JOHNSON & WALES UNIVERSITY

IRB Process Overview[1]

This document provides an overview of operational procedures of JWU's IRB and is intended to provide guidance for navigating the institutional review of research process at JWU. Questions about this process should be emailed to the IRB Chair at institutionalreviewboard@jwu.edu.

A. Submission and Preliminary Review of Research Proposal Applications (RPA):

1. Prior to completing an IRB application, a Principal Investigator (PI) must:
   a. Access resources available through JWU's IRB web page.
   b. Review Frequently Asked Questions (FAQs) on JWU's IRB web page.
   c. Create an account and complete the basic training modules through Collaborative Institutional Training Initiative (CITI).[1] The guide to creating a CITI account is available here. Create an account and complete the basic training modules through Collaborative Institutional Training Initiative (CITI).[2] (Note that an equivalent human subjects training certification can be used if approval is granted by the IRB chair prior to RPA submission.)

2. The PI must then complete the RPA and submit it through JWU's IRB web page. The following documents must be submitted as attachments to the RPA:
   a. Any funding application related to the research;
   b. Proposed instruments for data collection, if any;
   c. Proposed confidentiality statement, if any;
   d. Proposed recruitment materials, if any;
   e. Proposed consent forms or an application for waiver of consent requirements;
   f. CITI Training Certification; and
   g. Short biography of all investigators.

3. A staff member in the Office of the University Provost (the Provost's Office) will conduct a preliminary review of each application to ensure it is complete. Incomplete applications will be returned to PIs for revision. Applications determined to be complete will be assigned an official record number, entered into the IRB application log maintained by the Provost's Office, and forwarded to the IRB chair.

4. An RPA must be received a minimum of 15 working days in advance of a scheduled IRB meeting to be considered for placement on the agenda. (See the schedule at JWU's IRB web page.)

B. Initial Review of Applications and Category Assignment by IRB Chair:

1. The IRB chair (or in some cases the IRB chair's designee) will review the completed application and provide any feedback before assigning the application to one of the categories listed below and will then notify the PI of that determination. The IRB chair reserves the right to request clarification of any application prior to making category assignment.

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[1] JWU requires investigators to complete appropriate trainings — or acceptable "refresher" trainings, if applicable — at least once every three years. If you have already completed the required CITI training modules within the past three years, please submit that certificate with your application. If you have completed some other training program in human subjects protections and responsible conduct of research within the past three years and believe that that training would be comparable to, or exceed, what JWU requires through CITI, then please send a description of the training and proof of completion to the IRB at institutionalreviewboard@jwu.edu. The IRB chair or designee will review the training and the credential and will let you know either that they satisfy JWU's requirements or that you will have to complete additional training.

a. **Exempt**: Research involving activities that will pose minimal or no physical, economic, or reputational risk to human subjects.

Exempt research projects will usually fall into at least one of the following categories:[2]

i. Research, conducted in established or commonly accepted educational settings that **specifically involves typical** educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

ii. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;
   b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.[3]

iii. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that

[2] Some of these exemptions may not apply in studies involving prisoners or children.
[3] Limited IRB review is a process that is required only for certain exemptions and does not require an IRB to consider all of the IRB approval criteria in 42 CFR § 46.111. Limited IRB review may be done via the expedited review mechanism, that is, by the IRB chair or an experienced IRB member designated by the chair (although it can also be conducted by the full IRB). Continuing review is not required.

there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

iv. Research involving the use of secondary data that includes identifiable private information or biospecimens if at least one of the following applies:
   a) The identifiable private information or identifiable biospecimens are publicly available;
   b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);
   d) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* (The PI should contact the IRB chair for assistance in interpreting applicable laws if the study might be eligible for this exemption.)

v. Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

vi. Research involving taste and food quality evaluation and consumer acceptance studies:
   a) If wholesome foods without additives are consumed, or
   b) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. (The PI should contact the IRB chair for assistance in interpreting applicable laws if the study might be eligible for this exemption.)

vii. Storage and maintenance of identifiable private information or identifiable biospecimens when research subjects have provided broad consent, and the study has undergone limited IRB review to ensure that:
   a) broad consent was obtained and documented; and
   b) if there is a change in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.[4]

viii. Research that will involve secondary analysis of existing private identifiable data or biospecimens provided that:
   a) broad consent was obtained from, or consent was waived by, the subjects; and
   b) full documentation of such consent or waiver has been completed; and
   c) the project has undergone limited IRB approval to ensure that
      - there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data; and
      - the research to be conducted is within the scope of the broad consent; and
   d) the investigator does not include returning individual research results to subjects as part of the study plan unless required by law.

In general, the IRB will not consider a project exempt if it includes any planned degree of deception (unless predicted for and approved by subjects in advance), involves sensitive information (except as noted in paragraphs B.1.a.ii and B.1.a.iii, above),[5] involves more than very minimal risk to participants, or includes protected classes or vulnerable populations.[6]

b. **Expedited review:** Allowed for research when identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

[4] Broad consent pertains to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal or for materials that are collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research. In many cases, it may be preferable to undertake secondary research using non-identifiable private information or biospecimens. If broad consent is necessary, or expected to be necessary in the future, please consult with the IRB chair or administrator to create a consent form that complies with regulations at 45 CFR 46.116(d).

[5] "Sensitive information" would include information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

[6] Vulnerable populations are defined by JWU to include children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, students, or employees, clients, or patients of the PI's institution.

Low-risk projects eligible for expedited review will usually fall into at least one of the following categories:

i. Clinical studies of some drugs and medical devices.
ii. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture with some restrictions related to population and amounts to be collected.
iii. Prospective collection of biological specimens for research purposes by noninvasive means.
iv. Collection of data through noninvasive procedures that are routinely employed in clinical practice and that do not involve general anesthesia, sedation, microwaves, or x-rays.
v. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes.
vi. Collection of data from voice, video, digital, or image recordings made for research purposes.
vii. Research on individual or group characteristics or behavior or research employing surveys, interviews, oral histories, focus groups, program evaluations, human factors evaluations, or quality assurance methodologies.
viii. Continuing review of research previously approved by the full IRB as follows:[7]
    a) The research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or
    b) no participants have been enrolled, and no additional risks have been identified; or
    c) the remaining research activities are limited to data analysis.
ix. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories B.1.a.ii through B.1.a.viii (above) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited review may also be used when minor changes are made to a previously approved research project, as long as the project is within the originally approved investigation period. (Note that projects initially determined to be exempt as explained above are also exempt from such review.) **See section L. Modification and Extension Requests, below** for additional information on expedited review.

To qualify for expedited review, the PI must implement reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

c. **Full Board Review**: Research that presents more than minimal risk for human subjects or involves sensitive[2] topics or vulnerable populations or is otherwise non-exempt or ineligible for expedited review. Research that meets the aforementioned

[7] See J, Continuing Review, which states that "Research that was, and remains, eligible for expedited review and that involves no more than minimal risk" is not subject to continuing review. Accordingly, if a study's continuing review may be handled using the expedited review procedure as stated in this section, then that study will not be subject to any additional continuing review unless the PI modifies the research in a way that increases risk or otherwise negates its expedited-review-eligible status.

criteria for expedited review may also be subject to full board review if the reviewer determines that the study involves more than minimal risk, documents the rationale for that determination, and submits that documentation to the IRB for inclusion in the official record maintained by the Provost's Office.

2. Once assigned to a category, the application review process will proceed according the following processes.

C. Procedure for Reviewing Exempt Applications

1. The IRB chair will determine whether or not a research protocol is exempt from expedited or full review. Although the protocol may be exempt from expedited or full review as defined in this document, the chair will review the protocol for compliance with university policies and procedures. The **IRB chair will notify the PI, via email,** of both this determination and a forthcoming review for **compliance with university policies and procedures**.

2. In accordance with requirements stated in exempt research categories ii, iii, vii, and viii (above), the IRB chair or, at the chair's discretion, a qualified IRB member or the full IRB, will undertake limited IRB review.

3. Following review, the PI will receive official notification from the IRB chair concerning the result of the review: Approved, Modifications required, or Declined.[8] This information will be entered in the official log maintained by the Provost's Office.

4. **Each month, the IRB chair will report on Exempt projects to the full IRB through meeting agendas or monthly reports (when the IRB is not convened). Reporting will include the official record number of the proposal and the title of the study**, the study abstract (taken from the IRB application), the name of the reviewer, and the result of the review, will be included as part of the official meeting record maintained by the Provost's Office.

D. Procedure for Reviewing Expedited Applications

1. Applications containing research protocols suitable for expedited review will normally be reviewed by the IRB chair; however, at the chair's discretion, such reviews may be assigned to another member of the IRB (voting or non-voting, excluding ex-officio members) to conduct outside of the monthly IRB meeting. After determining that the protocol is eligible for expedited review, the IRB chair will notify the PI, via email, both of this determination and a forthcoming review for compliance with university policies and procedures.

2. Following review, the PI will receive official notification from the IRB chair concerning the result of the review: Approved, Modifications required, or Declined.[9] This information will be entered in the official log maintained by the Provost's Office.

3. **Each month, the IRB chair will report on expedited projects to the full IRB through meeting agendas or monthly reports (when the IRB is not convened). Reporting will include the**

[8] The reviewer may decline a proposal for reasons related to compliance with JWU's policies and procedures. If the reviewer recommends that the application be "Declined" for reasons related to protection of human subjects or for other reasons, he or she will refer the application to the IRB for full review according to the IRB's regular procedures. Such referral is required by regulation for federally funded projects granted expedited status.

[9] The reviewer may decline a proposal for reasons related to compliance with JWU's policies and procedures. If the reviewer recommends that the application be "Declined" for reasons related to protection of human subjects or for other reasons, he or she will refer the application to the IRB for full review according to the IRB's regular procedures. Such referral is required by regulation for federally funded projects granted expedited status.

official record number of the proposal, the title of the study, and the result of the review, will be included as part of the official meeting record maintained by the Provost's Office.

E. Procedure for Applications Requiring Full Review

1. Applications containing research protocols requiring full review by the IRB will be assigned Full Board by the IRB chair. Prior to the study being reviewed by a convened IRB, the IRB chair will notify the PI, via email, that their study has been classified a full board review.

3. All IRB members will review all applications requiring full review and prepare to participate in IRB meeting discussions.

2. The IRB will approve a proposal only if:

   a. Risks to subjects are minimized:
      i. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
      ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
   c. Selection of subjects is equitable.
   d. To the extent required, informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with 45 CFR § 46.116, or other applicable federal regulation. Outside of special cases described in federal regulation, the IRB will approve an alteration or waiver of the generally applicable criteria for informed consent only upon finding and documenting that:
      i. The research involves no more than minimal risk to the subjects;
      ii. The research could not practicably be carried out without the requested waiver or alteration;
      iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
      iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
      v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
   e. Informed consent will be appropriately documented or appropriately waived under 45 CFR § 46.117, or other applicable federal regulation. If the documentation requirement is waived, the IRB may require that the PI provide a written summary of the research. The IRB will approve waiver of the documentation if it makes any of the following findings:
      i. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
      ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
      iii. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there

is an appropriate alternative mechanism for documenting that informed consent was obtained.

f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
i. A consideration of other specific provisions relevant to a particular proposal, including whether appropriate determinations regarding FDA applications have been made for FDA-regulated research.

4. During the IRB meeting, the **IRB chair** will present the proposal and facilitate the discussion. Upon establishment of a quorum, the IRB will vote on the proposal, and the results will be recorded in the minutes. All actions taken during an IRB meeting are considered binding.

5. Within five business days after the IRB review, the PI will receive official notification from the IRB chair concerning the result of the review: Approved, Modifications required, or Declined. This information will be entered in the official log and record maintained by the Provost's Office.

F. Official IRB Actions Following Proposal Review

The review of an IRB application will result in one of the following actions, communicated by the IRB chair to the PI:

- **Approved** indicates that there are no concerns with the study proposed in the application, and the PI may commence the planned inquiry.
- **Modification required** indicates that there are **concerns** with the proposed **study** that must be resolved before approval can be granted. Specifics of the required modification(s) and process for resubmission will be communicated by the IRB chair.
- **Declined** indicates that the proposal is not approved. All decisions of the IRB are final.

IRB approval will be granted in one-year increments and **will expire at midnight on the eve of the one-year anniversary of the date on which such approval was formally granted. This may be the date of the IRB meeting or the date that the IRB chair or designee determined that the PI met a minor condition for approval. (For more information and examples of approval and expiration dates, see the appendix at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html.)** At this time, projects will be considered closed by the IRB chair and the Provost unless an extension has been granted (see L. Modification and Extension Requests) or the project is subject to continuing review (see J. Continuing Review).

G. Monthly Meetings of the IRB

a. By **July 1st** of each calendar year, the IRB chair will establish the following academic year's schedule of monthly meetings. The list of meeting dates will be published on JWU's IRB web page and posted on the IRB ulearn Organization web page.

H. Special Meetings of the IRB

1. Special meetings may be convened at the discretion of the IRB chair as needed to support institutional initiatives and ensure efficient conduct of IRB business. Examples of

circumstances that may warrant the scheduling of a special meeting of the IRB include **but are not limited to**:

a. The need to consider time-sensitive proposals that must be reviewed outside of the established IRB monthly meeting schedule (e.g., a deadline associated with an external grant proposal).
b. The need to act on unfinished business from a previous IRB meeting during which quorum was not reached or was lost during the meeting, thus prohibiting the IRB from taking official action.
c. The need to respond to urgent PI reporting or requests than cannot be postponed until the next monthly meeting of the IRB.

2. The IRB chair will communicate the need for a special meeting to IRB members by email and select a meeting time and date that will ensure a quorum of members will be present.

3. The agenda of a special meeting will be limited to items requiring immediate action.

4. IRB meeting documents will be available to IRB members through the IRB ulearn Organization no less than 24 hours before the special meeting.

5. Special meetings will follow the agenda prepared by the IRB chair, and official actions of the IRB will be recorded through the meeting minutes. This information will also be entered in the official log and record maintained by the Provost's Office.

6. Notification of IRB decisions will be communicated by the IRB chair within five business days following the procedure prescribed for monthly IRB meetings, unless special circumstances dictate a faster notification timeline.

I. Quorum

A quorum is attained when five voting members of the IRB are present.

J. Continuing Review

1. Continuing review, i.e., IRB's re-assessment of an approved study, is required at least annually and will be conducted with the same rigor and procedures (and according to the same operational by-laws) that apply to initial review.

2. Exceptions to the continuing review requirement:[10]
   a. Exempt research conditioned on limited IRB review.
   b. Research that was, and remains, eligible for expedited review and that involves no more than minimal risk.
   c. Studies for which all interventions have been completed and only involve analyzing data, even if the information or biospecimens are identifiable.
   d. Studies for which all interventions have been completed and now only involve accessing follow-up clinical data from clinical care procedures.

3. Continuing review will be conducted at a regularly scheduled IRB meeting unless required more frequently by the IRB. The following are among the criteria the IRB will consider when determining whether to require review more frequently than every 12 months.
   a. The nature of any risks posed by the research project
   b. The degree of uncertainty regarding the risks involved

[10] The IRB may override these exceptions provided that it has produced explicit, documented justification explaining why continuing review would enhance protection of research subjects.

c. The vulnerability of the subject population
d. The experience of the investigators in conducting research
e. The IRB's previous experience with the investigator(s) (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator)
f. The projected rate of enrollment
g. Whether the research project involves novel interventions

4. The IRB chair will include information on approval expiration and continuing review conditions (e.g., timing or a substantial change in the number of participating subjects) in the initial approval notification. Continuing review will be required until it falls into one of the exception categories stated earlier.

5. To apply for continuing review, the PI must complete a Continuing Review Request form and submit it through JWU's IRB web page no sooner than 45 days and no later than 30 days prior to the expiration date established for the approval term. Continuing Review Request forms will be processed according to the Procedure for Reviewing Expedited Applications or the Procedure for Applications Requiring Full Review as determined by the IRB chair and the Official IRB Actions Following Proposal Review.

6. The IRB may suspend or terminate approval of research that is either not being conducted according to its requirements or that the IRB believes to be putting subjects or others at unreasonable risk. In such cases, the IRB will follow applicable procedures for Reporting Unanticipated Problems, Adverse Events, and Noncompliance. Alternatively, the IRB may require observation and assessment by a third party of any or all aspects of the research and human-subjects protection and will notify the PI of that determination and the terms of continuing review.

K. Verification of No Material Changes Since Previous IRB Review Procedure

1. **At any time during the course of a research project, the IRB chair, a study's lead reviewer, or a convened IRB may request independent verification that no material changes have occurred since the previous review. Reasons for such verification may include, without limitation,**
   a. **random audits of research studies;**
   b. **concerns raised about possible changes occurring without IRB approval;**
   c. **a suspected or verified change in the risk/benefit analysis;**
   d. **a significant, unexpected decrease in subject participation or retention or other matters related to subjects' consent or wellbeing; and**
   e. **concerns about scientific validity in highly complex or specialized research.**

2. **The IRB will notify the PI of its intention to seek independent verification and its rationale and will inform the PI of any limitations it is placing on its approval pending the outcome of independent verification. The PI will be expected to provide access to records, forms, data, grant proposals and reports, opportunities to observe the consenting process, sponsors, or other information requested by the IRB for verification purposes.**

3. **If the results indicate that material changes have occurred without IRB approval, the IRB will follow procedures for Reporting Unanticipated Problems, Adverse Events, and Noncompliance.**

L. Modifications to the study Reasons for such verification may include, without limitation, random audits of research studies; concerns raised about possible changes occurring without IRB approval; a suspected or verified change in the risk/benefit analysis; a significant, unexpected decrease in subject

participation or retention or other matters related to subjects' consent or wellbeing; and concerns about scientific validity in highly complex or specialized research.

1. Request**s for protocol modifications,** study extensions **or substantive changes to the study design/execution** are made via submission of an Amendment form and will be **reviewed** by the IRB chair to determine the extent of the proposed changes. The PI may not implement modifications without approval unless they are necessary to eliminate apparent immediate hazards to subjects or property.

2. If the proposed modifications are not significant, the review will be conducted by the IRB chair using expedited review procedures. Examples of modifications that are not usually considered significant include the following:
   a. **changes in study personnel**
   b. changes in procedures or survey questions that would result in reduced risk or would otherwise qualify the study for expedited review
   c. increased clarity or comprehensibility of survey questions
   d. corrected typographical errors in surveys or consent forms

3. Requests for significant modifications to the previously approved study will be assigned and reviewed according to the criteria and procedures described in this document for new IRB applications. Significant modifications would include changes in PIs, the overall scope of work, funding source(s) or availability, facility availability or other changes that may significantly affect the study or subjects' involvement or security.

4. Following review, the PI will receive official notification from the IRB chair concerning the result of the review: Approved, Modifications required, or Declined.[5] This information will be entered in the official log maintained by the Provost's Office.

5. The IRB chair will provide a summary of all activity related to modification and extension requests as part of the meeting support documents prepared for each monthly meeting.

M. Reporting Unanticipated Problems, Adverse Events, and Noncompliance

1. Anyone associated with a research project should report unanticipated problems, adverse events, and instances of noncompliance[11] (collectively, "Reportable Occurrences") that are associated with that research project.

2. Reporting requirements are as follows:
   a. PIs must report by completing and submitting the Reportable Occurrences Form (ROF) to the IRB chair through JWU's IRB web page.
   b. **Any other persons associated or involved with the project, other than the PI,** must report by: (1) contacting the PI (who should report as stated above) or (2) contacting the IRB chair at institutionalreviewboard@jwu.edu.

3. Reporters must report Reportable Events within three business days after their discovery.

[11] For purposes of these procedures, "noncompliance" is defined as a failure to satisfy the law or to observe the IRB's determinations or requirements; JWU's policies and procedures, including those set forth in this document; or one or more terms of a research-related agreement with an external entity. "Serious noncompliance" occurs when such failure significantly alters risks or benefits to subjects or to JWU or the IRB's integrity. "Continuing noncompliance" occurs when there is a pattern of noncompliance or refusal to resolve an issue of noncompliance as directed by the IRB.

4. When a ROF or other report is received, the IRB chair will, within two business days, notify the ex-officio member representing the Provost's Office, who will work with the IRB chair and the PI to confirm or determine the seriousness and type of the Reportable Event and the need to notify other university stakeholders such as the Office of the General Counsel, Equity & Compliance Services, Risk Management, Information Technology, Human Resources, Campus Safety & Security, and/or the IRB.

5. Within five business days after the PI is notified, the IRB chair and others the IRB chair may consult, will review the ROF or other documentation and make one of the following determinations:

    a. *The event is not a Reportable Event.* In this case, the IRB chair will communicate with the PI to determine an appropriate plan for addressing the event and, if applicable, document that plan in writing and submit it to the PI. This information will also be entered in the official log and record maintained by the Provost's Office.
    b. *The event is a Reportable Event.*
        i. In this case the IRB chair will communicate with the PI to gather additional information **about/regarding** the incident, if necessary, and will share the ROF and all other information and relevant documentation (which might include some or all of the research record) with the IRB. **The IRB** will review the matter within 10 days.
        ii. The IRB chair may require that research activities under inquiry be suspended immediately with appropriate notification to subjects if, in the IRB chair's judgement, there is significant immediate potential for harm to subjects or the university.
        iii. The IRB will conduct an investigation and will collaborate with the PI as necessary to determine an appropriate plan for addressing the Reportable Event. Depending on the seriousness of the circumstances, the cause(s), and the risk to subjects, the IRB may take one or more of the following actions:
            a) Require that the PI and other personnel complete additional training
            b) Require modifications to, suspend or terminate the research
            c) Require modifications to the consent process
            d) Require that subjects be notified and, possibly, asked to sign new consent forms
            e) Undertake additional monitoring and/or audits
            f) Require additional remedies to be determined based on the circumstances
        iv. If the project is federally funded, the IRB chair will report to the federal Office of Human Research Protections (OHRP) the Reportable Event if it qualifies as an unanticipated problem or constitutes continuing or serious noncompliance. The report shall be made no later than one month after the IRB learns about it and will include the following, at minimum, which will be shared with the PI and be reported to and entered into the official log and record maintained by the Provost's Office:
            a) Name of the institution conducting the research;
            b) Title of the research project and/or grant proposal;
            c) Name of the PI on the protocol;
            d) Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
            e) A detailed description of the Reportable Event; and

f) The actions the institution is taking or plans to take to address the issue.

v. The IRB is responsible for alerting the sponsor of any Reportable Event.

vi. If the Reportable Event meets the definition of an adverse event, the sponsor is responsible for reporting it to the Food and Drug Administration (FDA).

N. Suspension or Termination of Approval

1. The IRB may suspend approval of all or some of a research project's activities and may require that those activities temporarily cease and that subjects, if any, are notified in cases where research is not being conducted according to the IRB's requirements or is associated with unexpected serious harm to subjects or serious or continuing noncompliance. The IRB may permit the research project to resume when the PI has resolved, or demonstrated sufficient progress toward resolution of, the IRB's concerns related to those activities' compliance with laws and/or university policies or their actual or potential adverse effect(s) on research subjects or others associated with the project.

2. The IRB may terminate approval of all or some of a research project's activities and thus require that those activities cease and that subjects are notified. If the PI wishes to resume a research project that has been terminated, the PI must submit it as a new project.

3. When issuing a suspension or termination order, the IRB will primarily consider the protection of subjects' rights, welfare and personal information and must approve all plans for subjects' withdrawal or reassignment and subsequent communications with those subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action.

4. For federally funded projects, JWU is required by law to report to the OHRP suspension or termination of IRB approval for any reason, including notice of a serious adverse event, an unanticipated problem, or serious or continuing noncompliance. The IRB chair will report the suspension or termination and will include the following, at minimum, in this report:
    a. Name of the institution conducting the research;
    b. Title of the research project and/or grant proposal that was suspended or terminated;
    c. Name of the principal investigator on the protocol;
    d. Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
    e. A detailed description of the reason for the suspension or termination; and
    f. The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.).

This information will also be entered into the official record maintained by the Provost's Office and shared with the PI and administrators in the Office of the General Counsel, Risk Management, Information Technology, Human Resources, and other departments as deemed necessary by the IRB chair.

O. Closure Reporting

1. Guidance for reporting the conclusion of a project will be communicated by the IRB chair in writing.

2. The PI is responsible for completing and submitting a **Closure** form through JWU's IRB web page.

3. The original **Closure** form will be retained as part of the IRB archive and serve to formally document closure of the project file. This information will also be entered in the official log and record maintained by the Provost's Office.

4. Periodically, PIs with open RPAs will be contacted concerning the status of their studies and be directed to comply with closure reporting requirements as outlined in the IRB chair approval letter.

P. Inventory of IRB Forms

The following forms and reporting requirements support and document the work of the IRB. All IRB members must be familiar with the purpose and requirements of each:

- Research Proposal Application (RPA)
- Consent Form Template
- Amendment Form
- Reportable Occurrences Form
- Continuing Review Form
- Closure Form
- Faculty Advisor Authorization

Q. IRB Terms and Definitions

1. A catalog of terms and definitions used by the JWU IRB can be found on the JWU IRB webpage.

2. See the Office for Human Research Protections website for FAQs, informational videos, guidance and other resources.

[1] If a clinical investigation is conducted or supported by an agency that has adopted the Common Rule (45 C.F.R part 46) and involves an FDA-regulated product, then the study is subject to both 45 CFR part 46 and 21 CFR parts 50 and 56. Where the regulations differ, the regulations that offer the greater protection to human subjects will be followed. This might affect the degree of IRB oversight, consent form contents, terms for continuing review, and other requirements described in these procedures.

[2] JWU requires investigators to complete appropriate trainings — or acceptable "refresher" trainings, if applicable — at least once every three years. If you have already completed the required CITI training modules within the past three years, please submit that certificate with your application. If you have completed some other training program in human subjects protections and responsible conduct of research within the past three years and believe that that training would be comparable to, or exceed, what JWU requires through CITI, then please send a description of the training and proof of completion to the IRB at institutionalreviewboard@jwu.edu. The IRB chair or designee will review the training and the credential and will let you know either that they satisfy JWU's requirements or that you will have to complete additional training.