researchers shall use the approved format of the Investigational Review Board in order to apply for approval of research. As an aid in determining whether or not an activity is research and what type of review can be done by the WDH-IRB see Appendix VII. Human Subject Regulations Decision Charts. These charts are provided by OHRP.
2. The submission must include the following:
 - a. Protocol Summary and Consent Forms (See Section O. Protocol Summary Guidelines and Appendix IV))
 - b. HIPAA Compliance Form (Appendix V)
 - c. Survey instruments

- d. Additional forms depending on protocol specifics
 - i. Request for Waiver of Consent, Authorization, and/or Documentation of Consent (Appendix VI)
 - ii. Application For Use Of Existing Data Or Biological Materials (Appendix I)
 - iii. The submission must be complete and given to the Chair of the IRB or his designee at least two weeks prior to the meeting of the IRB. Submissions that are not complete will be given back to the investigator for completion.
3. The Chair of the IRB or his designee shall review all applications for quality and completeness and determine whether the protocol may be exempt from full board review, an expedited review, is a high-risk study (which needs a higher level of review outside of the department, such as review by a federal agency), or may go to the IRB as a routine submission for review at a regular meeting or via e-mail.
4. Principle Investigators will be notified of the meeting time and location for the IRB review of their submissions and encouraged to attend the meeting to facilitate review through responding to questions and clarification of protocol components. If an e-mail review is done to facilitate quick review of a protocol the investigator will be notified via e-mail of all comments and questions and be given the opportunity to offer comment.
5. Reviewers for each protocol will examine the research proposal for scientific integrity, risk/benefit analysis, and safety of human subjects, ethical treatment of research participants, and justice and equity in selection of research subjects.
6. The IRB shall have authority to approve, require modification (to secure approval), or disapprove all research activities covered by this policy.
7. The IRB shall require that information given to subjects as part of informed consent is in accordance with CFR 46.116.
8. Final determination of approval will be made at a meeting of the IRB or via e-mail discussion if extenuating circumstance makes a face-to-face meeting impracticable within a reasonable time. Discussion will center on whether the protocol should be approved, amended, or tabled.
9. The IRB shall notify the investigators of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
10. Once approved the chair or his/her designee will issue a letter of approval to the principle investigator. If the board requires amendments, the chair will issue a conditional approval letter outlining a request for modifications, clarifications or additional information necessary before a full approval can be issued. Once the chair or his/her designee determines that these requests have been met a letter of full approval is issued.

C. Criteria for Research Exempt from Full Board Review

Unless otherwise required by WDH Director, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from full board review. Protocols should be submitted to the WDH IRB Chair or his/her designee for determination of qualification for this exemption.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices including:
 - a. Research on regular and special education instructional strategies
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects
 - b. Any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not already disallowed under paragraph 2 (b) of this section, if:
 - a. The human subjects are elected or appointed public officials or candidates for public office
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are designed to study, evaluate, or otherwise examine:
 - a. Public benefit or service programs
 - b. Procedures for obtaining benefits or services under those programs
 - c. Possible changes in or alternatives to those programs or procedures
 - d. Possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies

- a. If wholesome foods without additives are consumed
 - b. If a food is consumed that contains a food ingredient at or below the level for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.
 8. The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed and all other requirements above had been met.

D. Criteria for Expedited Review

1. The IRB may rule that a proposal is of minimal risk and qualifies for an expedited review if research involves no more than minimal risk and the only involvement of human subjects is in one or more of the federally specified categories described in item C5 of this section.
2. Review of an expedited protocol shall be completed by one legal and one scientific member of the IRB. However, if the reviewers desire for the protocol to be reviewed by the full board it is no longer eligible for the expedited review process.
3. The reviewers are to receive a copy of the consent document and a summary of the protocol. These documents are to be completed in sufficient detail for the reviewer to determine the appropriateness of the study. In addition, the complete documentation should be available to all board members for their review, both before and at the meeting.
4. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.
5. Research activities that involve no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories may be considered for expedited review. The activities listed should not be deemed to be of minimal risk simply because they are included in this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- a. Clinical studies of drugs and medical devices only when condition (i) or (ii) is met.
 - (i) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (ii) Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (i) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (ii) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- c. Prospective collection of biological specimens for research purposes by noninvasive means. Such as: Hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva, etc.
- d. Collection of data through noninvasive procedures, not involving general anesthesia or sedation, routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- f. Collection of data from voice, video, digital, or image recordings made for research purposes.
- g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- h. Continuing review of research previously approved by the convened IRB as follows:
 - (i) Where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects
 - (ii) Where the remaining research activities are limited to data analysis.
 - (iii) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through

eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

E. Criteria for Tabling Studies

1. The risks, benefits, or both cannot be determined.
2. The protocol needs substantial change to the research design in order to improve the risks, benefits, or both.
3. The informed consent needs substantial changes.
4. The selection of subjects is not equitable.
5. Based on IRB consensus the potential for undue coercion exists.

F. Criteria for Disapproval of Studies

1. The project violates laws or regulations established by the Federal Government, the State of Wyoming, or the Wyoming Department of Health
2. If, in the judgment of the IRB, the risk(s) created to the subjects outweigh the benefits to be obtained.
3. If, in the process of conducting research, unnecessary risks are imposed.
4. The selection of subjects for human research is not equitable.
5. Informed consent by experimental subject is not obtained and appropriately documented unless specifically waived by the IRB.
6. The IRB judges that payment or other offered inducements are likely to influence subjects unduly.
7. Recruitment of subjects involves coercion.
8. The research is poorly or improperly designed and will not produce useful information.

G. Continuing Review of Studies

1. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but no less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Criteria for continuing review shall ensure:
 - a. Risks to subjects are minimized.
 - b. Risks to subjects are reasonable in relation to anticipated benefits.
 - c. Selection of subjects is equitable.
 - d. Informed consent is adequate and appropriately documented.
 - e. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
 - f. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - g. Appropriate safeguards have been included to protect vulnerable subjects.
 - h. A written progress report from the clinical investigator which includes:
 - (i) Number of subjects entered into the research study

- (ii) A summary description of subject experiences (benefits, adverse reactions)
- (iii) Number of withdrawals from research
- (iv) Reasons for withdrawals
- (v) The research results obtained thus far
- (vi) A current risk-benefit assessment based on study results
- (vii) Any new information since the last IRB review
- (viii) A copy of the consent document currently in use
- (ix) Statement if information contained in the consent document is still accurate and complete
- (x) Any requests for protocol changes, with an application for amendment.

H. IRB Decisional Guidelines

1. The IRB is to ensure that the investigator minimizes risks to subjects by evaluating protocols for the following:
 - a. Use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
 - b. Whenever appropriate, by using procedures already performed (e.g. standard or routine clinical procedures), on the subjects for diagnosis or treatment purposes.
2. Risks to subjects are to be reasonable in relation to anticipated benefits to the subjects, and the importance of the knowledge that may reasonably be expected to result.
 - a. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive if not participating in research).
 - b. The IRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is to be just and equitable.
 - a. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
 - b. The IRB shall be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, and minority/under-represented or economically or educationally disadvantaged persons.
 - c. Vulnerable populations should be provided necessary protections while not being unduly excluded from the study design.
4. The IRB review shall also ensure the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects and that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data as indicated in the Health Insurance Portability and Accountability Act.
5. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or

economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these persons.

6. Informed consent will be sought from each prospective subject or the subject's legally authorized representative prior to the subject's involvement in any research, unless a waiver of consent has been approved.
7. The IRB may approve a consent and authorization procedure which does not include, or which alters, some or all of the elements of informed consent set forth in Section I Informed Consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
 - a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - i. Public benefit or service programs
 - ii. Procedures for obtaining benefits or services under those programs
 - iii. Possible changes in or alternatives to those programs or procedures
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs
 - b. The research could not practicably be carried out without the waiver or alteration.
8. The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section (I. Informed Consent), or waive the requirements to obtain informed consent provided the IRB finds and documents that:
 - a. The research involves no more than minimal risks to subjects
 - b. No protected health information is disclosed or collected from participants.
 - c. Data collected can not be linked back to a single individual
 - d. The waiver or alteration will not adversely affect the rights and welfare of subjects
 - e. The research could not practicably be carried out without the waiver or alteration
 - f. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
9. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to the subjects.
 - a. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action.
 - b. Suspension shall be reported promptly to the investigator, agency director, the division administrator and the immediate supervisor of the principle investigator.

I. Informed Consent

1. Informed consent will be appropriately documented by the use of a written consent form approved by the IRB and signed by the subject or subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form shall be one of the following:

- a. A written consent document that embodies the elements of informed consent required by CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed
 - b. A short form written consent document stating that the elements of informed consent required by CFR 46.116 have been presented orally to the subjects or the subject's legally authorized representative. When this method is used, there shall be two witnesses to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
2. Waiver of Consent may be requested in writing using the Request for Waiver of Consent, Authorization, and/or Documentation of Consent Form. The IRB may waive the requirement to obtain a signed informed consent document for some or all of the participants if the study meets one of the following conditions:
 - a. The only record linking the participant to the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Under this condition, each participant is read an informed consent statement witnessed by two study team members. The IRB must review and approve the oral consent document.
 - b. The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context.
 - c. The research is minimal risk and involves either; i) no collection of protected health information, or ii) no collection of individual identifiers which could link PHI to an individual participant.
 - d. In cases in which the consent documentation requirement is waived, the IRB may require the investigator to provide the subjects with a written statement regarding the research.
3. The informed consent document shall include the following information:
 - a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - b. A description of any reasonably foreseeable risks or discomforts to the subject;
 - c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
 - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available

- if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g. An explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
3. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - a. A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - c. Any additional costs to the subject that may result from participation in the research;
 - d. The consequences of a subject's decision to withdraw from research and procedure for orderly termination of participation by the subject;
 - e. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
 - f. The approximate number of subjects involved in the study.
 4. Passive consent, which includes the concept of offering the opportunity for a participant to "opt-out" of the research by contacting the PI, should not be used unless traditional written informed consent can not be obtained and participation would not be possible otherwise.
 5. Investigators may seek consent only under circumstances that provide the prospective subject or his/her representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence.
 6. The information must be written in language that is understandable to the subject or representative (at no higher than an eighth grade reading level or as appropriate for the targeted participants).
 7. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appear to release the investigator, sponsor, institution, or agents from liability for negligence.
 8. Deception: If in a behavioral research protocol the practice of deception is used as a necessary component of the research protocol the Informed Consent must include the following language:

“You should be aware that, in order to complete this study, the investigator cannot inform you of all its details. For this reason, certain details have been left out of the description of the study. However, the investigator will be happy to explain these details to you at the end of your participation (end of the study). In addition, you are free to choose not to participate if you do not like this use of deception, or for any other reason, and your refusal will not be held against you in any way”.

J. Authorization of Disclosure of PHI

1. Authorization of disclosure of PHI will be appropriately documented by incorporation of written authorization into the informed consent document as approved by the IRB and signed by the subject or subject’s legally authorized representative. A copy shall be given to the person signing the form.
2. The Investigator may submit a Request for Waiver of Consent, Authorization, and/or Documentation of Consent (Appendix VI) and the IRB may approve a waiver or alteration in the authorization procedure provided that the following conditions are met:
 - a. The research could not practicably be conducted without access to the protected health information.
 - b. Privacy risks to individuals whose protected health information is to be used are reasonable in relation to the anticipated benefits (if any) and the importance of the knowledge expected from the research.
 - c. There is a detailed plan to protect the identifiers from improper use and disclosure.
 - d. There is a detailed plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
 - e. Investigators verify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research.
 - f. Pursuant to 45 CFR 164.528 If a protocol is granted a “Waiver of Consent and/or Authorization” by the WDH, IRB, the PI must be prepared to provide the following information for any PHI disclosed outside WDH should a disclosure occur:
 - i. The date of the disclosure
 - ii. The name, title, and contact number of the WDH workforce member making the disclosure
 - iii. The name of the entity or person who received the protected patient information, and, if known, the address of such entity or person
 - iv. A brief description of the protected patient information disclosed
 - v. A brief statement of the purpose of the disclosure that reasonably describes the basis for the disclosure

K. Protected Classes

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The Department of Health and Human Services regulations set forth specific provisions on research involving fetuses, pregnant women, and human in vitro fertilizations, prisoners, and children. In general, these special regulations allow IRB’s to approve research that is of

minimal risk or that will benefit the subjects directly. Investigations involving these subjects that presents significantly greater than minimal risk without direct benefit to them must be reviewed and approved by the Secretary of Health and Human Services, in consultation with appropriate experts.

1. Pregnant Women and Fetuses

Research involving the human fetus raises special concerns for IRB reviewers. The fetus has a unique and inextricable relationship to the mother. It cannot consent to be a research subject. The fetus may also be an indirect subject of research when women who may be pregnant participate. The Wyoming Department of Health will not approve research specific to the human fetus. Research in which the welfare of a fetus in utero must be considered may involve the fetus either directly or indirectly. The research may be directed toward the pregnant woman (in which case the fetus is indirectly involved), the fetus (in which case it is directly involved) or both. Where it is directed towards both the pregnant woman and fetus in utero, the regulations pertaining to both subjects apply.

- a. Special regulatory requirements govern the participation of pregnant women in research.
 - i. Research involving women who are or may become pregnant receives special attention because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus.
 - ii. In the case of a pregnant woman, IRB review must determine when the informed consent of the father to the research is required.
 - iii. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent and because of the need to prevent harm or injury to future members of society.
- b. Studies in which pregnancy is coincidental to subject selection:
 - i. Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. DHHS regulations require that, when appropriate, subjects be provided a "statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable" as part of the informed consent process.
 - ii. IRB review shall include determination of whether the mother's participation would pose any risk to the fetus or nursing infant.
 - iii. In some studies, IRB review may need to ensure that nonpregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research.
 - iv. As is appropriate, subjects should be advised to notify the investigator immediately should they become pregnant.
 - v. In some instances there may be potential risk sufficient to justify requiring that pregnant women either be specifically excluded from the research or studied separately.
- c. Studies directed primarily toward the mother's health.
 - i. Many women enter pregnancy with health problems or develop new ones during pregnancy. Some problems are affected positively or negatively by pregnancy; others are unaffected. In research undertaken to meet the health problems of a

pregnant woman, her needs generally take precedence over those of the fetus (45CFR 46.207), except, perhaps, where the health benefit to the woman is minimal and risk to the fetus is high.

If, for example, an experimental drug were considered necessary to improve a pregnant woman's condition, her consent alone would be sufficient to authorize its administration - even though it might have unknown or greater than minimal risk for the fetus.

ii. IRB review will attempt to ensure that the risk to the fetus is minimized, consistent with achieving the research objective.

d. Studies directed toward pregnancy:

i. In studies conducted to address the normal and abnormal processes of pregnancy, labor, and delivery the primary requirement for approval is determination that the risk to the fetus is "minimal."

ii. When IRB review cannot conclude that fetal risk is minimal, a conditional approval may be granted subject to the review and approval by the secretary of the Department of Health and Human Services.

iii. The primary consideration in review of studies in this category is whether the risks to the subjects are so outweighed by the sum of the benefit to the subjects and the importance of the knowledge to be gained as to warrant modification or waiver. A further consideration is whether the benefits of the research can be gained without the modification or waiver.

2. Children

a. The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children (45 CFR Part 46, Subpart D). The IRB must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the child-subject or to society as a whole. In calculating the degree of risk and benefit, the IRB should weigh the circumstance of the subjects under study, the magnitude of risks they may accrue from the research procedures, and the potential benefits the research may provide to the subjects or class of subjects.

b. The federal regulations require IRB's to classify research involving children into one of four categories and to document their discussion of the risks and benefits of the research study. The four categories of research involving children that may be approved by the IRB, based on degree of risk and benefit to individual subjects, are as follows:

i. Research not involving greater than minimal risk (45 CFR 46.404).

ii. Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subjects. Research in this category is approvable provided: (a) the risk is justified by the anticipatory benefit to the subject; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach (45 CFR 46.405).

iii. Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research in this category is approvable

provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subjects disorder or condition.

- iv. Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
 - c. In all cases, the IRB must determine that adequate provisions have been made for soliciting the assent of children and the permission of their parents or legal guardians. (45 CFR 46.408).
 - d. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the adolescents who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law.
 - e. Children who are wards of the State may be included in research if the research is related to their status as wards; or conducted in a setting where the majority of children involved as subjects are not wards. If research is approved for a child who is a ward, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with research, the investigator(s), or the guardian organization.
3. Prisoners
- a. If a protocol includes the use of prisoners as subjects, both the general DHHS regulations governing research with human subjects and the special ones dealing specifically with prisoners apply, including:
 - i. The research under review represents one of the categories of research permissible under §46.306(a)(2) as listed below in this section.
 - ii. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired
 - iii. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - iv. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless

- the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project
- v. The information is presented in language which is understandable to the subject population
 - vi. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole
 - vii. Each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole
 - viii. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
- b. Only certain kinds of research conducted or supported by DHHS as permissible under §46.306(a)(2) may involve prisoners as subjects:
 - i. Studies (involving no more than minimal risk or inconvenience) of the possible causes, effects, and processes of incarceration and criminal behavior
 - ii. Studies (involving no more than minimal risk or inconvenience) of prisons as institutional structures or of prisoners as incarcerated persons
 - iii. Research on particular conditions affecting prisoners as a class (providing the Secretary, HHS, has consulted with appropriate experts and published her/his intent to support such research in the *Federal Register*)
 - iv. Research involving a therapy is likely to benefit the prisoner subject (and if therapeutic research also involves nontherapeutic research with a control group, the Secretary, HHS, must also consult with appropriate experts and publish her/his intent to support the research in the *Federal Register*.)
 - c. The Federal Bureau of Prisons places special restrictions on research that takes place in the Bureau of Prisons. Those regulations are published at 28 CFR part 512. The restrictions apply to any research involving inmates in the custody of the Attorney General, and assigned to the Bureau of Prisons, regardless of the institution in which the inmate is incarcerated (e.g., even if the inmate is resident in a state institution). The policy on medical experimentation and pharmaceutical testing generally prohibits biomedical research and drug testing on its inmates, although individual prisoners in need of medical treatment and who qualify for experimental therapy may participate in DHHS - approved clinical trails “when recommended by the responsible physician and approved by the (Federal Bureau of Prisons) Medical Director.

5. Cognitively Impaired Persons

IRB review associated with studies involving cognitively impaired individuals will address the special issues of this group including the following.

- a. Unlike research involving children, prisoners, and fetuses, however, no additional DHHS regulations specifically govern research involving persons who are cognitively impaired.
- b. The predominant ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or who are substance abusers is that their

disorder may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation.

- c. Many individuals with disabilities affecting their reasoning powers may be residents of institutions responsible for their total care and treatment. The impact of institutionalization may further compromise their ability to exercise free choice. It is important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics.
- d. As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Mental disability alone should not disqualify a person from consenting to participation in research; rather, there should be specific evidence of individual's incapacity to understand and to make a choice before they are deemed unable to consent.
- e. Persons formally adjudged incompetent must have a court appointed guardian who must be consulted on their behalf. Officials of the Wyoming Department of Health may not make substitutionary judgments. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

5. Elderly/Aged Persons

- a. As the American population ages, research on the aging process and conditions and diseases that disproportionately affect the elderly has become increasingly important.
- b. The participation of older subjects in research poses several issues; primary among them is the question of whether and when the elderly need special protections.
 - i. The IRB must maintain its balance between the need for protection and the need to provide respect for persons.
 - ii. There are no specific regulations governing research with elderly subjects.
 - iii. There are two circumstances in which the elderly may need protection: cognitive impairment and institutionalization. Under those conditions the same considerations are applicable as with any other, nonelderly subject in the same circumstance.

6. Minorities

- a. The participation in research by members of racial and ethnic minority groups raises concerns about appropriate levels of inclusion and generalizability of study results.
- b. The involvement of minorities raises concerns about the selection of subjects, the possibility of special vulnerability on the part of some prospective subjects, and about consent and the relative strengths or weaknesses of vulnerable groups in the consent process.
- c. The inclusion of minorities in research is important, both to ensure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden. Most diseases affect all population groups, minority and nonminority alike. For generalizability purposes, investigators must include the widest possible range of population groups. Research designs that include diverse study populations are, therefore, highly desirable, the IRB shall require investigators

to justify protocols that call for homogeneous study population. They should also be aware of the implications of various recruiting strategies and be prepared to suggest alternative recruitment methods so as to ensure the appropriate diverse or focused subject populations.

7. Students, Employees, and Normal Volunteers

- a. The involvement of students, employees, and normal volunteers in research may present special concerns with which the IRB should be familiar. Federal regulations do not provide explicit protections for subjects in these categories.
- b. Normal Volunteers:
 - i. Volunteers for whom no therapeutic benefit can result from participation in research should be exposed to risks that are minimized to the greatest extent possible.
 - ii. The altruistic motivation of the normal volunteer's agreement to participate (i.e., of contributing to scientific knowledge for the benefit of society) heightens concern for the risks to which such participants should ethically be exposed.
 - iii. Consent must be free of coercion or undue inducement to participate.
 - iv. The IRB must ensure that any monetary payments to subjects are not so great as to constitute an undue inducement.
- c. Students:
 - i. Student agreement to participate in research may not be freely given. Students may volunteer to participate out of the belief that participating will result in receiving better grades, recommendations, employment, or the like, or that failure to participate will negatively affect their relationship with the investigator or faculty generally.
 - ii. The IRB is charged with responsibility to ensure that coercion and/or undue influence are not allowed in any research proposal.
- d. Employees:
 - i. The issues with respect to employees as research subjects are essentially identical to those involving students: coercion or undue influence, and confidentiality.
 - ii. The difficulty of maintaining confidentiality with personal medical information or research data is heightened with the department of health being a public health institution.

L. Investigator Responsibilities for Study Design and Informed Consent

1. Investigator's have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of the Federal Wide Assurance of WDH.
2. Investigators are expected to be knowledgeable about the requirements of the Federal regulations, applicable state law, the Federal Wide Assurance of WDH.
3. The investigator is responsible for conducting their research according to the WDH-IRB approved protocol and complying with all IRB determinations.

4. Ensuring that each potential subject understands the nature of research and of the subject's participation and taking whatever steps are necessary to gain their comprehension.
5. Providing a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the WDH-IRB.
6. Promptly reporting proposed changes in previously approved protocols to the WDH-IRB. Proposed changes may not be initiated prior to IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject(s). In the case of an apparent immediate hazard the PI must report to the IRB steps taken to mitigate hazard(s) or risk(s) and propose amendments to the protocol, which will protect human subjects.
7. Reporting progress of approved research to the IRB, as often as the manner prescribed by the IRB.
8. Promptly reporting to the IRB any unanticipated problems involving risks to subjects or others.
9. Whenever emergency care is initiated prior to IRB review and approval, the patient may *not* be considered to be a *research subject*. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity. DHHS regulations for the protection of human subjects do not permit *research* activities to be started, even in an emergency, without prior IRB review and approval. If the emergency care involves drugs, devices, or biologics that are considered to be investigational by the Federal Food and Drug Administration (FDA), then it may be necessary to meet FDA requirements to use the investigational article for emergency purposes.
10. Principle Investigators are required to immediately report (within five days) to the IRB all adverse events and the events which preceded, steps taken to mitigate risk to the patient, and subsequent changes made to protect all patients.

M. Administrative Responsibility

1. The Director of the Wyoming Department of Health (or designee) may require that the support for any project be terminated or suspended when he/she finds there has been a material failure to comply with the terms of this policy.
2. In making decisions about supporting or approving applications or proposals covered by this policy the Director of the Wyoming Department of Health (or designee) may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under the previous paragraph and whether the applicant or person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the

judgment of the administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects.

3. With respect to any research or any class of research projects the Director of the Department of Health (or designee) may impose additional conditions prior to or at the time of approval when in the judgment of the director additional conditions are necessary for the protection of human subjects.
4. If an unanticipated problem arises which involves risks to human subjects or others, this shall be reported to the FDA (21 CFR 56.108(b)(1)). The study will also be examined in order to reconsider approval of the study, require modifications to the study or, revise the continuing review timetable.

N. Human Specimen Banking Guidelines

1. Biological Materials may be banked or archived when collected during an approved research protocol subject to informed consent for such activities
2. Study participants must be informed, with each protocol, what procedures and sample collections are likely to occur in the protocol and if biological materials are being archived or banked. This should be clearly stated in the consent form document.
3. The Consent document must clearly state what will happen with those samples after the completion of the research project including a statement if biological materials will be archived for use in future research studies and how the archived materials will be identifiable for future use.
4. Archived Biological Materials collected and or used as Research Samples
 - a. Unidentified samples: Sometimes termed “anonymous”, these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens.
 - b. Unlinked samples: Sometimes termed “anonymized” these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.
 - c. Coded samples: Sometimes termed “linked” or “identifiable”, these samples are supplied by repositories to investigators from identified specimen with a code rather than with personally identifying information, such as a name or Social Security Number
 - d. Identified samples: These samples are supplied by repositories from identified specimens with a personal identifier (such as a name or patient number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained.

O. Use of Data On File or Archived/Banked Biological Material

1. IRB review and approval is required even when proposed research has no direct involvement of human participants **but** where research involves the use of personal

information or biological material, that has been previously collected, for either research or non-research purposes, or material that will otherwise be discarded, is used for research. Use of this type of data or material can be exempt from the informed consent requirements.

2. Determination of qualification for exemption from informed consent requirements.
 - a. Existing biological specimens or data are materials already collected prior to the initiation of the research using these materials.
 - b. Based on 45 CFR 46.101 (b) (4) the IRB can exempt research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the one of the following is true :
 - i. These sources are publicly available
 - ii. The information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the subject.
 - iii. If the study material is not publicly available or if the researcher records information in a manner that participants can be identified, **even indirectly**, it is research that requires full **IRB approval**. In this case, informed consent is required unless permission to use the material for research was in place at the time the data or specimens were obtained, or the research meets the criteria for waiver of informed consent.
 - iv. If the biological specimens or data are not in existence at the time the research is initiated, the only permissible way the material could be acquired without direct involvement of the participants in the research is for non-research purposes, such as during the course of the delivery of health care.
3. Requests for use of archived or banked biological specimens must include a WDH-IRB Application For Use Of Existing Data Or Biological Materials, along with a Protocol Summary and if applicable a Business Associate Agreement.
4. WDH-IRB expects that the arrangements made by investigators to acquire data on file or some of existing biological specimens for research be documented as well as the priority of the health care-related use of the data or specimens.
5. To ensure compliance of non-agency research with federal privacy regulations a Business Associate Agreement should also be executed fully prior to release of either data or biological material to a researcher who is not affiliated directly with the WDH.
6. If the material is to be acquired for research purposes, and participants can be identified the WDH-IRB Protocol Submission Guidelines should be used to apply to the WDH-IRB along with a specific informed consent, for routine review and approval.

VI. Protocol Summary Guideline

A summary of the research project must be submitted for each IRB application and should include the following.

1. Name, title, program, address, phone number, fax number and e-mail address of principal investigator and co-investigators.
 2. Title of protocol
 3. Anticipated start date and project duration.
 4. Purpose of research project.
 5. Description of human subject participation:
 6. Age-range and gender of preferred subjects
 7. How subjects will be selected and solicited for participation
 8. The number of subjects expected to be involved
 9. Incentive, if any, for subject participation
 10. Description of special classes of subjects, such as human fetus, in utero and ex utero, fetal material and placenta; pregnant women; children and minors; cognitively impaired persons; prisoners or incarcerated juveniles; traumatized or terminally ill patients; elderly/aged persons; minorities; students or employees; and international subjects
 11. Criteria for potential subjects to be included or excluded from the subject pool
 12. Procedure: brief explanation of the research procedures including: (describe only points that apply to the submitted protocol):
 - a. Description of subjects' participation and what subjects will be expected to do in the study
 - b. If applicable, description of what non-participants will do while other subjects participate in the research procedures (for example, in a classroom where some children may not have parental consent to participate or choose not to participate)
 - c. Details of what subjects will be told about the research project
 - d. Description of deception, if any, and procedures to debrief subjects
 - e. Reasonable estimate of time involved including frequency and duration
 - f. Location where research will take place
 - g. Method of data collection (survey, instruments, interview questions, etc.)
 - h. When and how subjects may terminate participation, and/or under what circumstances procedures may be stopped
 - i. Description of biological samples to be taken, if any, procedures to obtain samples, and qualification of person(s) obtaining samples
 - j. Description of equipment, if any, to be used on or by subjects
7. Description of the extent to which subjects will be identified, directly or indirectly through codes or identifiers, including:
 - a. Whether or not subjects will be identified, either by name, appearance, or nature of data
 - b. Procedure to protect privacy and confidentiality
 - c. How and where collected data will be stored and for how long
 - d. Who will have access to the data and under what circumstances
 - e. Any other aspects regarding confidentiality

8. Description of any benefits to the subjects or to others which may reasonably be expected from the research, including:
 - a. Direct benefits to subjects (including any medical and/or monetary compensation)
 - b. Indirect benefits (to class of participants represented, general body of knowledge, or society-at-large)

9. Description of any reasonably foreseeable risks or discomforts to the subjects as a result of each procedure, including exposure to minor pain, discomfort, injury from invasive medical procedures, or harm from possible side effects of drugs.
Consider all of the following but describe only points that apply to the submitted protocol:
 - a. All projects are deemed to involve some level of risk to human subjects, however obvious or obscure. Even studies involving data collection through survey or questionnaire involve some risk to the subject either through the process of filling out the questionnaire or release of their personal information, remembering a painful event or discussing a lost relative, all those activities should be considered as potentially risk evoking for the participant, thus **there is always some risk to the subjects of a study**, the risk should be considered as minimal at least, but may be greater based on the study elements.
 - b. Minimal risk is involved when the proposed research is viewed as involving little or no risk to human subjects. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 - c. Whether the research may involve greater than minimal risk, and what protection and/or treatment will be provided to subjects in the event of a research-related injury, including who will pay for necessary treatment and the availability of other financial compensation.
 - d. The likelihood, severity, duration, and effects of each potential risk. Common risks may include physical injury or harm; psychological trauma, stress or harm; social (invasion of privacy or breach of confidentiality) and/or related economic harm; legal risks (such as state or local law requirement to report child abuse or neglect).
 - e. Description of methods to minimize risks, including how and by whom treatment may be offered, and qualifications of persons performing procedures or collecting data
 - f. Description of treatment available, referrals for treatment and/or counseling, including estimate of costs involved and who will be responsible for those costs)

10. Description of procedure to obtain informed consent, if applicable, or other information to be provided to participant in lieu of obtaining a signed consent

form in instances where one may not be required, or if requirement to obtain informed consent is requested to be waived, including

- a. How and by whom will subjects be approached to obtain consent
 - b. How information will be relayed to subject (read to, allowed to read, audiotaped, videotaped)
 - c. Description of feedback, debriefing, or counseling referral to be provided
 - d. Procedure to obtain assent of children of an age and mental capacity deemed capable of providing such
11. Attach copies of survey instruments, interview questions, tests, and other pertinent documentation that will be used to conduct the research.
12. The name and phone number of an appropriate person to contact for more information about the study must appear on information letters or survey instruments for projects where a consent form is not required or the requirement is waived.
13. If subjects will be solicited through an institution such as a school, hospital, medical clinic, state agency, or if the research will be conducted at such an institution, provide a letter of agreement/approval to do so from an authorized representative of that institution.
- a. Clinical/hospital data obtained by the Dept of Health authorized by Wyoming statute requires approval of the WDH program manager or State Health Officer.
 - b. Letters of agreement/approval from the individuals at the institution that will work directly with the researcher either by allowing access to the subjects (i.e. teacher allowing access to classroom, physician office at which subjects will be interviewed).
 - c. Letters of agreement/approval from the individuals at the institution that will be actively participating by collecting consent forms, distributing surveys, or collecting data.



**Wyoming Department of Health
Institutional Review Board**

INSTRUCTIONS FOR COMPLETION OF RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION APPLICATION

INTENDED USE OF THIS APPLICATION:

This application should be submitted along with a WDH-IRB Table of Elements for Protocol Summary when proposed research has no direct involvement of human participants but where personal information or biological material, that has been collected, or will be collected, for non-research purposes, or material that will otherwise be discarded, is used for the research.

DETERMINATION OF QUALIFICATION:

Existing biological specimens or data are materials already collected prior to the initiation of the research using these materials. Based on 45 CFR 46.101 (b) (4) which allows an IRB to exempt research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the one of the following is true :

- These sources are publicly available
- The information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the subject.

It is important to note that only the IRB has the power to grant this exemption and it does not mean that such activities are exempt from IRB review.

DISQUALIFICATION:

If the study material is not publicly available or if the researcher records information in a manner that participants can be identified, **even indirectly**, it is research that requires **IRB approval**. In this case, informed consent is required unless permission to use the material for research was in place at the time the data or specimens were obtained, or the research meets the criteria for waiver of informed consent. If the biological specimens or data are not in existence at the time the research is initiated, the only permissible way the material could be acquired without direct involvement of the participants in the research is for non-research purposes, such as during the course of the delivery of health care.

DOCUMENTATION:

- The WDH-IRB expects that the arrangements made by investigators to acquire data on file or some of existing biological specimens for research be documented as well as the priority of the health care-related use of the data or specimens.
 - A Business Associate Agreement should also be executed fully prior to release of either data or biological material to ensure researcher compliance with federal privacy regulations.
 - If the material is to be acquired for research purposes, and participants can be identified the WDH-IRB Protocol Submission Guidelines should be used to apply to the WDH-IRB along with a specific informed consent, for routine review and approval.



**Wyoming Department of Health
Institutional Review Board**

**RESEARCH THAT DOES NOT INVOLVE DIRECT
HUMAN SUBJECT PARTICIPATION APPLICATION**

Attach this application to a WDH-IRB Table of Elements for Protocol Summary and submit to the IRB for approval prior to collection or release of any data or material. Once approval has been issued a Business Associate Agreement must be executed and a copy submitted to the IRB for its files.

STUDY OVERVIEW

- 1. Name, title, program, address, phone number, fax number and e-mail address of principal investigator and co-investigators).**
- 2. Title of protocol**
- 3. Anticipated start date and project duration.**
- 4. Purpose of research project.**

SPECIFICS OF USE OF EXISTING DATA OR BIOLOGICAL MATERIALS

- 1. State why & how the existing data or biological materials were collected, or how data or biological materials to be used in this research will be collected for non-research purposes.**
- 2. Were the existing data or specimens originally stored in a way that could reveal the identity of the person from whom the material originated? YES NO**
- 3. Will the research records carry any identifiers that could link the information to the person, from whom the material originated? YES NO (If yes discontinue application, submit protocol for IRB Review)**
- 4. What type of data and/or biological specimens will be used for research?**
- 5. From how many persons did/will the data or biological specimens originate?**

- 6. From what source(s) will the data or biological specimens be procured?**
- 7. How will the investigators gain access to the data or biological specimens?**
- 8. If the data or biological specimens were originally collected for non-research purposes, have the persons from whom the material originated agreed that the material might also be used for research purposes? YES NO**
- 9. Does use of the data or biological specimens involve information, which if revealed, could place someone at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputation? YES NO**
- 10. How will the permission of the persons, from whom the data or biological specimens originated, be obtained to use the material for research purposes?**
- 11. What measures will be taken to keep the research records confidential?**
- 12. Describe any access that researchers will have to information that is not essential to the research, what will be done with this non-essential information, and how it will be protected.**
- 13. Could the research to be conducted on the data or biological specimens reveal information of potential benefit to the persons from whom the material originated? YES NO (If YES, describe plans to inform participants about their rights)**
- 14. Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor? YES NO (If YES, describe plans to inform participants about their rights)**
- 15. Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor? YES NO (If YES, describe plans to inform participants about their rights)**

APPENDIX II. Application for Continuing Review or Study Closure: Instructions

Wyoming Department of Health Institutional Review Board Application for Continuing Review or Study Closure: Instructions

Submit the following to the IRB: the completed Application for Continuing Review or Study Closure, a copy of the currently approved informed consent document, and any other supporting material.

General Instructions: This form should be completed one month prior to expiration of a study to ensure continuing approval. The form may be completed electronically, but a printed copy containing an original signature of the PI must be submitted for the files. Continuing review will be done at the IRB meeting following receipt of the completed form. Investigators will be notified of the date and time of the continuing review meeting should they wish to attend. Please forward signed hard copy to Dr. Sandra Novick at:

WDH IRB
211 West 19th Street, Suite 120.
Cheyenne WY 82001

Header. The header, which is located at the top of the Application for Continuing Review or Study Closure has a place to list the IRB#, the date of IRB expiration, the PI and the study title. Place your cursor directly on the header and double-click. Once the header is open for editing purposes, input the information.

Status of the Research. **Please check the appropriate box that best describes the status of the research project. This form can also be used to close out the research project with the IRB.**

Close the Study. **If closing the study completely, please provide a final study report with this application that includes the total number of consented participants, any withdrawals with an explanation for each, and any other pertinent material as it becomes available.**

3. Summary of the Progress Since Initial IRB Review or Last IRB Continuing Review.

- A. Maximum Approved.** The maximum number of participants at WDH and non-WDH sites that have been previously approved by the IRB to be **consented by this PI** for the life of the study has been provided electronically on the Application for Continuing Review. This is the number of participants approved by the WDH IRB for the entire length of the research study, not an annual accrual number. Please verify that this number is correct. If not, notify the IRB at the time of continuing review.
- B. Total Consented To Date.** Provide the total number of participants who have been **consented to date by this PI**, including any withdrawals or consented screen failures. Withdrawals can include those initiated by the participant, the PI or the sponsor. This number should include all participants who will sign a consent form for this study. (For example, if a participant signs a consent form and is then screened out, that participant should be counted as consented. However, on the continuing review application, that participant would be indicated as a “consented screen failure”. If a participant signs a consent document, then is screened out and is instructed to try again in a couple of weeks, and then meets screening criteria, that participant is only counted once. Or, if a participant needs to be re-consented because of new risks or additional information, that participant would only be counted once.)
- C. Total Consented Since Initial IRB Review or Previous IRB Continuing Review Approval.** Provide the total number of participants **consented by this PI since the last review**, including any withdrawals or consented screen failures. Withdrawals can include those initiated by the participant, the PI or the sponsor. This number should include all participants who will sign a consent form for this study (see 3.B. for details).
- i. Of the total number of participants consented by this PI since the previous IRB continuing review approval, indicate how many of these participants have completed the study or have participated in the study beyond screening.

- ii. Of the total number of participants consented by this PI since the previous IRB continuing review approval, indicate how many of these participants consented were withdrawals. Withdrawals can include those initiated by the participant, the PI or the sponsor. Include an explanation for each withdrawal (not screen failures) in your summary below in 3.
- D. Summary of Study Activities/Status Report.** Provide a summary of study activities and a status report of the study to date since the last IRB continuing review approval including any recruitment activities and any new findings. Include any activities at other sites in which the PI is responsible.
- 4. Safety Reporting.** List each unanticipated problem to participants and others and each serious adverse event that has occurred and indicate if these events/problems have been reported previously to the IRB.
- 5. Findings.** List and describe any reports, publications, clinical findings, etc. that have occurred since the last IRB continuing review approval which may impact the study. Note any event or discovery that may change the risk-benefit ratio of the study including favorable reports.
- 6. Complaints.** Describe any complaints about the research project that may have occurred since the last review.
- 7. Study Modifications.** Indicate if any modifications have been made to the study since the initial IRB review or any previous IRB continuing review approval occurred. Also indicate if the IRB was notified of those modifications and describe the modifications. Include any attachments as necessary to fully show how the modifications may have affected the study.
- 8. Consent Document.** Attach a **copy** of the currently approved informed consent document(s).
- 9. Investigator's Conflict of Interest Statement.** Identify whether or not the Investigator or any Key Study Personnel have a potential conflict of interest.
- 10. Contact Information.** Provide the Principal Investigator's e-mail address, phone number, fax number and pager number if available. If the contact person is different than the PI, provide the study contact's name, e-mail address, phone number, fax number and pager number.
- 11. Principal Investigator's Assurance Statement.** Carefully read this entire statement prior to signing.

APPENDIX III. Application for Continuing Review or Study Closure

**Wyoming Department of Health Institutional Review Board
Application for Continuing Review or Study Closure**

Please complete ALL sections of this form whether applying for Continuing Review or Study Closure.

1. STATUS OF THE RESEARCH

Check the one choice that best describes the current state of this research study:

- No participants have been enrolled to date.
- Recruitment and/or enrollment of new participants or review of records/specimens continue.
- Study is no longer enrolling, but participants still receive research-related interventions, (e.g., still receiving treatment, obtaining blood draws)
- Study is no longer enrolling and participants have completed research-related interventions. The study remains active only for long-term follow-up.
- Study enrollment is permanently closed, participants have completed all research-related interventions, and long-term follow-up has been completed. The remaining research activities are limited only to data analysis that may require contact with records or specimens.

2. CLOSE THE STUDY

Please provide a final study report, progress reports, and publications to the IRB as they become available.

- Close the study. Enrollment and follow-up are complete and no further contact with participants/records/specimens is anticipated. Describe the reason for closure (i.e., enrollment goals achieved, reason for early termination) :

- Raw Data was destroyed as indicated in the study protocol
If Raw Data has not been destroyed please describe how & when it will be according to the study protocol approved by IRB.

3. SUMMARY OF PROGRESS SINCE INITIAL IRB REVIEW OR PREVIOUS CONTINUING REVIEW APPROVAL

Record numbers reflective of activities where a WDH investigator is involved in the conduct of the research or is responsible for regulatory reporting (i.e., adverse events, progress reports):

- _____ Total number of participants approved by WDH IRB
- _____ Total number of participants consented to participate to date, including withdrawals
- _____ Total number of participants consented since the previous IRB continuing review approval*
- _____ Total number of participants that consented but did not complete the study since the previous IRB continuing review approval* (include explanation for each)

Provide a description of study activities to date, including any difficulties in recruiting subjects, in the space below:

Select one answer for each question:

4. Yes No Since the initial IRB review or previous IRB continuing review approval, have any unanticipated problems involving risks to participants and/or serious, unanticipated and research-related adverse events occurred?

If "Yes", attach all written summaries and/or progress reports since previous IRB continuing review approval.

_____ Total number of events/problems since initial review or previous IRB continuing review

- 4a. Yes No Have these events been reported previously to the IRB?

5. Yes No Have any relevant clinical findings, literature, reports or other information (particularly information about risks associated with the research) become available since the last IRB continuing review approval*? If "Yes", please describe:

6. Yes No Have there been any complaints about this research since the last IRB continuing review approval*? If "Yes", please describe:

7. Yes No Have there been any modifications to this research study since the initial IRB review or last IRB continuing review approval*? If "Yes", please answer question 7a. & describe all modifications:

7a. Yes No Was the IRB notified about the modifications at the time they were implemented? If no please explain why not:

8. Yes No Did the IRB require the use of a written informed consent document for this study? If "Yes", submit a copy of the currently approved informed consent document.

9. INVESTIGATOR'S CONFLICT OF INTEREST STATEMENT

Yes No Do you or any other person responsible for the design, conduct, or reporting of the research have an economic interest in, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If "Yes" and the IRB has not yet been notified, submit a letter to the IRB describing the conflict immediately.

10. CONTACT INFORMATION

Principal Investigator's e-mail address: _____

Phone #: _____ Fax #: _____ Pager #: _____

Study contact name (if different than PI):

Study contact e-mail address: _____

Phone #: _____ Fax #: _____ Pager #: _____

In addition to the above responses, I confirm that a current IRB-approved consent form has been signed, dated, and is retained in my files for every participant enrolled in this study and a copy was provided to the person who signed the form (if use of a consent form was required). I also confirm that no changes to study procedures or the consent form(s) were initiated without prior IRB approval.

Principal Investigator's Signature

Date

APPENDIX IV. Informed Consent Template

CONSENT FORM *OUTLINE*

I. General purpose of the study:

Why are you conducting this study? What do you hope to gain from this study? Why should subjects participate?

II. Procedure:

How and where will the study be conducted? Who will be conducting the study? What will the subject be expected to do? How much of the subject's time is needed?

III. Disclosure of risks/description of benefits:

As appropriate, state whether risks involved in participation are minimal, or if the project involves more than minimal risk. Describe in detail all potential risks of the study, and procedures to minimize risks. List any direct/indirect benefits to the subject.

IV. Confidentiality:

What level of confidentiality will be afforded to subjects? How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept? Will the data be used for research purposes at any time other than the purpose(s) stated above?

V. Freedom of consent:

Include a statement such as: "My participation (my child's participation) is voluntary and my (my child's) refusal to participate will not involve penalty or loss of benefits to which I am (my child is) otherwise entitled, and I (my child) may discontinue participation at any time without penalty or loss of benefits to which I am (my child is) otherwise entitled."

For studies involving classroom students: "I understand that my (my child's) refusal to participate or my (my child's) withdrawal at any point will not affect my (my child's) course grade or class standing."

This statement should be written in language appropriate for the age and level of education of the subjects.

VI. Questions about the research:

Include name, address and phone number where principal investigator/faculty advisor can be reached during normal business hours.

Participant signature

Date

VII. Parental consent required for all subjects under 18 years of age.

EXAMPLE:

As parent or legal guardian, I hereby give my permission for

_____ to participate in the research described above.

Parent/legal guardian signature

Date

APPENDIX V. HIPAA Compliance

**Wyoming Department of Health
Institutional Review Board
HIPAA Compliance**

1. Indicate your sources of Protected Health Information (PHI):

- Interview or written instrument used with participants
 - Hospital /Medical records
 - Physician/Clinic records
 - Mental Health records
 - Billing records
 - Lab, Pathology and/or Radiology results
 - Biological samples obtained from subjects for clinical purposes
 - Data previously collected for research purposes
 - Other (describe) _____
-

2. Identify all WDH affiliated individuals who will be requesting authorization to access the participants' PHI:

Name (First, Middle, Last)/Degree	Division or Affiliation	Role in Project

3. Identify all Non-WDH affiliated individuals/institutions to which PHI may be disclosed (e.g., study sponsors, consultants, contractors, publications, future collaborators, etc.):

Name of Individual/Institution	Business Associate Agreement
	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> In Contract <input type="checkbox"/> N/A
	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> In Contract <input type="checkbox"/> N/A
	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> In Contract <input type="checkbox"/> N/A
	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> In Contract <input type="checkbox"/> N/A

If PHI is disclosed to Individuals or Institutions outside of WDH, a “Business Associate Agreement” is required. If disclosed information is coded, a BAA is not required.

4. Indicate when PHI will no longer be used or disclosed (please select one):

- Specific date _____
- Closure of the study
- Destruction of the database/registry
- Years after closure of the study
- No expiration date (only available for databases/registries)
- Specimen processing is complete
- Completion of data collection
- Other _____

5. Indicate if individual authorization to use or disclose PHI is required, or if a request for waiver of authorization to access PHI is requested:

Individual Authorization from Study Participant
(individual authorization is incorporated in the IRB consent form template)

Waiver of Authorization requested

(if “Yes”, complete the “Request for Waiver of Consent and/or Authorization”

Please be aware, if a protocol is granted a “Waiver of Consent and/or Authorization” by the WDH, IRB, the PI must be prepared to provide the following information for any PHI disclosed outside WDH should a disclosure occur:

1. *The date of the disclosure;*
2. *The name, title, and contact number of the WDH workforce member making the disclosure;*
3. *The name of the entity or person who received the protected patient information, and, if known, the address of such entity or person;*
4. *A brief description of the protected patient information disclosed; and*
5. *A brief statement of the purpose of the disclosure that reasonably describes the basis for the disclosure.*

This mandate is pursuant to 45 CFR 164.528, which states that an individual has the right to request and receive an accounting from the covered entity (WDH) of all possible disclosures of their private health information that was permitted without the individual's authorization.

Definitions and Conditions

Protected Health Information (PHI): is individually identifiable health information that is or has been collected or maintained by WDH or an agent acting under contract or on behalf of WDH, including information that is collected for research purposes only, and **can be linked** back to the individual participant. Once this has occurred, use or disclosure of such information must follow federal privacy guidelines.

Business Associate Agreement: Sets forth the terms and conditions pursuant to which the Covered Entity (WDH) will allow the use and disclosure of a limited data set to the data recipient.

Individual Authorization: The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself.

Waiver of Authorization: The following three criteria must be satisfied in order to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - a. an adequate plan to protect the identifiers from improper use and disclosure;
 - b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and,
 - c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

APPENDIX VI. Request for Waiver of Consent, Authorization, and/or Documentation of Consent

**Wyoming Department of Health
Institutional Review Board**

**Request for Waiver of Consent,
Authorization, and/or Documentation of Consent**

Please check the appropriate category and answer the corresponding questions.

Request for Waiver of Documentation of Informed Consent.

The IRB may waive the requirement to obtain a signed informed consent document for some or all of the participants if the study meets one of the following conditions:

1. The only record linking the participant to the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Under this condition, use of oral consent is appropriate. Each participant must be read an informed consent statement witnessed and signed by two study team members. The IRB must review and approve the oral consent document.

Does this study involve procedures that would be minimal risk except for the linking of the consent document to private information? Yes No

If "Yes", describe the potential harm to the subject that could result from a breach of confidentiality?

2. The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context.

Does this study involve procedures that, outside of the research context, would require written consent? Yes No

If "Yes", waiver of documentation is not appropriate.

3. The research is minimal risk and involves **either**; a) no collection of protected health information, or b) no collection of individual identifiers which could link PHI to an individual participant.

Does this study involve collection of protected health information? Yes No

If collecting PHI, does this study involve collection of individual identifiers or specific demographic information which could link PHI to an individual participant?

Yes No

If "Yes" to both questions above, waiver of documentation is not appropriate.

***Request for Waiver of Authorization.**

Note: Authorization only applies when protected health information (PHI) will be created, used, or disclosed in the course of the research.

The IRB may approve a waiver or alteration in the Authorization procedure provided that the following conditions are met:

1. Explain why the research could not practicably be conducted without access to the protected health information.
2. Describe how the privacy risks to individuals whose protected health information is to be used are reasonable in relation to the anticipated benefits (if any) and the importance of the knowledge expected from the research.
3. Describe the plan to protect the identifiers from improper use and disclosure.
4. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
5. Verify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research.

Please be aware, if a protocol is granted a “Waiver of Consent and/or Authorization” by the WDH, IRB, the PI must be prepared to provide the following information for any PHI disclosed outside WDH should a disclosure occur:

1. *The date of the disclosure;*
2. *The name, title, and contact number of the WDH workforce member making the disclosure;*
3. *The name of the entity or person who received the protected patient information, and, if known, the address of such entity or person;*
4. *A brief description of the protected patient information disclosed; and*
5. *A brief statement of the purpose of the disclosure that reasonably describes the basis for the disclosure.*

This mandate is pursuant to 45 CFR 164.528, which states that an individual has the right to request and receive an accounting from the covered entity (WDH) of all possible disclosures of his/her protected health information that was permitted without the individual's authorization.

APPENDIX VII. Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions. These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at [OHRP Policy Guidance by Topic](#). The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

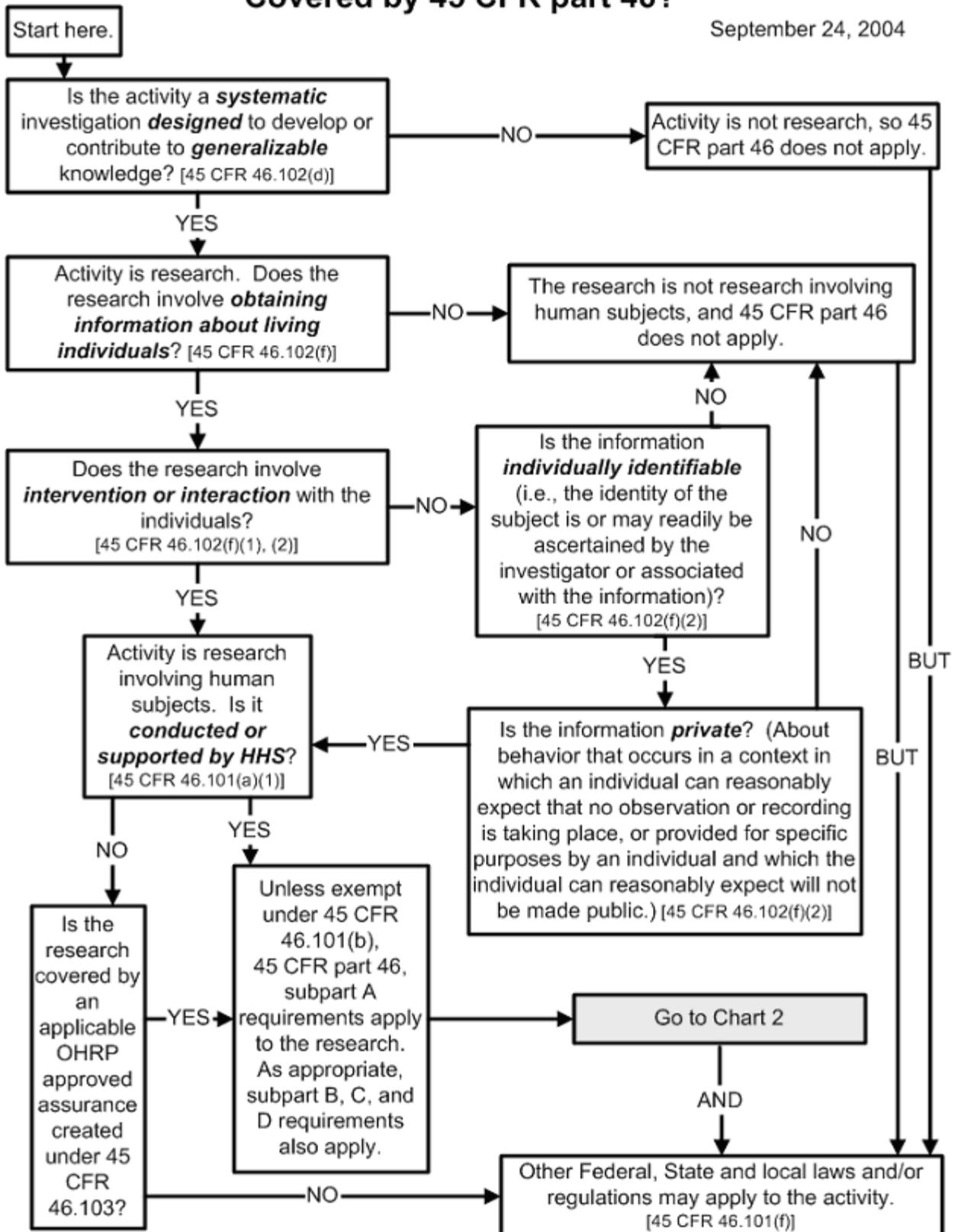


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

September 24, 2004

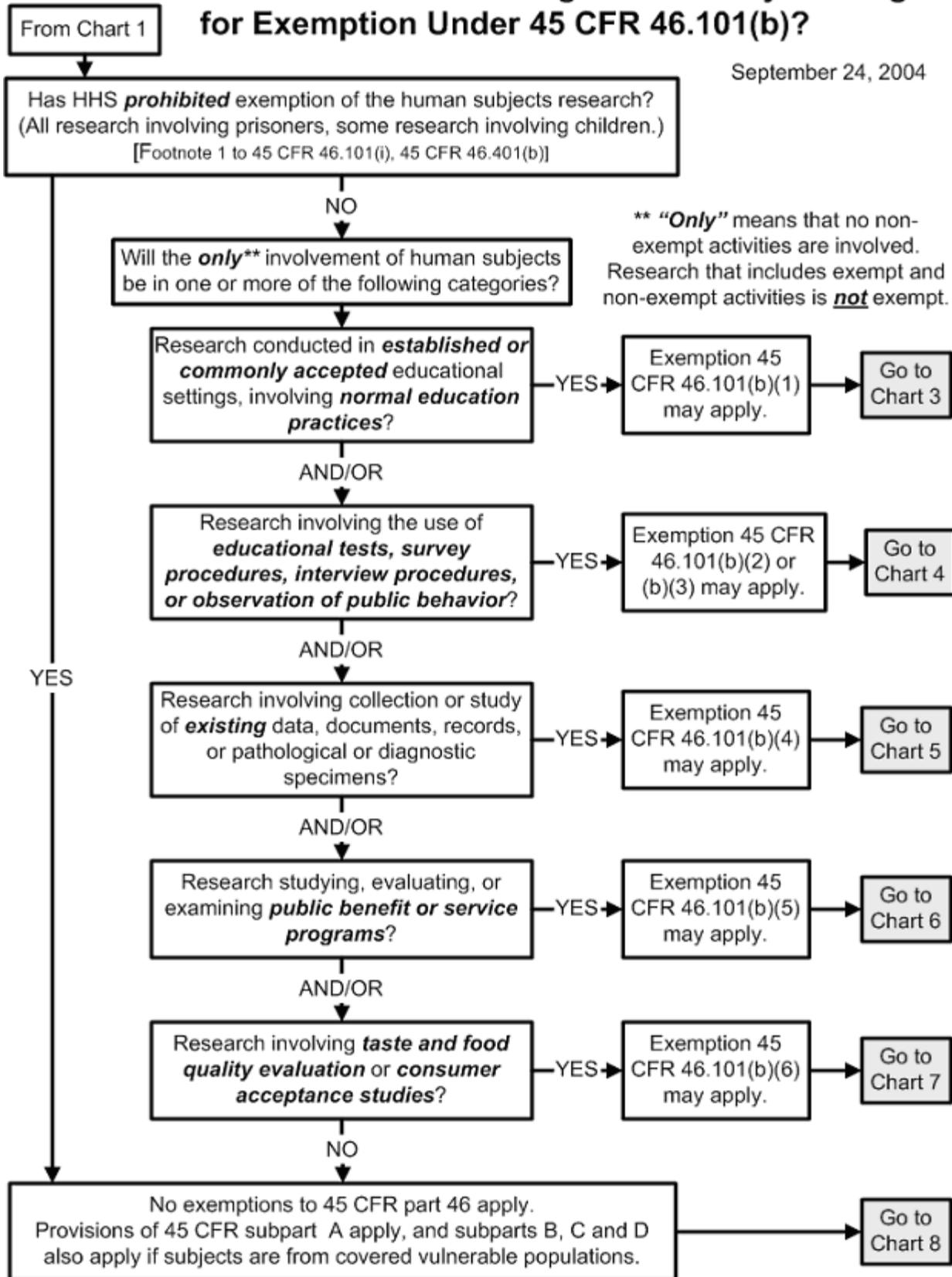
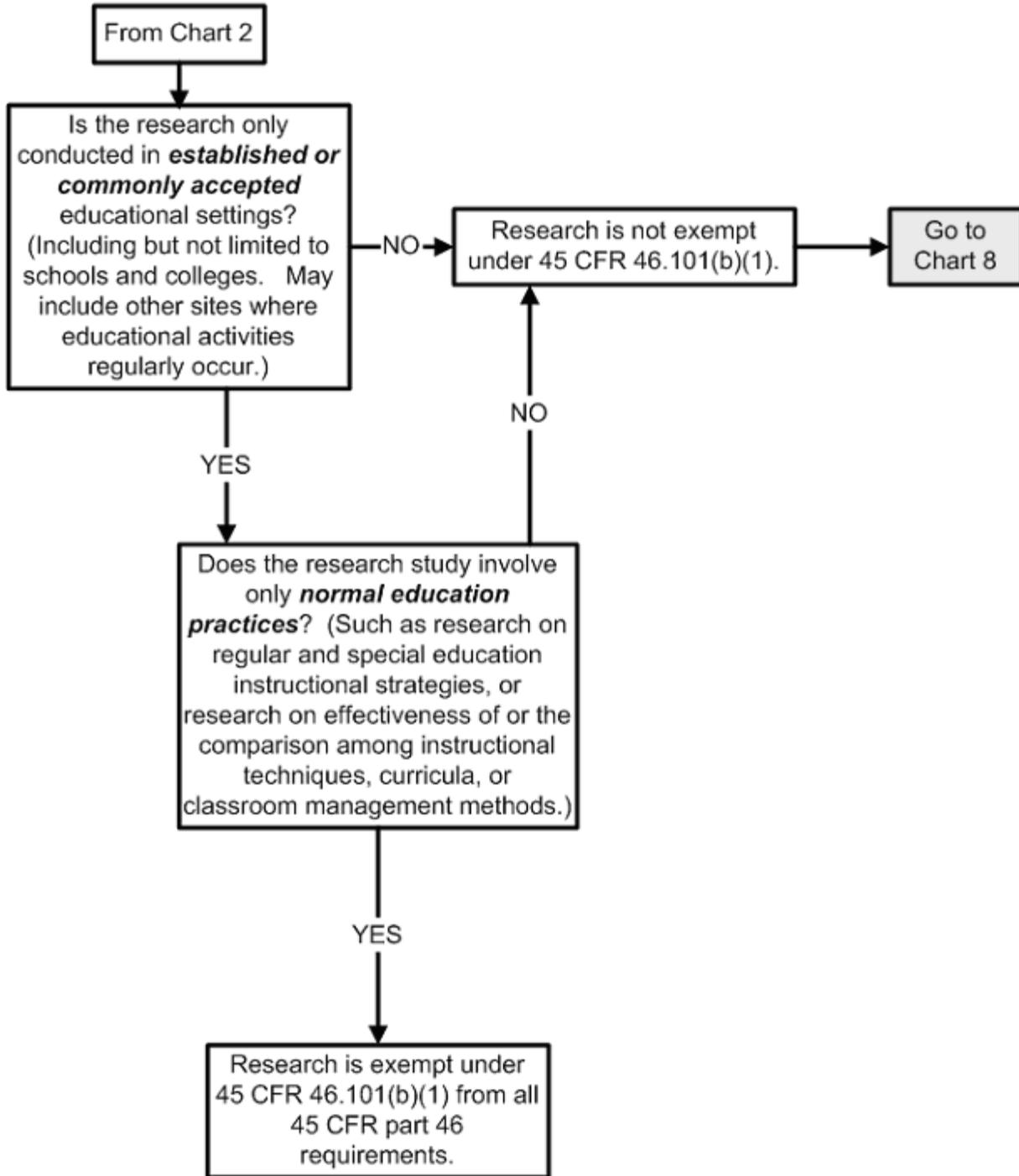
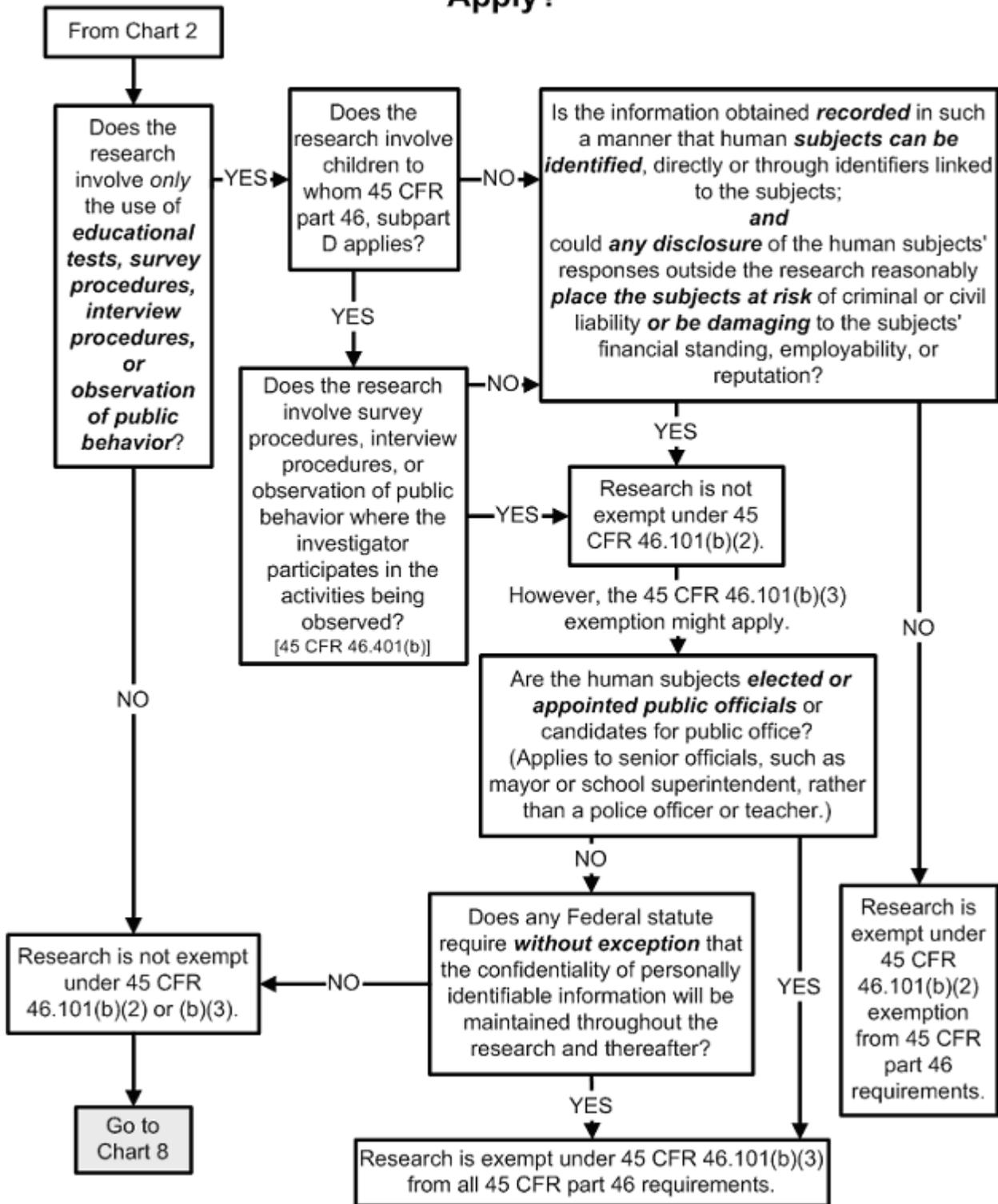


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



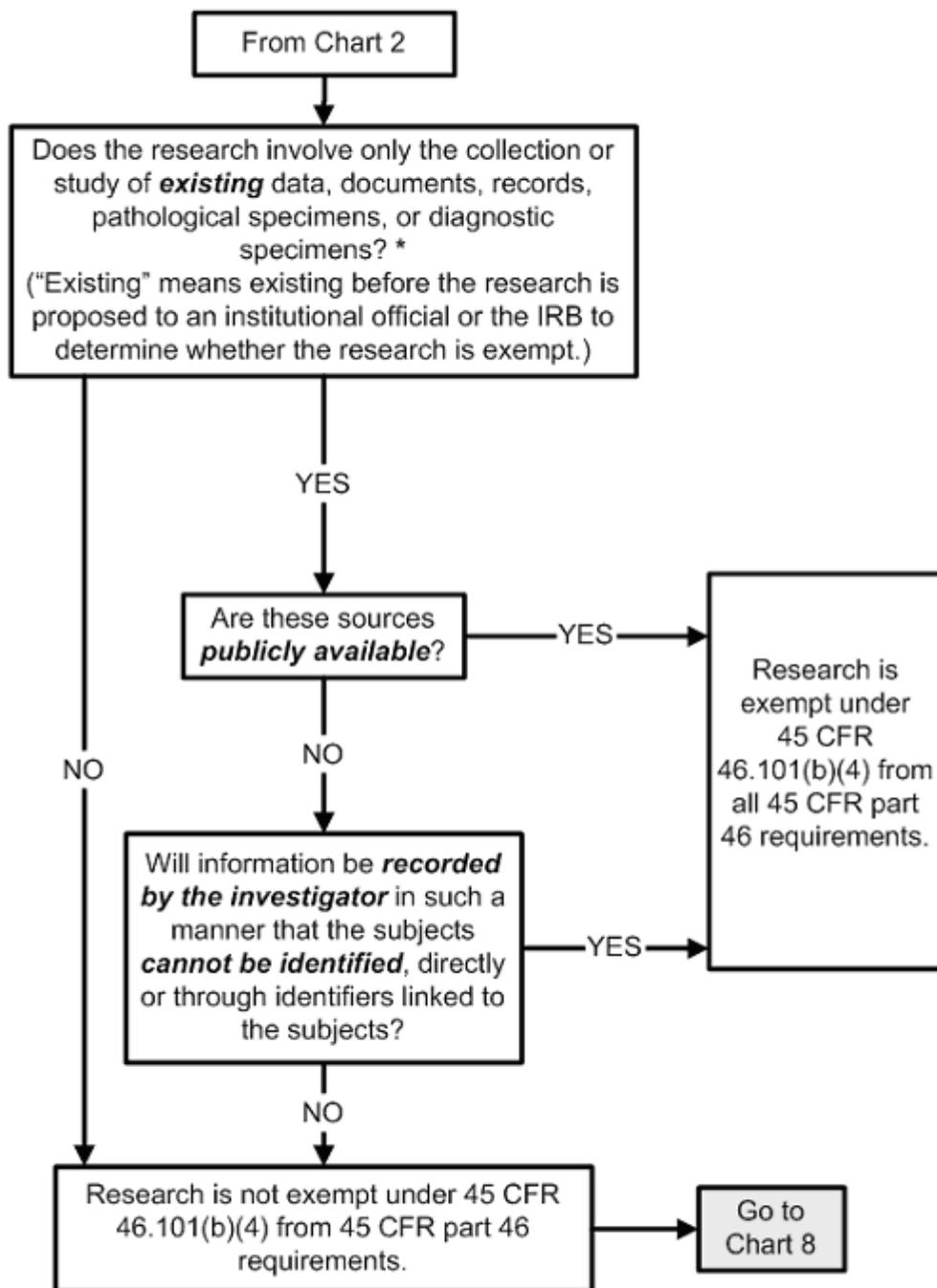
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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



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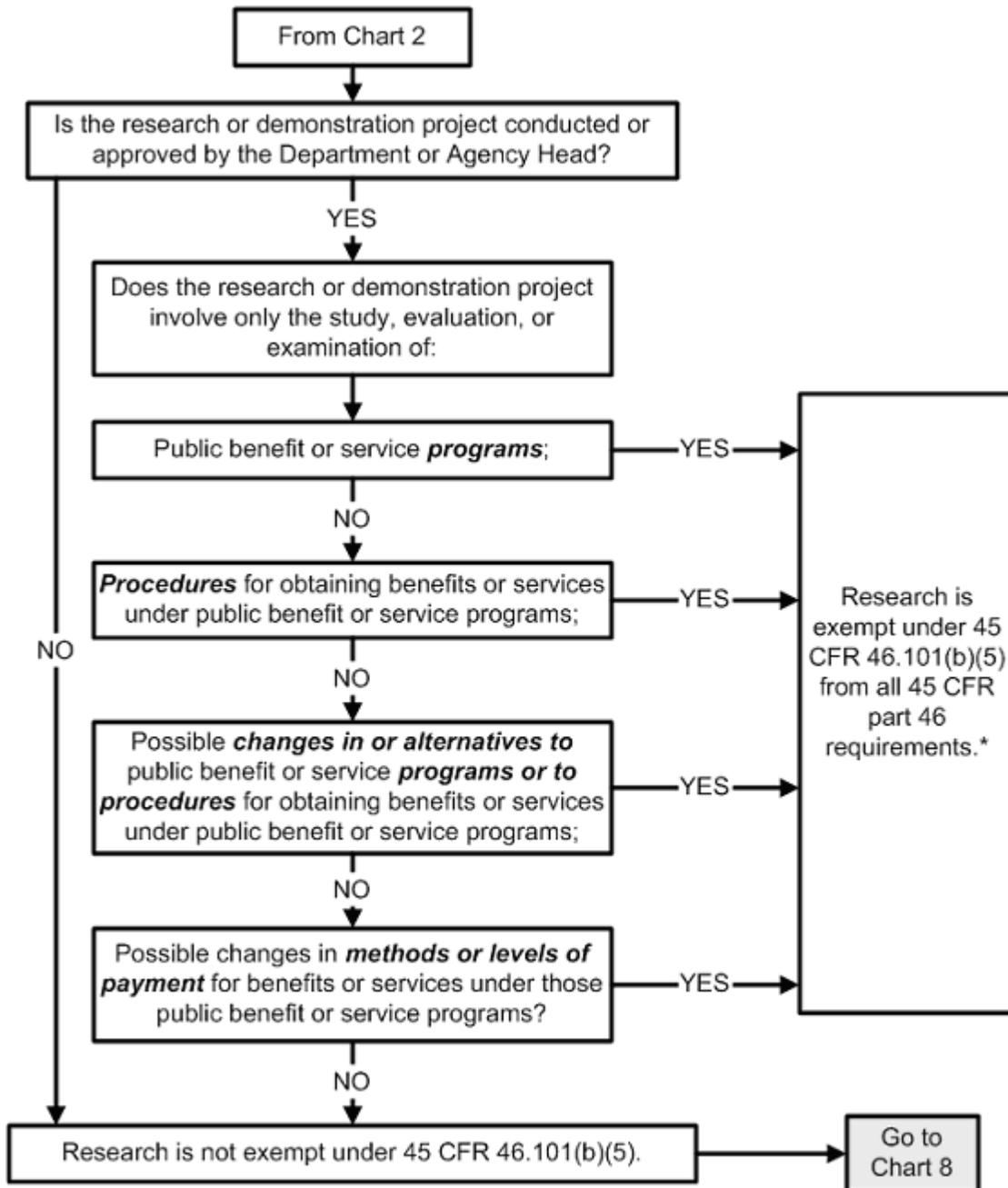
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and #stem, and on coded data or specimens at #coded for further information on those topics.

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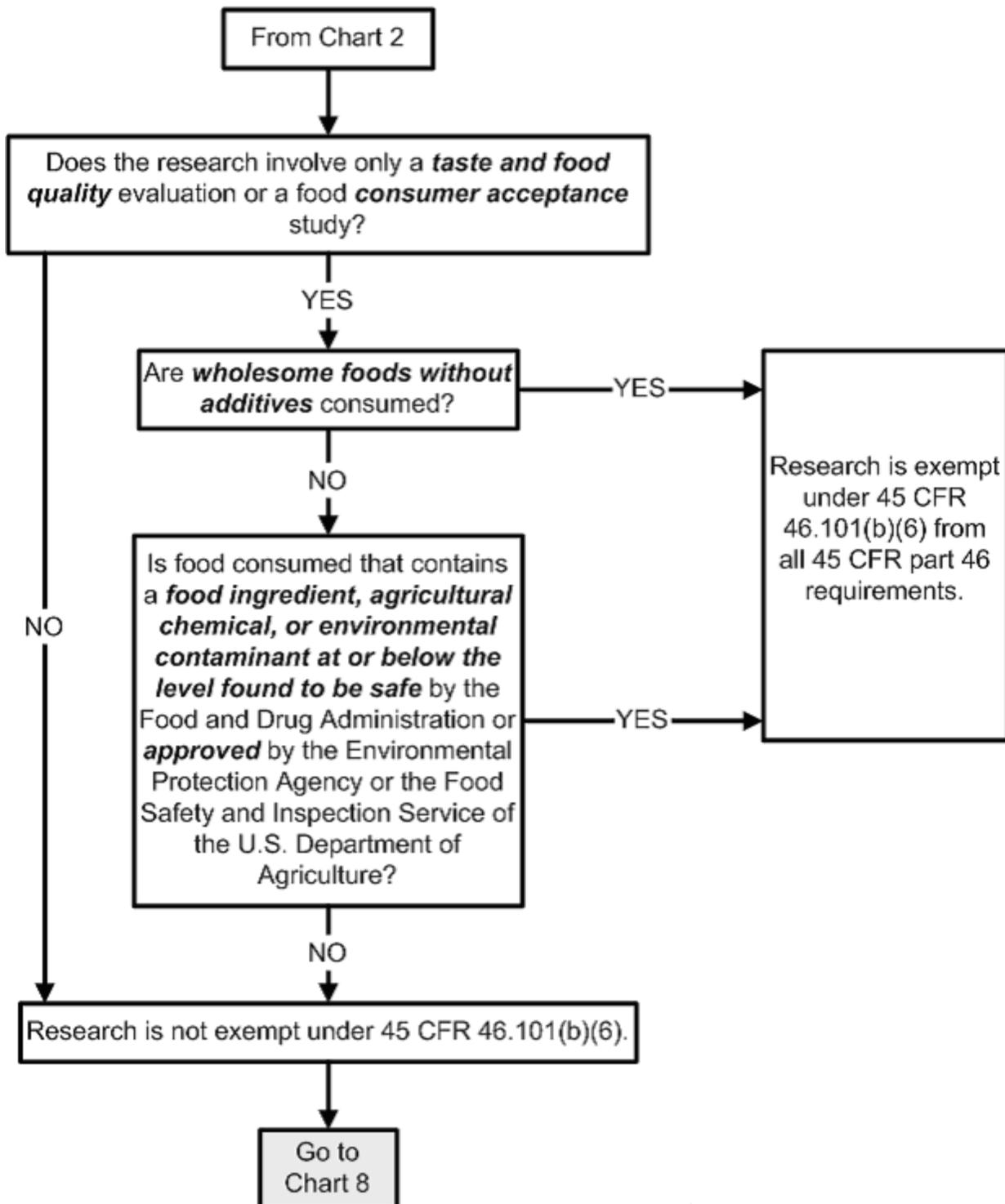
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See **OHRP** guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

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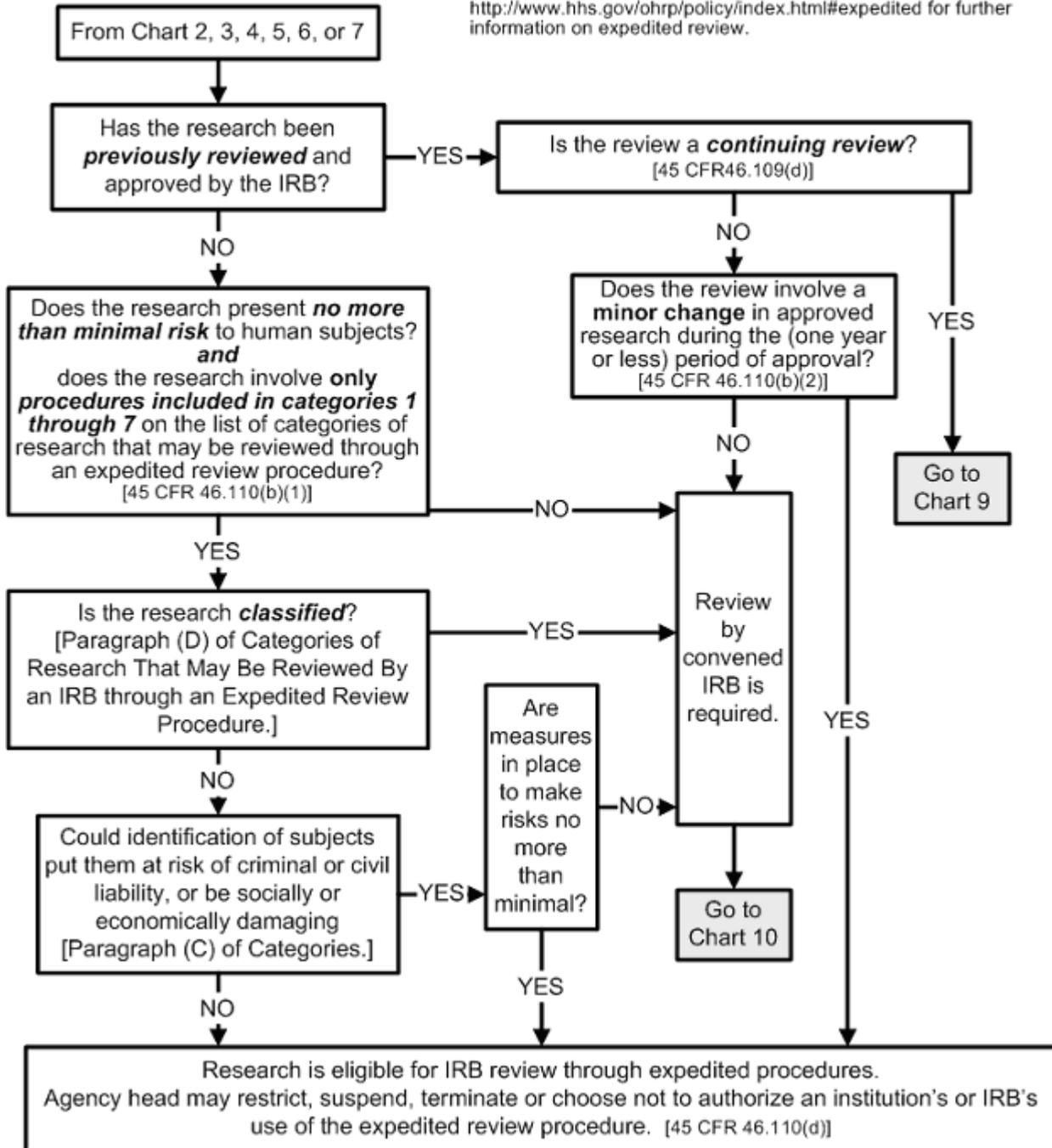
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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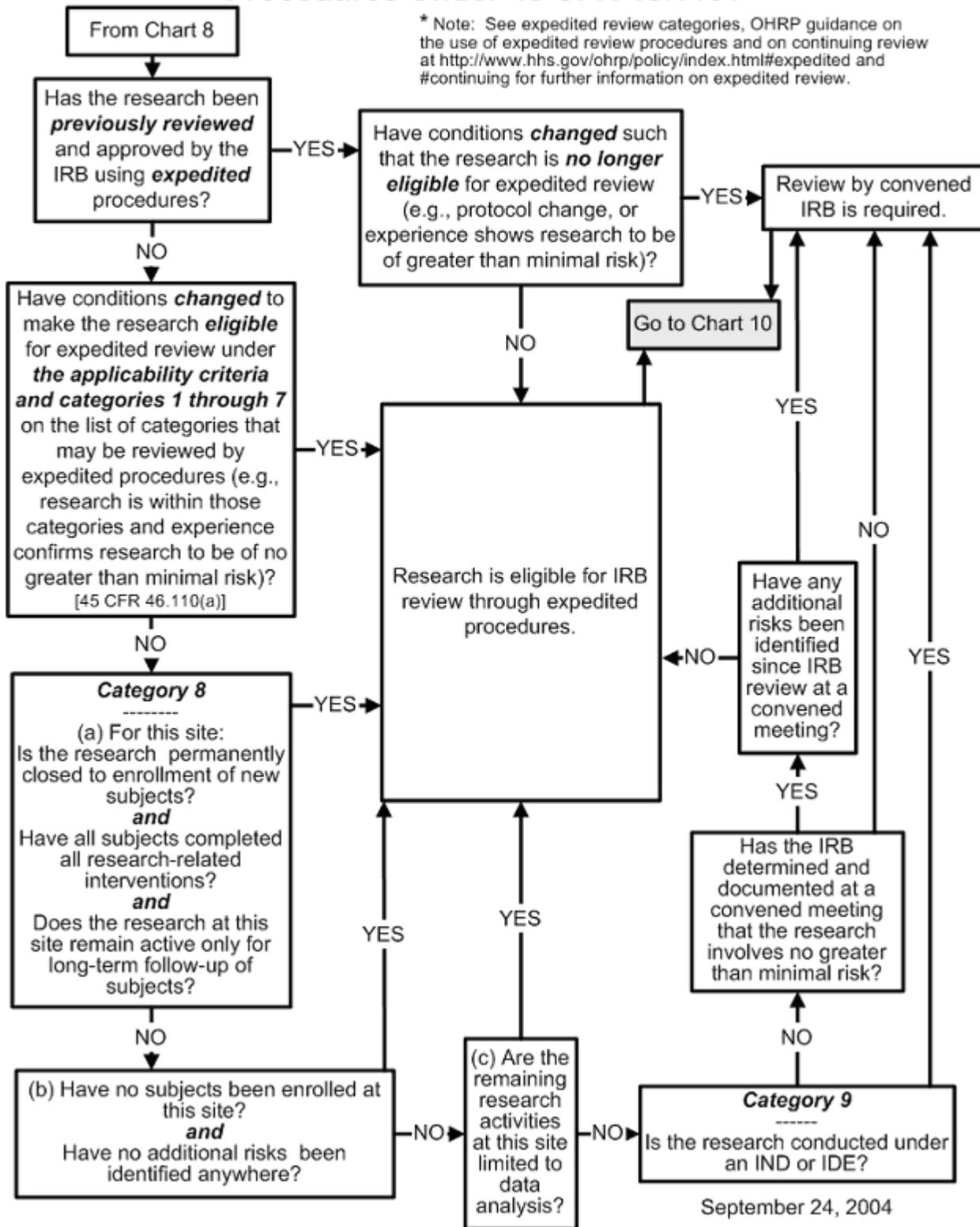
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



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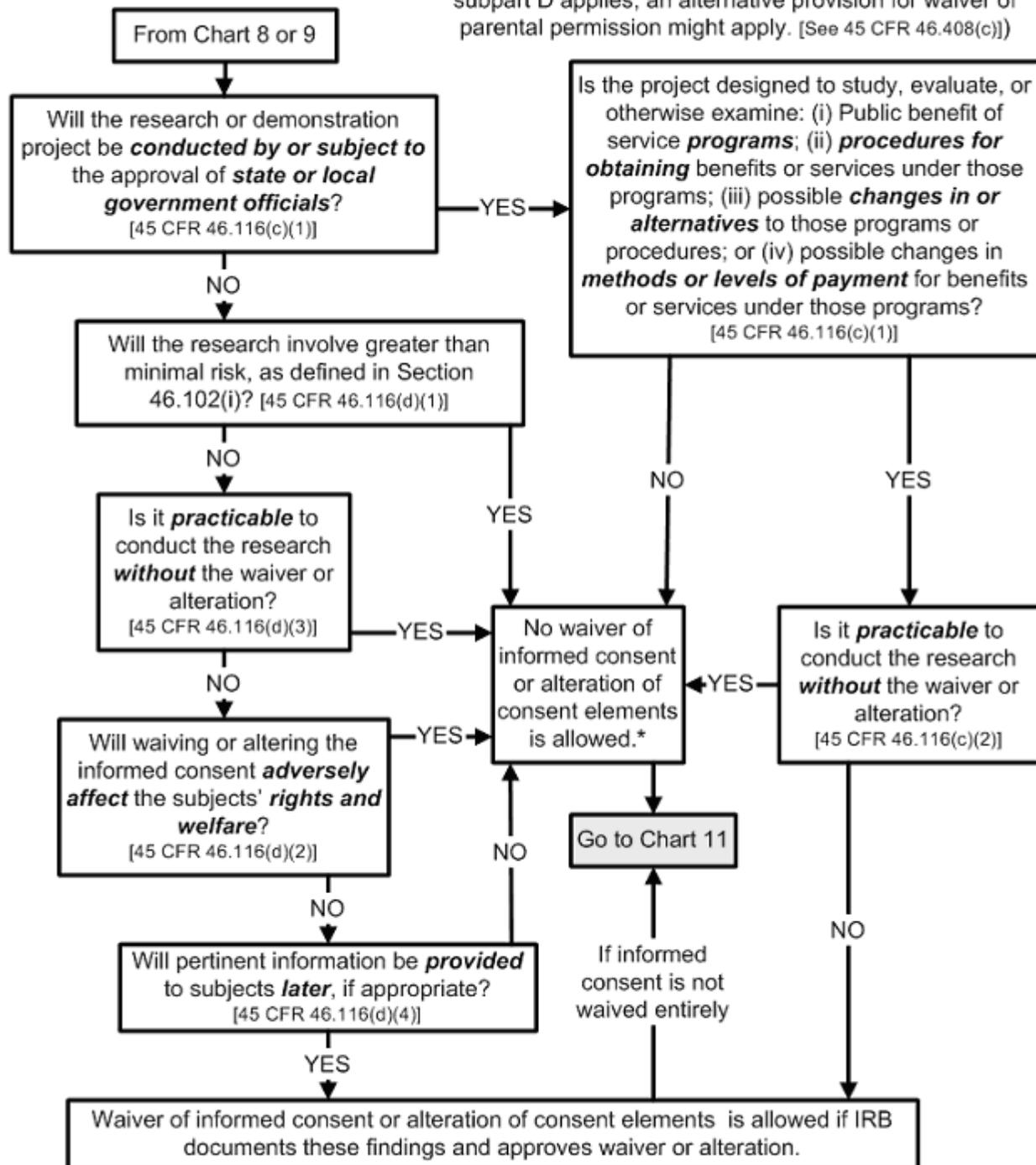
Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?



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Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

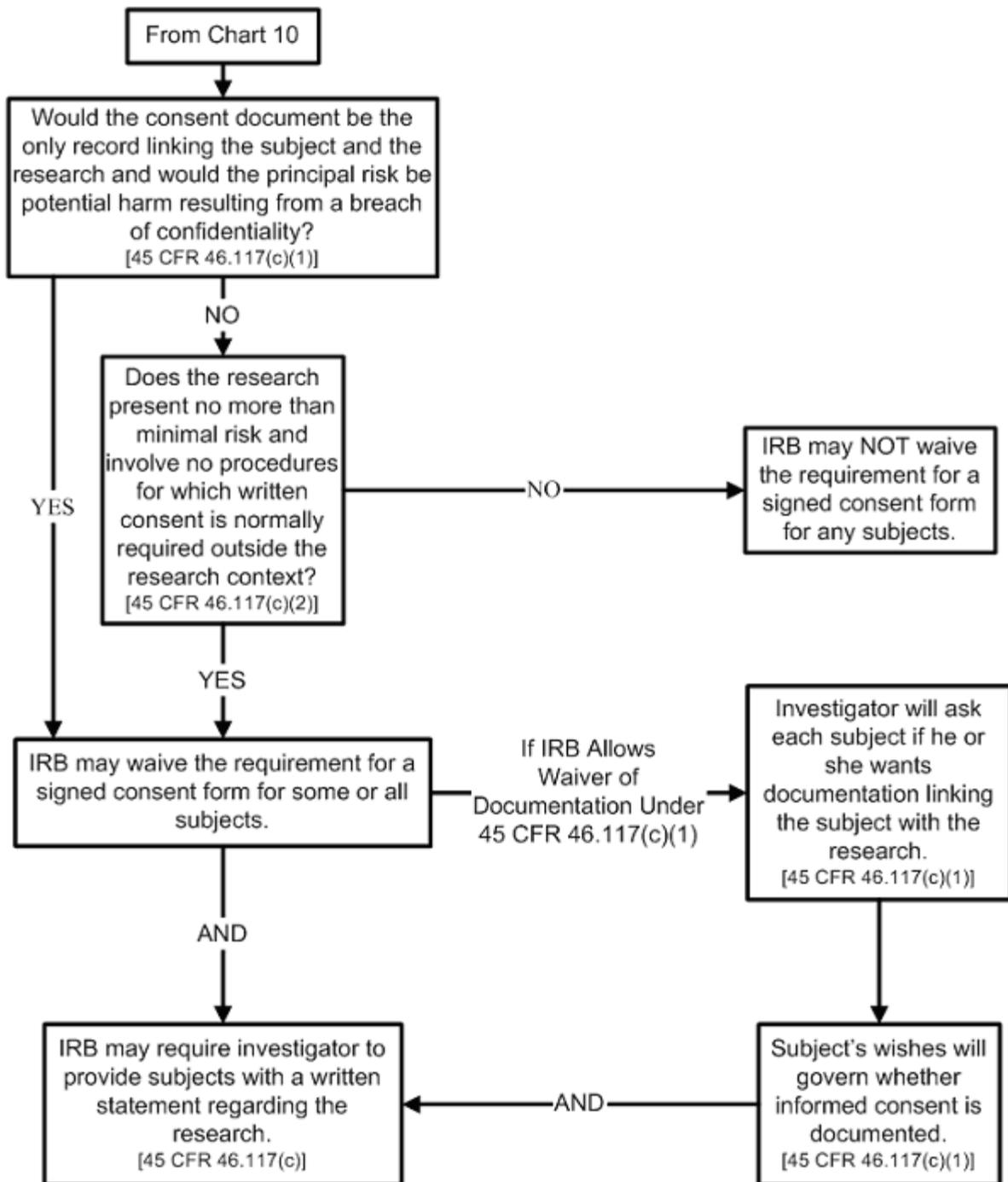
** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver.

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Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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