Lansing Community College
Institutional Review Board

I. INSTITUTIONAL AUTHORITY.

This policy establishes and empowers the Institutional Review Board (IRB) at Lansing Community College (LCC). The College’s IRB is responsible for review and approval of all behavioral or biomedical research activities involving human subjects at LCC, for LCC, or with LCC students and/or employees, with the core purpose of protecting the welfare of human subjects involved in such research.

II. PURPOSE.

The National Research Act, Public Law 93-348, mandates that an institutional review board (IRB) must be established and utilized by any college or university that receives federal funding for biomedical or behavioral research. Institutions found to be in noncompliance with regulations can lose federal funding of both its research and student programs. The rights and safety of all human subjects (defined as a living individual about whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information) shall be protected. Therefore, the purpose of the IRB at LCC is to ensure that no research (defined as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge) is done on any human subject which does not appropriately protect their rights and safety.

III. COMPOSITION OF THE IRB

The IRB is required to have at least 5 members with sufficient diversity with respect to gender, race, cultural background, and professional expertise to promote complete and adequate review of research activities commonly conducted at LCC. The IRB must include at least one member whose primary concerns, expertise, and education are in scientific areas; at least one member whose primary concerns, expertise, and education are in nonscientific areas; and at least one community member not currently affiliated with LCC as a student, employee or trustee, or as the parent or spouse of a student, employee or trustee. Membership shall include representatives from faculty, staff and/or administration.

The diversity of IRB membership should enable it to assess the ethical acceptability of a research proposal with respect to its:

- Scientific merit
- Sensitivity to community attitudes
- Safeguarding of research participants’ rights and welfare
• Institutional commitments and obligations
• Applicable law and regulations
• Standards of professional conduct and practice

Members and the Chair are appointed by the Provost for staggered terms of two years, and may be reappointed to successive terms. The Provost may also appoint alternate members to serve as back-up to absent or recused members of the IRB, provided each alternate member should have similar qualifications and characteristics as the member in whose place the alternate might be required to serve.

No person involved in research being reviewed by the IRB may serve on the IRB reviewing that research. An IRB member or alternate member with an interest in any research project subject to IRB review shall promptly disclose the interest and recuse themselves from review of such project. A recused individual shall not be present during discussions about, and shall not vote on, any proposal concerning a research project in which the individual has an interest, but the individual’s alternate may participate in discussion and voting if not also recused. A recused individual may provide answers to questions raised by other members of the IRB, but shall not engage in advocacy.

The IRB may invite individuals with needed expertise to provide input or counsel to the IRB as to any research activities under review.

IV. FUNCTIONAL RELATIONSHIPS OF THE IRB

A. The IRB resides administratively within the Center for Data Science. This structure provides for administrative coordination for the IRB with the various academic and administrative units at LCC.

B. The IRB advises and makes recommendations to the President, to the Provost, to policy and administrative bodies, and to any member of the LCC community on all matters related to the use of human subjects in research.

V. AUTHORITY OF THE IRB

The IRB is responsible for and authorized to engage in the following activities:

A. The IRB reviews all research projects and activities involving human subjects in accordance with the IRB’s established operating procedures, applicable federal regulations, and sponsor policies and guidelines.

B. The IRB provides continuing advice and counsel to personnel engaged in research activities involving human subjects.
C. The IRB has authority to approve, modify or disapprove of human subject research protocols, based upon consideration of any issue it deems relevant to protection of human subjects.

D. The IRB has authority to require progress reports from the investigators and to oversee the conduct of research activities.

E. The IRB has authority to suspend or terminate approval of a research study or activity, or to place restrictions on an activity or study, when this is deemed to be in the best interests of the subjects in that study.

F. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol, especially in cases where the subject is from a vulnerable population (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

G. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of ongoing research.

VI. STANDARDS FOR IRB REVIEW AND APPROVAL

Before any research is done at or through LCC using human subjects, the IRB must carefully examine research proposals to arrive at an independent determination that the research is exempt under applicable federal regulation or will meet the following ethical criteria as more fully defined by applicable federal regulation:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable.
- Informed consent is sought and acquired from each prospective subject or the subject's legally authorized representative.
- Informed consent is appropriately documented.
- When appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of subjects.
• When appropriate, there are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data.

• Additional safeguards are included to insure that members of vulnerable populations are not the subject of coercion or undue influence.

• All applicable federal, state or local laws which provide additional protections for human subjects are followed.

LCC prohibits any research on or about human subjects unless the research and research-related protocols have been reviewed and approved by the IRB at LCC. This is true whether or not the research has been approved by an IRB at another institution. Research being conducted at LCC and one or more other institutions with their own IRB must be approved by the IRB at all involved institutions. Research at LCC on or about human subjects must be conducted in strict compliance with the protocols approved by the IRB at LCC and with applicable federal regulations and LCC policies.

All operations of the IRB at LCC shall be conducted in accordance with applicable federal regulations (e.g., 45 C.F.R. §46.101 et seq.). The IRB shall be responsible for timely filing any written assurances required by federal regulations.

VII. IRB APPLICATION AND REVIEW PROCEDURE

The following procedure is to be followed in connection with all research projects that involve human subjects in any way:

A. The Principal Investigator (PI) must make an initial determination as to whether or not a research project requires IRB review or approval. All doubt must be resolved in favor of submitting an application for IRB review or approval. Note: The course instructor is responsible for making this determination with respect to course activities, such as students questioning, observing, and/or interacting with other individuals.

B. If a research project involves research about human subjects and arguably requires IRB approval or is arguably exempt, an application for IRB review must be submitted at least 30 days, and preferably 60 days, prior to the projected start of research.

C. To submit an IRB application, the PI must complete and file the Application for Approval to Use Human Subjects in Research with the IRB Chair (or other designated IRB member or IRB staff). IRB staff or IRB members will determine if the application is complete. Incomplete applications will be rejected and returned to the PI. Copies of all research proposals and related documents will be retained by the IRB staff.

D. Completed applications will be evaluated by IRB staff or IRB members to determine if they fall within one or more of the specified categories of exempt research per federal regulations, or if they should have either an expedited or full board review.
E. Exemption requests will be reviewed by the designated IRB member and/or IRB staff. Approval of an exemption request must describe the basis for the exemption. Denials will be forwarded to the IRB Chair for consideration under expedited review. The designated IRB member and/or IRB staff will promptly inform the PI of the exemption decision, in writing, with copies provided to all members of the IRB.

F. Expedited requests will be reviewed by the IRB Chair or the designated IRB member and/or IRB staff with sufficient experience. Approvals of expedited requests will be limited to projects where the research activities involve no more than minimal risk to subjects, or where the applicant is seeking minor changes in a current research project that was previously approved for one year or less, or as otherwise approved under federal regulations. Expedited review may result in approval or in modification of research activities to secure approval. Denials of expedited review will be forwarded for review and action by the full IRB. The reviewing individual will promptly inform the PI of the decision about expedited review, in writing, with copies provided to all members of the IRB.

G. The IRB will meet once a month to review applications if any are pending. Meetings shall be conducted in accordance with the Open Meetings Act, and may be attended by members of the public in addition to such individuals who may be invited to attend as resources to the IRB. The IRB may approve, require modifications in, or disapprove research activities, provided any such actions can be taken only by majority vote at a meeting at which a majority of the IRB (including at least one member whose primary concerns are in non-scientific areas) is present. Approval can be granted only if the IRB determines that all research and associated protocols satisfy requirements under applicable federal regulations and under this policy, or if modifications are imposed that satisfy such requirements. Approved applications may be valid for up to one year. Work on a project cannot extend beyond the date approved by the IRB. A renewal application must be filed if the work is to continue beyond the approved date. Federally funded research must be renewed on an annual basis. The IRB will promptly notify the PI of its decision concerning any application. If the IRB disapproves proposed research activities, the notification must include an explanation of the reason(s) for its decision and the PI must be given an opportunity to respond in person or in writing.

H. Work on a project cannot be modified from the approved protocols without advance approval by the IRB except when a change is necessary to eliminate apparent immediate hazards to the safety and well-being of research subjects. Otherwise, if any changes are to be made, a revised application must be submitted to the IRB and approval must be obtained before changes to the approved protocol are implemented.

I. No research can be conducted until the PI has received written confirmation from the IRB that the application is either exempt or approved, or in the case of renewals or modifications, until they are approved.
J. Research can be conducted only in strict compliance with protocols approved by the IRB, except when a change is necessary to eliminate apparent immediate hazards to the safety and well-being of research subjects. Every PI and every LCC employee involved in a research project is obligated to notify the IRB Chair in writing immediately upon learning of any research that is not conducted in compliance with current IRB approvals.

K. Every PI and every LCC employee involved in a research project involving human subjects is obligated to notify the IRB Chair in writing immediately upon learning of any unanticipated problems involving risks to subjects or others, so that the IRB can reassess the project and protocols and modify, suspend or terminate the project as appropriate.

L. The IRB will conduct continuing review of approved research activities at intervals appropriate to the degree of risk, but no less than once per year. The IRB review may involve IRB or third party observation of the research activities, including the consent process.

M. The IRB may suspend or terminate approval of research that is noncompliant with IRB requirements or federal regulations, or that is associated with unexpected serious harm to subjects. The IRB will promptly notify the PI in writing of any suspension or termination of approval and the reason(s) therefor, with copies provided to all members of the IRB and other LCC officials as appropriate.

N. The IRB will promptly notify interested federal departments or agencies in accordance with applicable federal regulations in the event of unanticipated problems involving risks to subjects or others, or serious noncompliance with policies or IRB determinations, or suspension or termination of IRB approvals.

VIII. NONCOMPLIANCE REVIEWS AND PROCEDURES

Information regarding noncompliance in human participant studies may come to the attention of the IRB through several pathways. These include information contained in new applications, continuing reviews, adverse experience reports, or reports from collaborators, employees, participants, or others.

The IRB Chair reviews all allegations of noncompliance. Investigations of allegations of noncompliance brought to the IRB will focus on the protection of study participants. The IRB Chair will oversee an appropriate investigation and make a determination as to whether the alleged practices appear to (1) cause injury or any other unanticipated problems involving risks to participants or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations. Upon finding persuasive evidence of noncompliance, the IRB Chair shall notify the Provost (or designated Institutional Official) and suspend the study procedures pending a timely investigation and review. The IRB Chair will also report any allegations of research misconduct to the Provost (or designated Institutional Official) for further action.
The procedures to be followed in an appropriate investigation into allegations of noncompliance are:

A. When made aware of a potential problem with compliance, an employee, student, research subject or other person involved in the research is required to compile relevant information, including a statement of concerns, and present the information to the IRB Chair.

B. The IRB Chair will promptly review the information presented and determine whether to pursue the matter with the PI via telephone call, e-mail, memorandum, or in person. Care should be taken to maintain confidentiality when leaving messages for the PI via voice mail or with secretarial and support staff.

C. The purpose of such contact is fact-finding, i.e., to determine whether the problem is intentional, unintentional and/or the result of mistake or lack of oversight.

D. The IRB Chair will document the outcome of any and all communications and discussions in writing, either by e-mail or memorandum, with a copy to the IRB files. Such documentation should be factual and objective, and include timelines for resolution (e.g. meeting dates, response deadlines, etc.).

E. When the initial inquiry does not result in prompt resolution of the matter, the IRB Chair will schedule a meeting with the PI to seek resolution as soon as practicable. Any discussions and efforts to achieve resolution will be documented by the IRB Chair in the IRB files, and presented to the IRB by the IRB Chair.

F. If review of relevant documents and meetings as described above do not lead to prompt resolution, the IRB Chair will present the unresolved matters and all related documents for review by the full IRB at the next available meeting. If a quorum of IRB members are present, and after discussion, the IRB shall determine appropriate actions.

G. The IRB has the authority to suspend or terminate IRB approval of protocols that are found to be noncompliant with institutional policies and procedures, state laws, and/or federal laws or regulations. The IRB may also recommend that the Provost (or designated Institutional Official) approve other non-disciplinary sanctions in addressing instances of noncompliance.

H. Non-disciplinary sanctions recommended to the Provost (or designated Institutional Official) by the IRB may include, but are not limited to the recommendation of routine compliance audits and restrictions on serving as an investigator on research involving human subjects. The Provost (or designated Institutional Official) will promptly advise the IRB whether other non-disciplinary sanctions are to be imposed by the IRB.
I. The Provost (or designated Institutional Official) will determine whether or not to seek disciplinary action against any employee or student involved in incidents of non-compliance. If the Provost determines to seek such disciplinary action, the Provost will promptly file a written complaint with College officials responsible for investigation of alleged misconduct and will promptly advise the IRB that such a complaint has been filed.

J. The IRB will promptly issue written notification of non-disciplinary actions taken to the PI, with copies to all IRB members and to the Provost (or designated Institutional Official).

K. College officials responsible for investigation of alleged misconduct will promptly notify the PI that a complaint has been filed, conduct such investigation as may be appropriate under applicable collective bargaining agreements and standards of due process, and impose such disciplinary action as may be appropriate. If disciplinary action is imposed, the responsible administrator will promptly notify the IRB of the action taken.

IX. IRB RECORDS

The IRB will make, and IRB staff will retain, minutes of all IRB meetings. The minutes will, at a minimum, show attendance at the meetings, actions taken by the IRB, how each member voted on issues before the IRB (for, against, abstain), the basis for requiring changes in or disapproving research, and a summary of the discussion and resolution of controverted issues. IRB staff shall also retain copies of all correspondence between PIs and the IRB, the IRB Chair or IRB staff; records of continuing review activities by the IRB; a list of IRB members and their qualifications; the IRB’s procedures in effect from time to time; and statements of significant new findings provided to subjects as required by applicable federal regulations. All such records shall be retained for a minimum of three years after completion of research to which they relate, or such longer period as may be required by Michigan law or LCC record retention policy.
Appendix A
The following information is provided by the Office for Human Subjects Protection (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/#c1).

Chart 1: Is an Activity Research Involving Human Subjects?

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

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

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

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

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

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

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

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

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

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here. Is it research?

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

Activity is research. Does the research involve human subjects?

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

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

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

Activity is research involving human subjects. Is it covered by the regulations?

Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

The research involving human subjects is covered by the regulations.

- 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)]

- 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)]

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

- The research involving human subjects is NOT covered by the regulations.

Go to Chart 2

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
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(i), 45 CFR 46.401(b)]

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?

YES

Exemption 45 CFR 46.101(b)(1) may apply. Go to Chart 3

NO

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

YES

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply. Go to Chart 4

NO

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

YES

Exemption 45 CFR 46.101(b)(4) may apply. Go to Chart 5

NO

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

YES

Exemption 45 CFR 46.101(b)(5) may apply. Go to Chart 6

NO

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

YES

Exemption 45 CFR 46.101(b)(6) may apply. Go to Chart 7

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. Go to Chart 8

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

YES  \rightarrow  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.)

YES  \rightarrow  Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

NO  \rightarrow  Research is not eligible for 45 CFR 46.101(b)(1) exemption.

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

NO  \rightarrow  Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

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

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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

Only research involving only educational tests or observation of public behavior without participation by the investigator in the activities being observed is exempt under 45 CFR 46.101(b)(2).

Research is not eligible for exemption 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 not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

No

Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

Yes

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 eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

Yes

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

No

Research is eligible for exemption under 45 CFR 46.101(b)(2) from 45 CFR part 46 requirements.

Yes

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

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

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

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies.

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

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

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

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:
      - Public benefit or service programs; **YES**
      - Procedures for obtaining benefits or services under public benefit or service programs; **YES**
      - 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**
  - NO
    - Research is not eligible for exemption under 45 CFR 46.101(b)(5).

- NO
  - Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*
  - Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.

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


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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?

- **YES**
  - Are *wholesome foods without additives* consumed?
    - **YES**
      - Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements.
      - Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
    - **NO**
      - 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?
        - **YES**
          - Research is eligible for exemption under 45 CFR 46.101(b)(6).
        - **NO**
          - Research is not eligible for exemption under 45 CFR 46.101(b)(6).

- **NO**
  - Go to Chart 8

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

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

From Chart 2, 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)]
  - **YES**: Does the review involve a *minor change* in approved research during the (one year or less) period of approval? [45 CFR 46.110(b)(2)]
  - **NO**: Review by convened IRB is required.
  - **YES**: Are measures in place to make risks no more than minimal?
    - **YES**: Go to Chart 9
    - **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**: Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. [45 CFR 46.110(d)]
      - **NO**: Go to Chart 10
  - **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(b)(1)]
    - **YES**: Is the research *classified*? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]
      - **YES**: Go to Chart 9
      - **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**: Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. [45 CFR 46.110(d)]
        - **NO**: Go to Chart 10
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?

NO

Yes

 Have 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)?

NO

Review by convened IRB is required.

YES

Go to Chart 10

Research is eligible for IRB review through expedited procedures.

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)]

YES

NO

Category 8

(a) For this site: Is the research permanently closed to enrollment of new subjects? and Have all subjects completed all research-related interventions? and Does the research at this site remain active only for long-term follow-up of subjects?

NO

(b) Have no subjects been enrolled at this site? and Have no additional risks been identified anywhere?

YES

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

NO

Category 9

Is the research conducted under an IND or IDE?

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

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

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)]

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)]

NO

Will waiving or altering the informed consent *adversely affect* the subjects’ *rights and welfare?*

[45 CFR 46.116(d)(2)]

NO

If informed consent is not waived entirely

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

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)]

YES

Is it *practicable* to conduct the research *without* the waiver or alteration?

[45 CFR 46.116(c)(2)]

NO

No waiver of informed consent or alteration of consent elements is allowed.*

YES

Go to Chart 11

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

February 16, 2016
Chart 11: May 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.

NO

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

AND

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

AND

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

END

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