Finlandia University Procedures for Conducting Research with Human Participants

This document describes the procedures that Finlandia University faculty, staff, and students are expected to follow to ensure that the rights of human participants in research are protected.

Prepared by the 2008-2009 IRB Committee

April 2009, Revised October 19, 2009

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Many forms of research in which humans are participants must be approved by the Finlandia University (FU) Institutional Review Board (IRB). The purpose of research review is to ensure that risks to human participants are minimized and benefits are maximized. The basic ethical principles underlying the acceptable conduct of research involving human subjects that have been adopted by the FU IRB are based on the "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research"[1] written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Those principles are **respect for persons, beneficence,** and **justice:**

> *Respect for persons* involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
>
> *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
>
> *Justice* requires that the benefits and burdens of research be distributed fairly.[2]

The procedures adopted by the FU IRB are guided by the regulations in Part 46 Title 45 of Federal Code of Regulations (45 CFR 46.101 - 46.409)[3]. The FU IRB is registered with the United States Department of Health and Human Services' Office for Human Research Protections[4] and is currently seeking approval of its assurance.

This procedural manual is meant to be a straightforward guide to getting IRB approval for human participants research affiliated with Finlandia University. See the Finlandia University IRB Procedures Manual for more specific information on the procedures adopted by the FU IRB. The next section of this manual gives a short overview of the FU IRB process. In the section following that, the researcher will find step-by-step information on how to submit a research proposal to the FU IRB. The final section discusses the rights and responsibilities of the researcher. Appendix A contains a set of decision charts that the FU IRB uses to determine whether a research activity qualifies as human participants research, whether the research is exempt from review, whether the research is eligible for expedited review, whether informed

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1 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. Department of Health, Education, and Welfare. Retrieved March 12, 2009 from, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

2 Penslar, R. L. (n.d.) *Institutional Review Board Guidebook.* Office for Human Research Protections, United States Department of Health and Human Services. Retrieved March 12, 2009 from, http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

3 See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

4 See http://www.hhs.gov/ohrp/

consent may be waived, and whether documentation of informed consent may be waived. Appendix B contains the IRB Project Application. Appendix C contains a template for an informed consent document. Appendix D documents the members of the IRB beginning in the 2009-2010 school year.

Any questions regarding these procedures should be directed to irb@finlandia.edu. All correspondence written to this address will be responded to, so if you do not get a response, please contact the IRB Administrator in person.

THE FINLANDIA UNIVERSITY IRB REVIEW PROCESS

Figure 1 below outlines the Finlandia University IRB review process. After a proposal is submitted, the IRB will check whether the principal investigator (PI)--the researcher responsible for the project--and all other researchers have documentation of IRB training on file. If there is not adequate documentation of training, the proposal is disapproved and returned to the PI. If there is documentation, the proposal goes to the IRB Chair who determines if the research is exempt from review. If it is exempt, the proposal goes to the Head Official (the Provost) for final institutional approval. If the proposal is not exempt, the IRB Chair determines whether the research is eligible for expedited review. If the proposal is eligible for expedited review, it will be reviewed by the IRB chair. If the proposal is approved by the IRB Chair, it will be forwarded to the Head Official for final institutional approval. If the proposal is not eligible for expedited review or it is not approved by the IRB chair, the proposal will be reviewed by the full IRB committee. If the proposal is approved, it will be forwarded to the Head Official for final institutional approval. If it is not approved by the full committee, the PI will be informed of the reason for disapproval in writing. The PI may make revisions and resubmit the proposal or make an appeal to the IRB committee. The FU IRB will strive come to a decision on a proposal within four or five weeks from submission of the proposal.

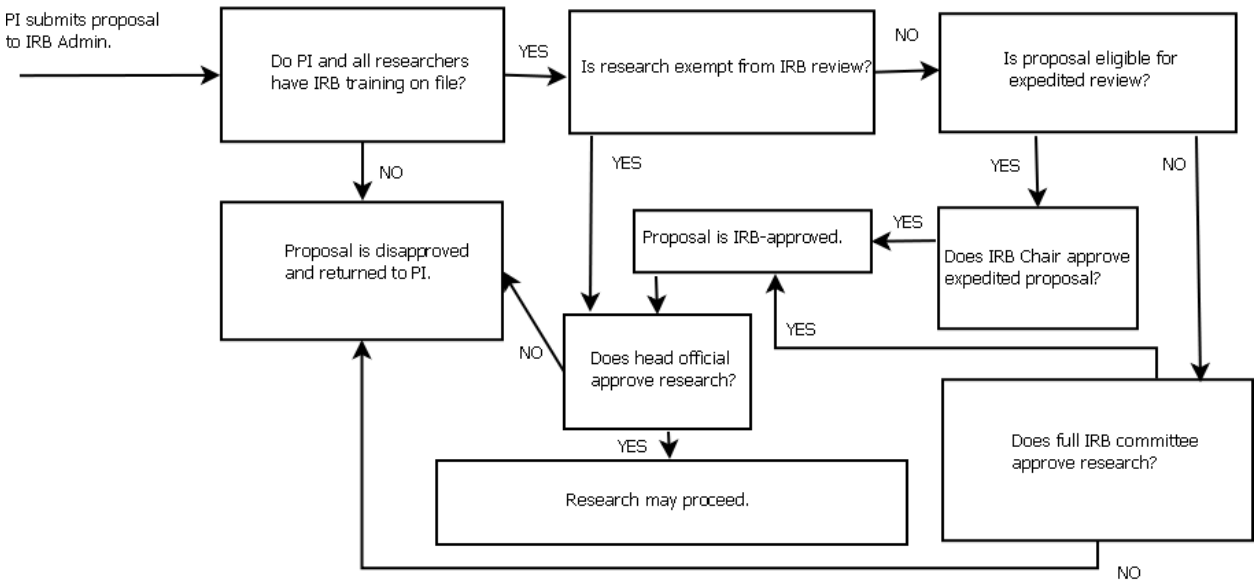


Figure 1. The Finlandia University IRB review process

STEP-BY-STEP INSTRUCTIONS FOR SUBMITTING A RESEARCH PROPOSAL

The steps for submitting a research proposal are outlined below:

1. Determine if the research activity qualifies as human participants research.

2. Have all researchers involved successfully complete IRB training and submit documentation to the IRB Committee.

3. Determine whether the research activity is exempt.

4. Determine whether the research activity is eligible for expedited review.

5. Determine whether informed consent can be waived.

6. Determine whether documentation of informed consent can be waived.

7. Determine whether vulnerable participants will be involved.

8. Complete and submit the IRB Project Application.

Step 1: Determine if the research activity qualifies as human participants research.

Not all research needs to be submitted to the FU IRB. The factors that determine whether your research activity qualifies as human participants research are listed below:

- Whether the activity is a systematic investigation designed to develop or contribute to generalizable knowledge. (The FU IRB considers institutional research or program evaluation, or systematic investigations conducted by students to be research.)
- Whether the research information about living individuals is obtained.
- Whether the information obtained is public or private.
- Whether the research involves intervention or interaction with individuals.
- Whether a Federal agency supports or sponsors the research.

See the Chart 1 in Appendix A to determine whether the research activity qualifies as human participants research? If the research qualifies as human participants research, go on to Step 2. If it *does not* qualify as human participants research, seek approval directly from the dean of your college and the Provost's office.

Step 2: Have all researchers involved successfully complete IRB training and submit documentation to the IRB Committee.

Like most other IRBs, the FU IRB requires all researchers involved in human participants research to have successfully completed IRB training within the past five years. Acceptable training includes successfully completing the NIH Office of Extramural Research's *Protecting Human Research Participants* (PHRP) training. Other IRB training certifications will be considered on an individual basis. To take the PHRP training, go to:

http://phrp.nihtraining.com/users/login.php

Register, then take the training. When you have successfully completed the training, you should get a certificate like the one below. Return it to the IRB Committee for archiving at irb@finlandia.edu or bring it in person to the current IRB Administrator.


Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Justus Randolph** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 03/12/2009

Certification Number: 201562

Figure 2. Example of documentation of successful IRB training completion.

Step 3. Determine Whether the Research is Exempt

All human participants research activities (see Chart 1 in Appendix A) need to have a proposal submitted to the FU IRB; however, not all research activities need to be formally reviewed by the IRB. Sometimes human participants research is exempt from review. Whether human participants research is exempt from review depends on the following factors (45 CFR 46:101):

> (b) Unless otherwise required by 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:

(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 paragraph (b)(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.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are 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.

(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 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.

Use Charts 2-7 in Appendix A to determine if your research activity is exempt from IRB review. If you do believe it is exempt, check "Exempt from review" and check the reason that you believe it is exempt in the *Category for Review* section when you fill out FU IRB Project Application, which can be found in Appendix C. **Please note that a proposal must be submitted to the FU IRB, even if you believe that your research is exempt from review.**

Step 4. Determine Whether the Research Activity is Eligible for Expedited Review

In some cases, research is eligible for expedited review, which is a review conducted only by the IRB Chair, rather than being reviewed by the entire IRB. The current circumstances under which research is eligible for expedited review is given below:

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the

amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group,

program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) 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.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.[5]

Use Chart 8 in Appendix A to determine if your research activity is eligible for expedited IRB review; use Chart 9 if you are making a protocol change and feel that the change is eligible for review. If you do believe it is eligible, check "Expedited review" and then check the reason that you believe it is eligible for expedited review when you fill out FU IRB Project Application, which can be found in Appendix C.

Step 5. Determine whether informed consent can be waived

Most human participants research requires that participants provide informed consent to participate in a study. Often an informed consent agreement is drawn up to help participants understand the study protocol, risks, and benefits. According to Federal regulations [45 CFR 46.116 (b)(c)], an informed consent agreement should have, at least, the following elements:

> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for

5 http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(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; 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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(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.

A template informed consent form can be found in Appendix C.

In some cases, informed consent can be waived. Under 45 CFR 46 (c)(d), informed consent can be waived under the following conditions:

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

See Chart 10 in Appendix A to help determine whether informed consent can be waived for your research activity. If you believe that it can be waived, please indicate this on the IRB Project Application.

Step 6: Determine Whether Documentation of Informed Consent can be Waived

In some cases, documentation of informed consent can be waived. According to 45 CFR 46.117 (c), informed consent can be waived under the following conditions:

(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.

See Chart 11 in Appendix A to determine if documentation of informed consent can be waived. If you believe it can, please indicate so on the IRB Project Application.

Step 7: Determine Whether Vulnerable Populations are Involved

If research involves vulnerable populations, (i.e., pregnant women, human fetuses, and neonates; prisoners; or children) require that the research take special precautions. If your research involves any of these vulnerable populations, please indicate which vulnerable populations on the IRB Project Application. More information on the vulnerable populations and what special precautions can be found from the links below:

- Pregnant women, human fetuses, and neonates (45 CFR 46.201-207):

  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb

- Prisoners (45 CFR 46.301-306):

  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc

- Children (45 CFR 46.401-409):

  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd

Step 7. Complete and Submit the IRB Project Application

The final step in submitting a proposal for initial review is to fill out the IRB Project Application in Appendix C and e-mail it to irb@finlandia.edu or deliver it in person to the current IRB administrator. Along with the actual project application, each proposal must include a brief summary of the project, a copy of the informed consent agreement (where applicable), and a copy of documents that participants will be exposed to (e.g., surveys, interview protocols, etc.). The brief summary of the project should include an explicit statement of methods, data collection, and how confidentiality of participants/data will be protected, including consent forms. The IRB will base its decision to approve or disapprove a proposal based on the following criteria (45 CFR 46.111):

a) 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 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 of therapies 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 responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account 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 will be 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 will be appropriately documented, in accordance with, and to the extent required by §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.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

RIGHTS AND RESPONSIBILITIES OF RESEARCHERS

Researchers have the right to a written explanation of why a proposal had been disapproved by the IRB. Researchers also have a right to appeal, one time, an IRB decision in writing or orally at the next full IRB meeting after the date of disapproval.

Researchers are obligated to exactly adhere to the protocol described in the IRB Project Application. Any

changes in protocol must be approved by the IRB prior to the changes being implemented. Researchers wishing to make protocol changes should submit another IRB Project Application that details the proposed protocol changes.

Researchers are obligated to maintain all necessary documentation for a period of at least three years after the study has ended. The documentation must be stored securely.

Most importantly, researchers are obligated to *immediately* report any unanticipated problems to the IRB committee. Failure to carry out the obligations of researchers mentioned above, serious noncompliance, or ongoing noncompliance may results in institutional reprimand.

The IRB reserves the right to audit a research project at anytime. An audit may consist of observing how protocols are carried out, interview with researchers, interviews with willing participants that are related only to the how the protocol was carried out, and the review of all documents that do not have personally identifying information except for informed consent releases.

Long-term projects will be re-reviewed at least once per year. The number of continuing reviews per year will depend on the amount of risk involved.

APPENDIX A: DECISION CHARTS

Note. These charts are from the Office of Human Research Protection. See http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

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

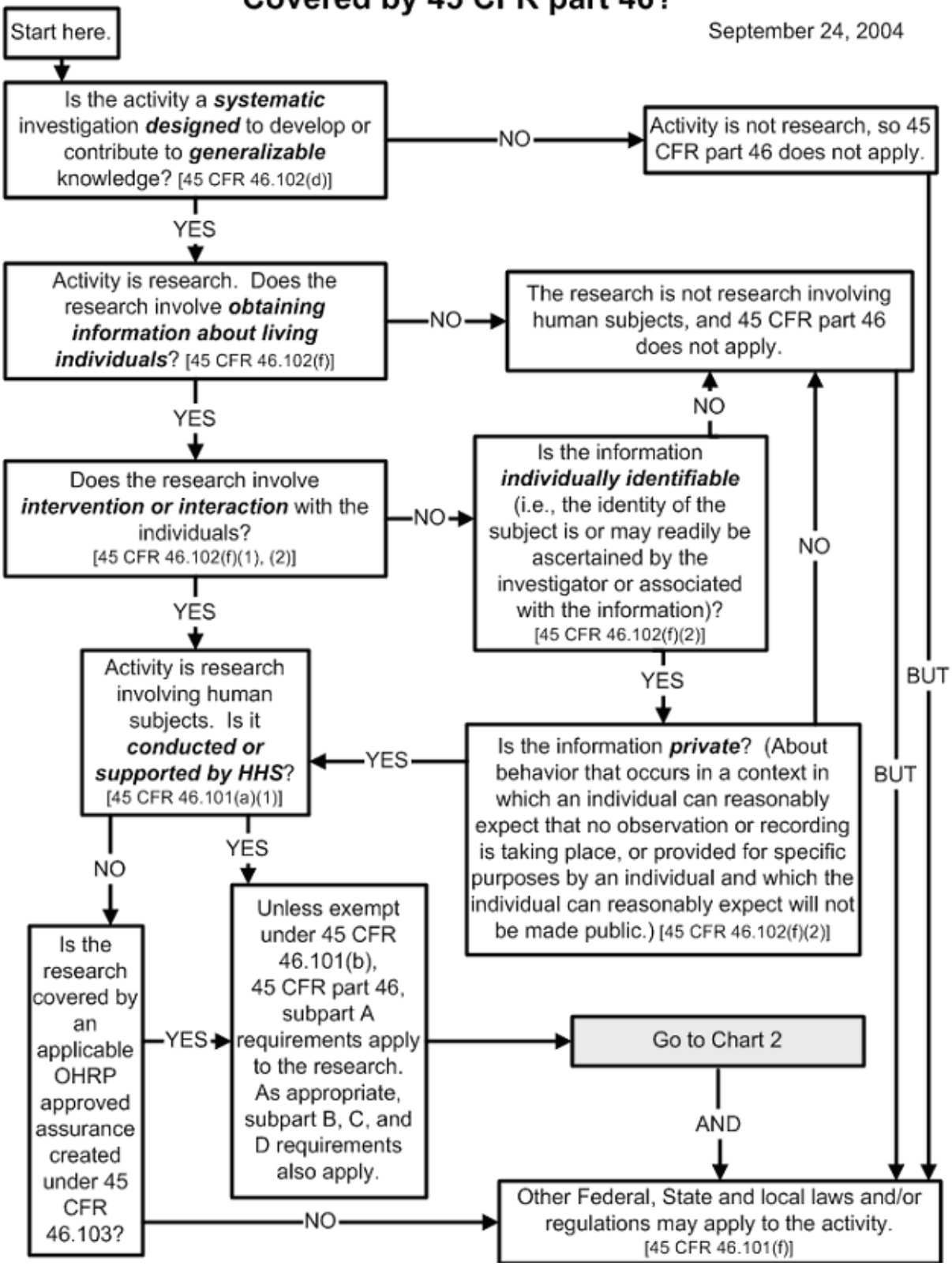


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

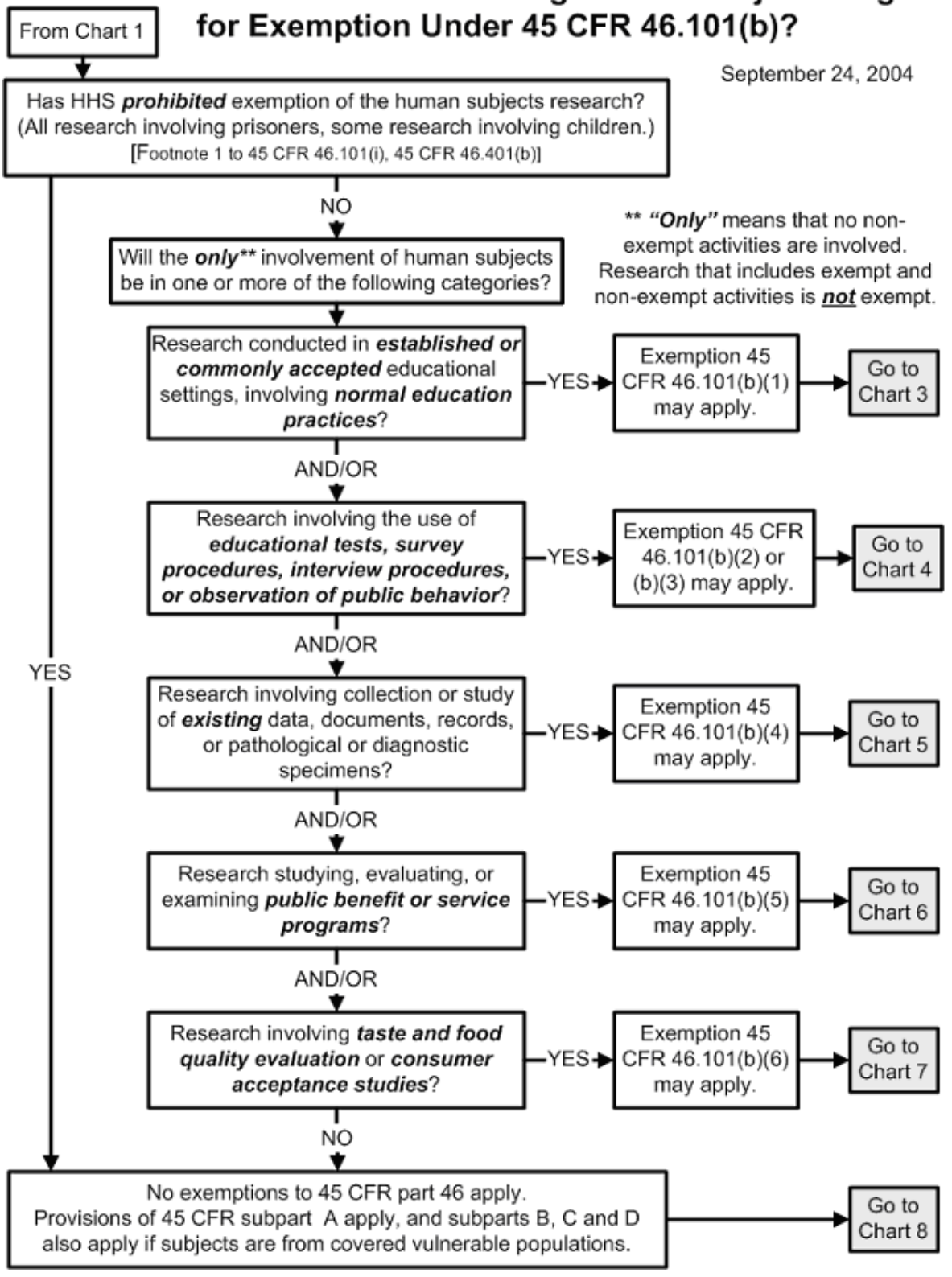
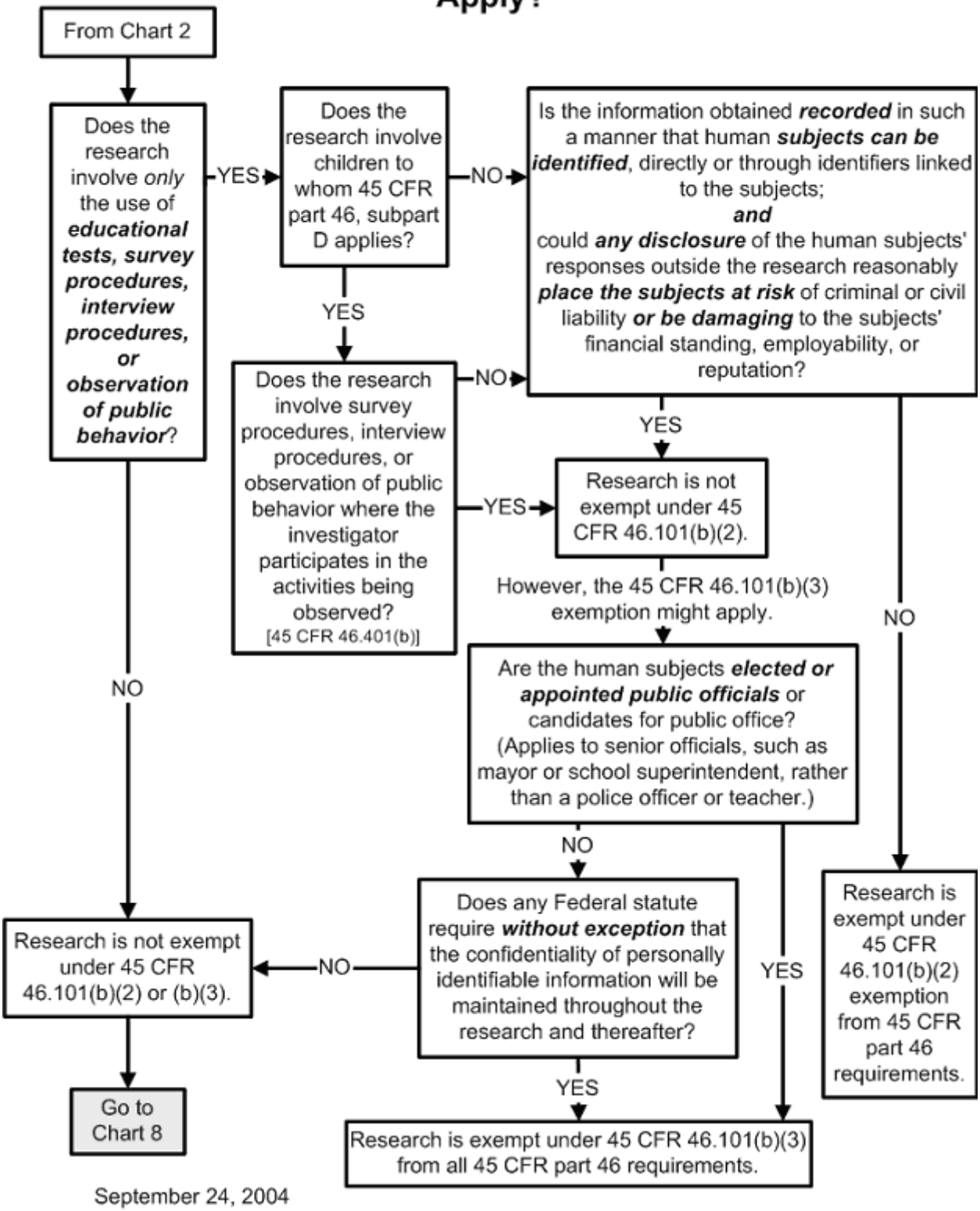
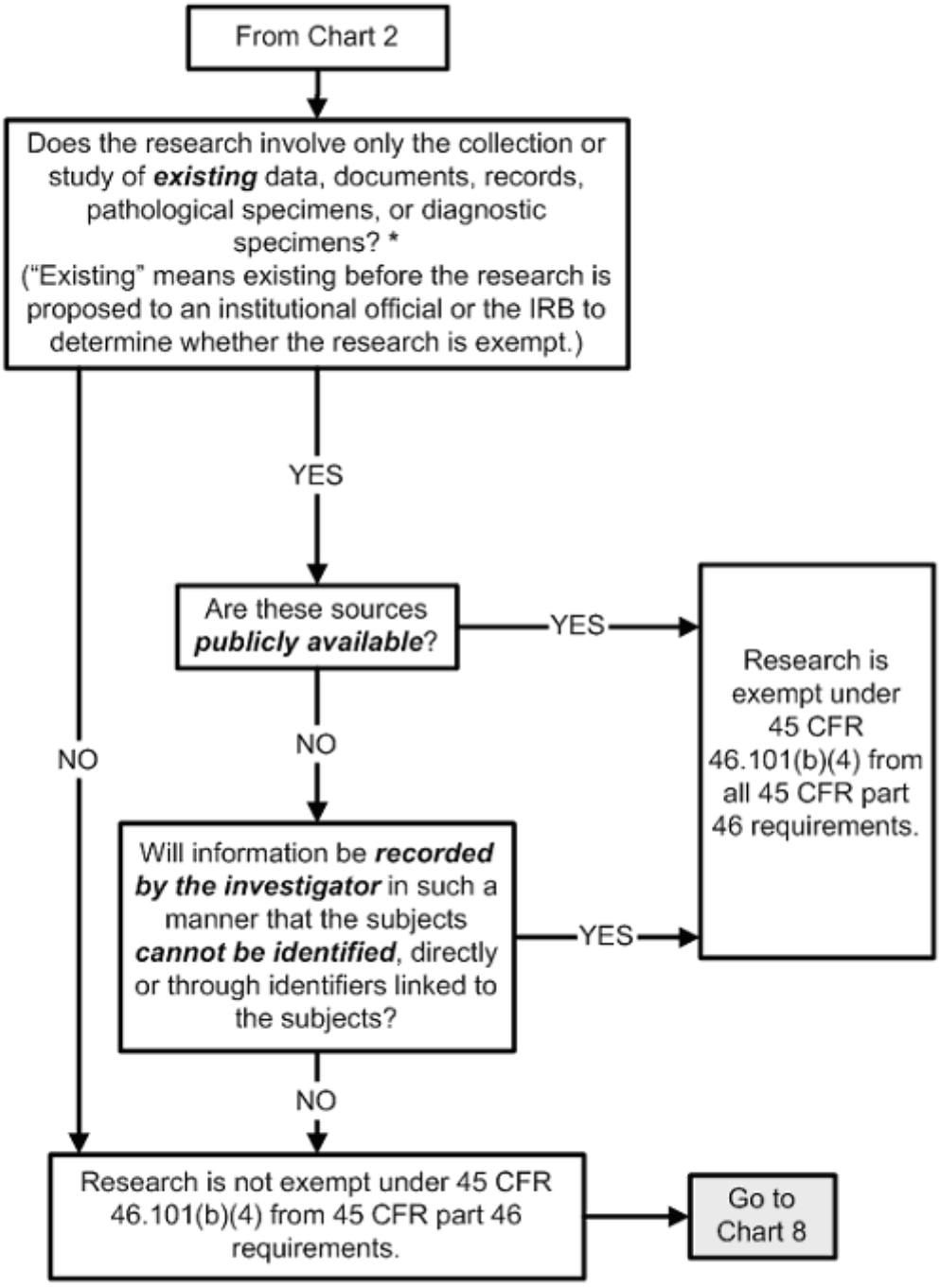


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



September 24, 2004

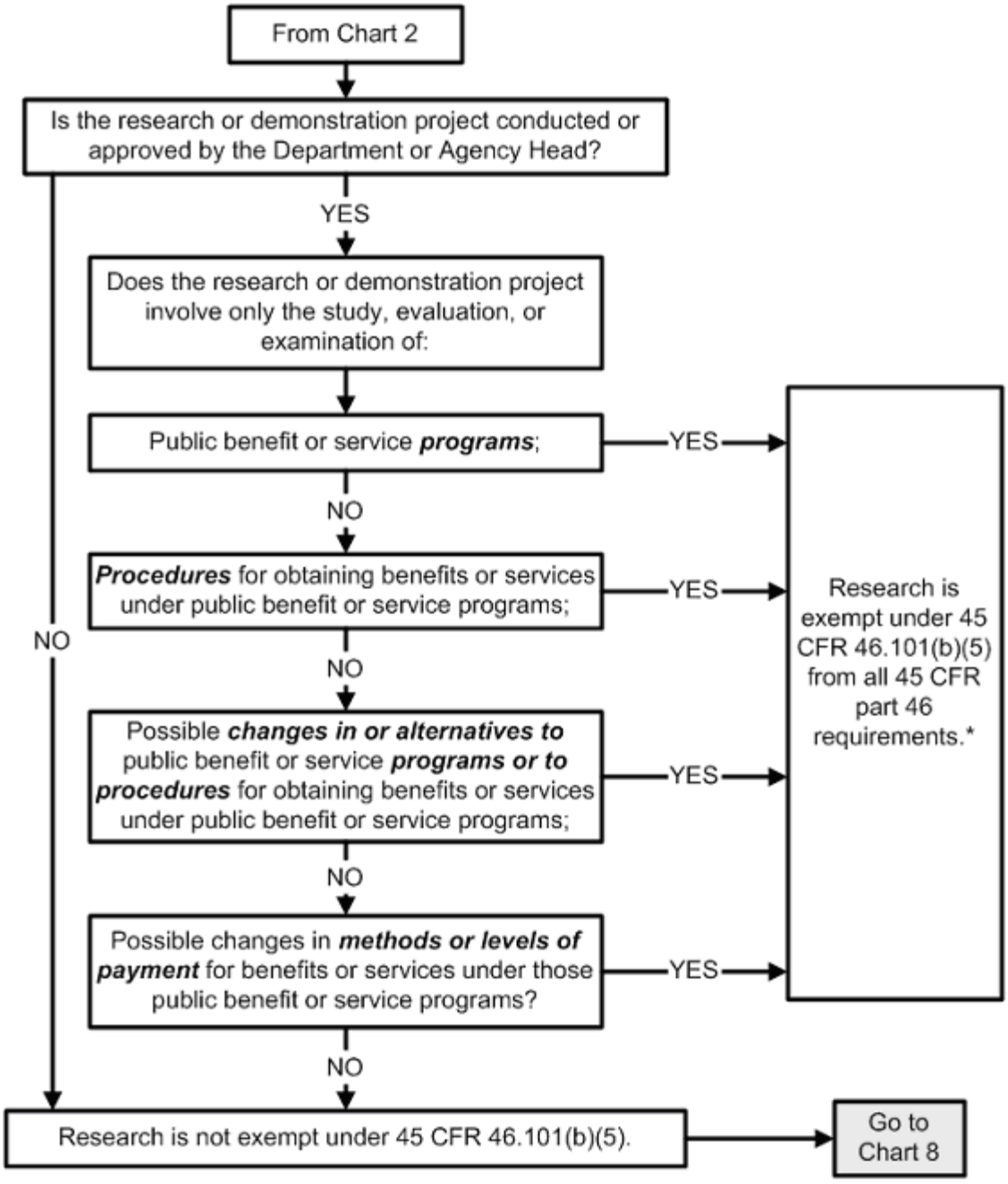
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* 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.

September 24, 2004

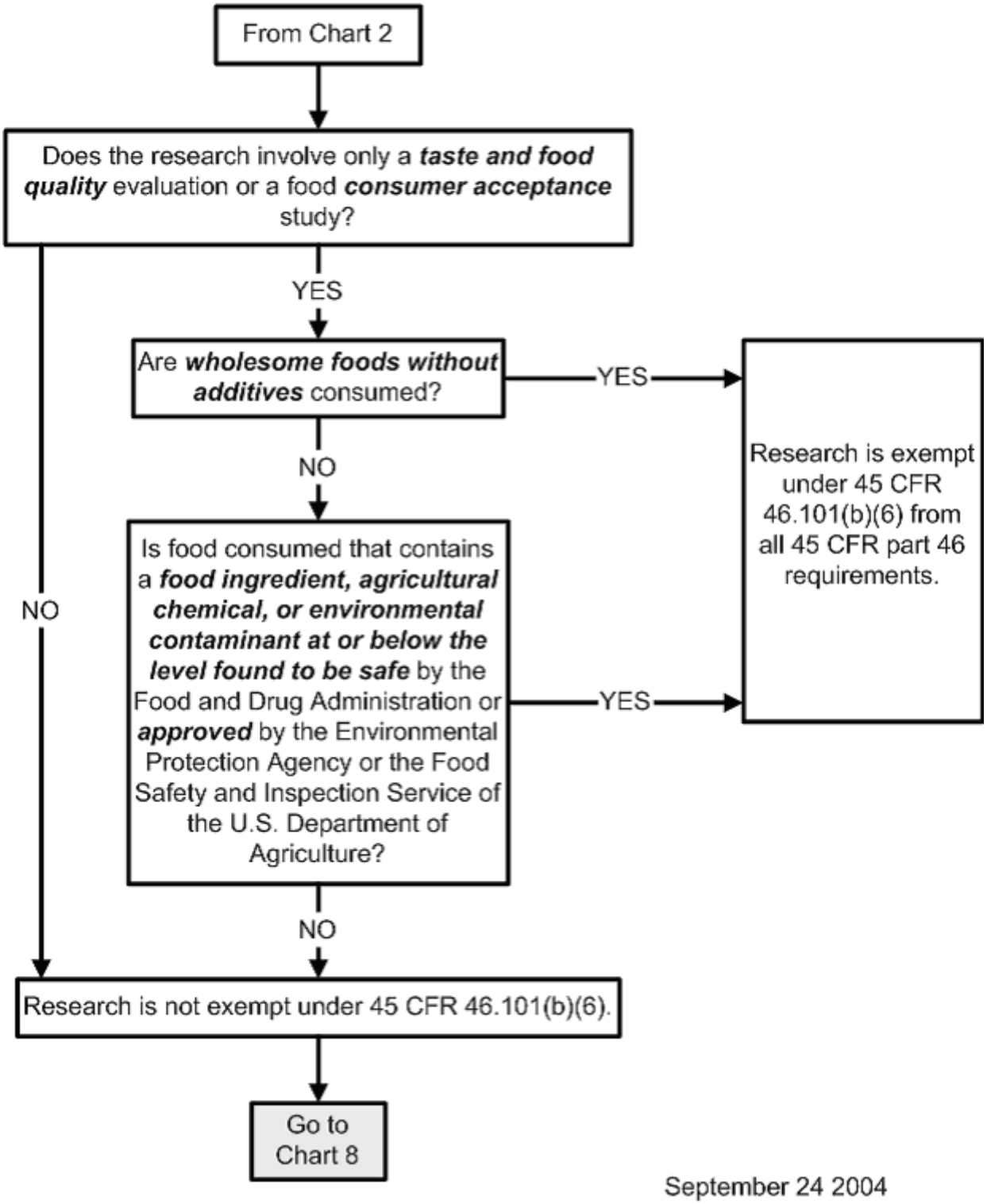
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



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

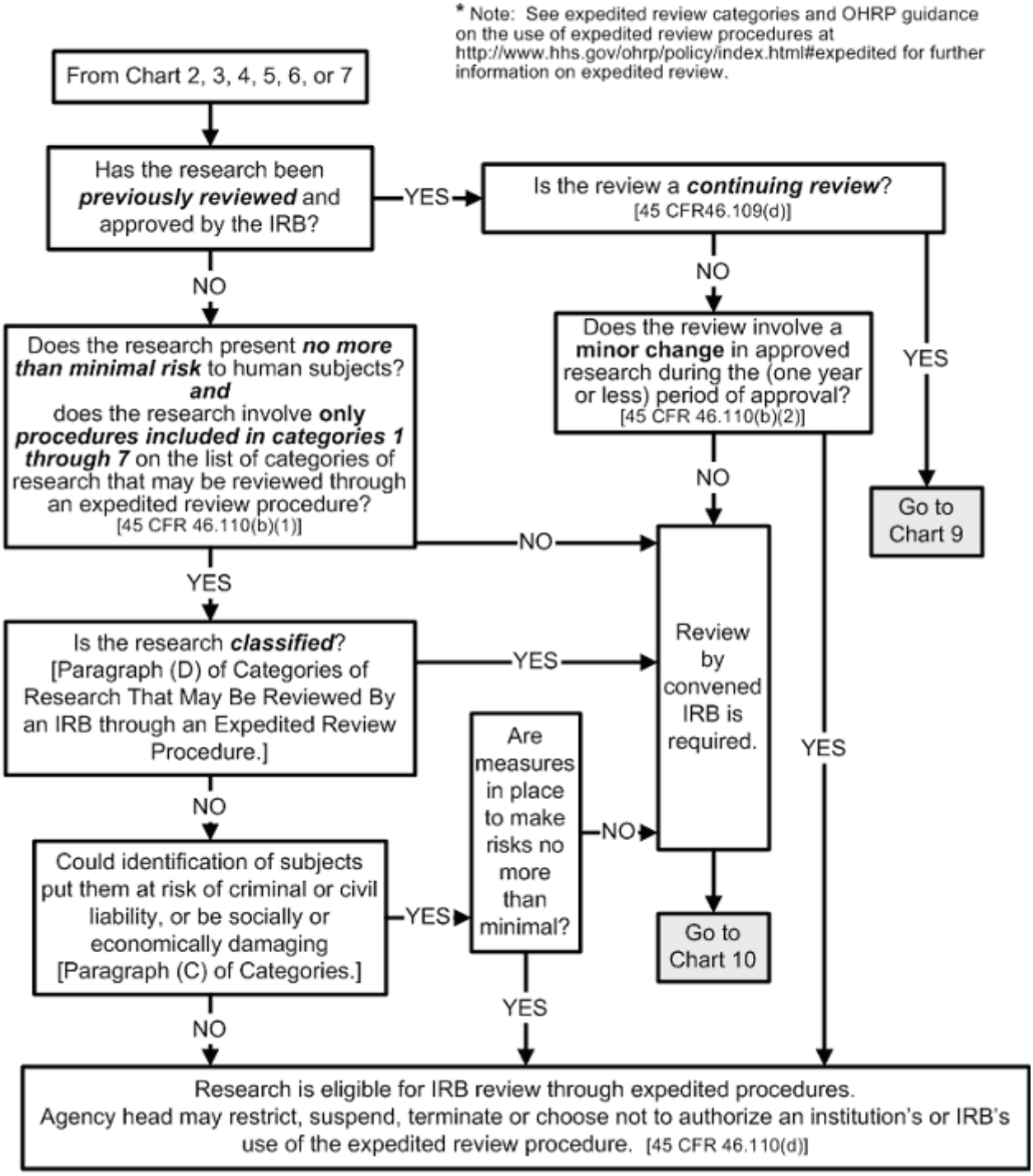
September 24, 2004

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



September 24 2004

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?

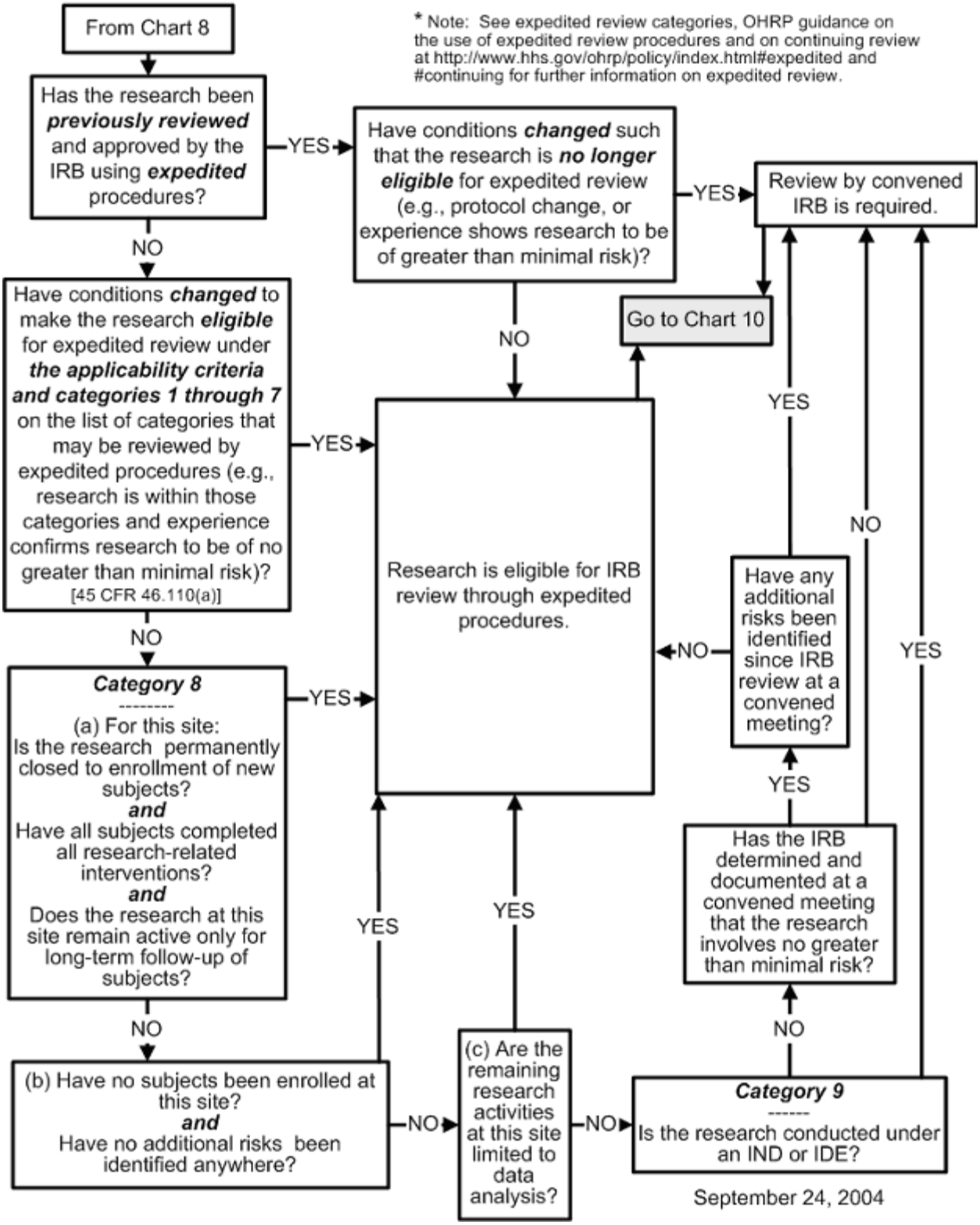
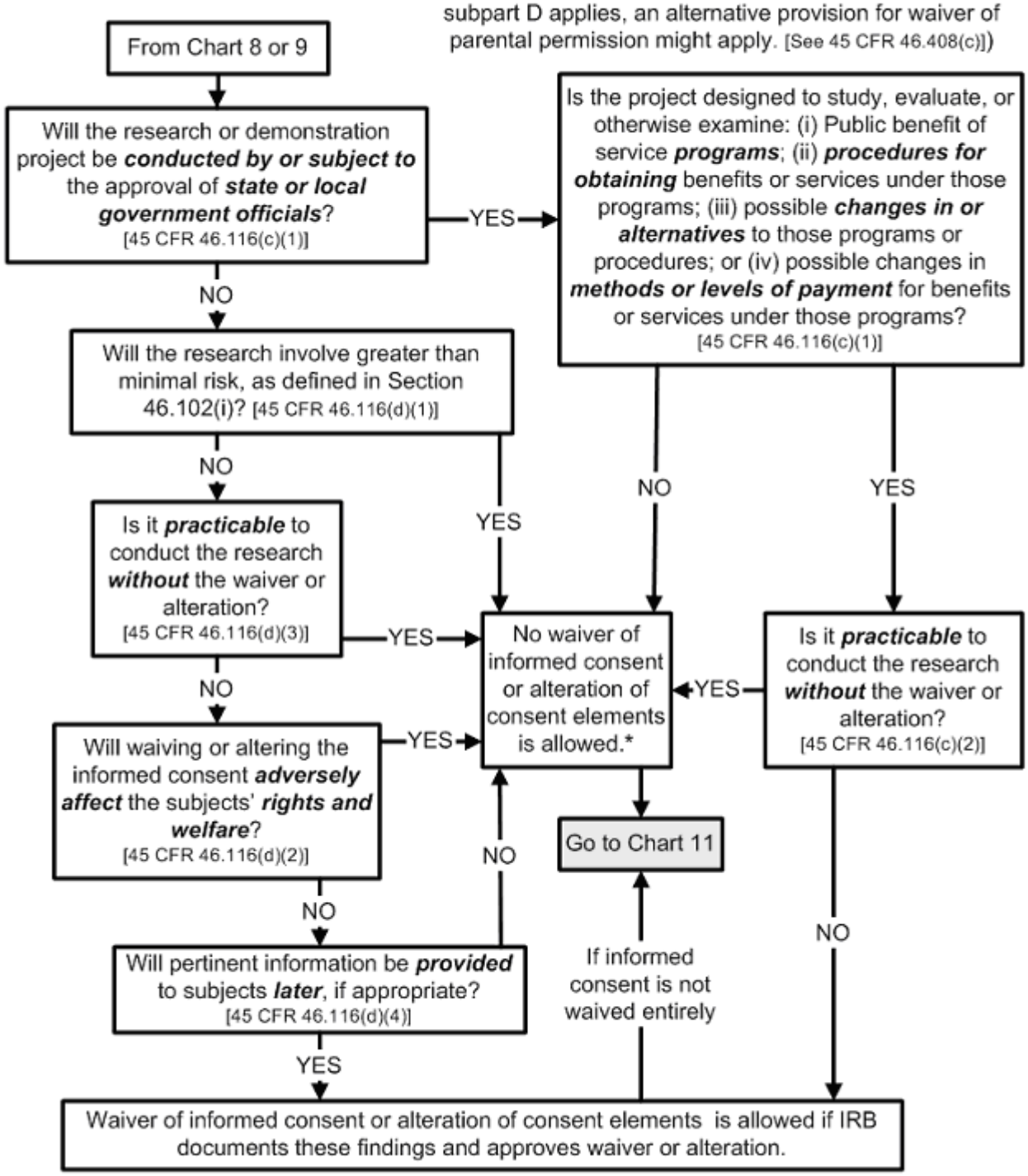


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

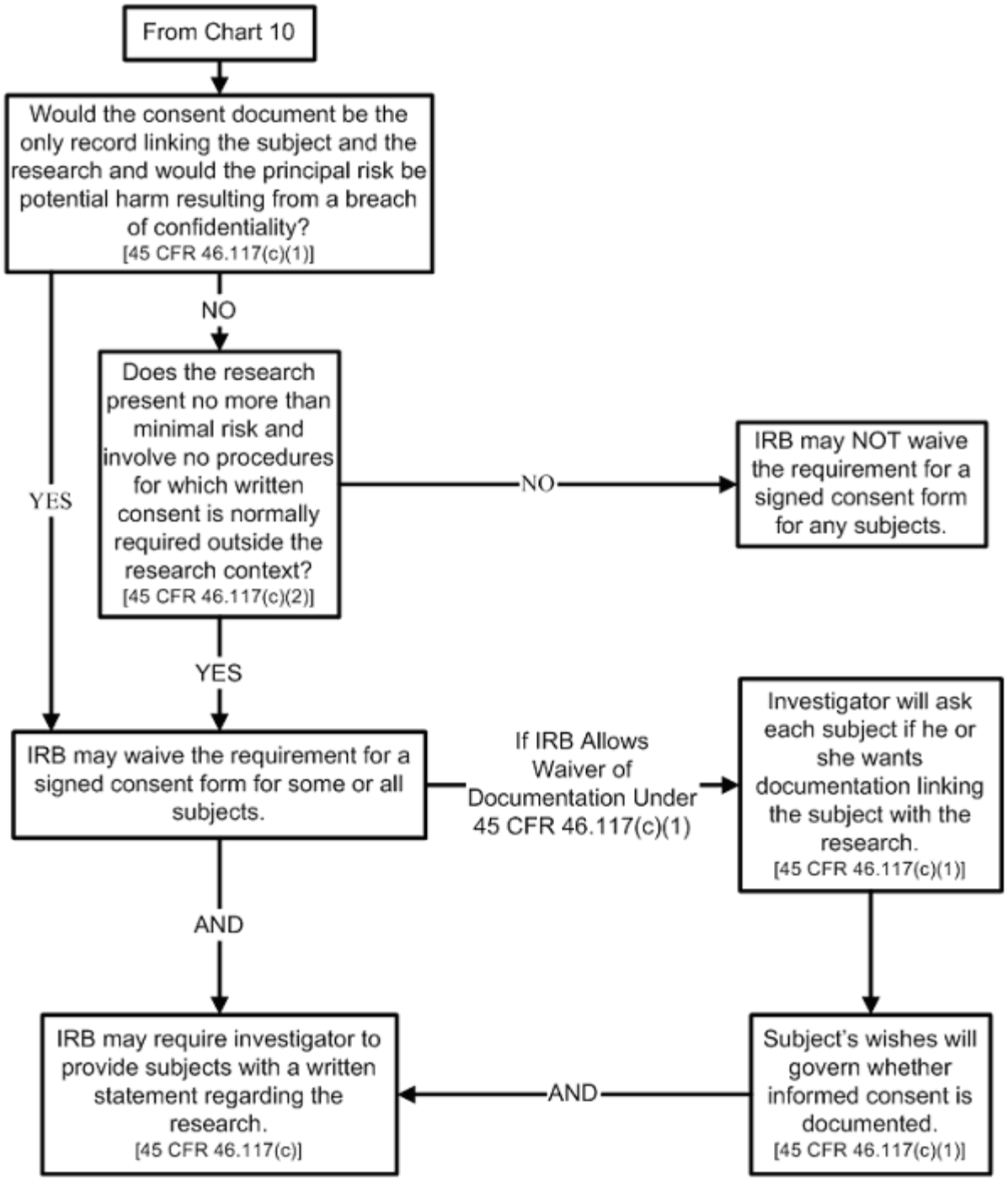
**(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



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

September 24, 2004

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



September 24, 2004

APPENDIX B

IRB Project Application

Note. The following application was adapted from a

Hawaii Pacific University Application

Finlandia University
Institutional Review Board
Project Application

Date:

Study Title:

Principal Investigator:

Phone:

E-mail:

Co-Researchers, if any:

Please attach a brief summary of the project. This should include an explicit statement of methods, data collection, and how confidentiality of subjects/data will be protected, including consent forms. Also, attach any relevant documents (e.g., informed consent forms, surveys, interview protocols, etc.)

Category for Review:

Check only one level of review (Exempt, Expedited, Full) for which you believe the project qualifies and each criterion that your project meets.

- **Exempt from review (nil or minimal risks, or already approved by an IRB)**

  — Research involves ONLY investigation into or comparison of normal instructional strategies.

  — Tests, interviews, and surveys are unlikely to elicit emotion or place subjects at risk of civil/criminal liability or damage to their reputation, financial standing, employability etc. AND information will not be recorded in such a way that subjects can be identified.

  — Research involves only the study or analysis of existing data, documents, records, or specimens that are publicly available or recorded in such a way that subjects cannot be identified.

  — If the study involves ingestion of food: only wholesome food without additives in excess of USDA recommended levels is consumed.

  — Brief informed consent will be done (except in the case of existing data etc).

— No use of vulnerable subjects will be done (except in the case of existing data, etc.)

— Has already been approve by IRB at_____

Include copy of signed IRB approval form.

- **Expedited review (minor risk study)**

— Research and data collection methods are unlikely to elicit strong emotion and deception is not involved.

— Research involves only noninvasive, painless, and non-disfiguring collection of physical samples, such as hair, sweat, excretia.

— No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, disabled, etc.)

— Data are recorded using noninvasive, painless, and non-disfiguring sensors or equipment, such as EKG, weighing scales, voice/video recording.

— Research involves only moderate levels of exercise in healthy volunteers.

— Research does not involve ingestion of drugs or use of hazardous devices.

— In using existing data, documents, records, or specimens with identifiers, procedures are in place to ensure confidentiality.

— Informed consent process will be done (attach copy of informed consent form).

— Data will be kept confidential and not reported in identifiable fashion.

- **Full review required (more than minor risk)**

Attach a statement that describe the use of vulnerable participants of the study procedures that and conditions that place subjects at risk. Describe the precautions that will be taken to minimize these risks. Attach a copy of the informed consent form that will be used.

Informed Consent

Please indicate if you will collect signed informed consents forms, request a waiver of informed consent, or a waiver of

documentation of informed consent. Check only one. Also, check all criterion for waivers that apply to your research project.

— **Signed informed consent forms will be collected.**

— **A waiver of informed consent is requested because:**

— (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and (2) The research could not practicably be carried out without the waiver or alteration.

— (2) The research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

__**A waiver of informed consent documentation is requested because:**

__(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; or

__(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.

Certification by Principal Investigator: The information I have provided represents a fair estimate of risks to human subjects.

_____ _____

Name Title Date

Certification by IRB Chair (or Acting IRB Chair): I have read this application and believe that it is:

— Exempt from IRB Review

— Appropriate for expedited review, and

— Approved

— Disapproved

— Appropriate for review by the full IRB, and

— Approved

— Disapproved

If the proposal is disapproved, the IRB will attach a statement explaining the reasons for not granting approval.

_____ _____

IRB Chair or Acting Chair Date

APPENDIX C

EXAMPLES OF INFORMED CONSENT FORMS

Note. This first form was adapted from an informed consent form template for Hawaii Pacific University. The second form was adapted from an e-mailed invitation follow-up to an online survey from The National Institute for Learning Outcomes Assessment (NILOA)

INFORMED CONSENT DOCUMENT

Project Title: [Title]

Investigators: [List all individuals (name and degree) who will obtain informed consent from subjects, including the Principal Investigator and other key personnel.]

PURPOSE

This study involves research. The purpose of the research is [general description of the project—what is being investigated, what knowledge is to be gained].

We are inviting people to participate in this research because they [complete this sentence by describing why people reading the consent are possible participants for your project. For example, . . . they have been diagnosed with lung cancer, . . . they are taking an introductory psychology class, . . . they are teachers in the Copper Country Intermediate School District, . . . they are joggers, . . . they are healthy adults in the community, etc.]. [If appropriate, indicate the total number of participants expected to participate in the study.]

This project will last for [length of time for one participant's participation. If more than one contact is involved in the study, indicate the length of time for each contact, and how long in between each contact].

PROCEDURES

Those agreeing to participate can expect the following to occur. [Describe step-by-step, what is going to happen to the research participant if he/she decides to participate. Describe any procedures that are experimental. Use subheadings as appropriate. For complex protocols, consider a table showing which procedures/tests are performed at each visit.]

RISKS

The possible risks associated with participating in this research are as follows. [Describe the risks—psychological, physical, pain, drug toxicity, emotional, legal, privacy issues, etc. If there are no known risks, state that there are no foreseeable risks for participating.]

BENEFITS

There [may be / will be – select the appropriate phrase] no personal benefit for participating in this study. However, it is hoped that in the future, society could benefit from the study by [describe the possible benefits to society. Note that compensation is not a benefit and should be described in the Costs and Compensation section.].

ALTERNATIVE TREATMENT [For treatment/therapy projects—omit if not applicable]

Instead of participating in this study, the alternative treatments are: [List the alternative treatments. If the subject can receive the same intervention without participating in the research, that fact should be noted.

Describe how alternative will be presented to the study subject.].

COSTS AND COMPENSATION

There [will / will not] be any costs to the participant for participating the research project. [Clearly describe any monetary costs to the participant, if there are any. If there are costs that might be covered by a medical or hospital insurance carrier, consider adding a sentence regarding checking with the insurance carrier prior to deciding whether to participate.]

Participants [will / will not] be compensated for their time and inconvenience for participating in this research project. [Clearly describe the monetary (total amount, average total amount, amount per visit, amount per hour, etc.) or non-monetary compensation. If compensation is pro-rated when a subject withdraws prior to completing the study, explain how it is prorated.]

CONFIDENTIALITY

Records of participation in this research project will be maintained and kept confidential to the extent permitted by law. However, federal government regulatory agencies [for drug/device studies add: the U.S. Food and Drug Administration.] and Finlandia University Institutional Review Board may inspect and copy a participant's record pertaining to the research, and these records may contain personal identifiers. [Describe the methods that will be used to ensure confidentiality—e.g., coded names or identification numbers, removal of all identifying information, secure storage area, etc.] In the event of any report or publication from this study, the identity of subjects will not be disclosed. Results will be reported in a summarized manner in such a way that subjects cannot be identified.

RESEARCH RELATED INJURY [This section may be eliminated if it does not apply.]

- In the event of research-related injury, medical treatment is available at [affiliated medical center].

- No compensation for treatment of research-related injury is available from Finlandia University unless the injury is proven to be the direct results of negligence by a University employee.

- The cost of treatment for any research-related illness or injury is the responsibility of the research participant and/or his/her medical or hospital insurance carrier.

  [Or—(Choose the phrase that applies to your study)

  The cost of treatment for any research-related illness or injury will be paid for by the sponsor, [name of sponsor], to the extent that these costs are not covered by the research participant's medical or hospital insurance carrier. [If the sponsor will not provide complete coverage, or if there are other restrictions, explain what will be covered.]

VOLUNTARY PARTICIPATION

All participation is voluntary. There is no penalty to anyone who decides not to participate. Nor will anyone be penalized if he or she decides to stop participation at any time during the research project. [If appropriate, describe the consequences of a participant's withdrawal and the procedures for withdrawing.]

QUESTIONS

Questions are encouraged. Questions about this research project and questions about the rights of research participants or research-related injury may be address to Finlandia University's IRB Chair [Give contact information for IRB chair here.]

Participant's name (printed): _____

_____ _____
Signature of participant Date

[Include a Legally Authorized Representative signature only if applicable to your study – see instruction at the beginning of this document.]

INVESTIGATOR STATEMENT

I have discussed the above points with the participant or legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and obligations involved in participation in this project.

Investigator's name (printed):_____

_____ _____
Signature of Investigator Date

Dear Colleague:

We are asking you to participate in a survey conducted by [organization], as previously announced by [organization]. We've not yet received your response and need your help. The questionnaire is at this site:

http://. . .

Things you should know—

• TIMING and PURPOSE: This questionnaire takes less than 15 minutes to complete and asks about the kinds of tools and approaches your institution is using to assess student learning.

• PARTICIPANTS: The same questions are being posed to senior academic officers like yourself at every accredited two- and four-year college and university in the US.

• RIGHTS as a RESEARCH PARTICIPANT: Your participation is voluntary and your responses will be confidential. Pseudonyms will be substituted for any identifying information, unless we explicitly obtain your permission to use your name.

• RECIPROCAL AGREEMENT: As a gesture of appreciation for your help, if you participate in this survey you will receive a pre-press report of the survey results.

• PROJECT INFORMATION: The survey is being conducted by [organization]. If you have any questions about the survey, please contact the [principal investigator (e-mail)]. For more information about [organization], go to [URL]

Thanks in advance for your help. Sincerely,

[Principal Investigator], [institution] [Co-Investigator], [institition]

On to the questionnaire—

Please do one or more of the following:

• Proceed to the questionnaire, if you haven't already done so, by clicking this link:

[Link]

• If another person at your institution is better positioned to respond, please forward this invitation.

If you have any questions about your rights as a research participant please contact [IRB chair-contact information].

APPENDIX D

IRB MEMBER ROSTER AND KEY PERSONNEL (2009-2010)

Voting Members	*Affiliated with Finlandia*	*Scientist*	*Degree*	*Specialty*	*E-mail / phone*
Justus Randolph (Chair)	Y	Y	Ph.D.	Research methods	justus.randolph@finlandia.edu (906) 487-7407
Hilary Sproule	Y	Y	B.SC.PT, M.H.S.A	Nursing, physical therapy	hilary.sproule@finlandia.edu (906) 487-7372
Christine O'Neil	Y	Y	Ph.D.	Sociology	christine.oneil@finlandia.edu (906) 487-7328
Brenda Parker	Y	Y	M.S.N.	Nursing	brenda.parker@finlandia.edu (906) 487-7323
Paul Saaranen	N	N	M.A., Ed. Specialist	Education administration/ Principal of E.B. Holman Elementary/Superintendent of Stanton Township Schools	(906) 482-2797

Head Official: Dr. Cameron Williams; Provost and Executive Vice President, cam.williams@finlandia.edu, (906) 487-7368
IRB Administrator: Terri Martin; Assistant to the Executive Vice President and Provost, terri.martin@finlandia.edu, (906) 487-7512
IRB e-mail: irb@finlandia.edu