Policy for the Protection of Human Subjects – Institutional Review Board (IRB)

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Institutional Review Board (IRB)

1. Formation of an Institutional Review Board (IRB)

   Whittier College will maintain an active IRB, in accordance with the federal requirements for the performance of federally-funded research involving human subjects (45 CFR Part 46, Subpart A, also called the Common Rule), which is codified for various agencies as listed below.

   The reference in the Code of Federal Regulations is shown below for each department and agency which has adopted the Common Rule:

7 CFR part 1c	Department of Agriculture
10 CFR part 745	Department of Energy
14 CFR part1230	National Aeronautics and Space Administration
15 CFR part 27	Department of Commerce
16 CFR part 1028	Consumer Product Safety Commission
22 CFR part 225	Agency for International Development
24 CFR part 60	Department of Housing and Urban Development
28 CFR part 46	Department of Justice
32 CFR part 219	Department of Defense
34 CFR part 97	Department of Education
38 CFR part 16	Department of Veterans Affairs

40 CFR part 26	Environmental Protection Agency
45 CFR part 46	Department of Health and Human Services
45 CFR part 46 (by Executive Order 12333)	Central Intelligence Agency
45 CFR part 690	National Science Foundation
49 CFR part 11	Department of Transportation

The Whittier College IRB will exist to review, evaluate, and approve/deny proposed research that will include human subjects.

1.1 Membership

There will be five members in the initial membership of the IRB. This is the minimum number of members required under the Common Rule. Membership will be determined by

- Willingness of the faculty or staff member to participate
- Ability to review proposed research and assess a project's compliance with Whittier College policies and standards, federal, state, and local regulations, and all applicable laws.
- His/her area(s) of interest/expertise.

1.1.1 Selection of Members

1.1.1.1 IRB Nominations

The Faculty Executive Committee (FEC) will make nominations of faculty to the Whittier College President based upon criteria in Section 1.1.2.

1.1.1.2 Non-affiliated Member Nomination

A member not affiliated with the Whittier College will be named by the President. The Vice President of Academic Affairs/Dean of Faculty will identify candidates according to Section 1.1.2.4, and make a recommendation to the President.

1.1.2 Member Characteristics **(45 CFR 46.107)**

1.1.2.1 General Faculty/Staff

Members will reflect a variety of backgrounds, experience, and expertise to cover disciplines and issues that are likely to be addressed in research proposals with human subjects. Members will be selected based upon qualifications that will lend credibility to the IRB as it makes judgments about proposed research. The IRB must be able to judge proposed research with regard to institutional policies, commitments, and rules, as well as with respect to regulations, applicable laws, and standards of professional conduct and practice.

1.1.2.2 Science/Non-science

Each IRB will have at least one member whose area of interest and expertise is some aspect of science. There will be at least one member whose area of interest and expertise is not science.

1.1.2.3 Human Subject Expertise

If a certain category of vulnerable human subject is regularly a common subject of research, the IRB will seek out and solicit membership of someone knowledgeable about that subject group. Examples of vulnerable subjects include those from the following list.

- Children,

- Prisoners,
- Pregnant women,
- Individuals diagnosed with clinical disorders,
- Handicapped or mentally disabled persons.

1.1.2.4 Non-affiliated Member

At least one member of the IRB will have no immediate affiliation with Whittier College (administration, faculty, staff, student, or contractor). Nor will that/those person(s) be part of the immediate family (spouse, parent, or child) of someone who is affiliated with Whittier College. This/these outside member(s) should be (a) spokesperson(s) on the IRB for community attitudes regarding human subjects and research projects. A member(s) will be selected based upon qualifications that will lend credibility to the IRB as it makes judgments about proposed research.

1.1.2.5 Diversity of Membership

Whittier College will maintain a balanced diversity in the IRB membership. The College will avoid an IRB that is all one gender or one profession. There is not a requirement to maintain specific ratios of gender, race, or cultural backgrounds when filling membership positions. Nor are certain positions designated for a specific gender, race, or cultural background.

1.1.3 Number of Members

The IRB has the option of increasing the membership number, if it believes such an increase is necessary. Examples of rationales for increasing membership may be because there is a wide range of research topics routinely being reviewed, there is an area of pertinent expertise missing or an ethnic, cultural, or community perspective is absent from the IRB membership. The

IRB must vote for an increase by a majority vote. Such a change to the membership number must also be approved by the Vice President of Academic Affairs/Dean of Faculty.

1.1.4 Conflicts of Interest

No IRB member may participate in the initial or continuing review of a project, where that member has a conflicting interest. A non-exhaustive list of examples follows.

1. The member is a proposer of the research,
2. The member has a vested personal interest in a specific outcome of the research,
3. The member maintains an interest in a competing group's or organization's research project or business,
4. The member has a history of publications regarding this or a similar topic, or
5. The member has some other comparable conflict.

A member, despite abstaining from participation because of a conflict of interest, may provide research proposal-specific information to the IRB upon request by one or more IRB members.

1.1.5 Non-voting Expert Consultant

The IRB may solicit a non-member expert consultant or consultants to provide knowledge, opinions, and advice when the IRB believes that a supplementary voice would help it to decide whether a specific proposal has flaws or is acceptable. The need to solicit an outside expert is determined by a majority vote of the IRB membership. Such an expert is not given a vote on the matter, but may provide information, suggestions, perspectives, viewpoints, open discussion, and recommendations to the IRB.

1.1.6 Term of IRB Membership

The standard term of IRB membership is three years. The membership terms shall not all begin at the same time. If a member is unable to fulfill the term of the position, the FEC will nominate a replacement for the remainder to the term, with final approval by the Vice President of Academic Affairs/Dean of Faculty.

1.1.7 Reporting of Membership to Agency

1.1.7.1 List of IRB Members

A list of IRB members must be reported to the funding agency or to the Office for Protection from Research Risks, National Institutes of Health, DHHS. The IRB will have a list available for distribution to potential researchers. The list must contain the following information.

Full Name of Member	Earned Degrees	Representative Capacity	Indicators of experience, e.g., board certifications, licenses, or other attributes that indicate the expected contribution to the IRB	Employment relationship to Whittier College, , e.g., full-time or part-time employee, member of board, paid or unpaid consultant

(45 CFR 46.103)

1.1.7.2 Membership Changes

Section 46.103(b)(3) specifies the need to inform the funding Department or Agency head if there is a change in the IRB membership. An exception is if the Department or Agency has accepted a Department of Health and Human Services (DHHS) approved assurance. In this case, the membership changes must be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

1.1.8 Training/Education of Key Personnel and IRB Members

Key personnel in the review and approval of proposals and the program to protect human subjects must undergo training/education per the Federalwide Assurance (FWA) requirements.

1.1.8.1 Key Personnel Training

The Institutional Signatory Official, the Human Protection Administrator, and the Chairperson of the IRB shall complete the Office of Human Research Protection (OHRP) Assurance Training Modules (see **http://137.187.172.153/CBTs/Assurance/login.asp**) to fulfill the FWA requirements for the protection of human subjects.

1.1.8.2 IRB Member Education/Training

Whittier College requires that its IRB members review relevant ethical principles and written IRB procedures, which incorporate relevant federal regulations, OHRP guidance, and other applicable guidance, state and local laws; and institutional policies for the protection of human subjects. To that end, members will read and become familiar with (1) the college policies, on human subjects research, which collect requirements for Whittier

College and its IRB regarding the protection of human subjects (Policy for the Protection of Human Subjects – Institutional Review Board, Policy for the Protection of Human Subjects – Applications and Exemptions, and Policy for the Protection of Human Subjects – Informed Consent), and (2) the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research, issued on April 18, 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for the Department of Health, Education, and Welfare).

2. Meetings

The IRB will have regularly scheduled monthly meetings to consider new research proposals that involve human subjects or to review previously approved projects as a follow up.

2.1. Quorum

No meeting shall proceed without the presence of a quorum of the membership. Fifty per cent or more of the membership will constitute a quorum, as long as at least one IRB member is present whose primary area of concern is in the non-scientific area. (**45 CFR 46.108**)

2.2. Notifications of Planned Absences

IRB members will notify the Chairperson as soon as possible if there is an anticipated absence from a scheduled IRB meeting.

2.3. Voting

Motions will pass or fail based upon a majority vote of those IRB members present at a meeting. (**45 CFR 46.108**)

2.4. Summer Break

The IRB will not have regular meetings during the summer months of June, July, and August, the break from the academic year.

2.5. Special Meetings

Special off-schedule meetings may be called when important and time-sensitive issues require discussion by the IRB.

2.6. Meeting Cancellations

In the absence of research proposals, project reviews, a quorum of members, or IRB administrative business, the meeting may be cancelled.

2.7. Tabling Items

An item may be tabled to the subsequent meeting if a key member for the discussion is unable to attend the meeting or additional information is required prior to a decision. For instance, the absence of the unaffiliated IRB member may cause deferral of the discussion of a project regarding persons unrelated to the college. Another example is insufficient or missing information about information that will be supplied to the subjects.

3. Review of Research Proposals

3.1. Function of the IRB

The IRB shall have the authority to approve, require modifications, or disapprove research proposals. It will have the authority to review or audit the performance of approved projects or designate others to assure that work is being performed in accordance with the practices that were approved.

3.2. Cooperative Projects

Whittier College may engage in a project that is planned in cooperation with another institution. Each institution is responsible for the well being of the subjects and assuring compliance with the Common Rule. For cooperative projects, the institutions may agree that the project may be reviewed jointly, one institution may rely upon the review of another qualified IRB, or some other satisfactory arrangement to avoid duplicating work may be made.

3.3. Independent Contractors

Whittier College shall require independent contractors to undergo review and approval by the IRB for elements of research projects that involve human subjects prior to beginning the work. This requirement shall be incorporated into the contract for the specified tasks. The Whittier College lead researcher is responsible to assure compliance with this requirement.

3.4. Submittals to IRB for Consideration

Researchers shall submit electronic copies of proposals and documents supporting proposals at least one week prior to the IRB meeting in order to be considered. These materials shall include the informed consent form and the accompanying information to be provided to the test subjects. (More detailed discussion of the Informed Consent process is in the “Informed Consent” procedure.) Electronic documents must be provided to the Chairperson by the specified deadline. The Chairperson will share the information with the other IRB members for individual review prior to discussion at the IRB meeting.

3.5. Initial Review of Research

The initial group review of a research proposal will occur at an IRB meeting. After review of the proposal and discussion of potential issues, the IRB members present at the meeting shall vote on whether or not the proposal is approved.

3.5.1. Criteria that Must be Met for Approval

The IRB must assure itself that the following criteria are met before a project is approved.

- The subject's risks are minimized by the use of sound research design and procedures utilized on the subjects during diagnosis and treatment.
- Subject's risks are commensurate with the anticipated benefits of the specific project. The IRB shall not consider long-term effects of applying the knowledge gained from the research project as part of the research risks within its purview.
- There is equitability in the selection of the subjects. The IRB should consider the research setting and purposes of the work, with a realization of special issues relating to vulnerable populations, such as children, prisoners, pregnant women, mentally challenged persons, educationally disadvantaged or economically disadvantaged persons.
- Each subject will have an informed consent form executed by the individual or a legally authorized representative. The IRB will determine if the informed consent form and informational materials meet the requirements under the Common Rule.
- Appropriate documentation of informed consent is planned.
- When appropriate for the type of research project, the research plan will have provisions for monitoring the safety of subjects during the testing.
- There are adequate plans for maintaining the confidentiality of the subjects and the data.
- Special safeguards are established to protect the rights and welfare of subjects when they are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally challenged persons, educationally disadvantaged or economically disadvantaged persons.

3.5.2. Whittier College Administration Review

The Administration of Whittier College may review research projects that have been approved by the IRB and further decide whether it will approve or disapprove a project. However, the Administration may not overrule a disapproval by the IRB with its own approval.

3.6. Projects Lacking Specific Plans for Human Subjects

Some projects are undertaken without definite or immediate plans for human subject research. Other projects may have no thought of human subject research until substantially into a project.

3.6.1. Projects Lacking Definite Plans for Human Subjects

Some projects have indefinite plans for human subject research following some initial research activity. However, no human subject research may begin until the project is reviewed and approved by the IRB in accordance with the Common Rule. **(45 CFR 46.118)**

3.6.2. Projects that Did Not Intend to Include Human Subjects

Before human subject research is initiated, the IRB must review the research and approve it. Certification must be sent to the funding Department or Agency that the project has been reviewed and approved by an IRB in accord with the Common Rule. **(45 CFR 46.119)**

3.7. Continuing Review of Research

Once research is approved by the IRB, the IRB involvement is not finished. The IRB will continue to monitor the project throughout its progress to assure itself that the project is taking place according to the agreed upon procedures and protocols. The IRB will require periodic updates on the project.

3.7.1. Routine Review Schedule

The routine review schedule for a project is one year. For example, a project approved in October will generally require an update of the project's status to the IRB during the following October. A project approved during a special meeting shall be revisited for review at the regular meeting preceding its anniversary of approval.

3.7.2. More Frequent Review Schedule

The IRB may establish a more frequent review schedule than once per year to obtain the status of a given project, or may call for an extra review as a follow-up. During the initial research project review, or during any subsequent review, if the IRB identifies specific issues, concerns, or interests requiring a follow-up discussion or an update on a project, a subsequent review month will be specified during the review.

3.7.3. Outside Verification

The IRB, the President of Whittier College, or the Vice President of Academic Affairs/Dean of Faculty may determine that a given project requires verification by someone other than the investigator to assure that the project is adhering to the practices discussed and approved by the IRB. This may extend to unannounced audits of the human subject research process. The IRB, the President of the Whittier College, or the Vice President of Academic Affairs/Dean of Faculty shall identify such outside parties, which may include themselves, to verify a project.

3.8. Expedited Reviews

Provision is made for expedited IRB reviews for certain categories of projects listed by the Secretary, Human Health Services, and periodically published in the Federal Register. An expedited review may be implemented by the IRB for the following.

- No more than minimal risks.
- Minor changes in approved research, within the authorized one-year or less period of research.

3.8.1. Expedited Review Process

The expedited review may be carried out by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among the IRB membership. This review group may exercise all of the authorities of the IRB except that it may not disapprove the research. Such disapproval may only occur at an IRB meeting. **(45 CFR 46.110)**

3.8.2. Reporting of Expedited Reviews

All expedited reviews will be included in the agenda for the next regular IRB meeting and decisions will be reported at that time. Documentation of the review will follow the standard process of creating a file and scheduling a review date.

3.8.3. Department or Agency Limitations on Expedited Reviews

The head of the funding Department or Agency may restrict, suspend, terminate, or eliminate the IRB's expedited review option. (**45 CFR 46.110**)

3.9. Reports of Findings and Actions

The researcher(s) will prepare and submit to the IRB reports of findings that are produced by the research project.

3.9.1. Immediate Notification

Any physical or psychological injury (as determined by a licensed practitioner) to a subject or researcher that occurs during a research project shall be reported immediately to the President of the College, the Vice President of Academic Affairs/Dean of Faculty, Campus

Safety (for on-campus or student-related issues), and the IRB Chair. The head of the funding Federal agency (if any) will be quickly notified of unanticipated problems by the researchers named in the grant.

3.9.2. "Near miss" Notification

"Near miss" events, where some happening almost injured someone, must also be reported to the IRB Chair.

3.9.3. Findings that Put a Subject at Risk

During the course of a research project, an investigator may discover that some element of the project puts a subject a greater risk than originally anticipated when the project was proposed. This type of information, where there is a change in the assessed risk, must be shared with the subject(s) and the IRB in a timely fashion. The IRB must reevaluate whether to approve the project. In the event that the project is approved, the subject, as always, still has an opportunity to withdraw.

3.10. IRB Notification of Procedural Change

The IRB must be notified in advance of any planned substantial change to the research proposal that may affect the human subjects. Examples of substantial changes include (1) a change from one site to a different type of site, (2) changing from one measure of self-esteem to another, (3) a significant change in age of students, e.g., age 8 to age 4. No investigator is authorized to modify significantly the research protocols that are described in the initially approved proposal. Examples that would trigger notification include such things as (1) a change to a more vulnerable population, (2) a change from one measure of self-esteem to another, when a new measure is being proposed for the first time, rather than using some standard measure, or (3) when there is a

change in language. An example that would not require notification is changing from one preschool to another, or even from kindergarten to preschool. In order to modify a protocol, a revised protocol must be reviewed by IRB and approved. This is not an exhaustive listing of examples. If there is a question, the IRB must be contacted to resolve the question. The only exception is if there is an urgent necessity to change the research activity to protect the subject(s) from a hazard.

3.11. Suspension or Termination of IRB Approval

The IRB may suspend or terminate a previously issued project approval if the research is being done in a fashion that is contrary to what the IRB approved. In addition, unforeseen safety issues are also grounds for suspension or termination of a project. The IRB will specify the reasons for the action in the notification of suspension or termination.

3.12. Department or Agency Notifications of Problems

The following events shall require prompt notification by the IRB to the funding Department or Agency with along with a delineation of the issues/problems and the project status.

- Problems arising from unexpected risks to subjects or others
- Any serious or continuing non-compliance with the Common Rule
- Any serious or continuing non-compliance with the IRB determinations
- Suspensions or terminations of projects.

4. Recordkeeping

Whittier College will provide meeting space, file space, and support staff for filing for the IRB.

4.1. IRB Files

The IRB will document and maintain copies of meeting agendas, meeting minutes, projects reviewed, actions taken, correspondence, and other IRB business.

4.1.1 Documents to be Maintained

The IRB will document and maintain records for all of its proceedings for a minimum of three years after the last activity regarding a project, i.e., three years after a project is rejected, or three years after an approved project is concluded. **(45 CFR 46.115(b))** The IRB will determine if it wishes this recordkeeping period to be longer or not. Some projects may have follow-on research, where it would be useful to have documentation of earlier decisions. The following items shall be maintained in the IRB files.

- A list of IRB members, per section 1.1.7.1 of this procedure.
- IRB Meeting Agendas,
- Copies of all Research Proposal materials that were submitted to the IRB, regardless of whether the proposal is approved or not,
- IRB Meeting Minutes, which will contain details about members in attendance, outside experts attending, actions taken, the vote on the actions (number for, against, and abstaining), the basis of required changes to the research, the basis of research disapproval, and a summary of controversial issues and their resolution.
- Rulings and comments by the IRB (such as suggested/recommended improvements), including a list of those present at the meeting and acting on the item,
- Points of contention or concern and unresolved issues about projects,
- Follow-up requests for additional information or project status,
- Responses to Follow-up requests,

- A current list of when a project has been an agenda item for each project file,
- Status/progress reports to the IRB about the project,
- General project progress reports to other parties,
- IRB correspondence with agencies, investigator(s), subject(s), and other pertinent parties regarding the project,
- Documents regarding proposed or existing projects that are submitted by consultants,
- Publications about the project results,
- Any media coverage of the project,
- Reports of injuries to subjects from project-related activities,
- Copies of all current IRB-related procedures and copies of all historical procedures under which the IRB operated.
- Copies of significant new findings that are provided to subjects as full disclosure information.

4.1.2. Accessibility of Records

All records shall be accessible for inspection and copying by IRB members, the President of the College, the Vice President of Academic Affairs/Dean of Faculty, and authorized representatives of the funding or approving Department or Agency at reasonable times and in a reasonable manner. **(45 CFR 46.115(b)**) Researchers shall have access to their own research. Other parties may access certain files with the written permission of the researcher.

5. Exemptions

Exemptions from the application of the Common Rule and the specified treatment of federally exempted research are listed in the policy titled “Application and Exemptions.”