

JUSTICE RESEARCH AND STATISTICS ASSOCIATION
Establishing an Institutional Review Board (IRB): Procedures and Resources

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A. IRB Overview

1. All Federally-funded research must comply with regulations designed to protect human subjects and ensure confidentiality of data. These regulations are set forth in Title 45, Part 46 (“Protection of Human Subjects”) of the Code of Federal Regulations (abbreviated as [45 CFR 46](#)). The regulations are promulgated by the Department of Health and Human Services (DHHS), and overseen by DHHS’s Office for Human Research Protections ([OHRP](#)).
2. 45 CFR 46 spells out: (1) definitions of “research” and “human subjects;” policy exemptions; requirements for Institutional Review Boards (IRBs); and requirements for informed consent (this is all contained in Subpart A). The regulations in Subpart A are also known as “The Common Rule” because they have been adopted by a number of Federal agencies; the Department of Justice’s version is found in [28 CFR 46](#). The DHHS regulation also provides additional protections for three special groups involved in research: (1) pregnant women, human fetuses and neonates (Subpart B); (2) biomedical and behavior research involving prisoners (Subpart C); and (3) children (Subpart D). Also relevant are the Justice Department’s requirements for confidentiality of identifiable research and statistical information, contained in [28 CFR 22](#).

B. What Does the IRB Review?

1. Any research involving human subjects must be reviewed by an IRB. The exemptions are research in educational settings, research involving educational tests, surveys or interviews with elected or appointed public officials, provided the information is kept confidential; research involving the collection or study of existing data or records if the data are publicly available or if the information does not include subject identifiers. Clarification on these and a number of other items can be found in the [Policy and Guidance](#) section of the OHRP Web site.
2. The IRB may establish an expedited review procedure that allows for review of certain projects by the IRB Chair or designated IRB member. Expedited review is available for research that involves no more than minimal risk or for minor changes in previously-approved research. A [list](#) of the types of projects eligible for expedited review is available from OHRP.

3. The IRB applies the following criteria when reviewing projects: risks to subjects are minimized and are reasonable in relation to anticipated benefits; selection of subjects is equitable; informed consent is obtained from each subject and appropriately documented; there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.
4. The IRB may approve, require modifications in, or disapprove research projects reviewed. A majority of voting members determines project approval.

C. IRB Membership

1. The IRB must consist of at least 5 members with varying backgrounds to allow for adequate review of research activities normally conducted by the SAC. Members should be diverse with regard to gender, race and cultural background.
2. The IRB cannot have members of a single profession. There must be at least one member of the IRB whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
3. The IRB can invite individuals with competence in particular areas to assist in the review of specific projects or issues. These individuals do not vote with the IRB.

D. IRB Administration

There should be an IRB administrator. That person should be responsible for maintaining adequate documentation of IRB activities, including: copies of research proposals reviewed; minutes of IRB meetings that show actions of IRB and record votes of members; a list of IRB members, including name, earned degrees, representative capacity (e.g., nonscientific member), indications of experience, and relationship between the member and the SAC, if any.

E. Steps in Establishing an IRB

1. For an IRB to be authorized to review research, it must have a written document, called an assurance, which states that the institution will abide by the requirements of the Common Rule and describes the institution's IRB, including its composition and procedures (see 28 CFR Part 46, especially sections 46.103, 46.107, and 46.108.). This assurance is really the codification of procedures that will be followed by the IRB. JRSA's assurance statement is attached. Note that the institution provides the assurance; the institution may be the SAC's parent agency. Also note that the official application for Assurance from OHRP is different from this assurance. You are not required to submit your written procedures to OHRP; rather, you submit a form attesting to your agency's willingness to comply with the requirements of 45 CFR 46 (see below).

2. Identify IRB members. Gather and keep on file resumes and provide official appointment letters from the head of the institution. Most grants now allow for funds to pay IRB members for their time.
3. Obtain approval for your assurance from OHRP. This is a two-step process. First, you [register the IRB](#) with OHRP (this can be done online).
4. When your IRB is registered it will be assigned a number by OHRP. Once you have this number, you can proceed to Step 2, which is to complete the Federalwide [Assurance Application](#). Once you receive approval of your assurance, your IRB is registered with OHRP and can begin to review research projects.

F. Resources for IRB Members

There are no specific requirements for providing information or training to IRB members. OHRP has an [online tutorial](#) that it recommends for IRB administrators and chairs. Below are some resources that might be of use to members.

1. General Web Resources

The [Office for Human Research Protections \(OHRP\) Web site](#) provides a wealth of information related to human subjects protections, including copies of regulations, decision charts for components of the Common Rule, policy guidance by topic area, frequently asked questions, and training materials.

A set of [Frequently Asked Questions](#) and vignettes regarding human subjects issues may be found on the Web site of the National Science Foundation.

The National Institutes of Health (NIH)'s Web site has a section on [Bioethics Resources on the Web](#).

2. Conferences and Online Training

A list of [OHRP-sponsored conferences](#) on human subjects issues may be found on their Web site. They also have online [Webinars](#) on a number of topics.

The [National Cancer Institute](#) has a tutorial on their Web site on protecting human research participants. So does the [Health Resources and Services Administration](#).

The [University of Minnesota's Web site](#) has a tutorial on the informed consent process.

**JUSTICE RESEARCH AND STATISTICS ASSOCIATION
INSTITUTIONAL REVIEW BOARD PROCEDURES**

ASSURANCE

The Justice Research and Statistics Association (JRSA) complies with all federal regulations related to the protection of human subjects. JRSA and the JRSA Institutional Review Board (IRB) will comply with all provisions of Title 45, Part 46, Subparts A – D of the Code of Federal Regulations (45 CFR 46), “Protection of Human Subjects.” Since most of JRSA’s federally-funded projects fall under the auspices of the Department of Justice, JRSA will comply with that department’s codification of Subpart A of these protections in 28 CFR 46 (also known as the Common Rule). JRSA and the IRB will also comply with 28 CFR Part 22, “Confidentiality of Identifiable Research and Statistical Information.”

MEETINGS

- A. Institutional Review Board (IRB) meetings will be convened by the IRB Chair, at the request of the IRB Administrator, to review and make decisions about proposed or continuing research and statistical activities relating to or conducted by the Justice Research and Statistics Association (JRSA). It may also be convened for other purposes, such as policy and procedural issues, or educational activities for IRB members or researchers. In addition, pursuant to a request by an IRB member and/or JRSA officials, IRB meetings may be convened by the IRB Chair, or by a majority of IRB members, to consider or review any matter relating to the protection of human subjects of JRSA-performed research and statistical activities.
- B. The IRB will review all proposed research and statistical activities at convened meetings at which a majority of members of the IRB are present, including at least one nonscientist member. A majority of members are needed for any official action. If any alternate member is officially replacing a nonscientist member for that meeting, he or she shall be counted as a member for purposes of a quorum and official actions.
- C. The IRB Chair will give permission to individuals who wish to observe IRB meetings. Visitors and nonvoting members may be present during official actions, at the discretion of the IRB Chair. When meetings are held via telephone, provisions will be made to allow visitors and nonvoting members to listen to the IRB meeting.
- D. Members must notify the IRB Chair of any conflict of interest with any project to be considered by the IRB at least a day before the IRB is scheduled to review it. Members will recuse themselves if they are directly involved in a project, supervise the project, or have any other conflict of interest, including a financial or other personal interest. The Chair will acknowledge the existence of a conflict of interest and will be noted in the minutes.

INITIAL FULL REVIEW OF RESEARCH AND STATISTICAL ACTIVITIES

- A. The IRB's initial full review of research or statistical activities will follow the criteria listed below for approval of activities, all of which must be satisfied for IRB approval of a research or statistical analysis (28 CFR section 46.111):
 - 1. Risks to subjects are minimized;
 - 2. Risks to subjects are reasonable in relation to anticipated benefits;
 - 3. Selection of subjects is equitable;
 - 4. Informed consent will be sought from each prospective human subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR section 46.117;
 - 5. Informed consent will be appropriately documented, in accordance with and to the extent required by 28 CFR section 46.116;
 - 6. When appropriate, the research or statistical protocol makes adequate provision for monitoring the data collected to ensure the safety of the human subjects, to protect the privacy of human research subjects, and to maintain the confidentiality of information identifiable to a private person that is collected in accordance with 28 CFR Part 22;

7. Additional safeguards may be provided to protect the rights and welfare of human subjects who are likely to be vulnerable to coercion and/or undue influence.
- B. The IRB will review research and statistical activities to determine whether the activities provide adequate protections for all human subjects involved in the activities.
- C. For a research or statistical activity to be approved, the activity must receive the approval of a majority of those IRB members present at the review (28 CFR section 46.108).
- D. The IRB may:
1. Approve the activities;
 2. Approve the activities with modifications;
 3. Disapprove the activities; or
 4. Defer its decisions with respect to any research or statistical activities it reviews.
- E. In addition to its approval authority, the IRB may make other decisions, including:
1. Requiring the provision of additional information (beyond the requirements of 28 CFR section 46.116) to research subjects when, in the judgment of the IRB, the information would likely add to the protection of the rights and welfare of the human subjects. When a child or minor is the prospective human subject, "informed consent" may take the form of child assent to participate in combination with parental or guardian permission for the child to participate in the research activities. The IRB will determine whether the procedure is appropriate for seeking informed consent from a child or minor for purposes of the particular research activities being reviewed. When persons with impaired decision making capabilities, including persons with physical, mental, emotional disabilities, are the prospective human subjects, the IRB will take into consideration such persons' impaired decision making capabilities, including whether the researcher contemplates seeking consent from legally authorized representatives on behalf of such persons as appropriate in individual cases, in order to determine whether the "informed consent" procedures proposed for the research or statistical activities may be approved.
 2. Altering or waiving the requirement for informed consent and/or the requirement for documentation of informed consent in accordance with 28 CFR section 46.116 and 28 CFR section 46.109 and section 46.117, respectively.
 3. Requiring monitoring of the consent process of the research or statistical activity by IRB members consistent with requirements of 28 CFR 22.
 4. Using sources other than the researchers to verify that, since previous IRB review, no material changes have occurred in the research or statistical activity that may necessitate additional safeguards to minimize the degree of risk to human subjects or that may necessitate reconsideration of the vulnerability of the human subjects to risk or harm (28 CFR section 46.103).
 5. Requiring prompt reporting to the IRB of proposed changes in already approved research or statistical activities, and requiring that no changes in the approved activities may be initiated without IRB review and approval except when necessary to alleviate apparent immediate risks or harms to the human subjects (28 CFR 46.103).
 6. Requiring prompt reporting to the IRB, of unanticipated problems involving risks to human subjects or others or any serious or continuing noncompliance with 28 CFR 46, Part A (the Common Rule), 28 CFR Part 22, or the requirements or determinations of the IRB (28 CFR 46.103).
 7. Suspending or terminating a previously approved activity if the research or statistical activity is not being conducted in accord with the IRB ' s requirements or the research or statistical activity has been associated with unexpected serious harm or risk to the human subjects (28 CFR section 46.113).
- F. When the IRB approves a research or statistical activity, it will also decide when the next review of the activity will occur, which must take place no later than a year from the date of the IRB's current approval decision. These same procedures (Initial Reviews) must be followed if researchers decide to involve human subjects in an

ongoing research or statistical activity that has not previously involved human subjects, or if the researchers propose to significantly revise the involvement of human subjects from that which was initially approved by the IRB.

EXEMPT RESEARCH/STATISTICAL ACTIVITIES

- A. The IRB must review the preliminary determination of exempt status made by the researchers proposing the project, and will be responsible for making the final determination of exemption from coverage of Common Rule policies set forth in 28 CFR Part 46.
- B. If the IRB determines that the proposed research or statistical activity is exempt, the IRB will notify the JRSA IRB Administrator in writing, and ensure that the finding of exemption is placed in the minutes of the next IRB meeting.
- C. If the IRB determines that the proposed research or statistical activity is not exempt from IRB review and approval, the IRB shall notify the Principal Investigator of that decision and will schedule review of the proposal for the next official meeting of the IRB, and notify the Principal Investigator and the JRSA IRB Administrator of the IRB's determination.

EXPEDITED REVIEW PROCEDURES FOR RESEARCH/STATISTICAL ANALYSIS INVOLVING NO MORE THAN MINIMAL RISK, AND FOR MINOR CHANGES IN APPROVED RESEARCH

- A. No new project subject to the review of the JRSA IRB will be eligible for expedited review.
- B. Minor changes in previously approved research activities that occur within the period for which approval is authorized will be eligible for expedited review. The IRB Chair or his/her designee may approve such changes.
- C. The IRB Chair or his/her designee may approve continuing reviews of qualified activities.

COOPERATIVE RESEARCH OR STATISTICAL PROJECTS

- A. When JRSA is engaging in a cooperative research/statistical project with another institution, i.e., any project which is covered by the Common Rule and involves more than one institution (as defined in Section 4(c), (i) of the OJP Instruction on the Protection of Human Subjects of Research and Statistical Activities), each institution is responsible for safeguarding the rights and welfare of human subjects involved in the project, and, at a minimum, the IRB will review all activities involving human subjects proposed to be performed or conducted by JRSA employees or other staff, to include contractual staff, except as specified in paragraph B below.
- B. With the concurrence of the JRSA Executive Director, the IRB Chair may choose to enter into a joint review arrangement with the IRB of the other institution, assuming the other institution's IRB is subject to, and adheres to, Common Rule policies and procedures, whereby either institution's IRB may review the entire project on behalf of both institutions.
- C. When JRSA has entered into a joint review arrangement with another institution's IRB for the review of a cooperative research/statistical project, the outside institution's IRB must agree to inform the JRSA IRB Chair, the JRSA IRB Administrator, and the Principal Investigator of its decisions, the rationale for the decisions, and any adverse reporting for any part of the cooperative project it has reviewed. These communications will be by written notification that is signed by the institution's IRB Chair.

SUSPENSION OR TERMINATION OF IRB APPROVAL

- A. The IRB may suspend or terminate approval of any research or statistical activity that is not being conducted in accord with its requirements or that has been associated with unexpected serious harm or risk to human subjects.

- B. The IRB's decision to suspend or terminate a research or statistical activity must receive the approval of a majority of those IRB members present at a convened meeting of the IRB.
- C. The IRB Chair may temporarily suspend research or statistical activities pending the next meeting of the IRB, which must be convened as expeditiously as possible.

CONTINUING REVIEW

- A. The IRB's continuing review of a research and statistical activity will take place at intervals appropriate to the degree of risk, the vulnerability of the human subjects, and the particular design of the activities, but no less than once a year from the date the research or statistical activity was previously approved by the IRB. **All** project activity previously approved by the IRB must cease on that date unless the research or statistical activity has undergone IRB continuing review and received IRB approval. It is the responsibility of the principal investigator, not the responsibility of the IRB, to comply with this requirement. Principal investigators are solely responsible for making timely application for continuing review to avoid project termination.
- B. The IRB may be convened into an interim review session by the IRB Chair at the request of any IRB member, the IRB Administrator or the JRSA Executive Director to consider any matter concerning the rights or welfare of any human subject.
- C. The IRB will use the same criteria to make decisions about continuing reviews as it does for initial reviews.
- D. The IRB will make its continuing review decisions using the materials submitted for the initial review, the records of the IRB's initial review, and any new information, that is relevant to the activity and the IRB's criteria for approval. For example, these materials may include any amendments to the research design, periodic updates and progress reports from the researcher, number of human subjects involved, any adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, complaints about the research, summary of recent literature or findings, especially about risks associated with the research, a copy of the current informed consent document, and any other relevant information.
- E. Within the period of IRB approval of a research activity, the IRB will review and approve proposed changes that are not minor before the changes can be implemented.

IRB NOTIFICATIONS

- A. The IRB will notify, in writing, both the Principal Investigator and the JRSA IRB Administrator of its decisions regarding a research or statistical activity it reviews.
- C. The IRB will attach to its notifications a copy of the record of the IRB's review of the activities, including:
 - 1. If the activities are approved, a copy of the certification of the IRB's approval will be attached to the notification, and the IRB will indicate the date by which the next continuing review must take place.
 - 2. If the activity is approved subject to modifications, the IRB will explain the required modifications and the basis for them.
 - 3. If the activity is disapproved, the IRB will explain the reasons for its decision, and will provide the researchers an opportunity to respond in person or in writing.
- C. When an activity is approved, the IRB will provide written notification to the Principal Investigator and the JRSA IRB Administrator directing them to report the following to the IRB:
 - 1. Any proposed changes in the approved activity that may affect the rights and welfare of any human subject;

2. Any unanticipated problems involving risks to human subjects and others, or any serious or continuing noncompliance with 28 CFR Part 22, 28 CFR Part 46 (the Common Rule), or the IRB's requirements (28 CFR section 46.103).
- D. When an activity is approved, the IRB will provide written notification to the Principal Investigator and the JRSA IRB Administrator to inform them that no changes may be made in an approved activity that may affect the rights and welfare of human subjects except when necessary to alleviate apparent immediate harms or risks to the human subjects [28 CFR section 46.103(b)(4)].
 - E. The IRB will promptly notify the Principal Investigator and the JRSA IRB Administrator of any unanticipated problems involving risks to human subjects or others, or any serious or continuing noncompliance with 28 CFR Part 22, 28 CFR Part 46 (the Common Rule), or the IRB's determinations of which it becomes aware (28 CFR section 46.103).
 - F. If the research or statistical activity is suspended or terminated by the IRB, the IRB will state the reasons for its decision and will report its decision in writing to the Principal Investigator and the JRSA IRB Administrator.

IRB RECORD PROCEDURES

- A. The JRSA IRB Administrator will, on behalf of the IRB, maintain records of IRB meetings in accord with the Common Rule's regulatory requirements for record keeping.
- B. The IRB shall keep copies of the following:
 1. All research and statistical proposals reviewed; accompanying scientific evaluations, if any; approved sample consent documents; progress reports submitted by researchers; and reports of injuries to human subjects.
 2. Detailed minutes of IRB meetings to show attendance at the meetings; actions taken by the IRB; the vote on each IRB action including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving a research or statistical activity; and a written summary of the discussion of issues and procedures of concern to the IRB, and their resolution.
 3. Records of continuing review activities.
 4. Copies of all correspondence between the IRB and the researchers/Human Subjects Protection Officers/Bureau and Program Offices.
 5. A list of IRB members with relevant background information in accordance with 28 CFR section 46.103(b)(3).
 6. Statements of significant new findings provided to human subjects in accordance with 28 CFR section 46.116(b)(5).
- C. Required records shall be retained by the IRB for at least three (3) years, and records relating to research and statistical activities that are conducted shall be retained for at least three (3) years after completion of the research or statistical activity.
- D. The required records to be kept by the IRB shall be located physically in the offices of JRSA, and shall be accessible for inspection and reproduction at reasonable times and in a reasonable manner upon written request to the IRB Chair.

REVIEW AND COMPLIANCE WITH IRB ACTIONS

Researchers must comply with all IRB actions, decisions, conditions, and requirements for all research and statistical activities subject to the authority of the IRB and not otherwise waived under 28 CFR section 46.101(i).