Walsh University
Institutional Review Board (IRB)
Procedure Manual

Updated 10/06/2020

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Mission of the Walsh University Institutional Review Board (IRB)

At Walsh University, the primary purpose of the Institutional Review Board (IRB) is to protect the welfare of human subjects in research. Federal and state regulations mandate that research involving human participants must be reviewed and approved by an IRB and may be subject to continuing review by the IRB. As an institution, Walsh University is committed to fostering the growth of human subjects' research by faculty, staff, and students for the greater good of humanity and for the pursuance of knowledge. The President, through the Chief Academic Officer and Institutional Official, grants authority to the IRB to approve of research involving human subjects. However, the Institutional Official, Chief Academic Officer and/or President may disapprove an application or research activity that has been approved by the IRB if the application is contradictory to the mission of the university.

Federal Governance

Walsh University, has committed to the U.S. Department of Health & Human Services (HHS) that it will comply with the requirements outlined in the HHS Protection of Human Subjects regulations at 45 CFR part 46. Walsh University's IRB has been reviewed and approved by HHS and issued a Federalwide Assurance (FWA). The HHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and, subpart D, additional protections for children.

What is Considered Human Subjects Research?

Research is considered to involve human subjects when a researcher (1) obtains information or biospecimens through intervention or interaction with a living individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR part 46).

1. Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

   Research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published.
   - Systematic Investigation: is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

2. Intervention: physical procedures by which information or biospecimens are gathered (for example, venipuncture) or manipulations of the subject or the subject's environment are performed for research purposes.

3. Interaction: communication or interpersonal contact between the researcher and the subject.

4. Identifiable: for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information or biospecimen.

5. Identifiable Private Information: private information for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information.

6. Identifiable Biospecimen: specimen for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information.

What is Not Typically Considered Human Subject Research?

1. Scholarly and journalistic activities: including the collection and use of information that focus directly on the specific individuals about whom the information is collected (not generalizable). Examples include: oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

2. Public health surveillance activities: limited to those activities conducted, supported, requested, ordered, required, or authorized by a public health authority.

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for criminal justice or investigative purposes: for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. This does not include social and behavioral studies of the causes of criminal behavior.

4. Authorized operational activities for national security purposes: authorized operation activities in support of intelligence, homeland security, defense, or other national security missions.

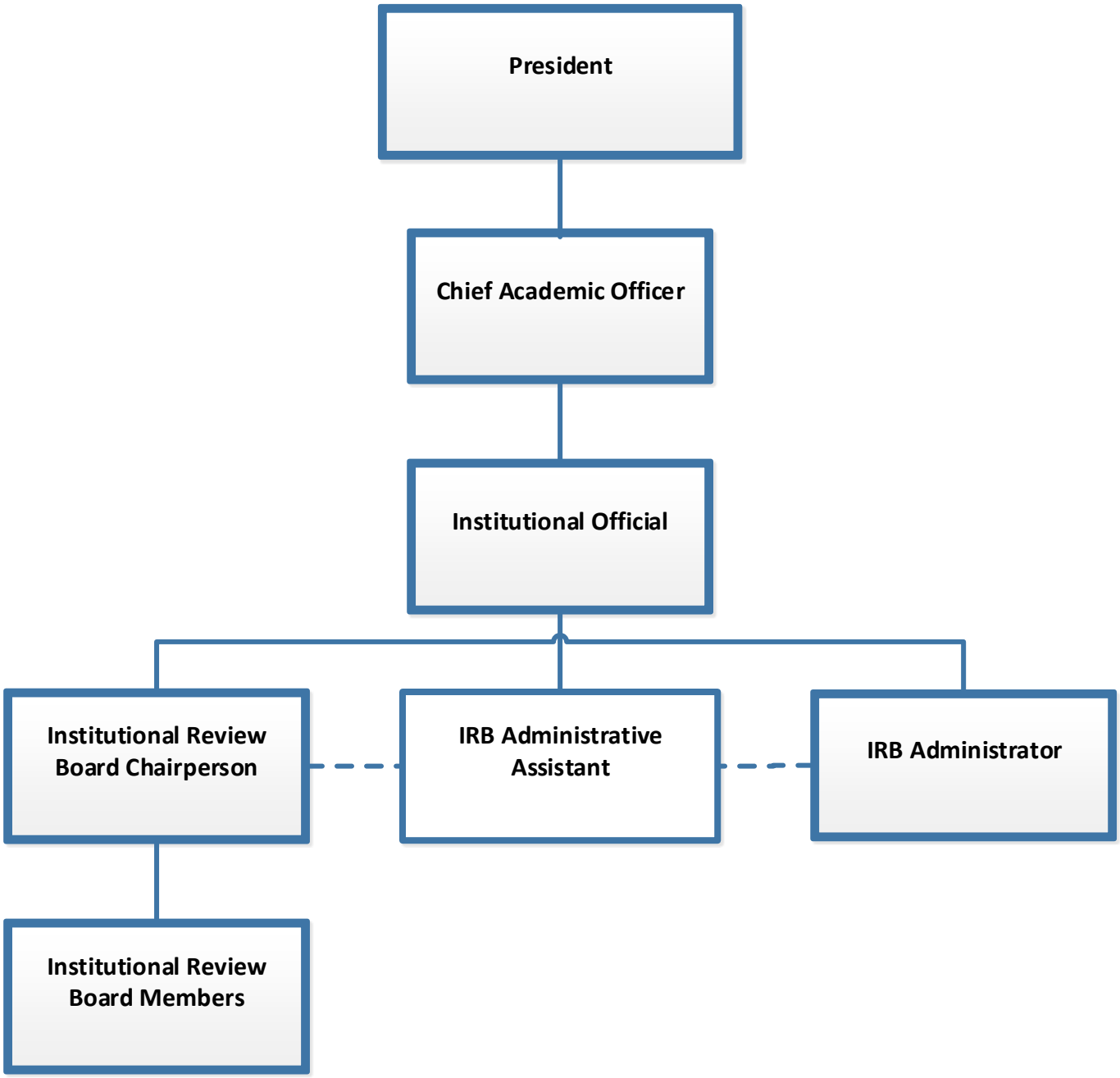
5. Secondary research use of nonidentifiable private information or nonidentifiable biospecimens.

IRB Organizational Structure

The IRB functions administratively through the Office of Academic Affairs. This structure provides for administrative coordination of the IRB with the various academic and administrative units in the university. The Chief Academic Officer, through the authority of the President, has direct supervisory authority of the Institutional Official. The IRB though the Institutional Official, IRB Chair, and IRB Administrator, advise and make recommendations to the Chief Academic Officer and/or President, to policy and administrative bodies, and to any member of the university community on all matters related to the use of human subjects in research. Revisions to policies and procedures are recommended by the Institutional Official, IRB Chair, and IRB Administrator and are approved by the Chief Academic Officer. Figure 1 outlines the organizational structure of the IRB.

The organizational structure of the IRB includes the: University President, Chief Academic Officer, Institutional Official, Institutional Review Board Chairperson, IRB Members, IRB Administrator, and the IRB Administrative Assistant.

Figure 1. Organizational Structure of the Institutional Review Board



IRB Responsibilities

Institutional review board membership is comprised of volunteers from the community and university. The IRB at Walsh University will:

1. Consist of at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
2. Be sufficiently qualified through the experience and expertise of its members (professional competence);
3. Make every effort to ensure the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;
4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
5. Include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and,
6. Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Positions and Appointments

Institutional Official
The Institutional Official is designated by the Chief Academic Officer. The Institutional Official position does not have a term limit.

IRB Chair
The Institutional Official and IRB Administrator are responsible for selecting the IRB Chair. The selection process is conducted in consultation with the Chief Academic Officer, Deans, Department Chairs, and other IRB Members.

The Institutional Official will appoint the IRB Chair. The IRB Chair a will receive an appointment letter after his/her appointment has been confirmed.

There is no specified time limit for serving as an IRB Chair. The IRB Chair is expected to hold the position for a minimum of 3 years; however, the IRB Chair may resign at any time by submitting a letter of resignation to the Institutional Official. The Institutional Official may remove the IRB Chair from the committee if he/she is not able to complete his/her responsibilities as IRB Chair.

Internal IRB Members
The IRB Chair and IRB Administrator are responsible for selecting Internal Members to serve on the IRB. The selection process is conducted in consultation with the Institutional Official, Chief Academic Officer, Deans, Department Chairs, and other IRB Members.

The IRB Chair will appoint the Internal IRB Members. The Internal IRB Members receive an appointment letter after their appointment is confirmed. The letter states the terms of service. Internal IRB Members serve a three-year term, which is consecutively renewable once, at the discretion of the IRB Chair and IRB Administrator. Internal IRB Members may resign at any time by submitting a letter of resignation to the

IRB Chair. The IRB Chair may remove an Internal Member from the committee if the member is not able to complete his/her responsibilities as an IRB Member.

External IRB Members
The IRB Chair and IRB Administrator are responsible for selecting External Members to serve on the IRB. The selection process is conducted in consultation with the Institutional Official, Chief Academic Officer, Deans, Department Chairs, and other IRB Members.

The IRB Chair will appoint the External IRB Members. The External IRB Members receive an appointment letter after their appointment is confirmed. The letter states the terms of service. The External IRB Members serve a three-year term. The External IRB Members have no term limits and their renewal is at the discretion of the IRB Chair and IRB Administrator. The External IRB Members may resign at any time by submitting a letter of resignation to the IRB Chair. The IRB Chair may remove an External Member from the committee if the member is not able to complete his/her responsibilities as an IRB Member.

Alternate IRB Members
Up to three Alternate IRB Members may be appointed by the IRB Chair and IRB Administrator. Alternates are appointed and function in the same manner as the primary IRB Members. The alternate's expertise is comparable to those of the primary member. The role of the Alternate Member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an Alternate Member substitutes for a primary member, the Alternate Member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an Alternate Member replaces a primary member.

Ad Hoc Consultant
At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research application and may be unable to make a fair and accurate determination of the risk- benefit ratio. For these applications, the IRB Chair and IRB Administrator, may call upon an Ad Hoc Consultant for assistance. The Ad Hoc Consultants are not considered IRB members, are utilized only for expert scientific review, have no voting rights, and must disclose any conflicts of interest with the application.

IRB Administrator
The IRB Administrator is designated by the Chief Academic Officer. The IRB Administrator position does not have a term limit.

IRB Administrative Assistant
The IRB Administrative Assistant is designated by the Chief Academic Officer. The IRB Administrative Assistant position does not have a term limit.

Position Responsibilities

IRB Overall
1. Safeguards the rights and welfare of human subjects.
2. Conducts review of initial application submissions, continuing reviews, and all revisions to applications of human subject research conducted by the researchers.
3. Approves, requires modifications to secure approval, defers (tables), or disapproves research activities overseen and conducted under the auspices of the university, regardless of location

of the research activities.

4. Analyzes applications systematically for benefits in relation to the potential risks involved in the research.
5. Reports in writing the findings and actions of the IRB to the researchers, Institutional Official, and to federal regulatory agencies or departments, as necessary.
6. Determines the interval at which ongoing studies need to be reviewed by the IRB.
7. Ensures prompt reporting of any changes in research activities to the IRB by researchers.
8. Ensures prompt reporting of adverse events to the IRB and federal agencies, where applicable, including:
   - Unanticipated problems involving risks to subjects or others.
   - Serious or continuing noncompliance with regulations.
   - Suspension or termination of IRB approval.
9. Suspends or terminates research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

Institutional Official

1. Ensures compliance with institutional policies and all applicable regulations for the protection of human research subjects.
2. Completes required human subjects research Collaborative Institutional Training Initiative (CITI) training.
3. Represents the institution in matters regarding human subject research and is the signatory authority for all the Federalwide Assurance to the Office for Human Research Protections.
4. Appoints and evaluates the IRB Chair with assistance from the IRB Administrator.
5. Reviews and evaluates internal reports and quality improvement activities.
6. Signs all correspondence and reports sent to federal regulatory agencies regarding researcher or institutional noncompliance.
7. Collaborates with the IRB Chair and IRB Administrator to provide continuing education for IRB Members.
8. Collaborates with the IRB Chair and IRB Administrator to resolve IRB-related issues with faculty or subjects.

IRB Chair

1. Serves as public spokesperson for the IRB.
2. Convenes meetings of the IRB.
3. Ensures adequate expertise for the review of applications.
4. Completes required human subjects research CITI training.
5. Appoints and evaluates IRB Members, Alternate Members, and Ad Hoc Consultants with assistance from the IRB Administrator.
6. Reviews applications, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB.
7. Delegates review responsibilities as necessary and applicable.
8. Maintains up-to-date knowledge of human subject regulations and pertinent events.
9. Consults with researchers as necessary.
10. Suspends the conduct of research when individuals are placed at an unacceptable level of risk.
11. Collaborates with the Institutional Official and IRB Administrator to provide continuing education for IRB Members.
12. Collaborates with the Institutional Official and IRB Administrator to resolve IRB-related issues with faculty or subjects.

13. Recognizes and supports partnership with Institutional Official to assure IRB efficiency and effectiveness.
14. Ensures that IRB Members with a conflict of interest are not present for any discussion and vote on research where he/she has a conflict.
15. Reviews copies of all IRB meeting minutes containing reports of IRB deliberations on human subject applications, the results of quality improvement audits, and noncompliance findings.

IRB Members (Internal & External)

1. Are familiar with IRB policies, procedures and federal, state, and local regulations, policies or guidelines relating to human subject research.
2. Completes required human subjects research CITI training.
3. Reviews submitted proposals as assigned by the IRB Chair or Chair's designee.
4. Attends IRB meetings and participates in the review of research applications.
5. Reviews meeting packets in advance of IRB meetings and are prepared for discussions on submitted applications.
6. Acts as a primary or secondary reviewer of applications when assigned.
7. Works with researchers to resolve issues related to IRB review.
8. Maintains confidentiality of IRB proceedings.
9. Discloses conflicts of interest, if applicable.

IRB Administrator

1. Is familiar with IRB policies, procedures and federal, state, and local regulations, policies or guidelines relating to human subject research.
2. Completes required human subjects research CITI training.
3. Reviews and checks incoming IRB applications for completeness, as needed; submits review comments.
4. Reviews, requests any necessary revisions, and approves exempt applications.
5. Assists the Institutional Official with the appointment and evaluation of the IRB Chair. Assists the IRB Chair with the appointment and evaluation of IRB Members, Alternate Members, and Ad Hoc Consultants.
6. Facilitates federal reporting, trainings, and quality improvement.
7. Maintains confidentiality of IRB proceedings.
8. Disclose conflicts of interest, if applicable.
9. Collaborates with the Institutional Official and IRB Chair to provide continuing education for IRB Members.
10. Collaborates with the Institutional Official and IRB Chair to resolve IRB-related issues with faculty or subjects.
11. Maintains the IRB's federal registration and Federalwide Assurance Number.

IRB Administrative Assistant

1. Verifies that CITI training has been completed for all researchers on an application.
2. Logs IRB applications, assigns application number, and posts applications with all submitted material to ECN for review.
3. Sends emails on behalf of the IRB Chair, Members, and Administrator for application revisions, approvals, and expirations.
4. Sends sixty and thirty day courtesy expiration notice emails to all researchers.
5. Records meeting minutes.
6. Maintains IRB files.

7. Answers IRB telephone line and fields questions.
8. Maintains confidentiality of IRB proceedings.
9. Completes required human subjects research CITI training.

IRB Records

An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by researchers, and reports of injuries to subjects.
2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
3. Copies of all correspondence between the IRB and the researchers.
4. A list of IRB Members.
5. Written procedures for the IRB.
6. Statements of significant new findings provided to subjects.
7. The rationale for an expedited reviewer's determination under that research appearing on the expedited review list is more than minimal risk.
8. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of 45 CFR part 46.
9. The records shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

IRB Website

The IRB website (https://www.walsh.edu/irb.html) contains up-to-date information including:

1. Human subject research definitions;
2. Steps to completing the IRB process;
3. Application forms;
4. Training requirements;
5. Policies and procedures
6. Meeting dates and deadlines;
7. IRB personnel names and contact information;
8. Helpful information; and,
9. Frequently asked questions.

Corresponding with the IRB

The IRB will communicate with researchers via email. Letters detailing required changes to a submitted IRB application and documentation approving an IRB application will be emailed to all researchers identified on the IRB application.

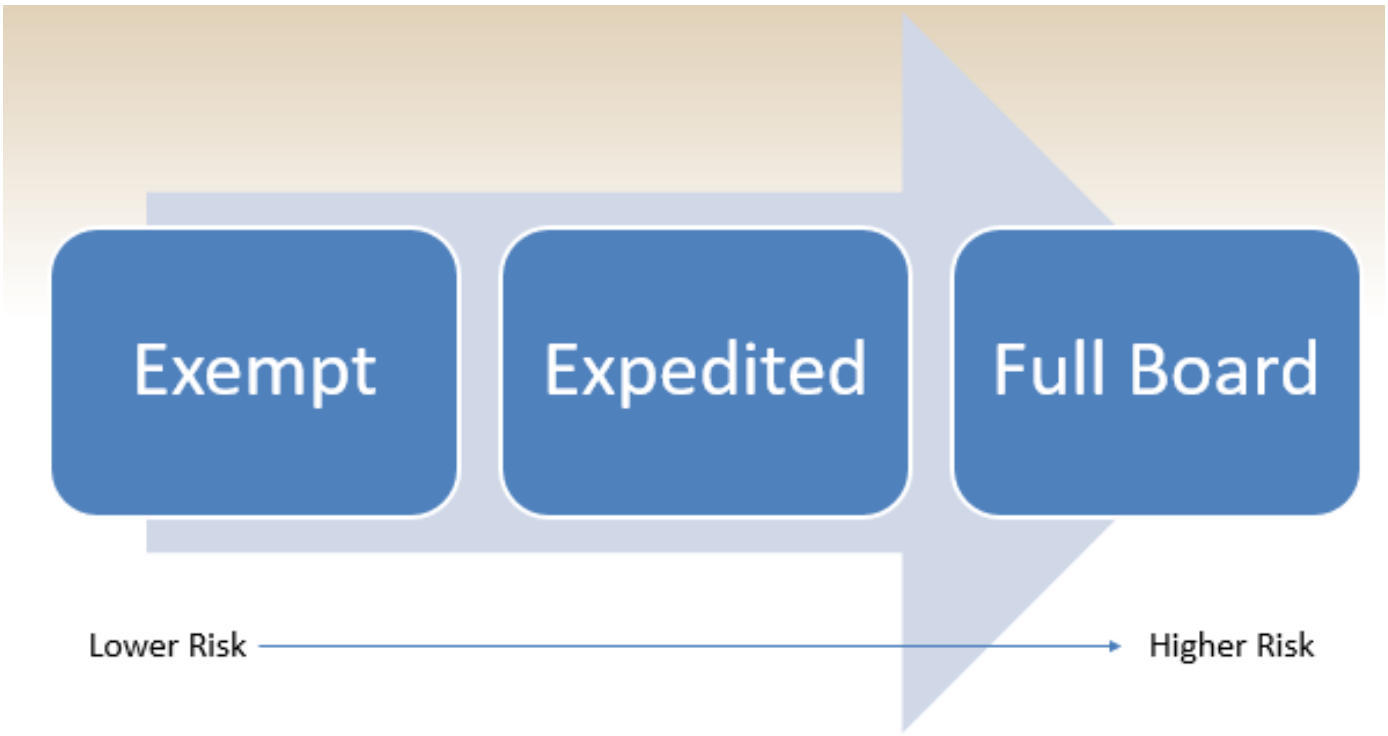
Researchers can contact the IRB via email (irb@walsh.edu) or via telephone (330-490-7443). IRB personnel's contact information is located on the IRB website (https://www.walsh.edu/irb-members.html).

IRB Review of Research

Research reviewed by the IRB will fall into one of three categories based upon the risk level to the human subjects involved in the research (Figure 2):

1. Exempt research contains minimal risk to human subjects.
2. Expedited research contains minimal to moderate risk.
3. Full board research contains moderate to high risk to human subjects.

Figure 2. IRB Review Category Continuum



Exempt Research

For research to be deemed exempt, it must fall into one of the following eight categories and contain minimal risks to the human subject participants.

Exemption 1: Educational setting.

Exemption 2: Interactions involving educational tests, surveys, interviews, public behavior observations.

Exemption 3: Benign behavioral interventions.

Exemption 4: Secondary research with identifiable private information or biospecimens.

Exemption 5: Conducted or supported by a Federal department or agency.

Exemption 6: For taste, food quality and consumer acceptance studies.

Exemption 7: Storage or maintenance or identifiable private information or biospecimens for secondary research with a broad consent form.

Exemption 8: Secondary research using identifiable private information or biospecimens with a broad consent form.

Vulnerable Populations

Research containing a vulnerable population typically requires expedited or full board review. The U.S. Department of Health & Human Services (HHS) regulations, 45 CFR part 46, specifies vulnerable populations that require additional protections when involved in human subjects research. These populations include: pregnant women, human fetuses, and neonates (subpart B); prisoners (subpart C); and, children (subpart D).

Expedited and Full Board Research

The IRB Chair determines if the research contains moderate or high risk and designates the application as requiring an expedited or full board review (see IRB Review Process).

Steps to Complete the IRB Process

1. All faculty, staff, students and external researcher(s) must complete and pass the Collaborative Institutional Training Initiative (CITI) course in human subjects research prior to submitting an IRB application. Applications submitted to the IRB are not considered complete until this training is completed. A copy of all CITI training completion certificates must be included with the IRB application (https://www.walsh.edu/irb-training.html).
2. Download and complete the appropriate IRB application (https://www.walsh.edu/irb-application.html).
3. Email completed applications and attachments to irb@walsh.edu.

Application Forms

There are two application forms for new IRB applications: the Application for Exemption and the Application for Initial Review (https://www.walsh.edu/irb-application.html). The Application for Exemption is utilized for exempt research. The Application for Exemption contains screening questions that allow the researcher(s) to self-determine if this level of review is appropriate for their research. The Application for Initial Review is utilized for expedited and full board research.

Typical Items Required for Inclusion in an IRB Application

Any materials received by a human subject must be reviewed and approved by the IRB. Typical documents include:

1. Statement of Informed Consent and/or Cover Letter;
2. Broad Consent, if applicable;
3. Assent forms, if applicable;
4. Copies of material given to the subjects and parents/guardians;
5. Participant recruitment materials such as fliers and advertisements;
6. Data collection forms including demographic data, questionnaires, surveys, and interview questions;
7. Scripts of verbal instructions and project information;
8. Supporting bibliography for literature review;
9. Collaborative Institutional Training Initiative (CITI) training completion certificates;
10. Grant proposal, if applicable; and,
11. If the research is being conducted at another location, documentation demonstrating the approval of the external site is required. This will minimally be a letter of support but may require another IRB's approval.

Required Consent Form Elements

Before involving a human subject in research, a researcher shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. The Common Rule (45 CFR part 46), outlines the required elements of a consent form. The Walsh University IRB has developed a sample consent form template for researchers to modify and use (https://www.walsh.edu/irb-application.html).

The required consent form elements include:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. The approximate number of subjects involved in the study;
3. A description of any reasonably foreseeable risks or discomforts to the subject;
4. A description of any benefits to the subject or to others that may reasonably be expected from the research;
5. Any additional costs to the subject that may result from participation in the research;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
8. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility;
9. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies;

10. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
11. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
12. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
13. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
14. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
15. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
16. If applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
17. If applicable, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
18. If applicable, a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; and,
19. If applicable, anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's or the legally authorized representative's consent.

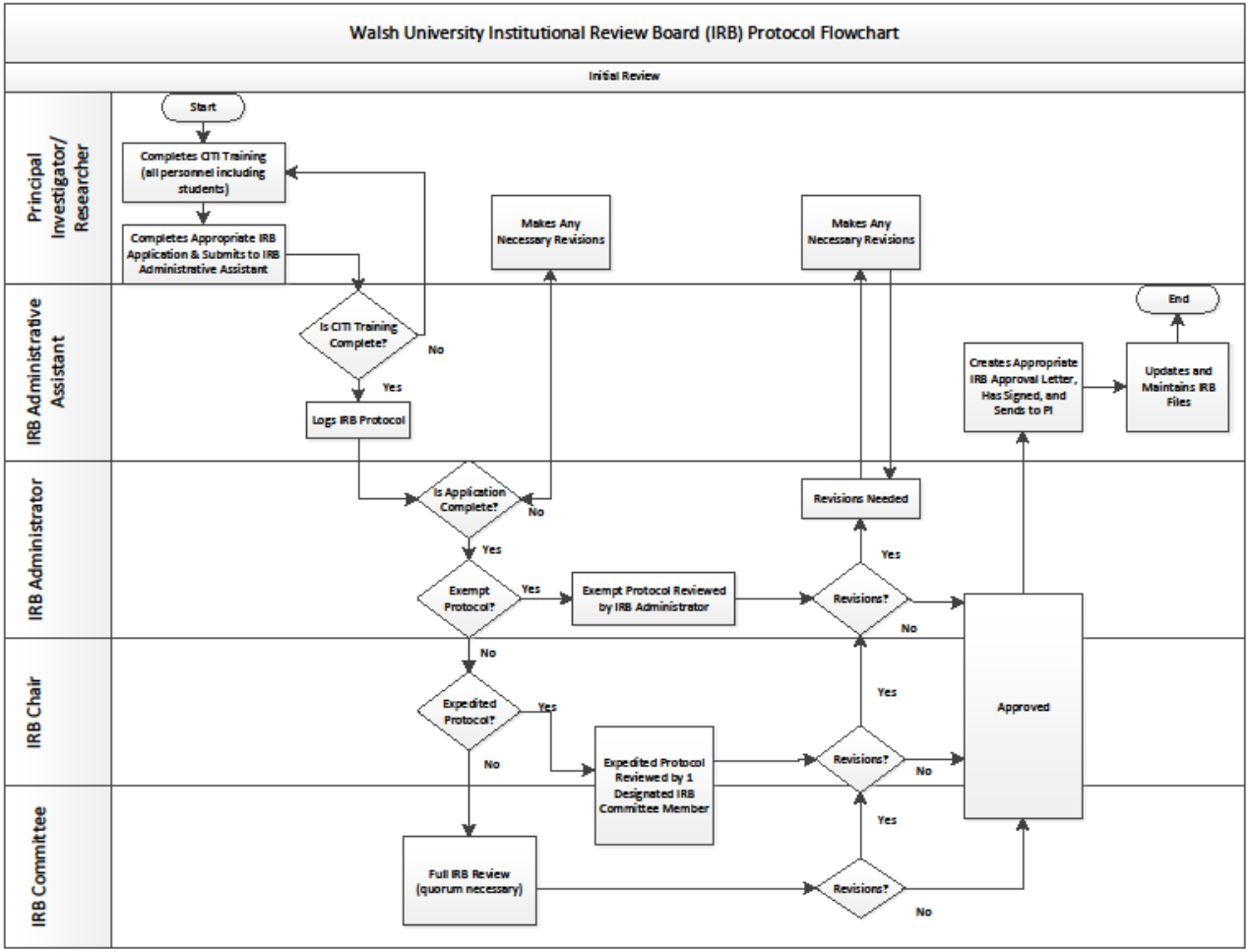
IRB Review Process

1. IRB applications are accepted and reviewed on a rolling basis.
2. Exempt applications can be reviewed by either the IRB Administrator, IRB Chair, or an IRB member.
3. Expedited applications are reviewed by one or two IRB Members.
4. Exempt and Expedited reviews are generally returned within one to two weeks, not including time for requested revisions.
5. If revisions are required, an email is sent to the researchers detailing the required revisions within their IRB application, consent form, and supporting documents.
6. Applications that are ineligible for Exempt or Expedited review are presented to the IRB for full committee review.
7. The IRB Chair assesses whether an application can be expedited or whether it requires a full board review and this cannot be determined until a complete application is submitted.
8. Full board applications must be received one week in advance of the IRB meeting dates to be considered that month (https://www.walsh.edu/irb-meetings.html).
9. If a researcher's application requires a full board review, the researcher has the option to attend the meeting to answer any questions/concerns in order to keep the process moving forward.

IRB New Application Flowchart

Figure 3 depicts the flow of IRB applications through the initial review process.

Figure 3. Walsh University Institutional Review Board (IRB) Application Flowchart



IRB Approval

IRB approval letters are emailed to all researchers identified on the IRB application. The approval letter will include:

1. The application name and number.
2. The date of the IRB review.
3. If the application is exempt, the exemption category is provided.
4. If the application requires subsequent reviews. Exempt and Expedited applications per 45 CFR part 46 do not require annual review; however, the IRB can elect to require it. Full Board applications are required per 45 CFR part 46 to have at least annual reviews.
5. The letter specifies that any changes to the application will require a formal application to, and approval of, the IRB prior to implementation of the change(s).
6. The date of research completion as identified in the IRB application. Prior to this date, the researcher may amend the application to extend the date of the project via an Amendment of Changes to an Approved Application form. Sixty (60) and 30 day courtesy expiration notices are emailed to all researchers. If an application expires, a new initial IRB application is required before the research can begin.
7. A Final Report/Closeout form is due within 30 days of the research completion. The courtesy expiration reminder email notes the date that the Final Report/Closeout forms are due.
8. IRB letters may contain provisional approval with elements that are required prior to full research commencing.

Ongoing IRB Requirements

Amendments or Changes to an Approved Application

Any changes to an approved IRB application requires a formal application to, and approval of, the IRB prior to implementation of the change(s). Changes include but are not limited to a change in:

1. Principal or co-investigators/researchers;
2. Approved application;
3. Risk level;
4. Consent form;
5. Project materials; or,
6. Research sites.

The Amendment or Changes to an Approved Application form can be found at: https://www.walsh.edu/irb-application.html.

Continuing Review Application

Approved applications requiring subsequent IRB review, as outlined in the IRB approval letter, must complete a Continuing Review Application prior to the expiration of the project. If an application expires prior to the Continuing Review Application approval by the IRB, a new Application for Initial Review will be required before the research can begin. The Continuing Review Application form can be found at: https://www.walsh.edu/irb-application.html.

Unanticipated Adverse Event

Researchers must report all potential unanticipated problems and events to the IRB. Unanticipated problems are defined as any incident, experience or outcome that meets all of the following criteria:

1. Unexpected (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied;
2. Related or probably related to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

The Unanticipated Adverse Event form can be found at: https://www.walsh.edu/irb-application.html. The IRB Chair and Institutional Official will review any submitted Unanticipated Adverse Event forms to determine next steps.

Final Report/Closeout
Within 30 days of research completion, a Final Report/Closeout form must be submitted to the IRB. The IRB Final Report Closeout form can be found at: https://www.walsh.edu/irb-application.html.

Resources

Walsh University IRB Website: https://www.walsh.edu/irb.html

Federal Regulations (45 CFR 46): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html

Office for Human Research Protections (OHRP) Human Subject Regulations Decision Charts: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

Questions and Concerns

Questions or concerns related to the IRB or research approved by the IRB can be directed to the IRB via email (irb@walsh.edu) or via telephone (330-490-7443) or the IRB Institutional Official or Chair IRB can be contacted directly (https://www.walsh.edu/irb-members.html).