IRB Guidebook 2021-2022
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Overview
The IRB Guidebook is an instruction tool for Roosevelt University IRB Committee members to use while serving of the Institutional Review Board (IRB). The Guidebook is based on the policies of the Roosevelt University IRB as applied to faculty, staff and student researchers. As per RU policy, this document is subject to change, as committee, federal, and state policies change.

Federal regulation (Title 45, Code of Federal Regulations, Part 46) requires that all institutions receiving federal funds which conduct research using living humans as subjects establish operate an Institutional Review Board (IRB). The purpose of the IRB is to ensure the protection of these human subjects. IRBs are guided by the ethical principles embodied in The Belmont Report and by additional local standards and expectations. Roosevelt University has a policy (Policies for the Protection of Human Subjects) that establishes our institution’s IRB. This policy provides both background and direction for the mission of the Roosevelt University IRB. This document, the IRB Guidebook of Procedures for the Protection of Human Research Subjects, describes how the Institutional Review Board at Roosevelt University will accomplish its mission.

Committee membership
IRB committee members include both expertise and representation in both scientific and non-scientific fields of study and/or knowledge. The minimum requirement for IRB Members is a total of five members. The Committee is currently made up of one unaffiliated community member, one student member and seven Roosevelt faculty members. The current IRB requires at least four faculty members and one unaffiliated community member present to make quorum and proceed with the meeting. The IRB consists of two IRB members who serve as alternate members, in the event a voting member cannot attend a meeting in person or via zoom.

Requirements for IRB Membership
- Valid and current certification of research ethics training (CITI training)
- Current full time? faculty member of Roosevelt faculty, recommended to serve on IRB by college dean and/or department chair and approved by Associate Provost of Research and Faculty Success.
- Availability to meet with IRB members monthly throughout the year either in person or via zoom.
- Willingness to serve on the IRB for a 3-year appointment.

Instructions for onboarding
Any faculty member interested to serve on the IRB in order to fulfill their service requirement must first contact their department chair or dean. When there are open positions on the IRB a call is sent to all deans and department chairs. Deans and/or department chairs will make a call
for interest by a method that works best for their college/department/unit. At this time, deans and department chairs will provide the name(s) of faculty members to IRB administrators whom they feel are best suited to serve on the IRB. A statement of interest to the dean or department chair or dean does not assure committee membership.

The IRB Chair and Associate Provost for Research and Faculty Success, in consultation with the IRB Administrator have final approval regarding new and continuing board members. There are considerations that must be made on behalf of researchers that the IRB Chair, AP for Faculty Research and Success and the IRB Administrator are privy to, namely board composition with regard to department representation, gender and ethnic diversity, and areas of expertise. If at all possible, the IRB Chair and administrator work to make sure that the board reflects the diversity of the student and faculty body, to the largest extent possible.

Once a request to join the IRB has been approved, the new member will receive a letter of confirmation from the AP for Faculty Research and Success, stating the term for service (3 years), the expectations of each member, and a schedule for meetings for the fiscal year. If the new member is not yet familiar with the online IRB submission system, a meeting with the IRB Administrator will be arranged to assist the new IRB member with navigating IRB Manager online submission platform. Part of the training will include how to access IRB applications, review them using the IRB checklist, and provide feedback as a primary or secondary reviewer.

New appointees will be assigned CITI training for IRB members and shall complete this training within one (two?) months of their appointment.

Instructions Expectations for participation in IRB meetings

Meetings are scheduled to be held in the same room for the entire year, beginning in fall (first meeting in September) and ending in the following summer (last meeting in August). The IRB Administrator, IRB Chair or Vice Chair will call the meeting to order once there is a quorum with a community member present. A meeting cannot commence unless a community member is actually present in person or via teleconference. The graduate assistant (when present) will take minutes that will be made available for viewing in IRB Manager immediately following the meeting. The notes will reflect all of the discussion related to each reviewed application, new business, and any other announcements or training conducted as part of the meeting. Voting on each reviewed application will be captured via IRB Manager and can be reviewed in the meeting tab by IRB members.

The convened IRB Committee only reviews studies requiring approval by the full board. Studies requiring approval by the full board include the following:

- Studies involving vulnerable populations (children, parolees, prisoners, and individuals with limited capacity to make determination to participation in a research study due to mental, physical or environmental conditions)
- Clinical trials
- Studies brought to the full board on the discretion of the IRB Administrator or IRB Chair due to problems with protocols that are of grave concern. Only a convened IRB has the authority to grant disapproval of a study.
IRB members may be notified to review expedited level studies outside of convened committee meetings at the discretion of the IRB Administrator and IRB Chair. The IRB Chair may assign an expedited review to an IRB committee member. Such reviews are not dependent on monthly review cycles and can be reviewed within 1-2 weeks of the application submission.

IRB Review Checklist - Each member will have access to their IRB Review Checklist for each application and can use the checklist as reference during the meetings. The checklist sets a baseline standard for all IRB application to be reviewed equitably. Items that do not meet the standard set by the IRB Review Checklist may receive at least conditional approval or no approval, depending on the severity of the concern. The IRB can pose questions to the study PI that will be communicated by the graduate assistant to the study PI in the official correspondence regarding the committee decision. The convened IRB may also decide to invite the study PI to the next IRB meeting, if the IRB deems it appropriate to do so.

There are three options for approval for each study that the committee must vote and approve to be most adequate:

- Approval – the study may commence as submitted
- Conditional approval – the study may receive approval if the study PI is responsive to concerns of the IRB
- No approval – the study will not be approved as submitted

Conditional approval may require the study PI to submit changes to the full board at the next meeting or submit changes to the IRB Administrator and receive approval upon submission of those changes. Studies that receive conditional approval typically have minor changes required as determined by IRB members that can be reviewed upon submittal by the IRB Administrator without full board review. Studies that involve protected populations are not appropriate for conditional approvals. The IRB Committee determines which conditional approval is most appropriate, depending on the severity of the presenting concern. At the vote on the application, these conditions are discussed, included in the vote and are also reflected in the meeting minutes. When the decision is communicated to the principal investigator, these conditions are included in the letter sent.

There are two outcomes for studies that are not approved by the IRB. A study may be fully rejected by the committee which will require resubmittal of a new application or appeal by the principal investigator. Studies that are not fully rejected but require changes with full board approval do not need to be submitted as a new application, however the PI must make changes and submit updated application/documents by the submission deadline of the next scheduled IRB meeting to be reviewed again by the full IRB.

One IRB member will be assigned as the primary reviewer for each application. During the meeting the assigned reviewer will present the application along with their checklist and any comments and concerns regarding the application. Once the application has been presented by the primary reviewer, comments will be opened up to the entire committee.

Post meeting processing – Each member must fill out and submit their IRB Review Checklist via IRB Manager to document their responses to each study either before the scheduled meeting
or within 48 hours of the concluded meeting. Any pending issues with regard to studies will be communicated to the IRB as part of post-meeting processing.

Faculty advisors and Study PI who are members of the IRB and present during meetings. Faculty advisors who are directly responsible for supporting a student as advisor or dissertation chair must recuse her/themselves/himself from voting on a study. Additional information that may inform study details may be shared. If the person serves on a dissertation committee and is not the faculty advisor or the dissertation chair, the committee member may participate in voting. If the committee member is a study PI or co-investigator for a study under review, they cannot vote on the study under review.

Navigating IRB Manager

Each IRB committee member has a designation as a member of the IRB within IRB Manager. This affords each member privileges to review past board meetings, receive and review IRB applications, and submit notation on each IRB application, which can be used during review of applications during convened committee meetings. IRB Manager can be accessed at this [link](#) using your Roosevelt username and password – no use of personal emails are allowed.

Quality assurance monitoring and reporting

At the end of each academic year the IRB Office will administer a survey to the IRB Committee and a separate survey to faculty, student and staff researchers. The survey for the IRB Committee will determine the extent to which the current practices established for the IRB (meeting structure and process, IRB Manager navigation, professional development opportunities, committee composition, regulatory compliance) are all carried out to the overall satisfaction of the IRB. The survey will be used to target and make changes to areas of improvement, as appropriate.

The survey of the research community to learn about the issues and questions of most concern to them, to learn what information is most useful to them, how they find the online submission system to be user-friendly, accessible, and to solicit feedback regarding their submission experience. The survey will also help the IRB Committee and IRB Office to understand how IRB Manager end users perceive their concerns are being addressed.

IRB Office support

IRB Committee members and the research community of Roosevelt can receive support for IRB Manager navigation and all other research-related inquiries by contacting the IRB Office at [research@roosevelt.edu](mailto:research@roosevelt.edu) or (312) 341-2449. The office has one dedicated graduate assistant that may be allocated in a supportive role. The graduate assistant is available to provide support to the IRB for 9 hours per week. The office hours are Tuesdays 11 – 2pm at the IRB Office, or via zoom.

Instructions for resignation from the IRB

Each committee member who receives a letter of confirmation of their service to the IRB must also tender their resignation on letterhead to be delivered via email to the attention of the IRB Chair and Senior Vice Provost for Academic Affairs. For RU faculty, the resignation must include an effective date and documentation of notification (cc on the letter) to their respective
department chair and dean. We kindly request that enough notice is given in order to maintain the required minimum number of committee members and to establish a quorum at the next full board meeting.

Decision Charts for IRB Committee

The following pages contain decision charts that can be used at your discretion while reviewing IRB applications.
Human Subject Regulations Decision Charts

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. The IRB Chair and IRB Office, and if necessary, in consultation with the OHRP, may advise on a particular case.

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: Does your study require Limited IRB Review?
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)?
Does your study require Limited IRB Review?

**What is limited IRB review?**
Limited IRB review is increased oversight by the IRB for low-risk research to ensure that either:
- The identifiable private information or biospecimens collected have the appropriate data security and privacy protections in place to reduce the chance of inappropriate disclosure; or
- Broad consent was obtained for the use of stored identifiable data or biospecimens.

*Explanation of the requirements for limited review can be found in the guidance on limited IRB on Inside Roosevelt.*

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Is the information being recorded in an identifiable manner AND would disclosure of responses place participants at risk of criminal or civil liability OR be damaging to financial standing, employability, educational advancement, or reputation (Category 2 or 3)?

Does your study qualify as exempt under category 2, 3, 7 or 8?*

Your study does not qualify for limited review.

Are there plans to store, maintain or use identifiable private information or identifiable biospecimens collected for non-research purposes and the information/specimens are obtained with a broad consent process (Category 7 or 8)?

Your study does not qualify for limited review.

Are there plans to return individual research results to participants as part of the study?

Your study does qualify for limited review.

Has there been any changes to your study since the initial submission that might warrant limited IRB review, such as changes to location for storage or protection of data?

Your study does not qualify for limited review. If there is a legal requirement to return research results, this must be specified.
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here. Is it research?

NO → Activity is not research, so 45 CFR part 46 does not apply.

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

NO → Activity is research. Does the research involve human subjects?

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

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

NO → Does the institution hold an FWA under which it applies 45 CFR 46 to all of its human subjects research regardless of the source of support?

YES → The research involving human subjects is covered by the regulations.

NO → The research involving human subjects is NOT covered by the regulations.

YES → Go to Chart 2

NO → 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)?

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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(l), 45 CFR 46.401(b)]

** "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?

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

- If not exempt under (b)(1) → 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

- If not exempt under (b)(2) or (b)(3) → 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

- If not exempt under (b)(4) → Research studying, evaluating, or examining public benefit or service programs?

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

- If not exempt under (b)(5) → 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

- If not exempt under (b)(6) → 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

YES
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

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 eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

NO

NO

Research is not eligible for 45 CFR 46.101(b)(1) exemption.

Next

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

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

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

- NO
  - Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).
  - Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

- YES
  - Does the research involve children to whom 45 CFR part 46, subpart D applies?
    - NO
      - 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 eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.
        - NO
          - 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).

    - YES
      - Research is not eligible for exemption under 45 CFR 46.101(b)(2).

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

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

NO

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

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

NO

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

YES

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

NO

Possible changes in methods or levels of payment for benefits or services under those 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?

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

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?

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(6).

YES

Go to Chart 8

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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)]

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.]

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

NO → 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)]

YES → Review by convened IRB is required.

NO → Go to Chart 9

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

From Chart 8

Has the research been \textit{previously reviewed} and approved by the IRB using \textit{expedited} procedures?

\textbf{NO}

Have conditions \textit{changed} to make the research \textit{eligible} for expedited review under the \textit{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)]

\textbf{NO}

\textbf{YES}

Research is eligible for IRB review through expedited procedures.

\textbf{NO}

\textbf{YES}

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

\textbf{NO}

\textbf{YES}

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

\textbf{NO}

\textbf{YES}

\textit{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)]

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

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

If informed consent is not waived entirely

NO

* 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.

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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.

AND

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

END

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NO

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

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)]

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