I. Institutional Review Board Rationale and Purpose:

CNM is required by the federal government to document compliance to human subjects protections when conducting research. The primary regulatory body is the Office of Human Research protection (OHRP), an office within the Department of Health and Human Services. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

OHRP regulations are based on the three principles found in the Belmont Report (1979), which are: Respect for persons, Beneficence, and Justice. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

CNM established the Institutional Review Board (IRB) to review all proposed research involving human subjects to ensure that individual’s rights and welfare are protected and all individuals are treated ethically. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects and to annually monitor compliance for research projects extending across academic years. In addition, the committee is to maintain currency with regard to federal requirements for the protection of human subjects, establish and modify review procedures and forms, and propose appropriate modifications and revisions of the CNM Administrative Procedures.

The role of the IRB does not include evaluating the soundness of the proposed research study, the merits of the research design, the potential contribution of the research to the scholarly literature, nor the impact of the research on college resources or reputation. Rather, 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. The decision of the Institutional Review Board is final. The board, at its discretion, may solicit input from the appropriate Vice President or Associate Vice President as necessary.

II. Institutional Review Board Definitions:

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

B. Human Subjects Research: Gathering data by interacting with live people generally qualifies as human research. As defined by US code 45 CFR 46102(f), a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or
interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for the information to constitute research involving human subjects. (US code 45 CFR 46.102(f).

C. **IRB Approval:** Means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. (US code 45 CFR 46.102(h).

D. **Minimal Risk:** Means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. (US code 45 CFR 46.102(i).

E. **Informed Consent:** The researcher must obtain legally effective informed consent in writing from all subjects and must allow subjects to terminate their participation in research and training programs at any time. The signed consent forms should be kept by the researcher in a locked cabinet for three years.

- No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective information consent of the subject or the subject’s legally authorized representative.
- In seeking informed consent, the following information shall be provided to each subject:
  - As statement that the study involved 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;
  - A description of any reasonably foreseeable risks or discomforts to the subject;
  - A description of any benefits to the subject or to others which may reasonably be expected from the research;
  - A disclosure of the appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - 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;

- 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
- 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.
- There are other aspects of informed consent that apply when appropriate and shall be provided to each subject. These additional elements can be found in US code 45 CFR 46.1116(b).

### III. Institutional Review Board Information:

#### A: Research Involving Human Subjects:

i. must conform to the moral and specific principles that justify such research

ii. should be conducted only by qualified persons and under the supervision of a senior researcher

iii. should not be carried out unless the importance of the research and its objectives is in proportion to the inherent risks to the research subjects

iv. should be preceded by careful assessment of the inherent risks in comparison to foreseeable benefits to the research subjects or to others

v. must respect the rights and privacy of research subjects and assure that maximum confidentiality of personal information will be maintained

#### B: Exempt Studies: According to Protection of Human Subjects, Title 45, CFR Part 46, Section 46.101, revised January 15, 2009, the following categories of research are exempt from institutional review:

- 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 institutional techniques, curricula, or classroom management methods.
- 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.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt 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.

- 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.

- 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 methods or levels of payment for benefit or services under those programs; or (iv) possible changes in methods or levels of payment for benefits or services under these programs.

- 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.

**C: Student Projects:** (required or for extra credit) involving observation or interaction with human subjects will be expected to conform to CNM's guidelines for confidentiality and research with human participants. Faculty should be familiar with both the College's guidelines for protecting human subjects, are responsible for teaching them to students, and are responsible for making sure all student projects under their jurisdiction conform to the appropriate standards.
IV. Institutional Review Board (IRB) Process:

Institutional Review Board information process is designed to meet three primary goals: protect human subjects, encourage research, and assure compliance with state and federal requirements.

A: Application Submission Timelines: All research activities involving the use of human subjects must be reviewed and approved by the IRB and the Vice president for Academic Affairs before data collection can begin. Investigators may not solicit subject participation or begin data collection until they have received both levels of written approvals and are informed by the IRB. The CNM IRB accepts and reviews proposals at anytime throughout the year. For routine proposals, the IRB often provides proposal evaluations and related decisions to the principal investigator(s) (PIs) within 14 - 28 working days of receipt.

Expedited reviews proposals are usually able to be reviewed via electronic distribution, and without a face-to-face meeting. Full review proposals may require a convened meeting to discuss the proposed research.

All application submissions must include a Certificate of Completion from the National Institutes of Health (NIH) web-based training course “Protecting Human Research Participants”. The course can be found at http://phrp.nihtraining.com/users/login.php. The certificate attached to the submission cannot be more than six months old.

B: External Researchers: Researchers who are not members of the CNM campus community may submit applications for Human Subjects Research Projects. These research projects are subject to the same process and scrutiny as internal research projects. In addition, external researchers must submit a copy of their organization’s IRB process proposal.

C: The IRB may use the expedited review procedure to review either both of the following of (a) or (b).

(a) Some or all the research appearing on the list and found by reviewer(s) to involve no more than minimal risk.
(b) Minor changes in previously approved research during the period (one year or less for which approval is authorized.
(c) The IRB shall adopt a method for keeping all members advised of research approvals which have been approved under the expedited review when the expedited review procedure is used.
(d) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through and expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the
FEDERAL REGISTER. A copy of the list is available from the office for Human Research Protections, HHS, or any successor office.

(e) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution’s or IRB’s use of the expedited review procedure.

Under the expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers, may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

D: Full Review: Full review requires a meeting of the board. A research activity may be disapproved only after review in accordance with non-expedited procedure set for the in 46.108(b) which states that except when an expedited review procedure is used, review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive approval of a majority of those members present at the meeting.

V. Institutional Review Board (IRB) membership:

The IRB is composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline’s work, administrators who generally have responsibilities to the research projects, and institutional researchers, and one member from outside CNM. The human subjects review process is administered through the Planning, Budget, and Institutional Research Office (PBIR). Faculty members are recruited and recommended through Faculty Senate. The Vice President of Academic Affairs assists in recruitment of IRB members who serve a two-year term. IRB records including applications, IRB membership lists, research reports, etc. are maintained in the IRB facilitator’s office for a period of three years.

The Institutional Review Board Membership consists of (as defined by US code 45 CFR 46.107):

(a) The Institutional Review Board shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such
as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one profession.

(c) The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member who primary concerns are on nonscientific areas.

(d) The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) The IRB may not have a member 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.

(f) The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The current membership of the team can be found on the CNM Institutional Review Board website.
VI. FAQs:

Q: How do I know if my study has to be reviewed by the Institutional Review Board (IRB)?
A: Most studies conducted by CNM faculty or administrators will need to be reviewed by the committee if human subjects or participants are involved. This provides a protection for both the participants and for the researcher in case any problems arise. If you are not sure, contact the IRB facilitator.

Q: What is an exempt study?
A: Exempt studies are those which the federal government permits to occur without institutional review. Studies are exempt when they involve (1) research in educational settings on standard teaching practices; (2) research involving educational tests, surveys, interviews, or observations, unless: (a) individual subjects can be identified, and (b) disclosure of responses could be damaging to subjects.

NOTE: Exempt studies still require review, but that review can be expedited.

Q: What materials do I need to submit to the IRB?
A: The IRB needs the IRB Application Form submitted electronically to the IRB facilitator: Accompanying the form should be the answers to the questions; the research protocol; the informed consent form; any interview questions, questionnaires, or tests being used; and the debriefing form, if required. For exempt studies, the application form only needs to be accompanied by a statement showing by which federal guideline the study is exempt and why, along with the research protocol and forms. The certificate of completion from the Web-based training course “Protecting Human Research Participants” should also be included with the application materials.

Q: Are there particular things the IRB looks for?
A: The IRB always looks for assurance that participants’ privacy will be protected, that there will be no possible coercion of subjects, and that participants will be protected from any possible harm during the course of the study. It is particularly important to protect students who are research participants through classes they are taking, i.e. students who are under the control of their professors and may consequently feel threatened. Also, whenever CNM students are participants, the IRB always requires that the consent form include the name, address, and telephone number of the IRB facilitator in case the student has any questions, concerns, or complaints.

Q: Will the IRB approve all studies submitted?
A: No, not necessarily. The IRB has three options. A study may be approved as submitted, it may be approved contingent upon certain changes, or it not be approved. The most common outcome is for the study to be approved contingent upon changes. The IRB works with the researcher to expedite this process. It is important for the researcher to also understand that the decision of the IRB is final. The IRB informs the researcher of the outcome. Any approvals the researcher may need from a department head, VP, or Dean needs to be secured before applying to the IRB for approval.

Q: How long does the approval process take?
A: The IRB recommends that proposals that require full review (i.e., those that are not exempt) be submitted to the IRB facilitator no less than one month prior to the desired implementation of the study. Exempt protocols are reviewed as they are submitted and typically responded to within 14-28 working days of receipt.

Q: Just what does the IRB approval mean?
A: IRB approval means that the study has been reviewed and found to follow the CNM Administrative Procedures. Approval does not mean that the IRB has passed judgment upon the research design except to determine that the design will not harm subjects or waste their time. Following notification of approval, the researcher may begin the study. Full approval does not
mean that anyone in the CNM community or in the desired target group must participate in the study. For example, faculty members who are approached by researchers to allow data collection in class are under no obligation to agree and should not feel that full approval requires or pressures them to participate.
VII. Human Subject Regulations Decision Charts

September 24, 2004

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

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

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at http://www.hhs.gov/ohrp/policy/index.html#topics OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

YES

Activity is research. Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

YES

Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(f)(1), (2)]

YES

Activity is research involving human subjects. Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

YES

Go to Chart 2

NO

Is the information individually identifiable? (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

NO

BUT

NO

BUT

YES

Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]

NO

Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.

NO

Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?

YES

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

NO

Activity is not research, so 45 CFR part 46 does not apply.
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.)

[Footnote 1 to 45 CFR 46.101(b), 45 CFR 46.401(b)]

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** “Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

NO

Will the only** involvement of human subjects be in one or more of the following categories?

Research conducted in established or commonly accepted educational settings, involving normal education practices?

AND/OR

Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

AND/OR

Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?

AND/OR

Research studying, evaluating, or examining public benefit or service programs?

AND/OR

Research involving taste and food quality evaluation or consumer acceptance studies?

NO

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

YES

Go to Chart 3

Exemption 45 CFR 46.101(b)(1) may apply.

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.

Exemption 45 CFR 46.101(b)(4) may apply.

Exemption 45 CFR 46.101(b)(5) may apply.

Go to Chart 7

Exemption 45 CFR 46.101(b)(6) may apply.
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only conducted in *established or commonly accepted* educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

NO → Research is not exempt under 45 CFR 46.101(b)(1). → Go to Chart 8

YES

Does the research study involve only *normal education practices*? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

NO

YES → Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.

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

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

YES

Does the research involve children to whom 45 CFR part 46, subpart D applies?

YES

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

YES

Research is not exempt under 45 CFR 46.101(b)(2).

However, the 45 CFR 46.101(b)(3) exemption might apply.

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

NO

Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

NO

Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

NO

Go to Chart 8

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

From Chart 2

Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *
(“Existing” means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Are these sources publicly available?

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.

NO

Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Go to Chart 8

NO

* 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#issues and #stem, and on coded data or specimens at #coded for further information on these topics.

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

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only the study, evaluation, or examination of:

YES

Public benefit or service programs;

NO

Procedures for obtaining benefits or services under public benefit or service programs;

YES

Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

YES

Research is not exempt under 45 CFR 46.101(b)(5).

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

YES

Go to Chart 8

NO

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

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

From Chart 2

Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

<table>
<thead>
<tr>
<th>YES</th>
<th>Are wholesome foods without additives consumed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.</td>
</tr>
<tr>
<td>NO</td>
<td>Is food consumed that contains a food ingredient, 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?</td>
</tr>
<tr>
<td>NO</td>
<td>Research is not exempt under 45 CFR 46.101(b)(6).</td>
</tr>
<tr>
<td></td>
<td>Go to Chart 8</td>
</tr>
</tbody>
</table>

September 24 2004
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

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

From Chart 2, 3, 4, 5, 6, or 7

Has the research been previously reviewed and approved by the IRB?

YES

Is the review a continuing review? [45 CFR 46.109(d)]

NO

Does the research present no more than minimal risk to human subjects and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(d)(1)]

YES

Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]

NO

Are measures in place to make risks no more than minimal?

YES

Review by convened IRB is required.

NO

Could identification of subjects put them at risk of criminal or civil liability or be socially or economically damaging? [Paragraph (C) of Categories.]

YES

Go to Chart 9

NO

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

From Chart 8
Has the research been previously reviewed and approved by the IRB using expedited procedures?

YES

NO

Have conditions changed to make the research eligible for expedited review under the applicability criteria and categories 1 through 7 on the list of categories that may be reviewed by expedited procedures (e.g., research is within those categories and experience confirms research to be of no greater than minimal risk)?

[45 CFR 46.110(a)]

NO

YES

Research is eligible for IRB review through expedited procedures.

Has conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?

Review by convened IRB is required.

NO

Go to Chart 10

YES

Has any additional risks been identified since IRB review at a convened meeting?

NO

YES

Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk?

NO

(c) Are the remaining research activities at this site limited to data analysis?

 Category 9

Is the research conducted under an IND or IDE?

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*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.
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)].

From Chart 8 or 9:

- Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? [45 CFR 46.116(c)(1)]
  - YES
  - Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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? [45 CFR 46.116(c)(1)]
  - NO
  - Will the research involve greater than minimal risk, as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]
    - NO
    - Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(d)(3)]
      - YES
      - No waiver of informed consent or alteration of consent elements is allowed.***
      - NO
      - Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? [45 CFR 46.116(d)(2)]
        - YES
        - Go to Chart 11
        - NO
        - Will pertinent information be provided to subjects later, if appropriate? [45 CFR 46.116(d)(4)]
          - NO
          - Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.
          - YES

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

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

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

IRB may require investigator to provide subjects with a written statement regarding the research. [45 CFR 46.117(c)]

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

YES

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

AND

Subject’s wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

September 24, 2004