Institutional Review Board (IRB) Operational Manual

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Mountain Empire Community College

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MOUNTAIN EMPIRE COMMUNITY COLLEGE
INSTITUTIONAL REVIEW BOARD

OPERATIONAL MANUAL

I. INTRODUCTION

The role of Mountain Empire Community College (MECC) in higher education is to focus on teaching and learning; research is not central to the College's mission. Although MECC encourages and supports the scholarly endeavors of its students, faculty, and staff, research is not an expectation. The College has an Institutional Research office and staff whose role is to conduct what is commonly termed 'institutional research.' Historically, this 'research' has primarily involved gathering enrollment and student outcome statistics (e.g., retention, transfer and completion rates). More recently, the College has moved toward a more 'data-driven' institutional model. In this capacity, MECC will conduct more targeted studies on teaching methods and the impact of student services on student success. As a result of this expansion of research activities, MECC created an Institutional Review Board to ensure that the rights of human research subjects are protected.

MECC's Institutional Review Board (IRB) reviews human subject research proposals to ensure that the rights and welfare of human subjects are protected by minimizing risks and ensuring informed and voluntary participation. The fundamental principle of human subject protection is that people should not (in most cases) be involved in research without their informed consent and that subjects should not incur increased risk of harm from their research participation beyond the normal risks inherent in everyday life.

The Institutional Review Board at Mountain Empire Community College has the responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove human subject research activities conducted by or through the College.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and risk to the participants.

II. Statement of Principles

UNDERLYING PRINCIPLES

Mountain Empire Community College has adapted the ethical principles for protection of human subjects as stated in the Code of Federal Regulations: 45 CFR §46. Created by the National Research Act in 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral

Research was established to enact these regulations. The Commission published The Belmont Report, which set forth the following basic ethical principles for the conduct of research involving human subjects:

- Respect for Persons – Acknowledgement of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy.
- Beneficence – A responsibility to do no harm, to maximize possible benefits, and to minimize possible harm.
- Justice – An expectation of fairness in distribution of benefits realized from research as well as its burdens.

APPLICATION

As stated in the Code of Federal Regulations, 45 CFR §46, it is the charge of the IRB to ensure that in the conduct of research

- Risks are minimized and reasonable in relation to anticipated benefits
- Subjects give *informed* consent
- Rights and welfare of the subjects are maintained

Mountain Empire Community College applies the following principles to all human subject research. No distinctions shall be drawn between funded and unfunded projects; sponsored or non-sponsored projects; projects carried out by students, faculty or other MECC employees; on campus or off campus projects; or various funding sources. Additionally, these principles apply to any human research conducted by others on the MECC campus or with MECC students or employees.

- Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
- Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
- Appropriate professional attention and facilities shall be provided to ensure the protection of the individual as a research subject.
- Adequate provisions should be made for recruiting a subject population that represents the population base in terms of gender and ethnicity unless scientifically justified.
- Research involving human subjects must be supervised by qualified persons as approved by the IRB.
- Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject's consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
- Any request by a subject for withdrawal from a research activity will be honored promptly with no penalty.
- All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted Board ***prior*** to project initiation or ***prior*** to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

III. THE MECC INSTITUTIONAL REVIEW BOARD

PURPOSE

The purpose of the Mountain Empire Community College Institutional Review Board is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research studies conducted by or with Mountain Empire Community College employees or students, or on the MECC campus.

AUTHORIZING REGULATIONS

1. Federal Register 56 (June 18, 1991): 28002-28032 [Federal Policy for the Protection of Human Subjects; Notices and Rules] (The Common Rule)
2. Title 45 Part 46 of the Code of Federal Regulations
    a. Codification of the Federal Policy for each of the departments and agencies adopting it is as follows:
        i. CFR Part 1c [Department of Agriculture]
        ii. 10 CFR Part 745 [Department of Energy]
        iii. 14 CFR Part 1230 [National Aeronautics and Space Administration]
        iv. 15 CFR Part 27 [Department of Commerce]
        v. 16 CFR Part 1028 [Consumer Product Safety Commission]
        vi. 22 CFR Part 225 [International Development Cooperation Agency] [Agency for International Development]
        vii. 24 CFR Part 60 [Department of Housing and Urban Development
        viii. 28 CFR Part 46 [Department of Justice]
        ix. 32 CFR Part 219 [Department of Defense]
        x. 34 CFR Part 97 [Department of Education]
        xi. 38 CFR Part 16 [Department of Veteran's Affairs]
        xii. 40 CFR Part 26 [Environmental Protection Agency]
        xiii. 45 CFR Part 46 [Department of Health and Human Services]
        xiv. 45 CFR Part 690 [National Science Foundation]
        xv. 49 CFR Part 11 [Department of Transportation]
    b. FDA regulations pertaining to research with human subjects are codified at
        i. 21 CFR Part 50 [Protection of Human Subjects]
        ii. 21 CFR Part 56 [Institutional Review Boards]

IV. IRB MEMBERSHIP

IRB Membership [45 CFR §46.107]

1. The IRB shall have at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular board member at a convened meeting.
2. The IRB shall be composed of members with varying backgrounds and expertise 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 its members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of the research in terms of institutional commitments and regulations, applicable law, ethical standards, and standards of professional conduct and practice.

3. The IRB must include both men and women, at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB may not consist entirely of members of one discipline. Every reasonable effort will be made to ensure that the IRB membership includes representation from each of the College's three academic divisions (Arts & Sciences, Health Sciences & Industrial Technology, and Business & Information Technology).
4. 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.
5. No person shall be excluded from serving on the IRB based on sex, race, color, or national origin.
6. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
7. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.
8. Potential members and alternates for the IRB will be identified by the IRB Manager, in consultation with the Vice President for Academic and Student Services and Division Deans. Candidates will be invited to serve for a term of three (3) years. Invitations will be issued as needed to fill vacant slots and ensure that the composition of the committee remains consistent with federal guidelines and MECC policy.
9. An IRB member's term of service may be terminated by written notice of the member to the Chair or by written notice from the Chair to the member. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair and IRB Manager must be informed so that a replacement member may be identified. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.
10. The IRB Chair shall be a voting member of the board, and shall be selected annually by a majority vote of the board. The Chair shall have the authority to sign all IRB action items. The Chair shall preside over all meetings of the IRB.
11. The IRB Vice Chair shall be a voting member of the board, and shall be selected annually by a majority vote of the board. The Vice Chair shall have the authority to sign all IRB action items in the absence of the Chair. The Vice Chair shall preside over all meetings of the IRB in the absence of the Chair.
12. Liability coverage for IRB members is provided through the Commonwealth of Virginia's liability insurance, whether or not the IRB member is an employee of MECC.

TRAINING AND EDUCATION

1. All IRB members are required to undergo formal training at the time of their initial appointment. Training options that satisfy this requirement include the National Institutes of Health (NIH) Protecting Human Research Participants Online Course.
2. IRB members must complete the *Documentation of Education on Human Subject Protection* form upon their initial appointment. (See forms.) They must participate in continuing education and submit a new documentation form at least once every three years during their service on the IRB.
3. IRB members may satisfy continuing education requirements either by re-taking the NIH training course (above) or by completing/attending other IRB training opportunities. Some examples of training options are included below.
    a. Continuing Education Resources:
        - OHRP Training Videos
        - OHRP Webinars
        - OHRP Institutional Review Board (IRB) Guidebook Online
        - Conferences and Research Community Forums sponsored by OHRP or other professional organizations
4. The IRB Manager will ensure compliance with continuing education requirements and maintain a log of training completion dates.

CONFLICT OF INTEREST

An IRB Member is said to have a conflicting interest whenever that IRB member, member's spouse, or member's dependent child:

1. is an investigator or sub-investigator on the project;
2. has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest;
3. acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. has identified himself or herself for any other reason as having a conflicting interest.

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of his or her position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which he or she is a member. An IRB member is responsible for notifying the IRB Chair immediately of a possible conflict of interest, so that an alternate can be identified to serve in the member's place on all matters relative to the conflict.

BOARD MEMBERS' RESPONSIBILITIES

It is each board member's responsibility to:

1. Participate in required trainings and submit the *Documentation of Education on the Protection of Human Subjects* form to the IRB Manager.
2. Review all materials on each application including the full proposal.
3. Protect the interests and welfare of research subjects.
4. Help researchers comply with ethical requirements and with federal and state regulations.

5. Help protect Mountain Empire Community College and its researchers from any potential liabilities to which they may be exposed.
6. Actively participate in board actions and determinations.

It is the responsibility of the IRB Chair to:

1. Make Human Subject Research determinations.
2. Initiate all board reviews.
3. Preside over all IRB meetings.
4. Ensure a majority of members participate in all board decisions with a majority of those present in agreement of determination.
5. Sign and submit the IRB determination letter to the Principal Investigator (PI).
6. Coordinate with the IRB Manager to ensure that all records are maintained as required by Title 45 Part 46 of the Code of Federal Regulations. (See reporting requirements.)

V. IRB ADMINISTRATION

The IRB shall function administratively through the Office of Institutional Advancement. The Grants Coordinator shall serve as the IRB Manager, coordinating all administrative functions of the IRB.

It is the responsibility of the IRB Manager to:

1. Oversee all IRB activities.
2. Accept IRB application packets and verify that all required materials are included.
3. Distribute applications packets to IRB Chair for consideration. Distribute application packets to other IRB members at the direction of the Chair.
4. Schedule IRB meetings as needed.
5. Distribute meeting notices to IRB members and investigators at least seven (7) days in advance of the meeting.
6. Distribute determination letters to PI and OHRP at the direction of the Chair.
7. Maintain required records and minutes of Board activities.
8. Submit required documentation to OHRP.
9. Assist with IRB training activities.
10. Maintain a log of IRB training completion dates.
11. Maintain the MECC IRB Operational Manual.
12. Design and maintain the IRB website, in cooperation with the MECC webmaster.

The Coordinator for Institutional Effectiveness will serve as a consultant to the IRB Manager or the full Institutional Review Board, as necessary, to provide insight into research design, data collection methods, and other technical considerations.

VI. IRB AUTHORITY

CHARGE

The MECC IRB is accountable to the U.S. Department of Health and Human Services Office of Human Research Protections (OHRP) for the oversight of all human subject research to ensure the ethical treatment of all human subjects.

The MECC IRB must review and approve ***all*** research involving the use of humans as research participants regardless of the source(s) of funds, if one or more of the following apply:

1. The research is sponsored by MECC,
2. The research is conducted by or under the direction of any employee, student, or agent of MECC, regardless of where the study is performed,
3. The research is conducted using college-owned facilities or equipment, or
4. The research involves the use of MECC's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as research requiring Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to seek guidance from the IRB Chair.

The IRB reviews all projects and programs involving human subjects in accordance with this Manual, applicable federal regulations, and sponsor policies and guidelines.

- The IRB shall have the authority to require progress reports from the investigators and oversee the conduct of the study.
- The IRB shall have the authority to seek verification, from sources other than the investigators, that no material changes have occurred since a previous IRB review, particularly in cases where (i) the project involves unusual levels or types of risks to subjects; (ii) the project is conducted by an investigator that has previously failed to comply with the requirements/determinations of the IRB and/or HHS regulations; or (iii) concerns have been raised, based upon information in continuing review reports or other sources, about possible material changes occurring without IRB approval.
- The IRB shall have the authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol.
- The IRB shall have the authority to access, and to duplicate, records related to any research approved by the IRB regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review and/or duplicate records in order to minimize potential disruption of ongoing research.

REVIEW BY INSTITUTION [45 CFR §46.112]

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials **may not** approve the research if it has been disapproved by an IRB.

REPORTING REQUIREMENTS

The institution must prepare and maintain adequate documentation of IRB activities [45 CFR §46.115]. In addition to the written IRB procedures and membership lists required by the assurance process [45 CFR §46.103(b)(3)], such documentation must include copies of all research proposals reviewed, sample

consent documents, minutes of IRB meetings, records of continuing review activities, progress reports, reports of injuries to subjects, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects (as required by 45 CFR §46.116(b)(5)).

Minutes of IRB meetings must be kept in sufficient detail to record the following information: attendance at each meeting, actions taken by the IRB, the vote on actions taken (including the number of members voting for, against, and abstaining), the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution [45 CFR §46.115(a)(2)].

IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained for three years after completion of the research project. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [45 CFR §45.115(b)].

REQUIRED ASSURANCES

Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56 FR 28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule [also known as 45 CFR §46]. (See 45 CFR §46.101(b) or Section XIII of this document for exemptions.) Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

MECC must have an Assurance of Compliance [OMB No. 0990-0263] that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

ACTIONS

A majority of the IRB members, including at least one member whose primary concerns are in nonscientific areas, must participate in all decisions and actions of the board, except in the case of an expedited review procedure (see page 10). Final approval of all actions, except an expedited review, shall require a majority of the members present or participating in the action. Meetings may be conducted in person or through a real-time telephone conference arrangement.

Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If, during an IRB meeting, the Chair moves the meeting to executive session, visitors will be asked to leave the room until the executive session has ended.

The IRB may take one of five actions, in writing, in regard to proposed human subject research:

1. Exempt from full review
2. Approve
3. Approve subject to requested changes/restrictions

a. The PI must respond to the IRB Chair regarding any requested changes or restrictions. If the IRB Chair determines that the responses are sufficient to address the concerns of the IRB, he/she may approve the protocol.

4. Disapprove and/or make recommendations of required changes for resubmission
5. Suspend or terminate as per 45 CFR §46.113

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 subjects. Any disapproval, suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Furthermore, the IRB may sanction the Principal Investigator as the board deems necessary to ensure continued human subject protection. All actions will be reported to the Office for Human Research Protections.

APPEALS

A Principal Investigator may appeal the decision of the IRB when a protocol has been (i) disapproved or (ii) approved subject to requested changes/restrictions and the PI and the Chair cannot come to agreement regarding the requested changes or restrictions. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad hoc* committee and final action by the IRB. Disapproval of a protocol by the IRB, following an appeal, cannot be overridden by any institutional official.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human subjects are those which involve Mountain Empire Community College and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, MECC may enter into a joint review arrangement, rely on the review of another institution's qualified IRB, or make similar arrangements for avoiding duplication of effort, under the following conditions:

- The cooperative arrangements are approved by the head of the Federal Department or Agency supporting the project;
- Both institutions have Federalwide Assurances (FWAs) approved by OHRP;
- Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and
- The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

VII. CONSIDERATIONS & TYPES OF REVIEW

REQUIRED CONSIDERATIONS

The *HHS Office of Human Research Protections IRB Guidebook* requires that IRBs

1. Consider the qualifications and professional development of the Principal Investigator and relate them to the degree of protocol complexity and risk to human subjects;
2. Consider requiring that less experienced research investigators be sponsored by seasoned researchers;
3. Consider directing that proposals requiring skills beyond those held by the Principal Investigator be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved;
4. Instruct investigators to prepare protocols, with complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure that pertinent laws and regulations are observed. Samples of informed consent must be included with protocols. Investigators are responsible for obtaining informed consent and ensuring that no human subject will be involved in the research before consent is obtained;
5. Ensure that the research plan addresses quality assurance standards set by the institution as well as applicable external standards;
6. Ensure that appropriate reviews for scientific merit be conducted before the research is approved;
7. Ensure that mechanisms are in place for monitoring the progress of the research.

For non-exempt research, the IRB must

1. Evaluate procedures
    a. How are subjects recruited?
    b. Are subjects equitably selected?
    c. What are the risks and are they minimized?
    d. Do the benefits outweigh the risks?
2. Evaluate the consent *process*
    a. Will subjects be fully informed of procedures and risks?
    b. Is consent written in appropriate understandable language?
    c. Is the subject's voluntary consent and withdrawal explained fully?
    d. How is informed consent obtained?
3. Evaluate the informed consent *document.* (See Section XIV.)

TYPES OF IRB REVIEW

1. Exempt Review
   (See 45 CFR §46.101(b) or Section XIII of this policy for a description of what qualifies as exempt research.)
    a. A research protocol can be submitted for an exempt review if the Chair anticipates that there will be no or few questions about a proposal and that the proposal is appropriate for consideration for exemption.
    b. The IRB Chair and/or IRB Manager will convene the Board and distribute the application materials for each member to review.

c. If a majority of members approve the exempt status, the research is approved as exempt.
d. If a majority of members have doubt of the project's qualification as exempt, the Chair may call for full board review of the proposal.
e. The term "exempt" refers to the requirement for continuing IRB review, but not the general requirements for informed consent and protection of subjects. Thus, even if the project is exempt, the PI must inform potential subjects of the proposed procedures and of their rights as subjects.
f. Exempted approvals expire one year after Board review. The PI must seek review annually for projects that last longer than one year. Additionally, the PI must ensure that progress reports and/or review applications are submitted more frequently if mandated by the IRB.

2. Expedited Review
    a. A research protocol may be considered for expedited review if it presents no more than minimal risk to subjects, or there are only minor changes to previously approved research during the period for which approval is authorized.
    b. Categories of research that may be considered for expedited review include (but are not limited to):
        i. Research has been reviewed and approved by another IRB;
        ii. Continuation review of research previously approved by the convened IRB as follows:
            1. where
                (i.) the research is permanently closed to the enrollment of new subjects;
                (ii.) all subjects have completed all research-related interventions; or
                (iii.) the research remains active only for long-term follow-up of subjects; or
            2. where no subjects have been enrolled and no additional risks have been identified; or
            3. where the remaining research activities are limited to data analysis.
    c. An expedited review will be conducted by two board members selected by the Chair. Both reviewers must agree in order for a proposal to be approved.
    d. In an expedited review, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A proposal may be disapproved **only** after review in accordance with the non-expedited procedure set forth in 45 CFR §46.108(b). If the reviewers choose not to approve the proposal, it will be referred to the IRB Chair with a request for a full board review.
    e. All IRB members will be advised of all proposals approved under the expedited review procedure [45 CFR §46.110(c)].

3. Full Board Review
    a. All proposed human subject research that does not meet the criteria for exemption or an expedited review, must be reviewed by a majority of the IRB members at a convened meeting referred to as a "full board review."
    b. Prior to the review meeting, the full board review application is previewed by the Chair or designee to determine if further documentation is needed.
    c. Once all materials are collected, the Chair and/or the IRB Manager will convene the Board and distribute the application materials for each member to review.

d. A majority of board members reviewing the proposal must agree on the board's determination.

VIII. CRITERIA FOR IRB APPROVAL OF RESEARCH [45 CFR §46.111]

REQUIREMENTS

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits the subjects would receive even if not participating in the research). The IRB should 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 responsibilities.
3. Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR **§**46.116.
5. Informed consent is documented, in accordance with, and to the extent required by 45 CFR **§**46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Other Considerations

1. The MECC IRB will make every effort to ensure that both the mental and physical well-being of the subjects are adequately protected and establish procedures to ensure the maintenance of proper records, the protection of anonymity, and the confidentiality of all data collected.
2. The MECC IRB will determine whether risks to subjects are reasonable relative to the anticipated benefits. The IRB shall not allow the use of human subjects in poorly designed projects that are unlikely to elicit meaningful results.
3. Ensure informed consent of subjects will be obtained through appropriate methods. The IRB will ensure that written consent is obtained from all subjects unless waived in accordance with 45 CFR **§**46.117 (c) (1) or (2).
4. As per 45 CFR **§**46.117 (c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

a. that the consent document is the only record linking the subject and the research and potential harm could result from a breach of confidentiality. In this case, each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern; or
b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. If the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. All projects using or collecting data about MECC students, faculty, or employees must have oversight by a designated MECC faculty member or administrator.

VULNERABLE SUBJECTS

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, the IRB must ensure that additional safeguards have been included in the study to protect the rights and welfare of these subjects. [45 CFR 46.203-46.207; 45 CFR 46.301-46.306; 45 CFR 46.401-46.409]

REVIEW INTERVAL

1. The review interval will be determined by the IRB at the time of approval.
2. The maximum interval for IRB review is one year.
3. A request for continuation must be submitted at least two months prior to the approval expiration date.
4. Even when subject activities are complete, but data is still being analyzed or any other aspect of the study is ongoing, the study must have IRB approval to continue.

IX. INVESTIGATOR'S RESPONSIBILITIES

Principal Investigator's Responsibilities

1. For any project involved with live human subjects/participants, it is the responsibility of the Principal Investigator (PI) to apply to the MECC Institutional Review Board for **Human Subject Research Determination**.
2. Should it be determined that a project meets the OHRP definition of Human Subject Research, no activity with the subjects may begin until IRB approval has been issued.
3. The PI must certify that they have completed human subjects protection training prior to receiving IRB approval. Documentation of such training must be provided to the IRB Manager. The Committee has the authority to require principal investigators to complete additional human subjects protection training. Requirements for additional training will be issued at the Committee's discretion, and will be based on an assessment of the individual investigator's background and qualifications, as well as the amount of time that has lapsed since the investigator's prior training.
4. The PI must ensure that all researchers working with the subjects and the project director of a human subject research project complete the National Institutes of Health Protecting Human

Research Participants Online Course, or other similar training. It is at the discretion of the PI as to what additional training may be required.

5. No contact with human subjects may be conducted until the PI's training on human subject protection is complete and the *Documentation of Training in Human Subject Protection* form has been submitted to the IRB Manager. (See forms.)
6. If it is determined that the study is human subject research, the PI must submit the appropriate applications to the IRB two (2) months prior to the anticipated start date of the project. No contact with human subjects may begin prior to IRB approval.
7. It is the PI's responsibility to submit the application for IRB continuation review at least two (2) months before the expiration of the existing IRB approval. The IRB can refuse to accept late applications.
8. All work on the project must stop on the IRB approval expiration date unless continuation has been formally approved.
9. The Principal Investigator must maintain records of all human subject research projects for a minimum of three (3) years after completion of the project.
10. The PI must ensure that the records are well organized and easily accessible by the IRB and the appropriate funding agent.
11. Principal Investigators, including those who are IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting.

X. IRB Procedures/Steps (The Approval Process)

Steps

1. The PI completes the *Human Subject Research Determination* form and proposal, and submits it to the IRB Manager.
    a. The *Human Subject Research Determination* form and proposal are distributed to the IRB Chair.
    b. If it is determined that the project is human subject research, the PI must submit his *Documentation of Training in Human Subject Protection* form with the certification of completion of the National Institutes of Health Online Course or other similar training. This certification must accompany all IRB applications for review.
2. If the proposal is determined to be human subject research, the PI completes the appropriate IRB review application form:
    a. Application for Exempt Review
    b. Application for Expedited or Continuation Review
    c. Application for Full Board Review
3. The PI gathers all required documentation as per the application checklist.
4. The PI submits the application packet to the IRB Manager.
5. IRB meetings are scheduled as needed.
6. The application packets are sent to the IRB Chair for review and distribution.
7. The IRB takes action within one month of application submission.
8. THE IRB MUST APPROVE THE RESEARCH PROJECT **BEFORE** THE RESEARCHER MAKES ANY CONTACT WITH THE SUBJECTS.
9. Approval is for a maximum of one year from the date of the IRB meeting considering the application.

10. If any work or data analysis is to continue after the approval expiration date, the PI MUST submit an application for board review **two (2) months prior** to the expiration date.
11. A project that requires a full board review for the original application must apply for a full board review for continuation unless it meets the criteria for expedited review.
12. Upon completion of the project, the PI should submit to the IRB the *Close Out Report* form. No approval is required by the IRB for close out.

CHECKLIST (SEE FORMS)

1. ☐ PI Certifications of Human Subject Protection Training
2. ☐ Completed and signed application for review
3. ☐ Research plan/proposal
4. ☐ Samples of informed consent/assent forms
5. ☐ Outline of information to be provided prior to subjects' agreement to participate
6. ☐ Instruments, surveys, questionnaires, etc.
7. ☐ Curriculum vitae

MODIFICATIONS

At the time of approval, Principal Investigators will be notified that changes in approved research may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects. The IRB categorizes amendments to research protocols as either minor or significant.

- Minor Change – A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Examples include:
    - Addition or deletion of study team members;
    - Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and design of the approved study;
    - Removal of research procedures that would thereby reduce the risk to subjects;
    - Addition of non-sensitive questions to unvalidated survey or interview procedures;
    - Addition of or revisions to recruitment materials or strategies;
    - Administrative changes to approved documents (e.g., spelling, grammatical, or typographical corrections.)

  Minor changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB Manager with the concurrence of the IRB Chair.

- Significant Change – A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples include:
    - Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
    - Addition of research procedures that involve greater than minimal risk to subjects;

- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Significant changes must be reviewed at the same level as the original protocol. However, if the original protocol was approved using the expedited review procedure, and the reviewers determine that the amendment will increase the level of risk beyond minimal risk, the amendment will be referred to the full board for consideration.

XI. DETERMINATION AS RESEARCH

CODE OF FEDERAL REGULATIONS

As defined in the Code of Federal Regulations, *research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purpose of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstrations and service programs may include research activities [45 CFR **§**46.102(d)].

It is generally accepted practice and discussed in the *Office of Human Research Protection IRB Guidebook* that the above is interpreted comprehensively to include as research any project in which any part of the project is to be a contribution to "generalizable knowledge" and/or its results are intended to probably be made public in some way, such as in a presentation at a conference or other professional meeting or if a model is designed that will be distributed to other organizations, or if the data or strategies could be utilized in some way by another institution. (See decision charts.)

FACTORS TO BE CONSIDERED IN DETERMINING WHETHER RESEARCH IS SUBJECT TO THIS POLICY

- Is the activity a <u>systematic</u> investigation <u>designed</u> to develop or contribute to <u>generalizable</u> knowledge? 45 CFR **§**46.102(d)
- Does the research involve obtaining information about living individuals? 45 CFR **§**46.102(f)
- Does the research involve intervention or interaction with the individuals? 45 CFR **§**46.1029(f)(1)(2)
- Is the information individually identifiable? (Private information must be individually identifiable in order for the obtaining of the information to constitute research involving human subjects [45 CFR **§**46.102(f)(2)].)
- Is the information private? (The designation of private would include behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or which the individual can reasonably expect will not be made public [45 CFR 46.102(f)(2)].)

XII. DETERMINATION AS HUMAN SUBJECTS

HUMAN SUBJECTS

Human subjects are individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information [45 CFR §46.102(f)].

Intervention includes both physical procedures by which data are gathered (for example, drawing blood) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between the investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Data is considered *identifiable* if the identity of the subject is associated with the information or may readily be ascertained by the investigator [45 CFR §46.102].

XIII. EXEMPTIONS

EXEMPTED RESEARCH ACTIVITIES

Unless otherwise required by federal department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy: (45 CFR §46.101)

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 exempt under 45 CFR 46.101 (b) if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) 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 the subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are 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, or (iv) 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, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe or an 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.

*These exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, individuals who are mentally impaired, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

Federal department or agency heads retain final judgment as to whether a particular activity is covered by this policy [45 CFR §46.101(c)].

The term "exempt" refers to the requirement for continuing IRB review, but not the general requirements for informed consent and protection of subjects. Thus, even if the project is exempt, the PI must inform potential subjects of the proposed procedures and of their rights as subjects and obtain informed consent.

XIV. INFORMED CONSENT

INFORMED CONSENT DEFINITION

Informed consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights or release or appear to release, the investigator, the sponsor, the institution or agents thereof from liability for negligence [45 CFR §116.21].

IRB CONSIDERATIONS

Investigators may seek consent only under circumstances that provide the prospective subject or his or her representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. 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 appears to release the investigator, sponsor, institution, or agents from liability for negligence [45 CFR §46.116].

FEDERAL REGULATIONS

Federal regulations require that certain information must be provided to each subject [45 CFR §46.116(a)]:

(1) 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;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) For research involving more than minimal risk, an explanation as to whether any compensation will be provided to the subject 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;
(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
(8) 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.

The regulations further provide that the following additional information be provided to subjects, where appropriate (such as when dealing with particularly vulnerable subjects or when the particular study warrants one or more of the following notices) [45 CFR §46.116(b)]:

(1) 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;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) 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
(6) The approximate number of subjects involved in the study.

As a general rule, the IRB will require the investigator to obtain a signed consent form from all research subjects. However, as per 45 CFR **§**46.117(c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

ASSENT

Assent is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in the research." Assent is generally required if:

1. Subjects are minors between the ages of 7 and 17. Children below the age of 7 are generally not asked to provide assent.
2. Subjects 18 or older are intellectually or emotionally impaired and not legally competent to give their informed consent.

In cases where the minor subjects are able to read and understand the informed consent document, they may provide assent on a form with a separate signature line for their parents/guardians.

The assent form must include:

1. Study Title
2. Study Purpose – Provide a brief explanation of the purpose of the study.
3. Procedures – Describe what the subject is being asked to do.
4. Withdrawal Privilege – Describe how a subject can stop participation later even if he/she agrees to start.
5. Voluntary Participation – Include a statement that the subject does not have to participate.
6. Confidentiality Statement – Indicate that the experimenter will not tell anyone (parents, teachers, etc.) what the subject says or does in the study.
7. Signature Lines – Include a signature line for the subject and for the investigator.
8. Date Line

It is important that the form is written using language that is appropriate for the age level and mental capacity of the subjects.

INFORMED CONSENT/ASSENT CHECKLIST

- ☐ Study/Project name
- ☐ Purpose of project
- ☐ Duration of subject's participation
- ☐ Description of procedures
- ☐ Possible risks

- ☐ Possible benefits
- ☐ Confidentiality statement
- ☐ Voluntary consent explanation
- ☐ Guarantee withdrawal statement
- ☐ Contact information
- ☐ Investigator's statement, signature, and date
- ☐ Participant's signature and date

Additional elements for assent of minors or vulnerable subjects:

- ☐ Child/subject's assent statement (if appropriate)
- ☐ Parent's permission statement (or responsible representative)

XV. Adverse Events

Adverse Events are events or circumstances that were unintended and unanticipated at the time the project was approved by the IRB. Any illness, injury, or trauma that required medical or psychological treatment must be reported to the IRB, to the funding agency, and in the Progress Report. (See forms.) Even those events that are not related to the project must be reported. For additional guidance, refer to OHRP's Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.

Unanticipated Event Requiring Reporting

Is the adverse event an unanticipated problem (which, therefore, must be reported)?

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

If the answer to all three questions is yes, then the adverse event is an unanticipated problem and must be reported to appropriate entities under the HHS regulations. 45 CFR 46.103(a) and 46.103(b)(5)(i)

Serious Adverse Event

Any event resulting in death, a life threatening situation, inpatient hospitalization, significant disability or birth defect must be reported to the IRB within **five (5) days** of the PI's knowledge of the event. A physician's comment is required and must be included with the report.

Unexpected Adverse Event

Any adverse event not listed in the current consent form must be reported to the IRB within **five (5) days**.

NEITHER SERIOUS NOR UNEXPECTED ADVERSE EVENT

Any adverse event which is neither *serious* nor *unexpected* must be reported to the IRB within **one (1) month**.

Examples

- A subject is identified as being in a high risk category that was not anticipated or planned in the selection of human subjects.
- A different use of data that originally planned causes a risk of loss of privacy or confidentiality for the human subjects.
- Participant consent was waived by IRB due to minimal risk, but, as the project evolves, is now determined to be needed.
- Although not occurring within the research activity, any automobile accident involving a subject as driver still needs to be reported. If numerous accidents by subjects in the same study were reported to the IRB, they could be a result of extreme stress caused by the study.

XVI. REFERENCES

TIDEWATER COMMUNITY COLLEGE, OFFICE OF GRANTS & SPONSORED PROGRAMS. (2007) *INSTITUTIONAL REVIEW BOARD GUIDELINES.* RETRIEVED APRIL 28, 2008, FROM HTTP://WWW.TCC.EDU/WELCOME/COLLEGEADMIN/GRANTS/IRB/IRB_GUIDELINES-07.PDF

SINCLAIR COMMUNITY COLLEGE, GRANTS DEVELOPMENT OFFICE. (2006). *INSTITUTIONAL REVIEW BOARD CHARTER AND STANDARD OPERATING PROCEDURES.* AVAILABLE FROM HTTP://WWW.SINCLAIR.EDU/ABOUT/OFFICES/GRANTS/PUB/COMPLIANCE/SINCLAIRCHARTER.DOC

APPENDIX 1 – TERMS & DEFINITIONS

ANONYMOUS DATA Data collected in a manner so the subjects cannot be identified, directly or through identifiers linked to the subject.

ASSENT Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. [OHRP IRB Guidebook Glossary]

ASSURANCE A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [45 CFR §46.103].

AUTHORIZED INSTITUTIONAL OFFICIAL An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. [OHRP IRB Guidebook Glossary]

BENEFICENCE An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. [Belmont Report]

BENEFIT A valued or desired outcome; an advantage. [OHRP IRB Guidebook Glossary]

CERTIFICATION The official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance [45 CFR §46.102].

COGNITIVELY IMPAIRED An individual who has either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished is considered cognitively impaired for IRB purposes. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. [OHRP IRB Guidebook Glossary]

COHORT A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences. [OHRP IRB Guidebook Glossary]

COMPETENCE Technically, a legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. [OHRP IRB Guidebook Glossary]

CONTRACT As used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant. (*Compare: Grant*) [OHRP IRB Guidebook Glossary]

DEPARTMENT OR AGENCY HEAD The head of any federal department or agency and any other officer or employee of any federal department or agency to whom authority has been delegated. [45 CFR §46.102(a)]

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

EQUITABLE Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed [45 CFR §46.111(a)(3)].

GRANT Financial support provided for a research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract*) [OHRP IRB Guidebook Glossary]

GUARDIAN An individual who is authorized under applicable state or local law to give permission on behalf of a child for general medical care [45 CFR §46.402(e)].

HUMAN SUBJECT A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Data is considered *identifiable* if the identity of the subject is associated with the information or may readily be ascertained by the investigator [45 CFR §46.102(f)].

INFORMED CONSENT A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [45 CFR §46.116].

INSTITUTION A public or private entity or agency (including federal, state, and other agencies) [45 CFR §46.102(b)].

INTERACTION Communication or interpersonal contact between investigator and subject.

INTERVENTION Includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

INVESTIGATOR Title/position of an individual who actually conducts an investigation using human subjects for research purposes [45 CFR §46.102(f)]. (See also: *Principal Investigator*) [OHRP IRB Guidebook Glossary]

IRB An institutional review board established in accord with and for the purposes expressed in this policy [45 CFR §46.102(g)].

IRB APPROVAL The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements [45 CFR §46.102(h)].

JUSTICE An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. [Belmont Report]

LEGALLY AUTHORIZED REPRESENTATIVE A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [45 CFR §46.102(c)].

MINIMAL RISK 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 [45 CFR §46.102(i)]. For example, the risk of drawing a small amount of blood from a health individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

MONITORING The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and its subject protections. [OHRP IRB Guidebook Glossary]

NONAFFILIATED MEMBER A member of an Institutional Review Board who has no ties to the parent institution, its staff, or its faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker). [OHRP IRB Guidebook Glossary]

OHRP Office of Human Research Protections, a division of the U.S. Department of Health and Human Services.

PERMISSION The agreement of parent(s) or guardian(s) to the participation of their child or ward in research [45 CFR §46.402(c)].

PRINCIPAL INVESTIGATOR The scientist or scholar who has primary responsibility for the design and conduct of a research project. (See also: *Investigator*) [OHRP IRB Guidebook Glossary]

PRIVATE INFORMATION Information is considered private if it includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual,

which that individual can reasonably expect will not be made public. It also includes information revealed by a primary research subject about another individual without the consent of that individual.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the process for informed consent, and the proposed methods of analysis that will be performed on the collected data. [OHRP IRB Guidebook Glossary]

RESEARCH A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities [45 CFR §46.102(d)].

RESEARCH SUBJECT TO REGULATION This and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor) [45 CFR §46.102(e)].

RISK The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: *Minimal Risk*) [OHRP IRB Guidebook Glossary]

SITE VISIT A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research. [OHRP IRB Guidebook Glossary]

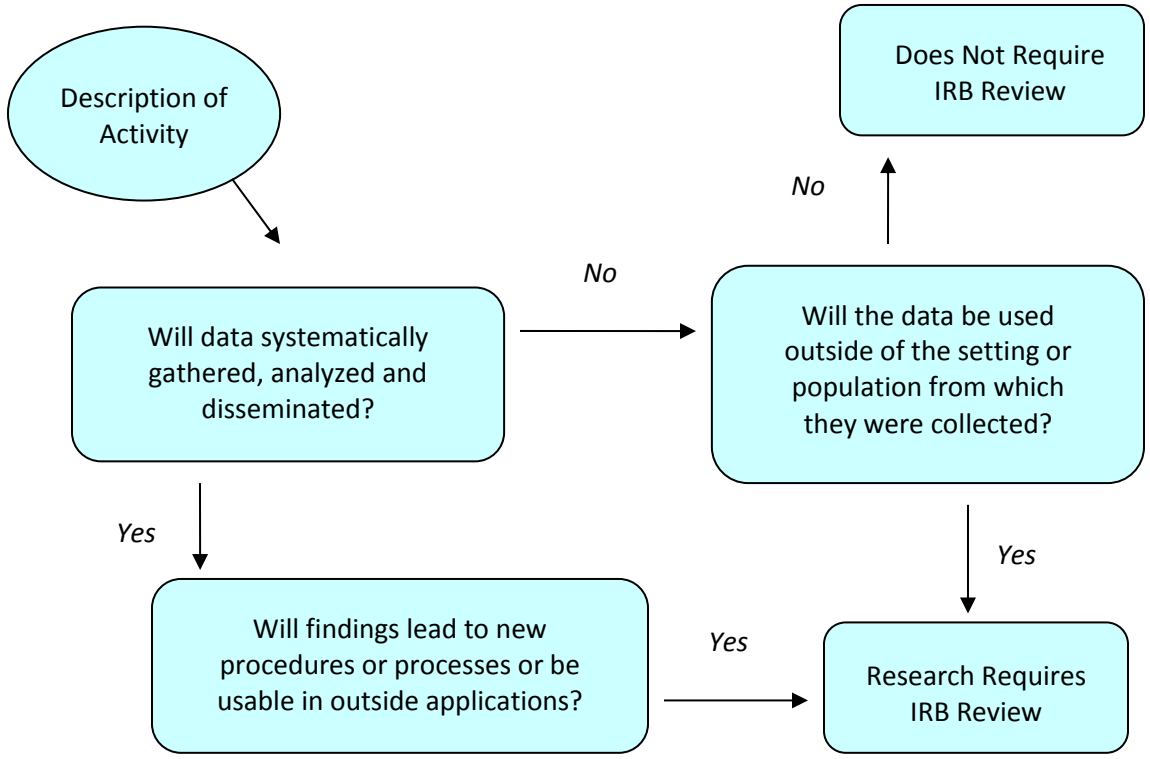
STATISTICAL SIGNIFICANCE A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level. [OHRP IRB Guidebook Glossary]

SURVEYS Studies designed to obtain information from a large number of respondents through questionnaires, interviews, door-to-door canvassing, or similar procedures. [OHRP IRB Guidebook Glossary]

VOLUNTARY Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. [OHRP IRB Guidebook Glossary]

APPENDIX 2 – DECISION CHARTS

WHAT CONSTITUTES RESEARCH AT MECC?



HUMAN SUBJECT REGULATIONS DECISION CHARTS (OHRP)

September 24, 2004

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 subject 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. OHRP welcomes comment on these decision charts. 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 OHRP decision 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. OHRP invites inquiries for additional information.

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?

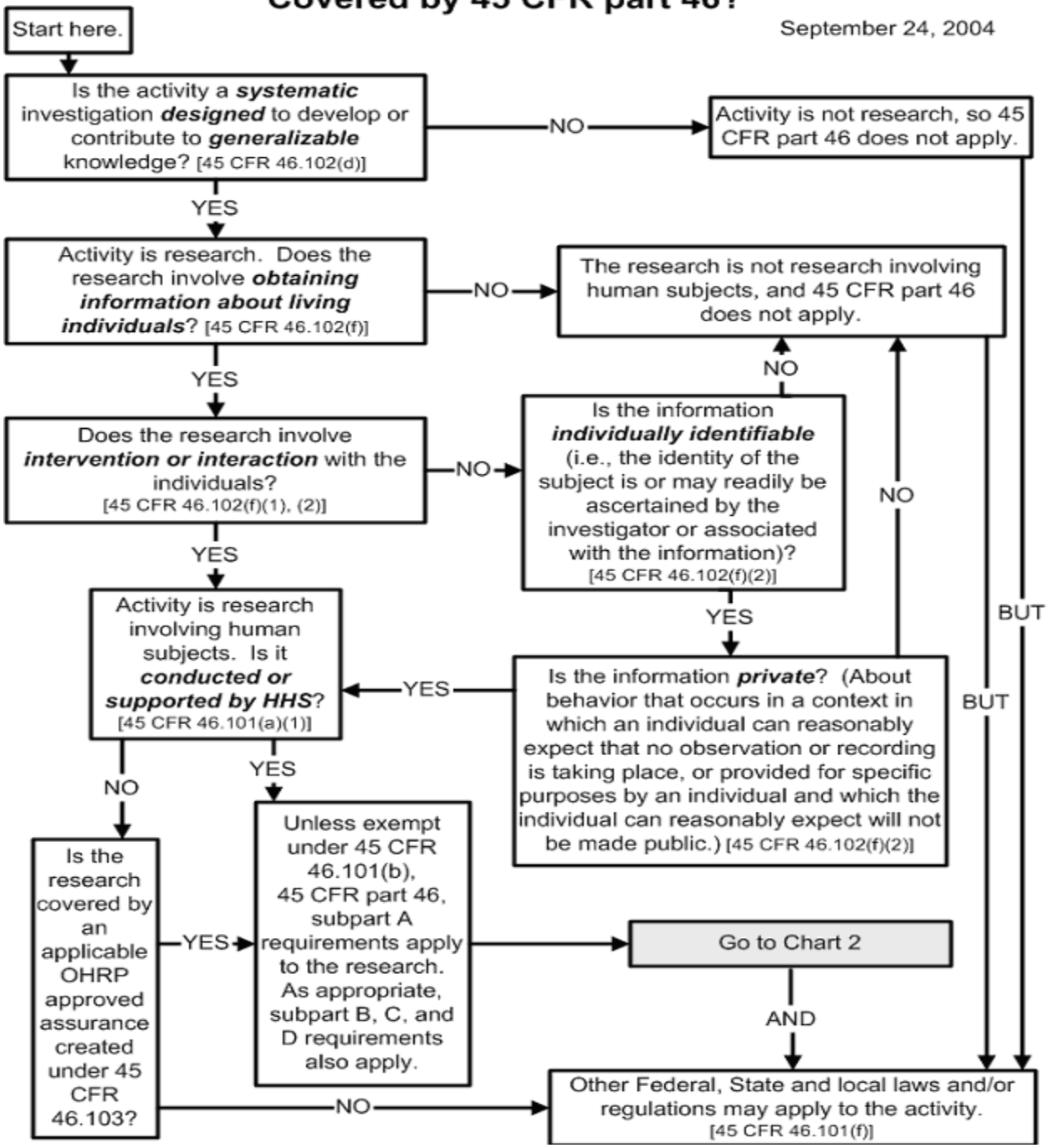


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

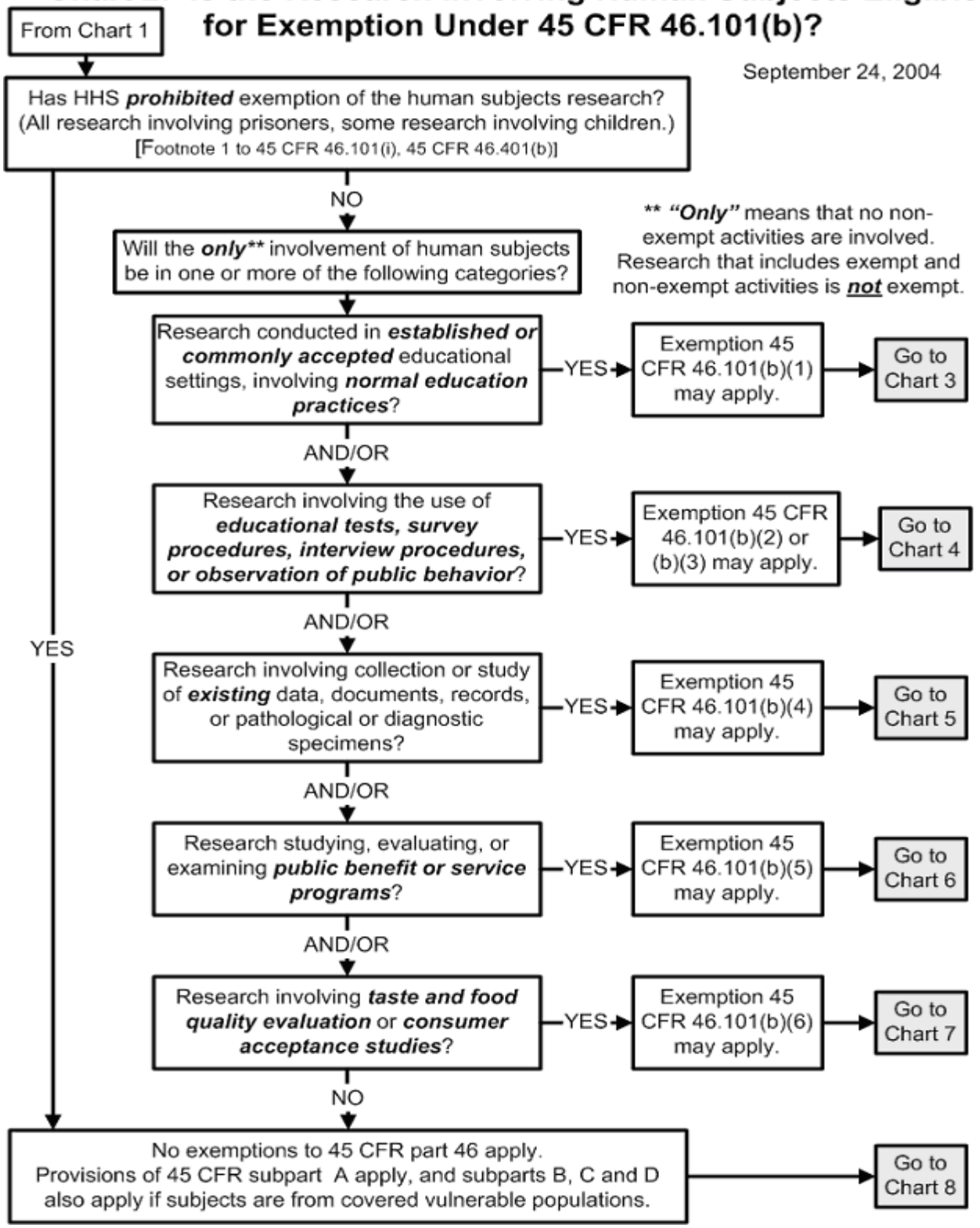


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

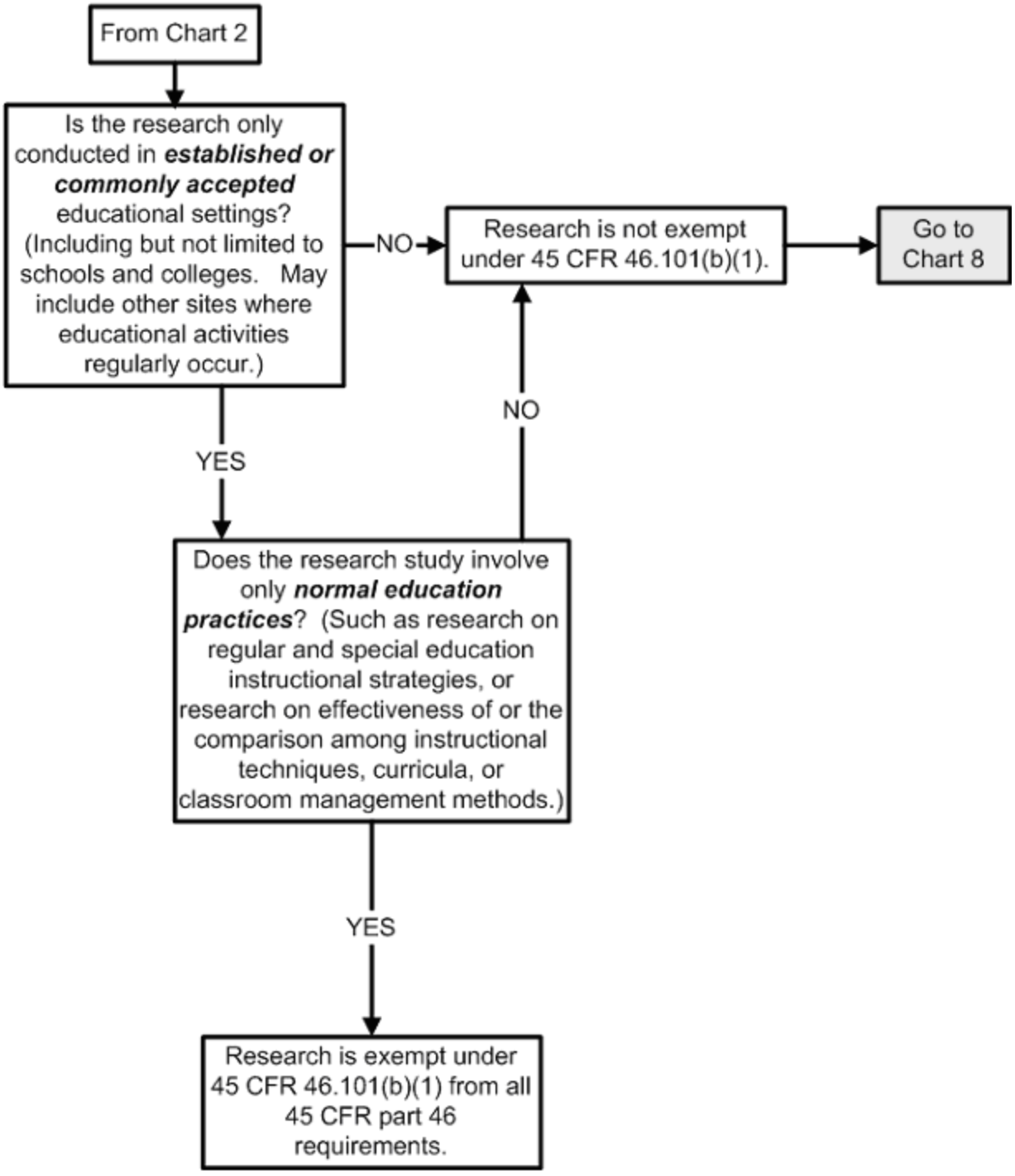


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

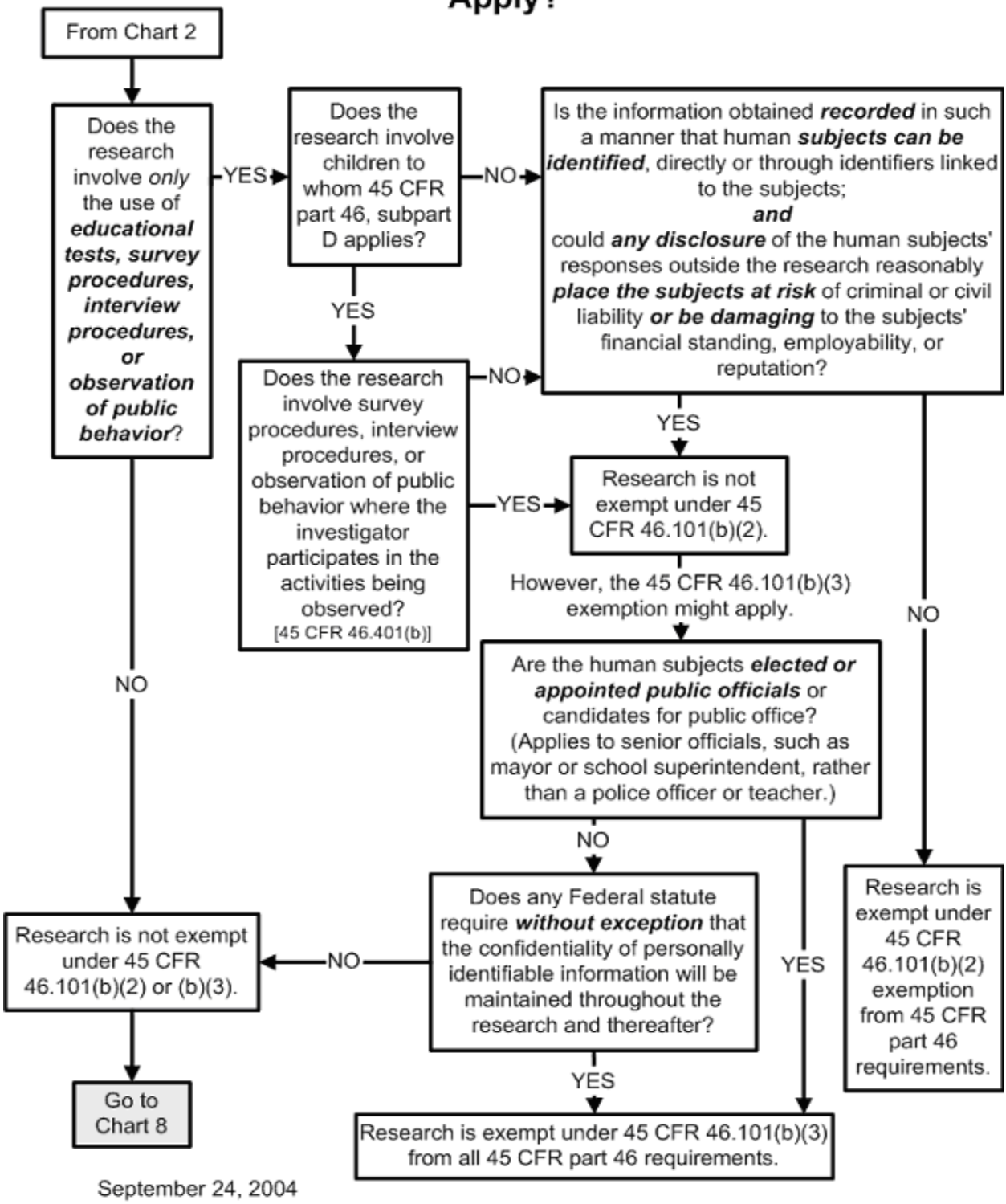


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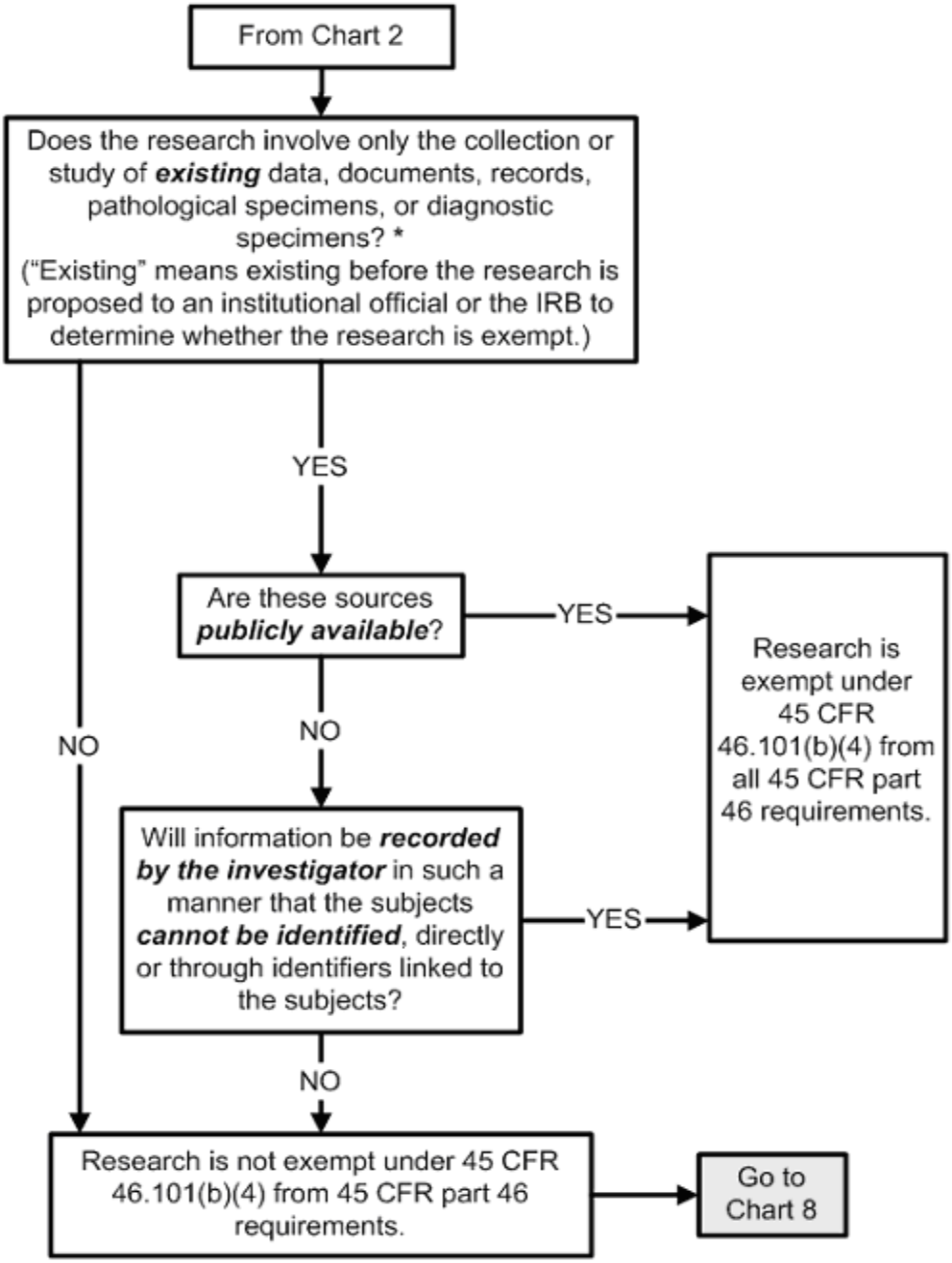
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



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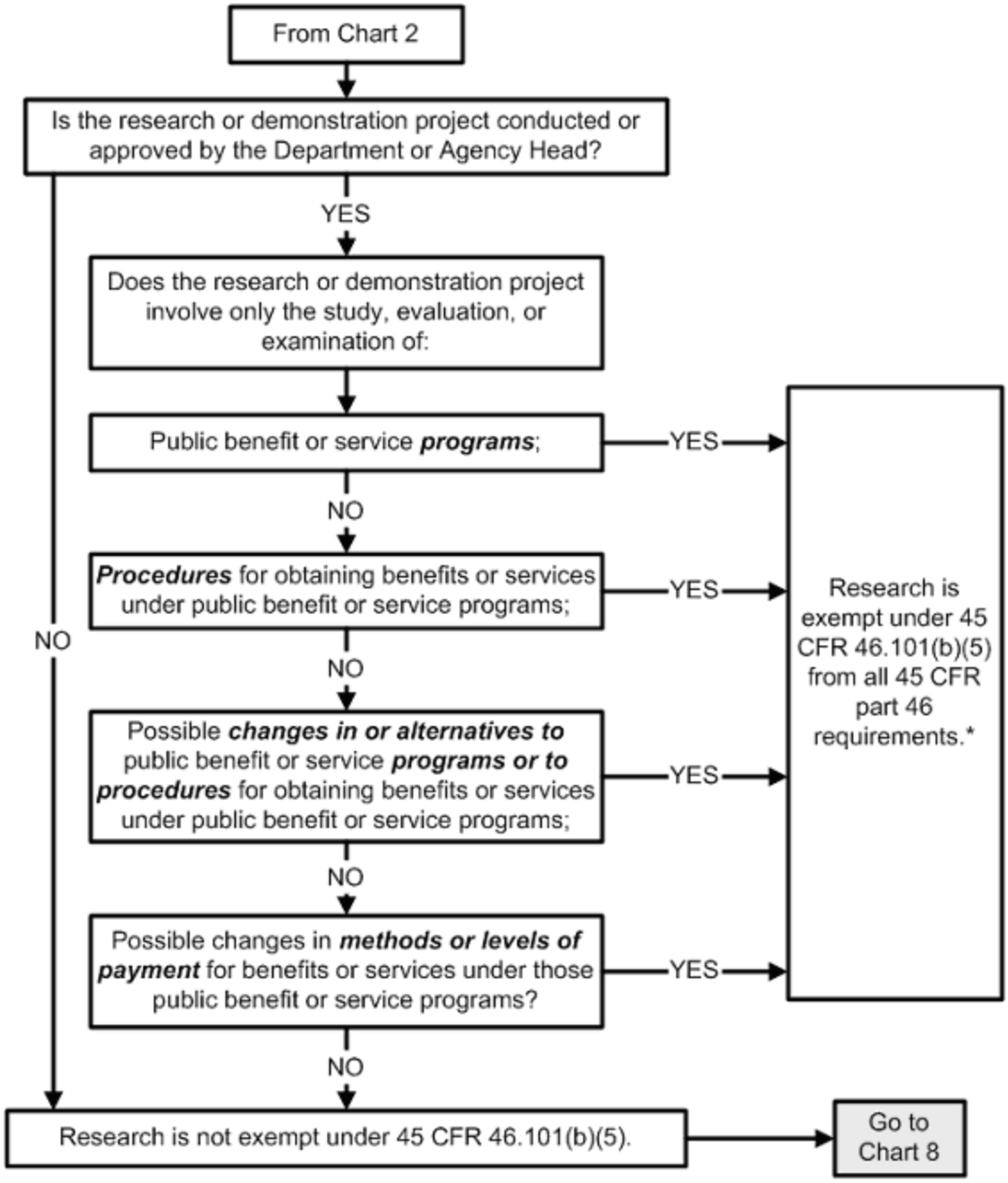
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* 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?

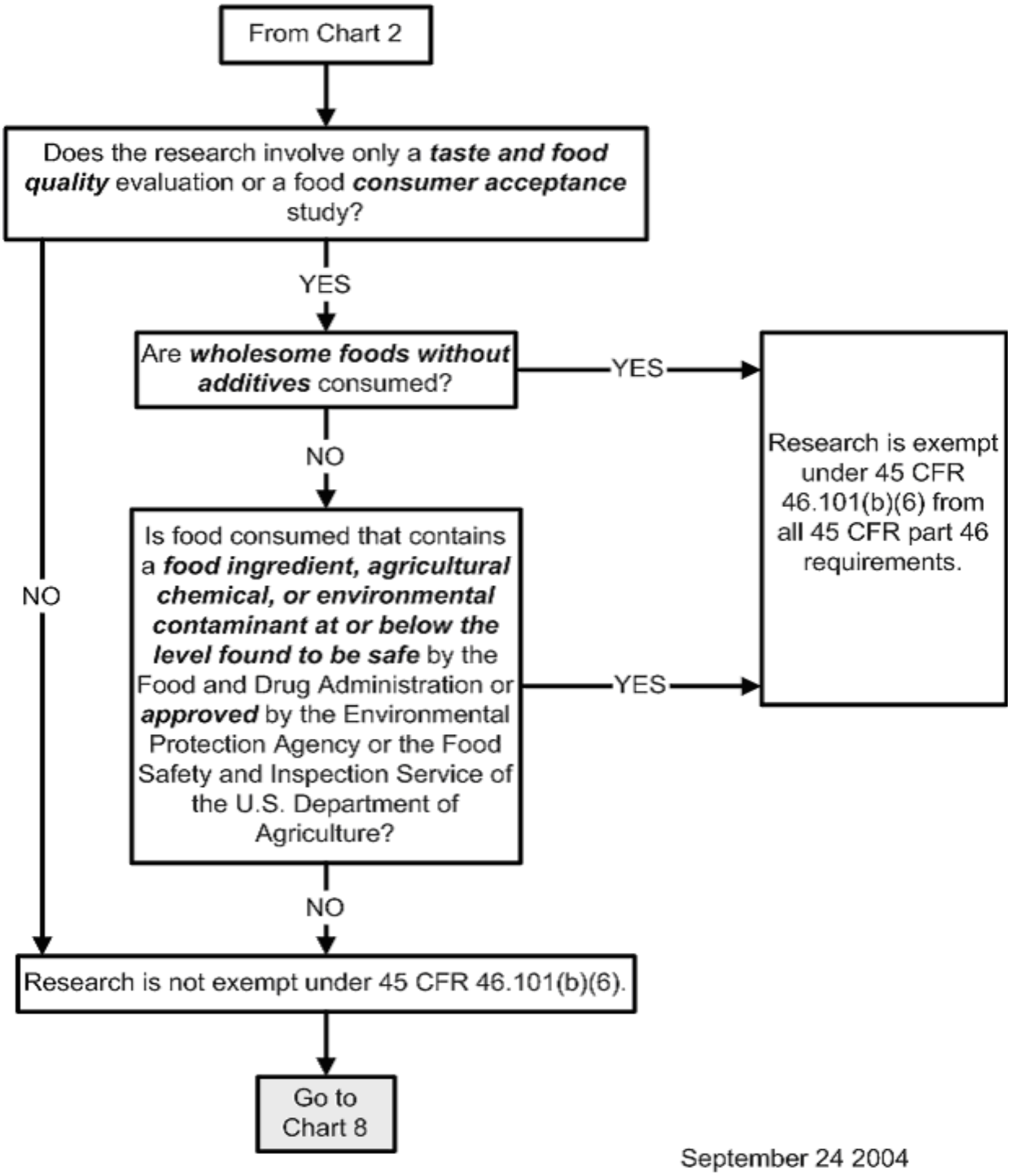

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Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

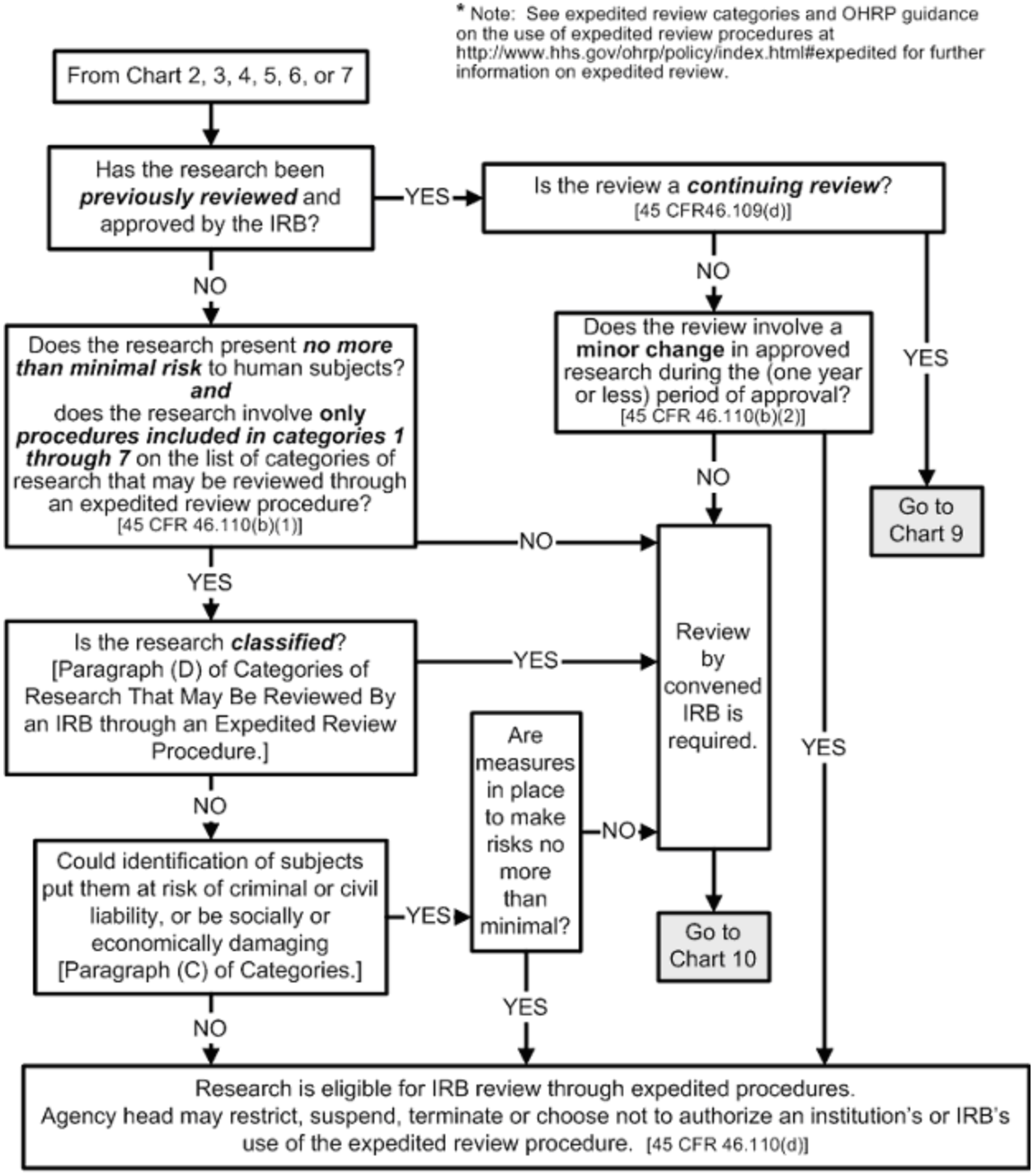

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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

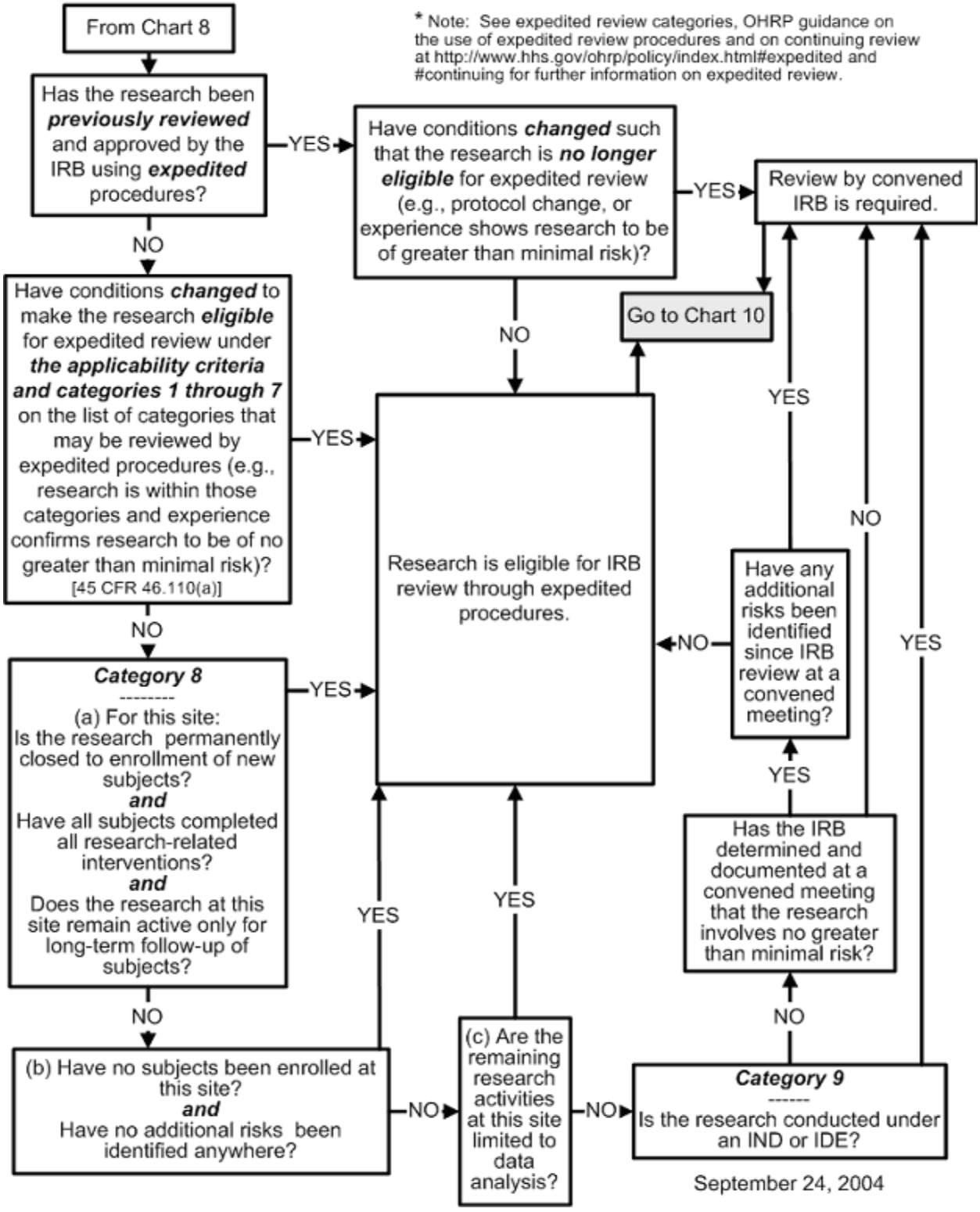
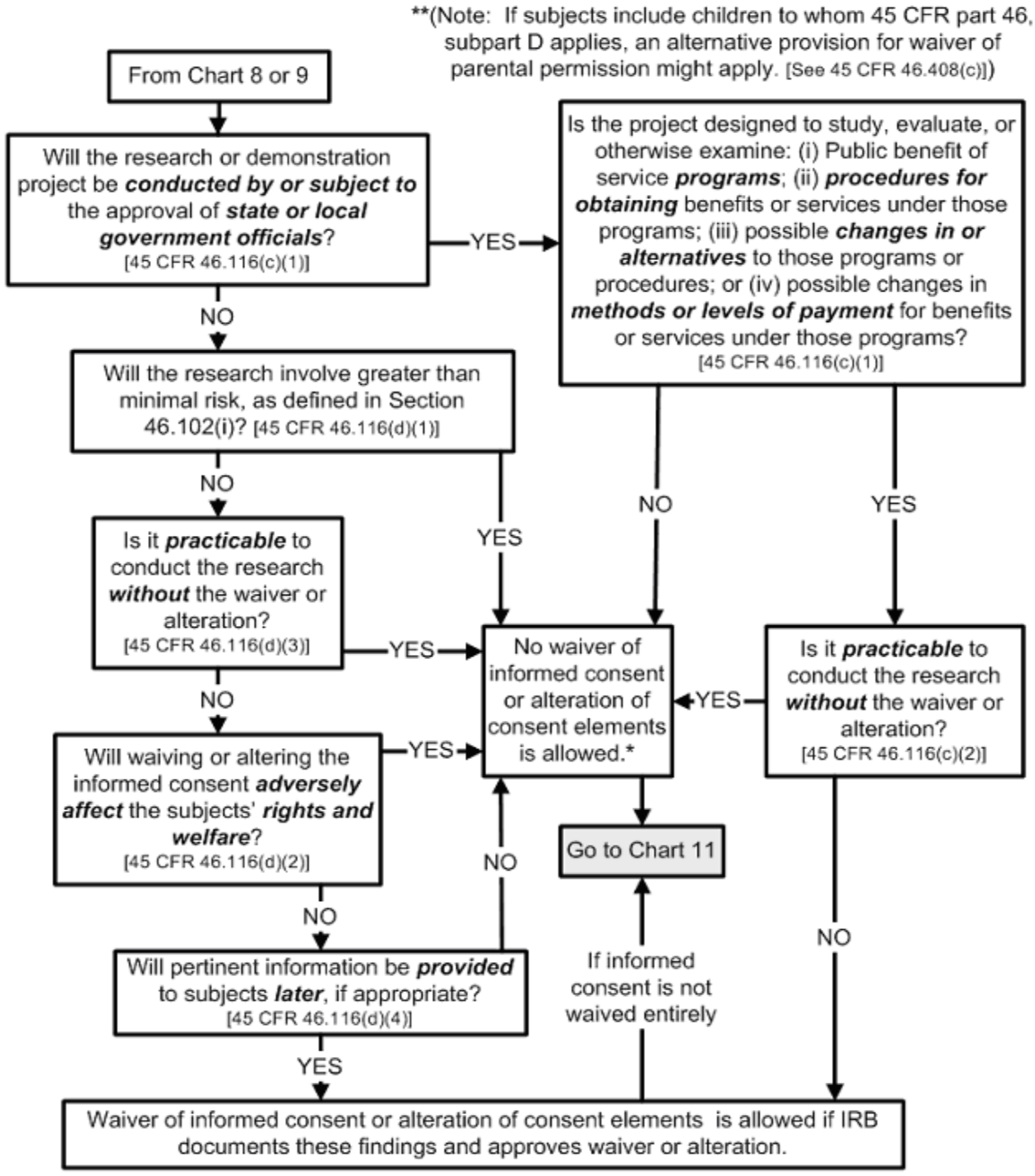


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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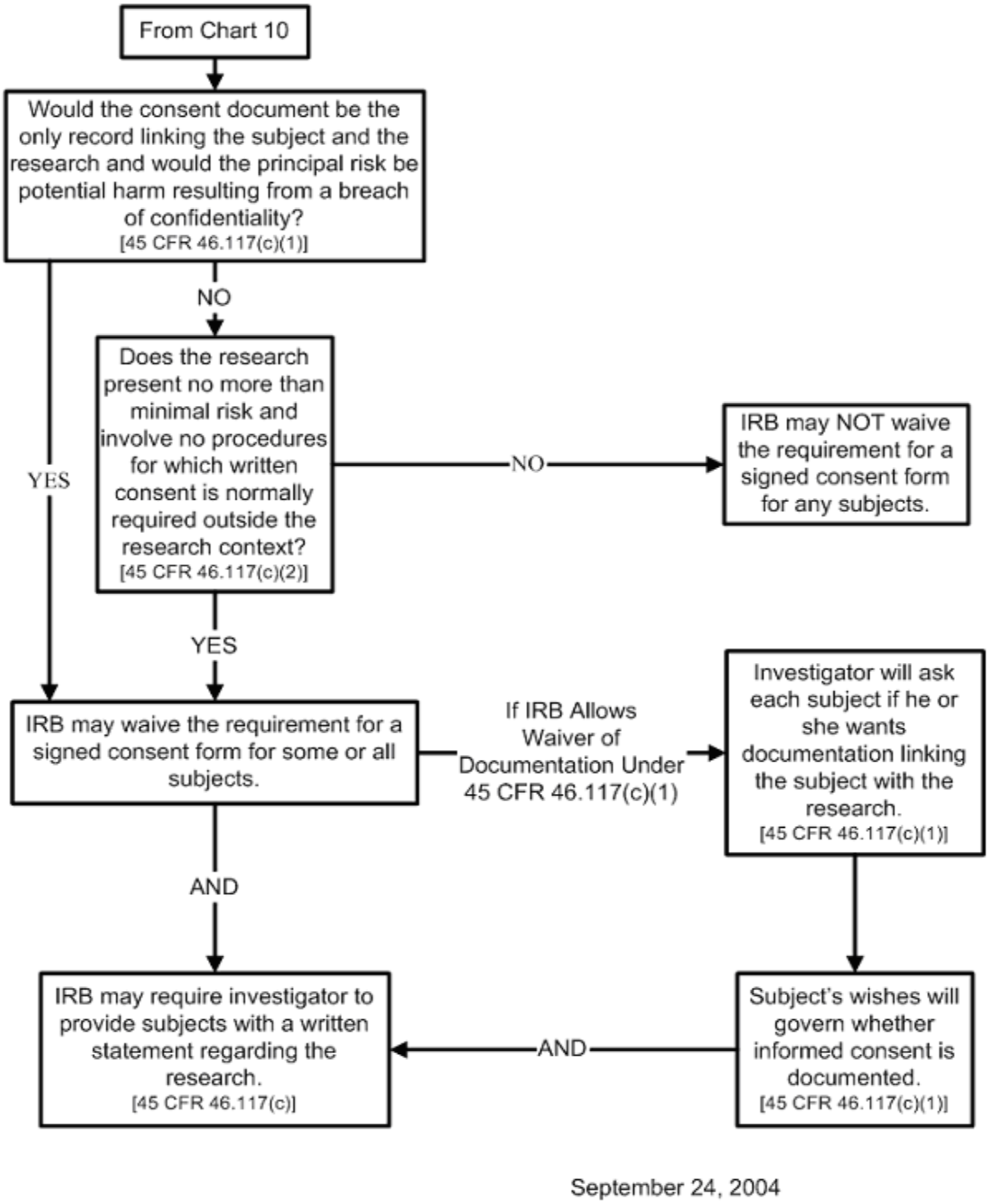
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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APPENDIX 3 – INFORMED CONSENT TEMPLATES & SAMPLES

The following templates and samples are offered as points of reference. The exact language is at the discretion of the researcher. The Institutional Review Board will evaluate the informed consent document and determine whether it meets the criteria outlined in Section XIV of these guidelines**.**

INFORMED CONSENT FORM (TEMPLATE)

Project Name:

Investigator(s): [*Provide name, phone number, and email information*]

Purpose and Benefits
You are invited to participate in a research study. The purpose of this study is to investigate [*here you explain the purpose of the study or as much information as you want participants to know going in. You should also describe any benefits the subject will receive for participation*].

Procedures
[*Explain what the participant should expect to do for the duration of the study. What will they be required to do? How long will it take? How many participants are anticipated?]*

Risks and Benefits
[*Describe any risks, both physical and psychological (e.g. stress), that the participant may experience during or after completion of the study. If there are no risks, say so. Describe benefits to the participant, to the investigators, and others*.]

Confidentiality
[*Describe the nature of data collection and storage in terms of confidentiality/anonymity. If personal information will be obtained, how long will it be kept and will it be linked to other data collected in the study? When will data be destroyed? Will information from the study be made public and what steps will be taken to ensure confidentiality of participant information?*]
For example: Your consent form will be separated from the questionnaire immediately upon collection. To further guarantee anonymity, no link will remain between your name and your data. Data will be stored securely and will be made available only to the persons listed above who are conducting the study. No reference will be made in oral or written reports that could link you to the study. Your confidential data may be used in future research, presentations or teaching opportunities.

Contact
If you have questions at any time about the study or the procedures, or if you experience adverse effects as a result of participating in this study, you may contact the investigator, [*John Doe, at jdoe@me.vccs.edu, or (276)523-2400*]. If you have questions about your rights as a participant, contact the Institutional Review Board Manager, Nikki Morrison, at nmorrison@me.vccs.edu or (276)523-2400 ext. 416.

Participation
Your participation in this study is voluntary. You may decline to participate without penalty. It is okay to say NO. Likewise, the investigator may terminate your participation in the study at any time if they observe potential problems with your continued participation.

Withdrawal guarantee
If you decide to participate, you may withdraw from the project at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed. Even if you say yes now, you are free to say NO later and walk away or withdraw from the project at any time. Your decision will not affect your relationship with Mountain Empire Community College or cause a loss of benefits to which you might otherwise be entitled.

Voluntary Consent
Your signature on this form indicates that you are at least 18 years of age and have understood to your satisfaction the information regarding participation in this research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities.

I have read the above information and agree to participate in this study. I have received a copy of this form.

Participant's Name (Print)
Participant's Signature
Date

This project was approved by the Mountain Empire Community College Institutional Review Board for Human Subject Protection on (Date) and expires on (Date).

Investigator's Statement
I certify that I have explained to this subject the nature and purpose of this project, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to participants and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's Name (Print)
Investigator's Signature
Date

Template may be modified for minor's assent. Language must be age appropriate and the form should include a space for a legally authorized representative to give consent.)

Copies to: Participant, Principal Investigator

SAMPLE INFORMED CONSENT/ASSENT LETTER

Dear Parents:

I will be conducting a research project designed to study how children think and develop strategies on games. I request permission for your child to participate. The study consists of two twenty-minute sessions where children will play tic-tac-toe one day and a guessing game the next day. The goals of the study are to detail the strategies of game-playing used by children of different ages and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity, and will accompany me only if he or she is willing to do so. Any child who expresses a desire to stop the activity or to return to the classroom will be escorted back immediately. I will conduct the sessions and my assistant will video the activity. Children's responses will be reported as group results only. Taped sessions will be used as examples of scoring procedures; however, the children will not be identified by name. The videos will be reviewed by the child's teacher and may be shown at professional conferences. To preserve confidentiality, only first names will be used to identify children. In addition to the game participation, I will need to look at the school's records to obtain the child's date of birth and scores on the Iowa Tests of Basic Skills.

Your decision whether or not to allow your child to participate in the study will in no way affect your child's standing in his or her class or school. At the conclusion of the study a summary of group results will be available to all interested parents and teachers.

Should you have any questions or desire further information, please call me at *[insert phone number.]*

Sincerely,

Jane Doe, Assistant Professor
Division of Arts & Sciences
Mountain Empire Community College

This project was approved by the Mountain Empire Community College Institutional Review Board for Human Subject Protection on *(Date)* and expires on *(Date).*

Contact Information
If you have questions at any time about the study or the procedures, or if you experience adverse effects as a result of participating in this study, you may contact the investigator, [*John Doe, at jdoe@me.vccs.edu, or (276)523-2400*.] If you have questions about your rights as a participant, contact the Institutional Review Board Manager, Nikki Morrison, at nmorrison@me.vccs.edu or (276)523-2400 ext. 416.

Parent's/Guardian's Consent
I, _____, do hereby state that I have read the material and understand the above. I give permission for my son or daughter, _____, to participate in this project.

Signed (parent or guardian)_____ Date_____

It is ethically essential that your son or daughter understand exactly what will be expected of him or her and willingly agree to participate. Your child must also understand that he or she can "call it quits" at any time. Please help explain the above project and have your son or daughter sign below if appropriate.

Subject's Assent

I, _____, voluntarily agree to play the games in this project and know that I may choose to drop out at any time.

Signed_____ Date_____

Investigator's Statement

I, _____, certify that I have explained to this subject, in age appropriate language, the nature and purpose of this project, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to participants and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions during the course of the study. I have witnessed the above signature(s) on this consent form.

Investigator's Signature_____ Date_____

SAMPLE INFORMED CONSENT FOR PHOTO/VIDEO/MEDIA MATERIALS

Date:

Project Title:

Principal Investigator:

Phone: **Email Address:**

Description

The researchers would like to take photographs or video recordings of you performing (*activity*) in order to illustrate the research in teaching, presentations, and/or publications. [*Describe the duration of the photography/video recording and other pertinent details.]*

Confidentiality

You would not be identified by name in any use of the photographs or video recordings. Even if you agree to be in the study, no photographs or video recordings will be taken of you unless you specifically agree to this. [*All consent material should always advise subjects how anonymity or confidentiality will be maintained. The confidentiality statement should address how the photographs or video recordings will be stored, how long they will be stored, and what will happen to them at the completion of the study*.]

Voluntary Consent

By signing below, you are granting to the researchers the right to use your likeness, image, appearance, and performance – whether recorded on or transferred to videotape, film, slides, photographs, or digital files – for presenting or publishing this research. No use of photos or video images will be made other than for professional presentations or publications. The researchers are unable to provide any monetary compensation for use of these materials. You can withdraw your voluntary consent at any time.

If you have any questions later on, please contact the researchers (*insert name(s) and contact information*). If at any time you feel pressured to participate, or if you have any questions about your rights or this form, you should contact the MECC Institutional Review Board Manager, Nikki Morrison, at nmorrison@mecc.edu or (276)523-2400 ext. 416.

Subject's Printed Name & Signature	**Date**
Parent/Legally Authorized Representative's Printed Name & Signature	**Date**
Investigator's Printed Name & Signature	**Date**