Central Virginia Community College Policies
II - General Administrative Policies
Institutional Review Board (IRB) Handbook

Policy #:	CVCC0054
Effective:	__/__/__
Last Reviewed/Revised:	09/20/2022
Responsible Dept.:	Institutional Effectiveness
Other Policy References:	NA

Institutional Review Board (IRB) Handbook

April 2016 Edition

ACKNOWLEDGEMENTS

Central Virginia Community College respectfully acknowledges and thanks Virginia Wester Community College for their permission to use their operating procedures and materials in the *Institutional Review Handbook*. Their support is greatly appreciated.

TABLE OF CONTENTS

INTRODUCTION

It is the mission of Central Virginia Community College (CVCC) to provide affordable, accessible, and quality educational opportunities and workforce training to meet individual, community, and global needs. Towards this goal, Central Virginia Community College encourages and supports the scholarly efforts of its faculty and students.

Scholarly work often involves the use of human subjects for data collection and analysis. The Central Virginia Community College Institutional Review Board (IRB) will serve as the "protective eye" to ensure that

- the rights and welfare of human subjects are protected;
- risks have been considered or minimized;
- the potential for benefit has been identified and maximized;
- all human subjects only volunteer to participate in research after being provided with legally effective informed consent; and
- any research is conducted in an ethical manner and in compliance with established standards, including handling all private information with confidentiality.

Central Virginia Community College's IRB is authorized to approve, review, require modifications in, or disapprove human subjects research activities conducted by or through the College. Central Virginia Community College's IRB will evaluate each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants. The primary purpose of the IRB will be to protect the welfare of human subjects used in research.

PRINCIPLES

Central Virginia Community College has adapted the ethical principles for protection of human subjects as stated in the Code of Federal Regulations, 45CFR46. 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 Federal Code of Regulations, 45CFR46, 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

To ensure that adequate safeguards are provided, Central Virginia Community College will follow the principles listed below which apply to all research and student projects involving human subjects:

- 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.

- Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

- Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

- Research involving Human Subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions and faculty members for undergraduate research projects.

- 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 consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

- All research programs that involve Human Subjects must be reviewed by and must receive approval of a formally constituted review **prior to** their initiation or **prior to** initiating any changes to the project. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

The purpose of the Central Virginia 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 Central Virginia Community Collegeemployees or students or on Central Virginia Community College campuses.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. The IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

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:

        1. CFR Part 1c [Department of Agriculture]
        2. 10 CFR Part 745 [Department of Energy]
        3. 14 CFR Part 1230 [National Aeronautics and Space Administration]
        4. 15 CFR Part 27 [Department of Commerce]
        5. 16 CFR Part 1028 [Consumer Product Safety Commission]
        6. 22 CFR Part 225 [International Development Cooperation Agency] [Agency for International Development]
        7. 24 CFR Part 60 [Department of Housing and Urban Development]
        8. 28 CFR Part 46 [Department of Justice]
        9. 32 CFR Part 219 [Department of Defense]
        10. 34 CFR Part 97 [Department of Education]
        11. 38 CFR Part 16 [Department of Veterans Affairs]
        12. 40 CFR Part 26 [Environmental Protection Agency]
        13. 45 CFR Part 46 [Department of Health and Human Services]

14. 45 CFR Part 690 [National Science Foundation]
15. 49 CFR Part 11 [Department of Transportation]

b. FDA regulations pertaining to research with human subjects are codified at:

1. 21 CFR Part 50 [Protection of Human Subjects]
2. 21 CFR Part 56 [Institutional Review Boards]

c. The Code of Virginia:

1. 32.1-162.16 Definitions
2. 32.1-162.17 Exemptions
3. 32.1-162.18 Informed consent
4. 32.1-162.19 Human research review committees
5. 32.1-162.20 Applicability of Federal policies

IRB MEMBERSHIP

CFR §46.107

1. The IRB is composed of five full-time employees with varying backgrounds and expertise to comprehend the nature of the research, as well as other competencies necessary to interpret regulations, relevant law, ethical standards, and standards of professional practice.

2. The IRB functions administratively through the Office of Institutional Effectiveness.

3. The IRB Chair is the Dean of Institutional Effectiveness.

4. The IRB Vice Chair is a voting member of the IRB and presides over all convened meetings in the absence of the Chair. The Vice Chair is the Director of Grants Development. The Vice Chair has authority to sign all IRB action items in the absence of the Chair.

5. Members will be invited to join the IRB by the Dean of Institutional Effectiveness for tenure of at least two years. The term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member is unable to attend meetings for an extended period, the Chair must be informed so that a replacement can be appointed. Tenure may be extended by recommendation of the IRB Chair and agreement by the member.

6. The IRB will include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and one at large member.

7. No person will be excluded from serving on the IRB based on sex, race, color, or national origin.

8. 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.

9. 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.

10. A majority of the members must participate in each board action.

11. IRB members do not receive compensation for their service.

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. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer.

EDUCATION AND TRAINING

1. All IRB members are required to undergo formal training at the time of their initial appointment. At a minimum, two group training activities and the National Institutes of Health Human Participant Protections Education for Research Teams online course are required.

   Approved training includes:

   a. The National Institutes of Health Human Participant Protections Education for Research Teams course
   http://phrp.nihtraining.com/users/login.php

   b. Office for Human Research Protections (OHRP) Training Module for Assurances
   http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

   c. Approved trainings hosted by CVCC or other IRB Institutions.

   d. Other educational materials:

      1. OHRP/PRIM&R "Investigator 101" CD ROM Ordering Information
      http://www.hhs.gov/ohrp/education/training/101cdrom.html

      2. IRB Guidebook and videos/webinars, "Protecting Human Subjects"
      http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm
      (Guidebook)
      http://www.hhs.gov/ohrp/education/training/ded_video.html
      (Videos and Webinars)

   e. Other educational opportunities:

      1. Research Community Forum (RCF's):
      http://www.hhs.gov/ohrp/education/conferences/index.html

      2. Conferences:
      http://www.hhs.gov/ohrp/education/conferences/index.html

2. The IRB Chair will maintain a log of training completion dates.

3. Continuing education of IRB members is accomplished through participation in regional IRB training, review of various online tutorials, and through Central Virginia Community College-provided IRB training activities.

4. IRB members must complete the *Documentation of Training in Human Subject Protection* and *Documentation of Education on the Protection of Human Subjects* forms once every three years (see Appendix 3).

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 Board Chair.

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 Central Virginia Community College and it's researchers from any potential liabilities to which they may be exposed.

6. Actively participate in board actions and determinations.

IRB CHAIR RESPONSIBLITIES

1. In cooperation with the Office of Grants Development, make Human Subject Research determinations.

2. Ensure all review submission materials are collected for board determination.

3. Initiate all board reviews.

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 Principle Investigator and the Office of Grants Development.

6. Ensure all records are maintained as required by Title 45 Part 46 of the Code of Federal Regulations (see "Reporting Requirements," below).

7. Assist in decisions on IRB applications.

AUTHORITY OF IRB

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

The CVCC IRB must review and approve any funded or non-funded research related to human subjects whether or not it is funded internally or externally by private or government funds if the research is

1. sponsored by CVCC;
2. performed by or involves CVCC faculty, staff and/or students regardless of where the study is performed; or
3. conducted using College-owned facilities or equipment.

§46.112 REVIEW BY INSTITUTION

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 not been approved by an IRB.

REPORTING REQUIREMENTS

The institution or, when appropriate, the IRB must prepare and maintain adequate documentation of IRB activities [Federal Policy §___.115]. In addition to the written IRB procedures and membership lists required by the assurance process [Federal Policy §___.103], such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects (as required by Federal Policy §___.116(b)(5)).

REQUIRED ASSURANCES

Research activities involving human subjects may not be conducted or supported by the departments and agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate IRB review and approval to the department or agency in accordance with the Common Rule.

Institutions must have an Assurance of Compliance 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 (see Appendix 3). [Office for Human Research Protections OMB No. 0990-0263]

ACTIONS

A majority of the IRB members must participate in all decisions and actions of the board. Final approval of all actions 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.

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

1. Exempt from full review
2. Approve
3. Approve contingent on requested changes
4. Disapprove and/or make recommendations of required changes for resubmission
5. Suspend or terminate as per §46.113

The IRB will 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 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.

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

IRB PROCEDURES

The *Health and Human Safety (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 be in place for monitoring the progress of the research.

For non-exempt research, the IRB must:

1. Review the proposal at a convened meeting

2. Evaluate the 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?

3. 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?

4. Evaluate the Informed Consent Form (see Appendix 2, page 42).

TYPES OF IRB REVIEW

Applications will be treated as exempt or non-exempt. Non-exempt protocols can be either expedited or Full Board Review. The Principal Investigator or Project Director **do not make the determination as to whether a project is exempt or non-exempt.**

1. Exempt Review

    a. A research protocol can be submitted for an exempt review if the Chair deems the project qualified.
    b. 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, he/she may call for an exempt review.
    c. The IRB Chair will distribute the application materials electronically, via mail, or by fax for each member to review and convene the board.
    d. If a majority of members approve the exempt status, the research is approved as exempt.
    e. If a majority of members have doubts of the project's qualification as exempt, the Chair may call for full board review of the proposal.
    f. 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.

g. Exempted approvals expire one year after board review. The PI must seek review annually for projects that last longer than a year. Additionally, the PI must ensure that progress reports and/or review applications are submitted more frequently if mandated by the IRB.

EXEMPTIONS

Under Federal regulations, certain types of research are exempt from Federal policy unless the appropriate Federal agency heads have determined otherwise [45 CFR 46.101].

Exempt types of research include:

a. 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.

b. 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.

c. 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 paragraph (2) of this section, 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.

d. 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 or Project Director in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

e. Research and demonstration projects which are conducted by or subject to the approval of 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.

f. 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 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.

2. <u>Expedited Review</u>

a. A research protocol may be considered for expedited review if

1. the research has been reviewed and approved by another IRB;

2. it is a continuation review of research previously approved by the convened IRB as follows:

(a) 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

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

b. An expedited review will be conducted by two board members selected by the Chair. Both reviewers must approve the proposal.

c. 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 research activity may be disapproved **only** after review in accordance with the non-expedited procedure set forth in 46.108(b).

3. Full Board Review

a. Protocols that involve more than minimal risk must go to Full Board Review.

b. 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.

c. Prior to the review meeting, the Full Board Review application is previewed by the Chair or designee to determine if further documentation is needed.

d. Once all materials are collected, the application is submitted to the full board for review requiring a majority of members to review proposal.

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

CRITERIA FOR IRB APPROVAL OF RESEARCH

§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 §46.116.

5. Informed consent is documented in accordance with and to the extent required by §46.116.

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 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 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 CFR §46.117 (c) (1) or (2).

4. As per 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 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 (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. 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 students, faculty, or employees must have oversight by a designated faculty member or administrator.

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 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.

PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

1. For any project involved with live human subjects/participants, it is the responsibility of the Principle Investigator (PI) to apply to the CVCC Institutional Review Board for **Human Subject Research Determination.**

2. Should it be determined that a project meets the Office for Human Research Protections (OHRP) definition of Human Subject Research, no activity with the subjects may begin until IRB approval has been issued.

3. Prior to submission for IRB review, the PI must complete IRB training to include, at a minimum, one Central Virginia Community College IRB Human Subject Protection Orientation and the National Institutes of Health Human Research Participants online course. The online course must be taken each year of the project. Link: http://phrp.nihtraining.com/users/login.php

4. The PI must ensure that all researchers working with the subjects and the project director of a human subject research project complete the CVCC IRB Human Subject Protection Orientation. It is at the discretion of the PI as to what other training may be required.

5. No contact with human subjects may be conducted until the PI's IRB training is complete and the *Documentation of Training in Human Subject Protection* form has been submitted to the Office of Grants Development (see appendix 3).

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. All application materials must be submitted no later than one (1) week prior to the regularly scheduled IRB review meeting to be considered at that meeting.

8. 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 for renewal or continuation.

9. All work on the project must stop on the IRB approval expiration date unless continuation has been formally approved.

10. Records of all PI and researchers' IRB training must be maintained in the Office of Institutional Effectiveness.

11. The PI must maintain records of all human subject research projects for a minimum of three (3) years after completion of the project.

THE APPROVAL PROCESS

1. The PI completes and submits electronically the *Human Subject Research Determination* form and proposal to _____.

    a. These are distributed to the Office of Grants Development and the IRB Chair or their designees.

    b. If it is determined that the project is human subject research, the PI must submit a Documentation of Training in Human Subject Protection form (see Appendix 3) with the certification of completion of the National Institutes of Health course *Participant Protections Education for Research Teams*. This certification must accompany all IRB applications for review.

2. If the proposal is determined a human subject research project, 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 electronically submits the application packet to the IRB email address.

5. IRB reviews will be scheduled. Deadline for submission of application and materials is one (1) week prior to the scheduled IRB review.

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 <u>BEFORE</u> 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 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 (see Appendix 3). No approval is required by the IRB.

CHECKLIST (SEE FORMS):

a. PI certifications of human subject protection training

b. Completed and signed application for review

c Research plan/proposal

d. Samples of informed consent/assent forms

e. Outline of information to be provided prior to subjects' agreement to participate

f. Instruments, surveys, questionnaires, etc.

g Curriculum vitae

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 generalized 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. [§46.102]

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 "generalized 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 Appendix 1).

FACTORS TO BE CONSIDERED

- Is the activity a systematic investigation designed to develop or contribute to generalized knowledge? 45 CFR 46.102(d)
- Does 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? 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.) 45CFD 46.102(f)(2)

DETERMINATION AS HUMAN SUBJECTS

HUMAN SUBJECTS

Human subjects are individuals whose physiologic 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 [Federal Policy §___.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. [§46.102]

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 preventive 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 [Federal Policy §116; 21 CFR 50.20 and 50.25].

IRB CONSIDERATIONS

Investigators may seek consent only under circumstances that provide the prospective subject or his/her representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. 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 [Federal Policy §___.116].

FEDERAL REGULATIONS

Federal regulations require that certain information must be provided to each subject: [Federal Policy §___.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 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.

(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: [Federal Policy §___.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.

(6) The approximate number of subjects involved in the study.

As per 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 determines either of the following:

(1) 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.

(2) 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 research." *IRB Guidebook:* http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm. 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 the case 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 – e.g., parents, teachers – 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 be written using language that is appropriate for the age level and mental capacity of the subjects.

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 requires medical or psychological treatment must be reported to the IRB, to the funding agency, and in the Progress Report (see Appendix 3). Even adverse events that are not related to the project must be reported.

UNANTICIPATED EVENT REQUIRING REPORTING

Is the adverse event an unanticipated problem and 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 Health and Human Safety (HHS) regulations. 45 CFR 46.103 (a) and 46.1203(b)(5)

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 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 than 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 later determined to be necessary.

- 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.

APPENDIX 1: DECISION CHARTS

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

September 24, 2004

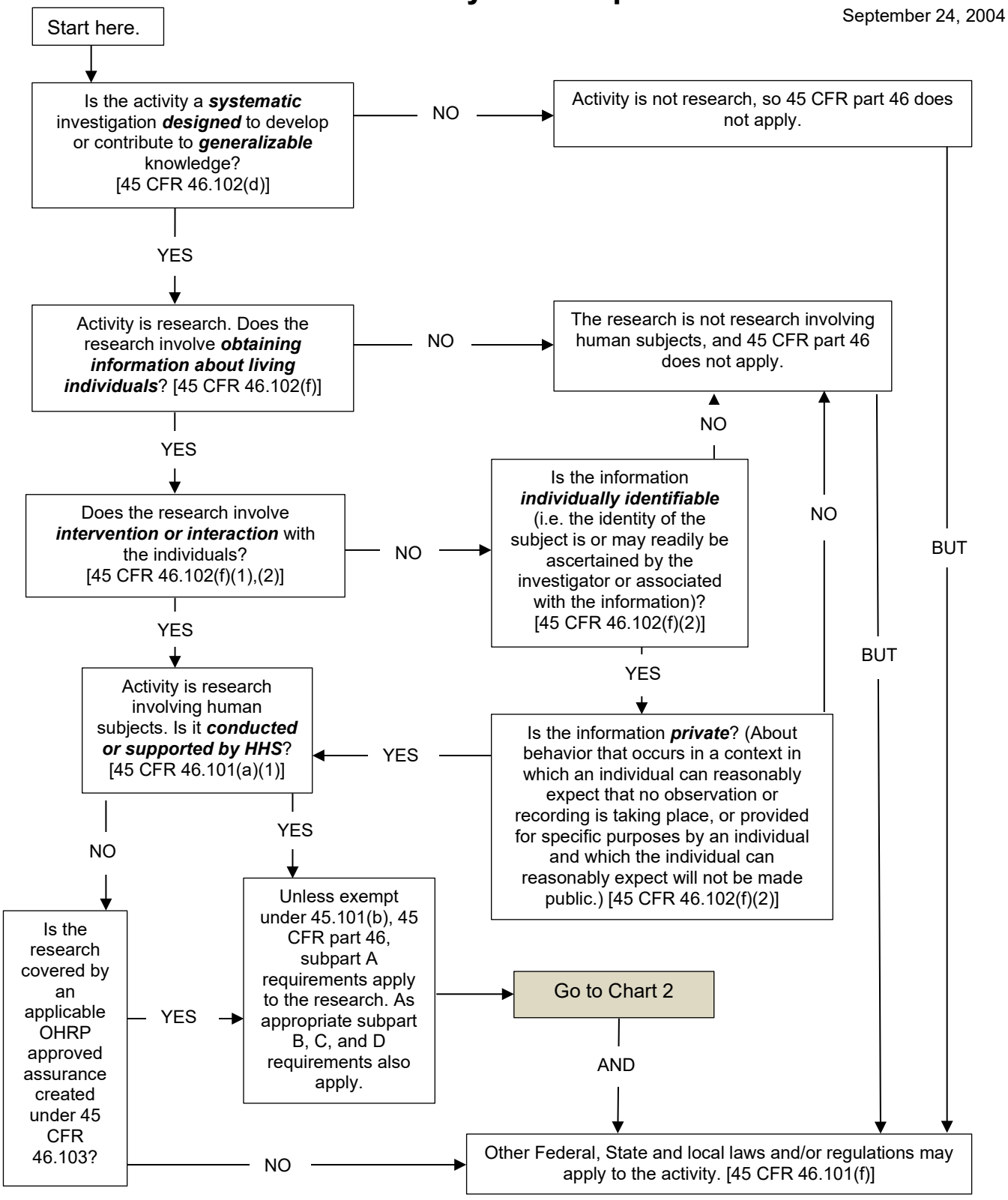


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption under 45 CFR 46.101(b)?

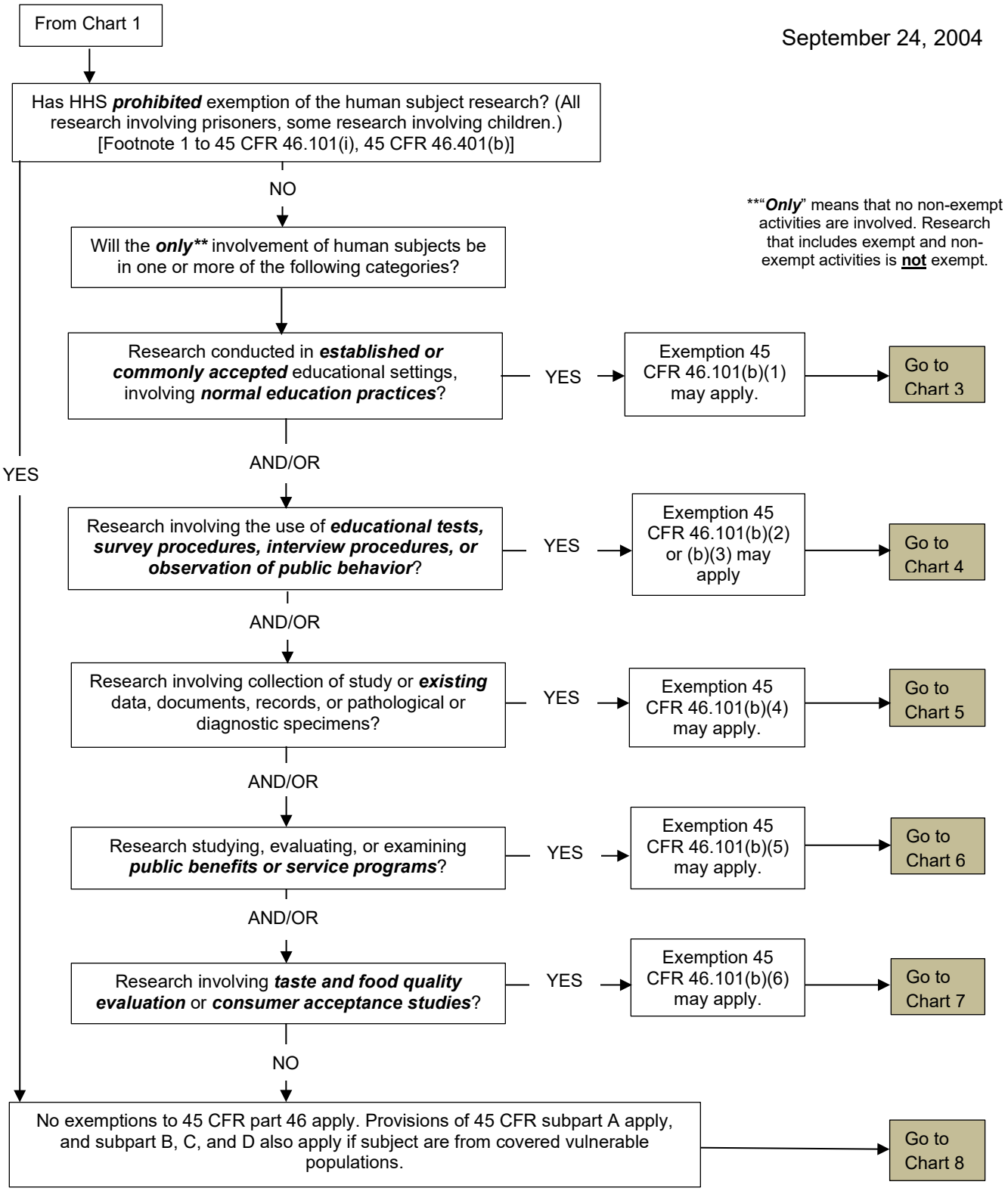
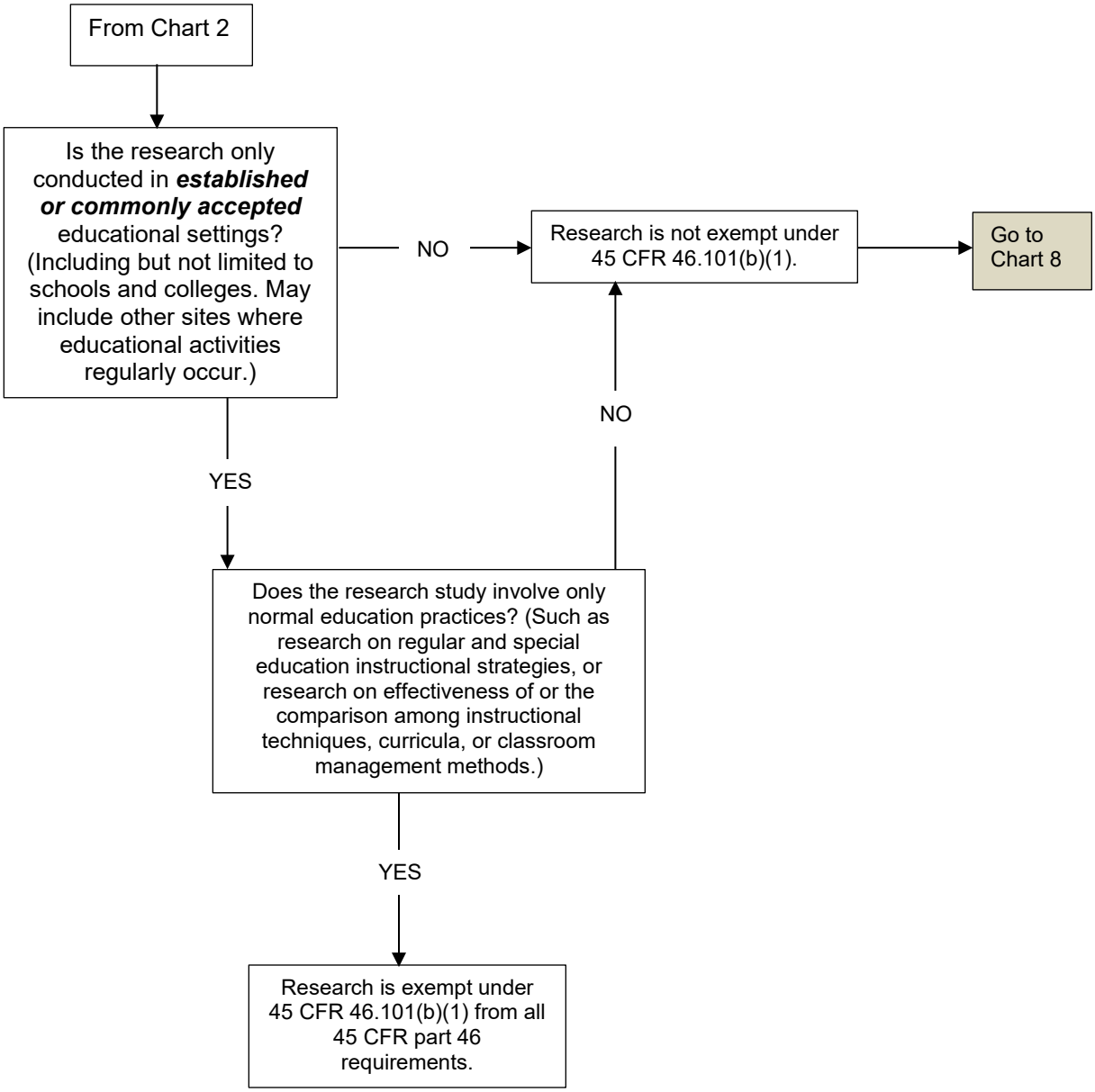


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Setting) Apply?



September 24, 2004

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

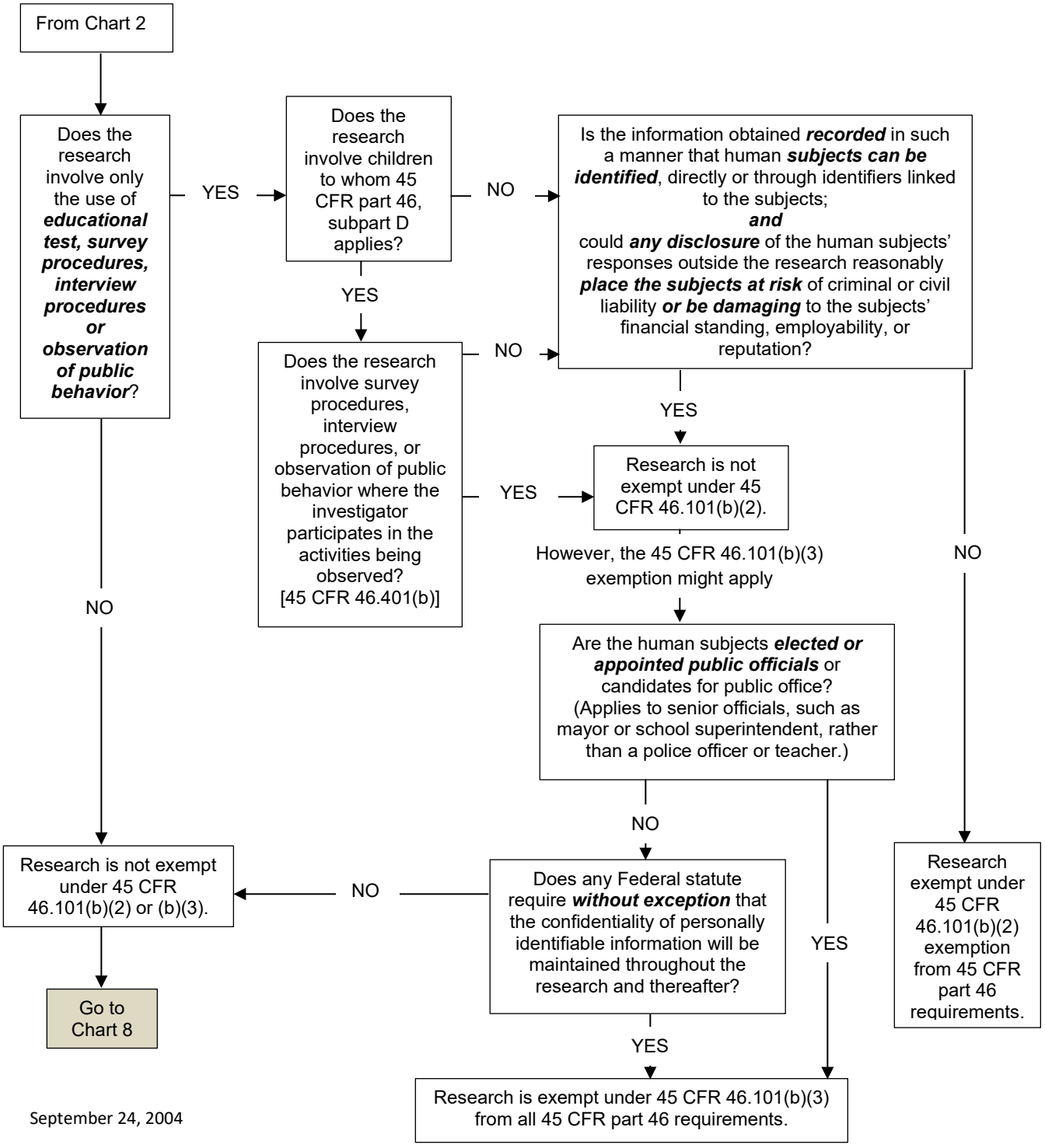
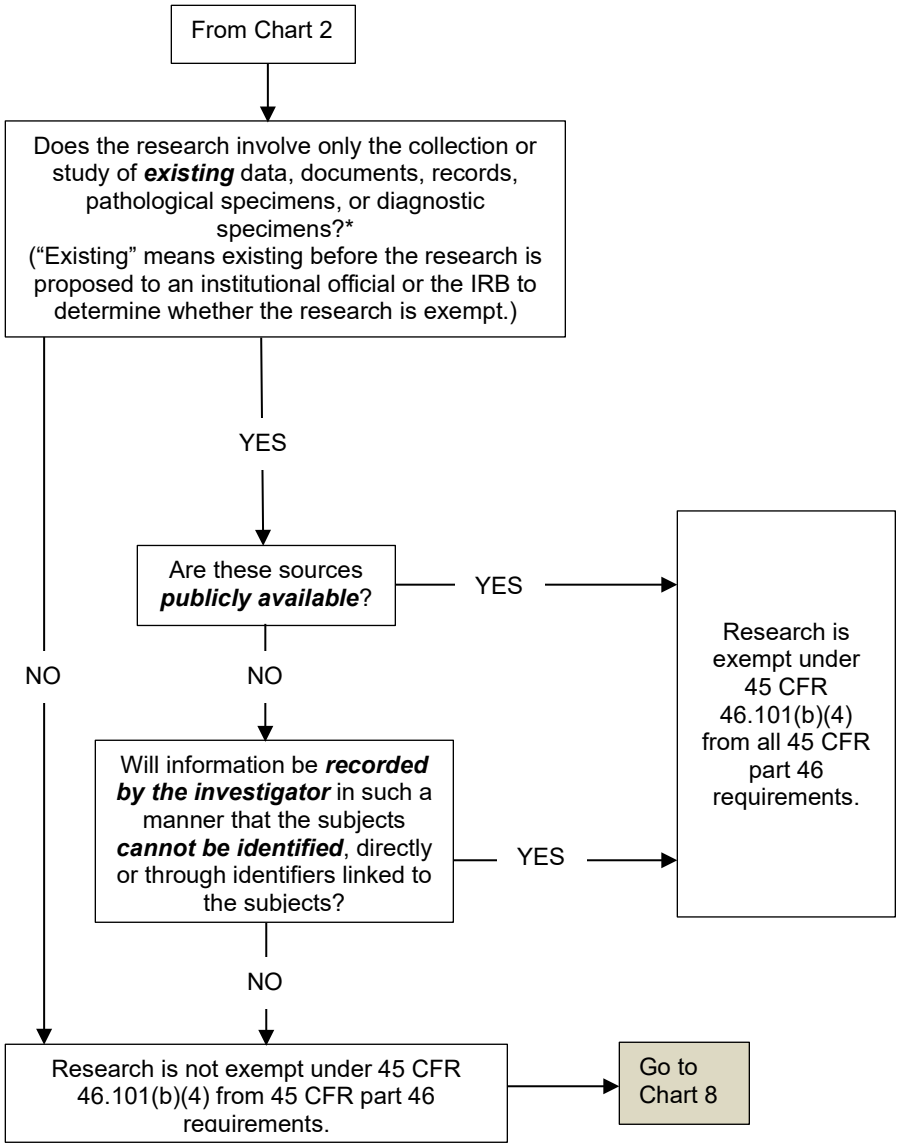


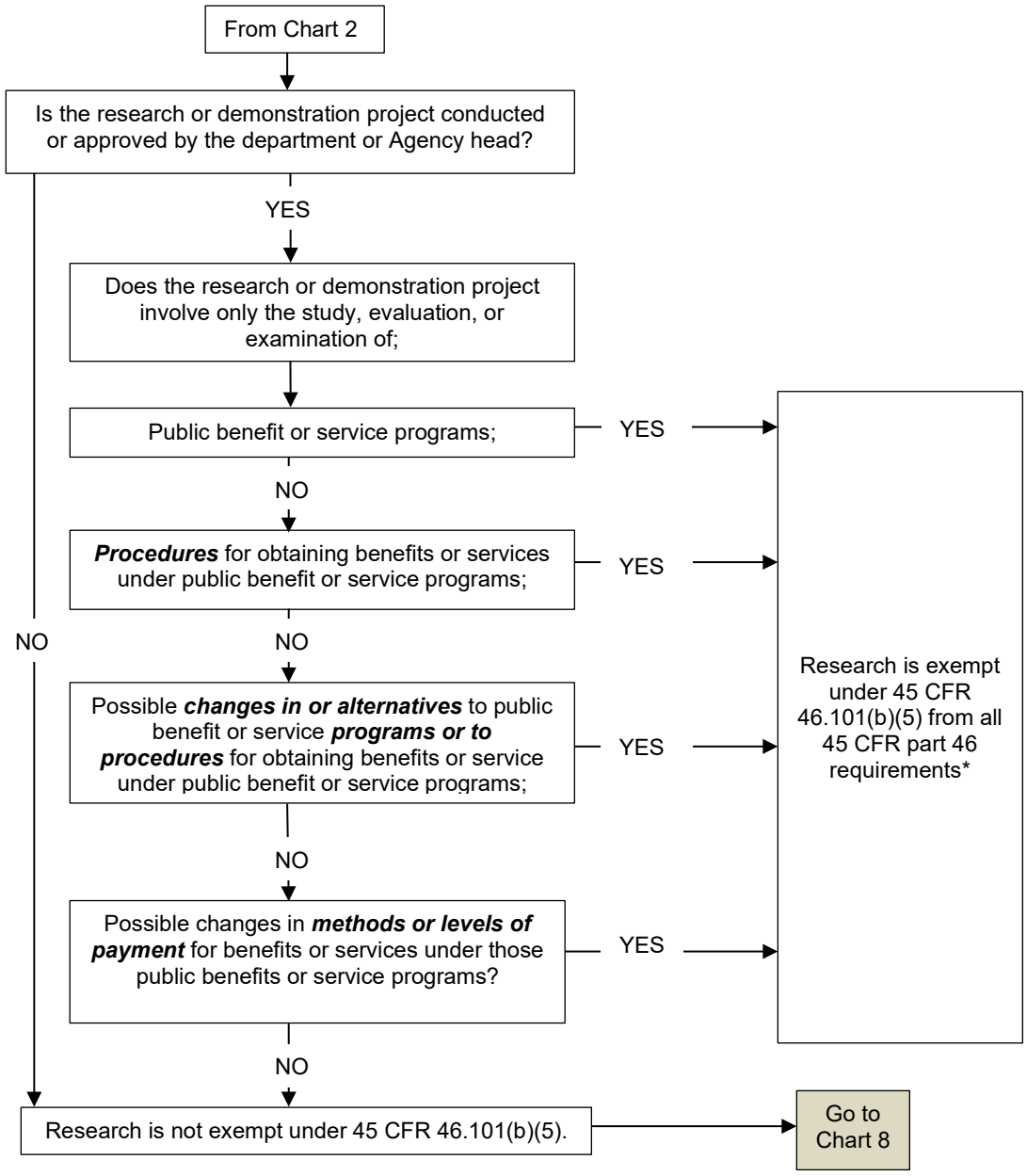
Chart 5: Does Exemption 45 CFR 26.101(b)(4) (for Existing Data Documents and Specimens) Apply?



*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

September 24, 2004

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.

September 24, 2004

Chart 7: Does Exemption 45 CFR 46. 101(b)(6) (for Taste and Acceptance Studies) Apply?

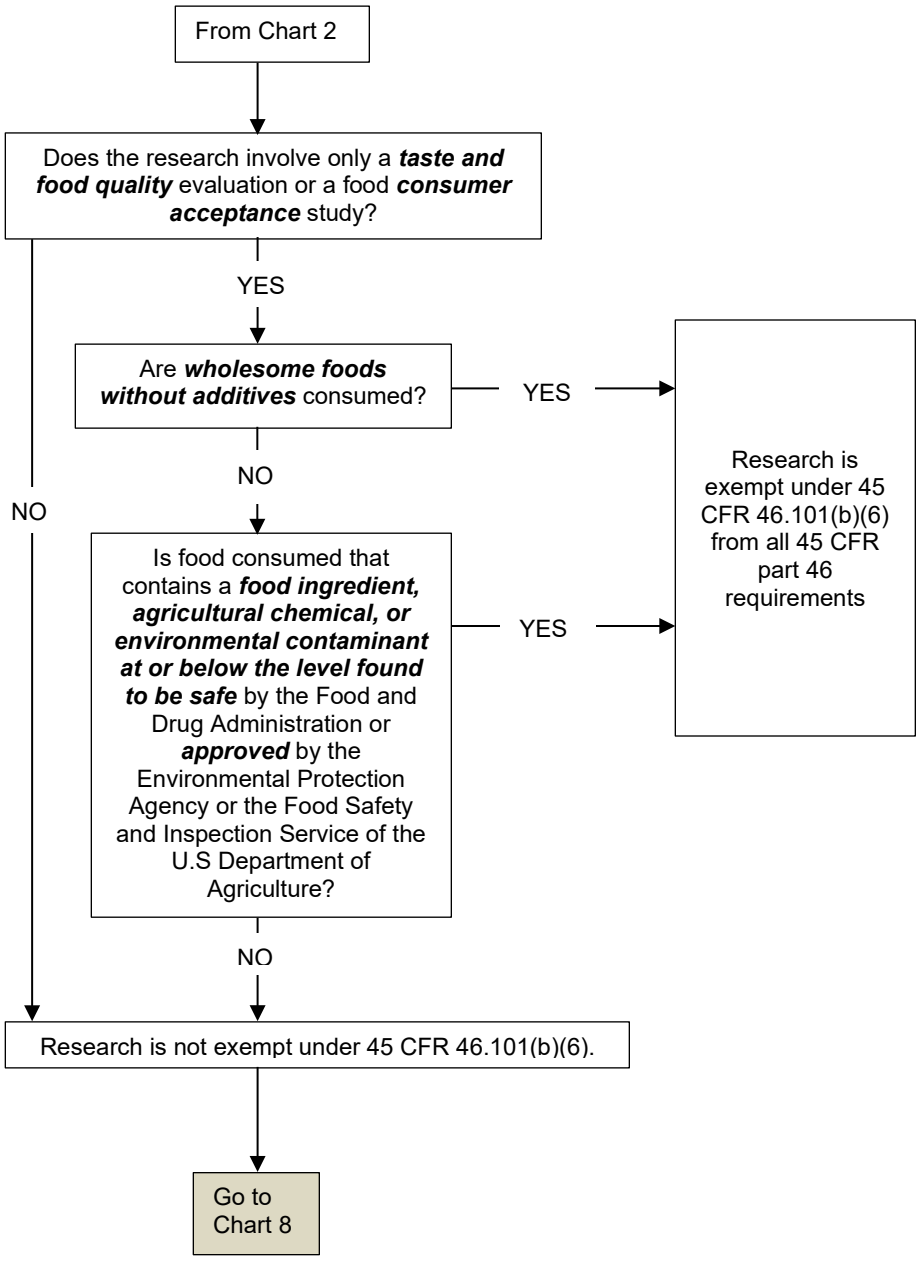
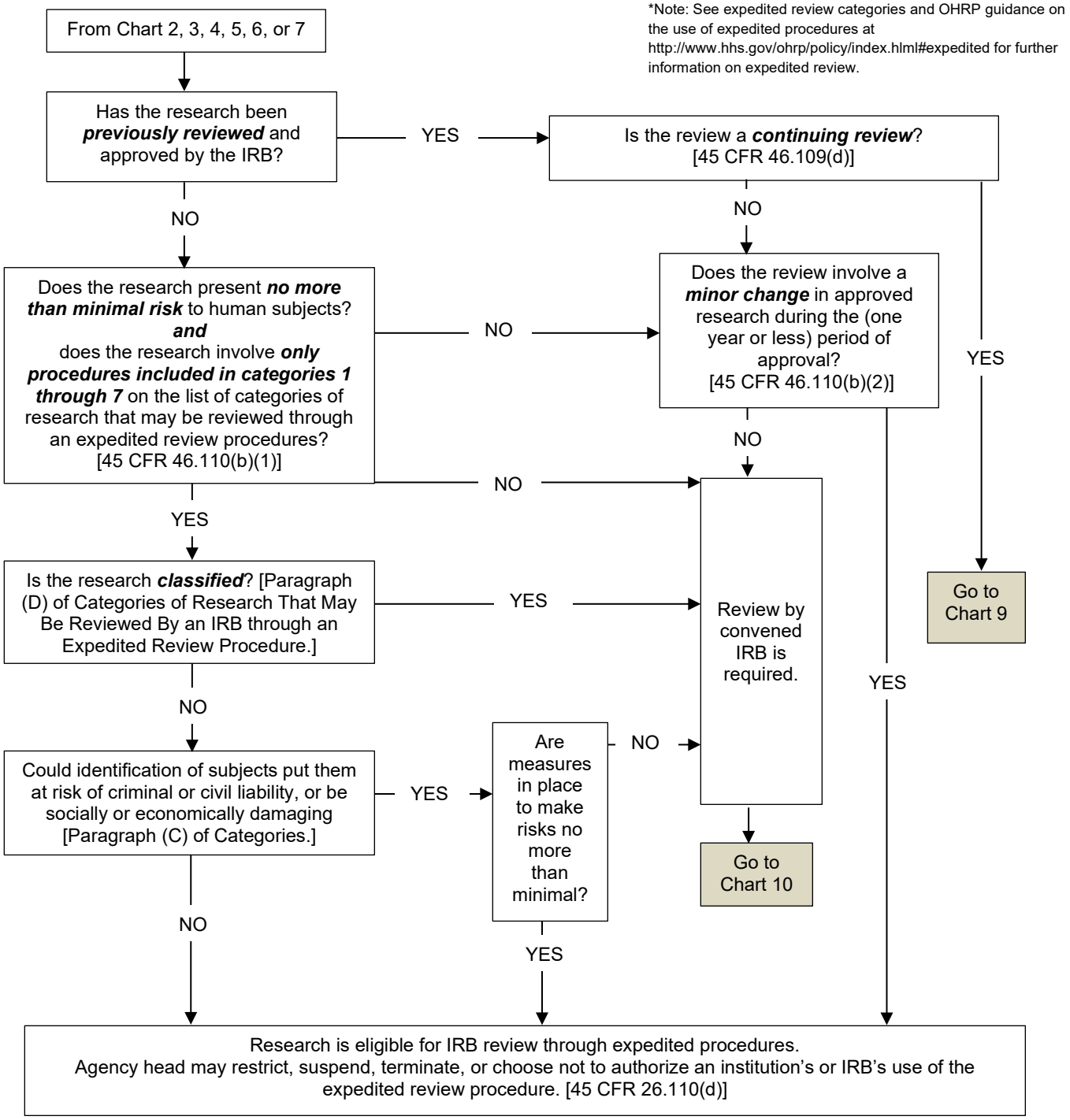
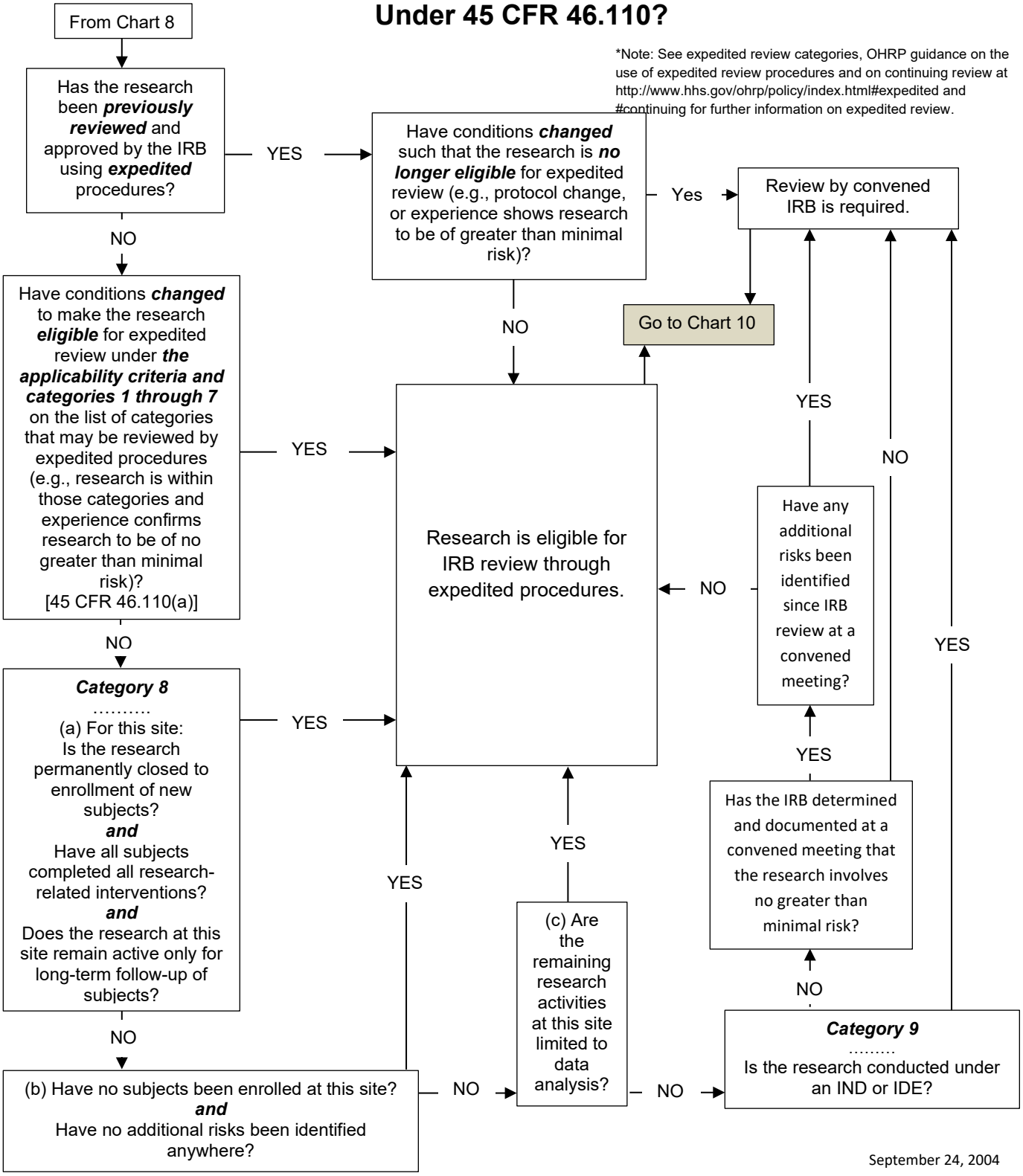


Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110*?



September 24, 2004

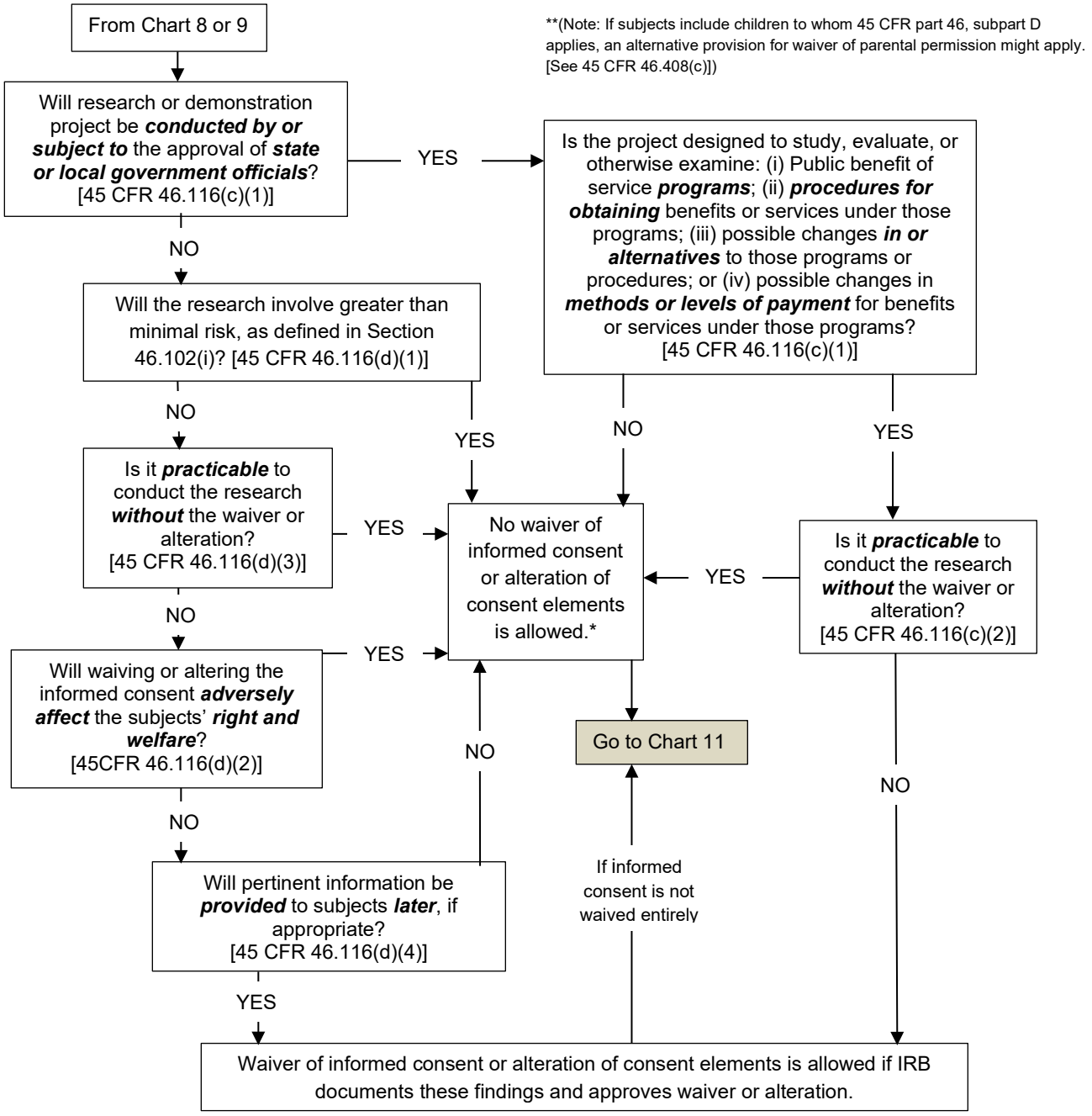
Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?



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

September 24, 2004

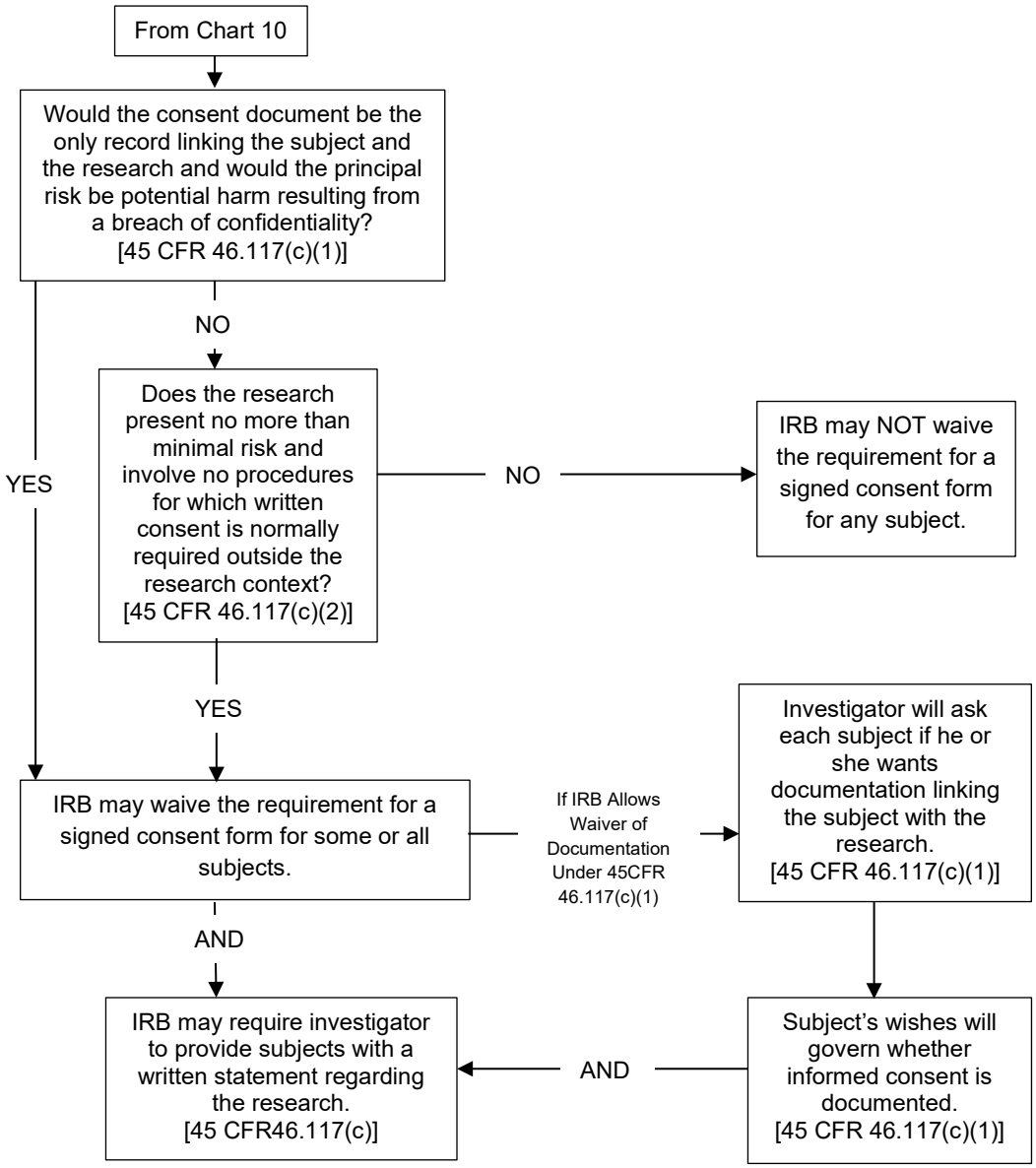
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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

September 24, 2004

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



September 24, 2004

APPENDIX 2: TEMPLATES

Central Virginia

Informed Consent / Assent Checklist

	Required Elements	Comments
	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)	

Central Virginia

Informed Consent Form

(Template)

Project Name: Project Name

Investigator(s): Provide name, phone number, and email of each individual.

Purpose and Benefits:
You are invited to participate in a research study. The purpose of this study is to investigate …
Explain the purpose of this study; provide as much information as you want for participants to know going in; explain any benefits the subject will receive for participation.

Procedures:
Explain what the participant should expect for the duration of the study. What will they be required to do? How long will it take the participant? 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 and/or the investigators or 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? What steps will be taken to ensure confidentiality of participant information?

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 its procedures, or if you experience adverse effects as a result of participating in this study, you may contact the faculty sponsor/investigator, Joe Smith, at joesmith@joesmith.com, or (206) 555-5555

If you have questions about your rights as a participant, contact the Institutional Review Board at _____, Director of Grants Development and Special Projects, at _____.

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 he or she observes 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 Central Virginia Community Collegeor 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

Note: Template can be modified for minor's assent. Language must be age-appropriate

This project was approved by the Central Virginia Community CollegeInstitutional Review Board for Human Subject Protection on (insert date) and expires on (insert date).

Investigator's Statement
I certify that I have explained to the 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

Copies to: Participant
Principal Investigator

APPENDIX 3: FORMS

APPLICATION FOR
HUMAN SUBJECT RESEARCH DETERMINATION
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? Describe purpose, not expectations.

Briefly describe the project

HUMAN SUBJECT RESEARCH DETERMINATION

1. Does the project involve obtaining information about living humans?	**Yes**	**No**
2. Does the project involve intervention or interactions with humans?	**Yes**	**No**
3. Is the information individually identifiable? (i.e., the identity of the subject is, or may be, readily ascertained by the investigator or associated with the information?)	**Yes**	**No**
The next question concerns private information. For this application, private information is defined as information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information for specific purposes that the individual can reasonably expect will not be made public.		
4. Is the information to be gathered private?	**Yes**	**No**
5. Will data be systematically gathered, analyzed, and disseminated?	**Yes**	**No**
6. Will the data be used outside of the setting or population from which they were collected?	**Yes**	**No**
7. Will the findings lead to new procedures or processes or be usable in outside applications?	**Yes**	**No**

APPLICATION FOR FULL BOARD REVIEW

Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

PARTICIPANT POPULATION

Age Range

- ☐ **Fetus**
- ☐ **Infant-5 years**
- ☐ **6-12 years**
- ☐ **13-17 years**
- ☐ **18-60 years**
- ☐ **Over 60 years**

Description of subjects (*Include characteristics pertinent to the subject*)

What is their relationship to CVCC?

Will all or any of the subjects fall into a "vulnerable" category? ☐ **Yes** ☐ **No**
If yes, check category(ies):

- ☐ **Mentally**
- ☐ **Incarcerated**
- ☐ **Elderly**
- ☐ **Pregnant**
- ☐ **Physically disabled**
- ☐ **Under 18 years of age**
- ☐ **Economically or educationally disadvantaged**
- ☐ **Other - explain**

How and where will they be recruited or selected?

Estimated number of participants in year one.

Estimated number of participants in all years.

APPLICATION FOR
EXEMPT REVIEW
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

APPLICATION FOR EXEMPT REVIEW

Federal Code of Regulations 45 CFR 46.101b identifies the following exempt categories. Unless otherwise required by department or agency, 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*)*

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.

Identify which exemption category(ies) apply to your project. Explain how your project meets the category.

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.** ☐ **Yes** ☐ **No**

   If yes, please explain.

APPLICATION FOR
EXPEDITED REVIEW
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

APPLICATION FOR EXPEDITED REVIEW

A project may be considered for expedited review if:

1. **The project has been reviewed and approved by another IRB**
2. **This is a continuing review of research previously approved by the convened IRB as follows:**

   (a) Where

   (i) The research is permanently closed to the enrollment of new subjects;
   (ii) All subjects have completed all research-related interventions; and
   (iii) The research remains active only for long-term follow-up of subjects; or

   (b) Where no subjects have been enrolled and no additional risks have been identified; or

   (c) Where the remaining research activities are limited to data analysis.

This project was previously approved by:

Date of approval:

Indicate year of project being considered for this review:

What is the estimated number of subjects for year of project being considered for this review?

APPLICATION FOR
WAIVER OF CONSENT
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

IRB Expiration Date

REQUEST FOR WAIVER OF CONSENT

1. **The activity in its entirety involves no greater than minimum risk to subjects.** ☐ **Yes** ☐ **No**
2. **The waiver of informed consent will not adversely affect the rights and welfare of the subjects.** ☐ **Yes** ☐ **No**
3. **It is not practicable to conduct the research without the waiver/alteration.** ☐ **Yes** ☐ **No**
4. **Wherever appropriate, subjects will be provided additional pertinent information after their participation.** ☐ **Yes** ☐ **No**

If you have selected the "yes" response to each of the four statements above:

A. Describe the reason the waiver is necessary.

B. Explain whether the entire informed consent is being waived or only certain required elements are to be waived. (If so, list which ones.)

APPLICATION FOR
MODIFICATION REQUEST
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

IRB Expiration Date

PROPOSED CHANGES

Describe in detail the proposed changes to include any change in title, methodology, sample size, sample population, assent or consent form, recruitment of subjects, principle investigators, etc.

Explain the reason for your request if it involves methodology or project design.

Do these changes pose additional risk to the participants? ☐ **Yes** ☐ **No**

If yes, please describe the risks involved.

NOTICE TO FUNDING AGENT

Have modifications been reported to the funding agent? ☐ **Yes** ☐ **No**

Do these changes require notification to or approval by the funding agent? ☐ **Yes** ☐ **No**

Does the funding agent approve these changes? ☐ **Yes** ☐ **No**

APPLICATION FOR
ADVERSE OR UNANTICIPATED EVENT REPORT
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Purpose: What is the reason for this project? ***(Describe purpose, not expectations)***

Briefly describe the project

IRB Expiration Date

ADVERSE OR UNANTICIPATED EVENT REPORT

Describe the adverse or unanticipated event and the action taken.

Did this event affect subjects in your project? ☐ **Yes** ☐ **No**

If yes, how many subjects were affected?

Will the event require changes in the consent forms? ☐ **Yes** ☐ **No**

If yes, submit copies of the revised forms to _____
or deliver to the Office of Grants Development.

Have you reported this event to the funding agent? ☐ **Yes** ☐ **No**

Does this event change the project in such a way as to require reporting to the funding agent? ☐ **Yes** ☐ **No**

PROGRESS REPORT
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Point of contact at the funding source:

Name
Address 1
Address 2
City **State** **Zip Code**
Phone
Email

Enter dates for the period of this report: **Start Date**
End Date

Please indicate the status of the project:

☐ **Active and open to subject enrollment (include copy of consent form)**
☐ **Active but closed to subject entry**

Date of closure to subject entry

Closure is: ☐ **Permanent**
☐ **Temporary**

Has the protocol or consent form changed in any way since the last approval? ☐ **Yes** ☐ **No**

During the time period of this report have you:

Actively enrolled subjects ☐ **Yes Number:** ☐ **No**

Collected follow up data **Yes** ☐ **Number:** **No** ☐ **Have**

any subjects withdrawn from the study? **Yes** ☐ **Number:** **No** ☐

CLOSE OUT REPORT
Institutional Review Board

Project Title **IRB Review #**

Responsible Principal Investigator **Date**

PI Email Address **Phone** **Fax**

Project Start Date **Project End Date**

Name of Funding Source **Type of Funding**

Indicate the number of subjects in the project:

Total number enrolled since last approval
Total number of all subjects to date

Enrollment numbers for the period of this report:

Male
Female
Black, Non-Hispanic
Hispanic
Native American/Alaskan
Asian/Pacific islander
Caucasian, Non-Hispanic
Other/Unknown

Submit a brief summary of project results. Please discuss any changes in procedures and anticipated risks or benefits.

Were there any medical, legal, or practical difficulties that have been encountered in the project aside from adverse events? (For example, difficulties would include complaints of subjects, logistic problems, or any difficulties that may pertain to the rights of subjects) ☐ **Yes** **Number:** ☐ **No**

Were there any adverse events encountered during this study? ☐ **Yes** **Number:** ☐ **No**

Have all adverse events been reported to the IRB? ☐ **Yes** ☐ **No**
If you answered "No," submit the appropriate form with an explanation.

Did you experience any problems with the consent process? ☐ **Yes** ☐ **No**
If yes, explain.

DOCUMENTATION OF
TRAINING IN HUMAN SUBJECT PROTECTION
(FOR INVESTIGATORS AND DIRECTORS) Institutional Review Board

The Federal Office for Human Research Protections (OHRP) requires Principle Investigators of Human Subject Research to demonstrate that they have completed education on the protection of human research participants. The education requirement must be fulfilled by completing an approved training hosted by CVCC and the following on-line course: The National Institutes of Health (NIH) course, *Protecting Human Research Participants (PHSRP) at* *http://phrp.nihtraining.com/users/login.php*

To document how you have fulfilled this requirement, please list below the education activities in the protection of human research subjects that you have completed. Examples of appropriate educational activities include:

- **Readings:** List books, brochures, or other materials concerning the use and protection of human research subjects that you have read and identify the author or source of these materials.
- **Courses:** List any courses, seminars, forums, or workshops you have attended on the protection of human research subjects and the date you attended. Identify the organization or office that provided the training.
- **Web-based Tutorial Programs:** Identify any tutorial program you have successfully completed and the web site. For example, the NIH Office of Human Subjects Research training module located at http:/ohsr.od.nih.gov.
- **Committee Participation:** If you have served on an Institutional Review Board at another institution, please identify the committee, your role, and the dates you served.
- **Video/CD:** List items such as the Office of Human Subject protection video/CD "Protecting Human Subjects."
- **Other:** List any other items or sources of training which have helped you fulfill the education requirement.

List of IRB education activities and dates completed:

NIH Human Protecting Human Research Participants online course	**Date**
	Date
	Date
	Date
	Date

DOCUMENTATION OF
EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS
For IRB Members Only

The Federal Office for Human Research Protections (OHRP) requires IRB members to demonstrate that they have completed education on the protection of human research participants. The education requirement may be fulfilled in a variety of ways. See the OHRP web site: http://www.hhs.gov/ohrp/education/.

At a minimum, two group training activities and the National Institutes of Health (NIH) Protecting Human Research Participants online course are required: http://phrp.nihtraining.com/users/login.php.

To document how you have fulfilled this requirement, please list below the education activities in the protection of human research subjects that you have completed during the last three years. Examples of appropriate educational activities include:

- **Readings:** List books, brochures, or other materials concerning the use and protection of human research subjects that you have read and identify the author or source of these materials.
- **Courses:** List any courses, seminars, forums, or workshops you have attended on the protection of human research subjects and the date you attended. Identify the organization or office that provided the training.
- **Web-based Tutorial Programs:** Identify any tutorial program you have successfully completed and the web site. For example, the NIH Office of Human Subjects Research training module located at. http://www.hhs.gov/ohrp/education/index.html.
- **Committee Participation:** If you have served on an Institutional Review Board at another institution, please identify the committee, your role, and the dates you served.
- **Video/CD:** List items such as the Office of Human Subject protection video/CD "Protecting Human Subjects."
- **Other:** List any other items or sources of training which have helped you fulfill the education requirement.

List of IRB education activities and dates completed:

NIH Protecting Human Research Participants online course **Date**

Date

Date

Date

APPENDIX 4: Acronyms and Glossary

ACRONYMNS

DHHS	Department of Health and Human Safety
FDA	Federal Drug Administration
FERPA	Family Educational Rights and Privacy Act
FWA	Federal-Wide Assurance
HIPPA	Health Insurance Portability and Accountability Act
HHS	Health and Human Safety
HSR	Human Subjects Research
IRB	Institutional Review Board
IRB	Handbook of Standard Procedures of Operation for the IRB
OHRP	Office for Human Research Protections (Federal office)

GLOSSARY

ADVERSE EVENT

An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

ASSENT

Explicit agreement by an individual not competent to give legally valid informed consent *(e.g.,* a child or cognitively impaired person) to participate in research.

AUTONOMY

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

BELMONT REPORT

A statement of basic ethical principles governing research involving Human Subjects issued by the National Commission for the Protection of Human Subjects.

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.

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.

CONFIDENTIALITY

Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

DEBRIEFING

Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

EXPEDITED REVIEW

Review of proposed research by the IRB Chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

FEDERAL-WIDE ASSURANCE (FWA)

Agreement that fulfills the requirements of 45CFR part 46 approved by the Secretary of Health and Human Services.

FULL BOARD REVIEW

Research that is reviewed at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

GRANT

Financial support provided for a project or 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.

GUARDIAN

An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

HUMAN SUBJECTS

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the 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.

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 preventive 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.

INSTITUTIONAL REVIEW BOARD

A specially constituted review body established or designated by an entity to protect the welfare of Human Subjects recruited to participate in biomedical or behavioral research.

JUSTICE

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

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.

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. For example, the risk of drawing a small amount of blood from a healthy 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 subject protections.

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services (DHHS), responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving Human Subjects.

PRIVACY

Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

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 treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

RESEARCH

A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalized knowledge.

RESPECT FOR PERSONS

An ethical principle discussed in the *Belmont Report* requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

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*.)

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.

APPENDIX 5: REFERENCES

International Ethical Guidelines for Biomedical Research Involving Human Subjects, a document developed by The World Health Organization in coordination with The Council of International Organizations of Medical Societies. (2002). Retrieved September 5, 2012, from http://www.who.int/ethics/research/en/

Marcicopa Community Colleges. Institutional Review Board. Retrieved September 5, 2012 from http://www.maricopa.edu/irb/

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research.* Retrieved September 5, 2012, from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

North Seattle Community College, Human Subjects Review Committee. (n.d.). *Codes of research ethics.* Retrieved September 5, 2012, from https://northseattle.edu/committees/human-subjects-review-committee

Office of Behavioral and Social Sciences Research, National Institutes of Health. (n.d.). *Is your research exempt from IRB review?* Retrieved September 5, 2012, from http://obssr.od.nih.gov/about_obssr/history/adherence_research_network/policy.aspx

Old Dominion University, Office of Research. (2012). *Procedures for the review of human subjects research.* Retrieved from http://ww2.odu.edu/ao/research/forms/index.shtml

Penslar, R.L. (n.d.). *IRB guidebook*. Retrieved September 5, 2012, 2009, from United States Department of Health & Human Services, Office for Human Research Protections (OHRP) from http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

Sinclair Community College, Grants Development Office. (2009). *Sinclair's operating procedures.* Available from http://www.sinclair.edu/about/offices/grants/compliance/irb/

Tidewater Community College, Grants Development Office (2007) Institutional Review Board Guidelines. http://www.tcc.edu/welcome/collegeadmin/grants/IRB/

Tuskegee University. (n.d.). *Research ethics: The Tuskegee syphilis study.* Retrieved September 5, 2012 from http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx

U.S. Dept. of Health & Human Services. (2012). Office for Human Research Protections (OHRP). Retrieved September 5, 2012, from http://www.hhs.gov/ohrp/

U.S. Dept. of Health and Human Services, National Institutes of Health. (2004). *Protecting personal health information in research: Understanding the HIPAA privacy rule.* Retrieved September 5, 2012 from http://privacyruleandresearch.nih.gov/pr_02.asp

United States Holocaust Memorial Museum. (n.d.). The Doctors Trial: The medical case of the subsequent Nuremberg proceedings. September 5, 2012, from http://www.ushmm.org/research/doctors/doctptx.htm

United States Department of Health & Human Services, Office for Human Research Protections. (September 24, 2004). *Human subject regulations decision charts.* Retrieved September 5, 2012 from http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Valencia Community College, Institutional Review Board. Retrieved September 5, 2012 from http://valenciacollege.edu/irb/