Authorization/Charge

In accordance with its Federalwide Assurance on file with Department of Health and Human Services, Antioch College has an Institutional Review Board for Human Participants (IRB). The IRB is charged with ensuring that those individuals participating in research are not subject to undue or inappropriate risks, that participation remains voluntary, and that the conduct of research is upheld to standards outlined in the Common Rule, state regulations, the Federalwide Assurance, and institutional policies. The primary mission of the IRB is to ensure the protection of rights, privacy and welfare of all human participants in research conducted by Antioch College faculty, professional staff, and students. Concurrent with Antioch’s commitment to the highest regard for the welfare of human participants is the goal of providing quality service to enhance the conduct of research. To achieve this goal, the IRB has the authority to review, approve, modify or disapprove research protocols submitted by faculty, staff and student investigators. The IRB is a standing committee of College faculty and staff. All IRB members receive training regarding ethical treatment of human participants evidenced by certification from the National Institute of Health (NIH).

Purpose of the IRB

The role of the IRB is to ensure that the welfare, rights and privacy of all human participants in research at Antioch College are consistently maintained. Moreover, the IRB aims to foster a research culture of respect, beneficence, and justice, and to respect the dignity and autonomy of individuals as defined in The Belmont Report issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These principles have been set forth in the Department of Health and Human Services, Code of Federal Regulations (Title 45, part 46 of the Code of Federal Regulations, or the “Common Rule”).

Purpose of the Policy Regarding the Protection of Human Participants

The purpose of this policy is to clearly detail the definitions, procedures, and regulations governing any research done at Antioch College which involves human participants. These procedures and regulations are intended to function both as a systematic means to protect the welfare, rights and privacy of human participants, as well as to assure the federal government that these measures are in place. This policy applies to ALL research involving human participants at Antioch College or under the auspice of Antioch College, regardless of the source of funding. This includes research conducted by individuals outside of  

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1 The basic formulation and structure of this policy was derived from several sources, including:
   a) Title 45 Code of Federal Regulations, part 46 (“The Common Rule”)
   c) The Institutional Review Board policies/procedures of:
      a. Cornell University
      b. Kenyon College
      c. Oberlin College
      d. The College of Wooster
the College either using human participants or pre-existing or unpublished data gathered from Antioch College. The intended audience for this policy includes research administrators, principal investigators (faculty, staff, and students), and IRB members. The policy describes the review process as well as the requirements and processes of submitting protocols.

**Human Participant Research Defined**

Human Participant Research is most broadly defined as a process of inquiry, observation or systematic investigation that collects data about individuals who can be individually identified, and that seeks to draw generalizations from the effort. Whether you wish to conduct research resulting in data that individually identifies your participants, or research with confidentiality or anonymity assurances in place, federal law provides participants certain rights and places certain responsibilities on researchers.

The following definitions of human research are derived from the Title 45 Code of Federal Regulations, part 46 ("The Common Rule"):  

- **Research** is a systematic investigation designed to contribute to generalizable knowledge.
- **Human participants** are living individuals about whom an investigator obtains data, either through an intervention, interaction or identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered and manipulation of the participant or the participant’s environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between the investigator and the participant (e.g., use of interviews or collection of survey data).
- **Identifiable 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, as well as information provided by an individual which they can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.
- **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 examinations or test).
- **Informed Consent** is a process facilitated by researchers that ensures participation in a research study is voluntary and based on (1) a disclosure of the information needed to make an informed decision; (2) an understanding of what has been disclosed (accounting for age and language barriers or ensuring the rights of vulnerable populations; and (3) promoting the voluntariness of the decision about whether or not to participate in the research (or to continue participating).

**Who Must Submit Protocols to the IRB**

At Antioch College, all faculty, staff, and student research that conforms to the definitions in the Common Rule must submit protocols for review by the IRB regardless of funding source (federal, state, local, private, or unsponsored) or curricular integration. The Antioch College IRB reviews protocol applications from all disciplines. In accordance with the Federal-Wide Assurance (FWA Number 00021224) issued to Antioch College by the Office for Human Research Protections (OHRP), DHHS, all human participants research funded by the federal government must be performed in accordance with Title 45 Code of Federal Regulations, part 46 (the “Common Rule”). In addition, the actions of Antioch
College officials, researchers, staff, and students must conform to all applicable federal, state, and local laws and regulations.

**Independent Faculty research** involving human participants conducted at research sites must have approval before research begins. Human participant research includes any research that involves identifiable human participants intended to result in generalizable knowledge, including interview-based research. IRB approval from a previous institution does not constitute IRB approval at Antioch College.

**Faculty-Student Collaborative Research**, whether on or off-campus, requires IRB approval. When involving rotating student participants or assistants the Principal Investigator need not reapply every quarter, assuming the research topic, methods, and protocols remain the same as in the approved project. However, Principal Investigators must train incoming student researchers on project protocol and submit the final signed page of the IRB application to the IRB Chair before new participants begin research.

**Student research** involving identifiable human participants intended to result in generalizable knowledge OR any research gleaning information from identifiable human participants that may be shared outside the classroom learning environment **must** be submitted for review at Antioch College. For example, a student oral history project featuring excerpts on a web page, or a student project on diversity presenting aggregate survey data at a research conference or public symposium **must** submit protocols and gain approval prior to engaging in research activities.

Students conducting research while in an **approved Co-op experience** under the auspices of an employer/supervisor’s research project are not required to submit an IRB proposal. (Co-op may require a copy of the supervising researcher’s IRB approval for the student’s co-op file.) Students conducting research during a **self-designed Co-op experience** are required to have IRB approval before the self-design application is approved.

**Please note that class assignments and senior project research involving information gleaned from human participants are typically subject to IRB approval as laid out in the Common Rule.** A thesis paper, a documentary media project with an intended public audience, or a new media project using interviews to explore a theme would all result from projects with IRB approval. Note that journalism—defined as a narrative exploring and documenting a particular current event and its context— is not considered research and is not subject to IRB review. Participant observation in a public place with no personally identifiable participants would not require IRB approval. Most research involving minors (including participant observation) will require IRB approval including the consent of their legal guardians, though certain educational research activities in educational settings can be exempt. Research involving incarcerated participants can never be exempt from IRB review.

Please consult the Office of Human Participant Protection charts at the end of this document to assess the likely status of your research project.

**Expedited Review and Exemptions**

The Antioch IRB committee strives to make the full review process as efficient as possible. **Expedited Review at Antioch College** is available when a project presumes minimal risk to participants. Expedited reviews use the standard IRB application but are reviewed only by the IRB Chair. If the IRB Chair finds the project protocol satisfy the Common Rule, the project will be approved. If the Chair has concerns
that any aspect of the Common Rule is not met, the application will be reviewed by the committee of
the whole in a standard review process. Please allow time for feedback and revisions.

Members of the Antioch community who feel no aspect of the Common Rule applies to their research
project are invited to apply for Exemption using the Request for Exempt Status form.

**Resubmissions to the IRB**

IRB approval is valid for one year. For multi-year studies, the researcher must resubmit an IRB proposal
annually. If significant changes are made to the study anytime during the research process, the research
proposal must be resubmitted to the IRB for a new review.

**Required Training**

Before commencing research, all College researchers must complete the training in human participant
research module provided by the National Institute of Health (NIH). To complete this training, researchers must register with the NIH and proceed through the online tutorial available at

**Duties of the IRB**

The FWA with OHRP/DHHS details the relationship of Antioch College and the Office for Human
Research Protections within the DHHS. This agreement and other DHHS policies empower the IRB with
the authority to review, approve, require modification in, or disapprove all research activities conducted
by Antioch College investigators. Specifically, the IRB will:

a) Determine what activities constitute research that involves the use of human participants
b) Review, approve, require modifications in (to secure approval), or disapprove all research
activities covered by the policy prior to the commencement of such research.
c) Require that voluntary informed consent is obtained from all human participants, and that the
information provided to participants as part of informed consent is in accordance with all
appropriate regulations and standards.
d) Notify investigators and the College in writing of its decision to approve or disapprove the
proposed research activity, or of modifications required to secure IRB approval of the research
activity. IRB approval means that the research has been reviewed and may be conducted within
the constraints set forth by the IRB and other appropriate requirements. If research is
disapproved, the IRB will include a statement of reasons for its decisions and give the
investigator an opportunity to respond in writing or in person.
e) Conduct continuing review of research covered by this policy at intervals appropriate to the
degree of risk, but not less than once per year, and have authority to observe or have a third
duly observe the consent process and the research.
f) Suspend or terminate approval of research that is not being conducted in accordance with the
IRB’s requirements or that has been associated with unanticipated harm to participants. Any
suspension of termination of approval shall include a statement of reasons for its decisions and
shall be reported promptly to the investigator and appropriate institutional officials.

The IRB meets twice monthly to review research submissions, and submissions are due 2 weeks prior to
IRB meeting dates.
IRB Membership and Infrastructure

The Antioch College Institutional Review Board for Human Participants consists of 5 members. As required by Title 45 Code of Federal Regulations, part 46 (“The Common Rule”), these members consist of:

a) Both men and women
b) One faculty member with a decidedly scientific interest
c) One faculty member with a decidedly non-scientific interest
d) One member who is not affiliated with Antioch College nor is a family member of anyone affiliated with Antioch College

By discretion, the IRB may 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. However, these individuals may not vote with the IRB.

Members will be appointed by the President upon recommendation of the Associate Dean of Faculty in consultation with the Vice-President of Academic Affairs. Members will serve terms of one to three years and should provide representations primarily from social, behavioral, and biological sciences.

Human Subject Regulations Decision Charts

The Office of Human Research Participant Decision Charts are incorporated in the following section as a reference and resource for research project planners. Further resources, including info on Informed Consent, can be accessed from the Office for Human Research Protections of the Department of Health and Human Services (http://www.hhs.gov/ohrp/policy/consent/index.html).
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 OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?
Chart 2: Is the Human Subjects Research Eligible for Exemption?
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?
Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
Chart 8: May the IRB Review Be Done by Expedited Procedures?
Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

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

- **NO** Activity is not research, so 45 CFR part 46 does not apply.
- **YES** Activity is research. Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]

  - **NO** The research is not research involving human subjects, and 45 CFR part 46 does not apply.
  - **YES** Does the research involve **intervention or interaction** with the individuals? [45 CFR 46.102(f)(1), (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** 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** Go to Chart 2
        - **YES** 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.

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

      - **NO** Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?
        - **NO** Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
        - **YES** Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

      - **YES** Go to Chart 2
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)]

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

From Chart 1

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?

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?

YES

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

Go to Chart 3

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

Go to Chart 4

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

Go to Chart 5

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

Go to Chart 6

Exemption 45 CFR 46.101(b)(6) may apply.

Go to Chart 7

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.

Go to Chart 8
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  ↓  NO

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  ↓  

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? NO → Research is not exempt under 45 CFR 46.101(b)(2).

NO → Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed? 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 not exempt under 45 CFR 46.101(b)(2) or (b)(3).

NO → Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter? YES → Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.

NO → In 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

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

NO

Go to Chart 8

* 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 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

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

NO

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

YES

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

NO

NO

Go to Chart 8

* 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?

YES

Are *wholesome foods without additives* consumed?

YES

Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

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

NO

Research is not exempt under 45 CFR 46.101(b)(6).

Go to Chart 8

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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(b)(1)]

**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**

Go to Chart 9

**YES**

Is the research *classified?*

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

**YES**

Review by convened IRB is required.

**NO**

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

**YES**

Go to Chart 10

**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**

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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?

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

Category 8

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?

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

NO

YES

Research is eligible for IRB review through expedited procedures.

YES

Review by convened IRB is required.

NO

GO to Chart 10

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

YES

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

NO

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

YES

NO
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**

Is it **practicable** to conduct the research **without** the waiver or alteration? [45 CFR 46.116(c)(2)]

**NO**

Go to Chart 11

**NO**

If informed consent is not waived entirely

Will pertinent information be **provided** to subjects **later**, if appropriate? [45 CFR 46.116(d)(4)]

**YES**

Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

**NO**

*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)]

AND

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)]

NO

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

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

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