PEPPERDINE
UNIVERSITY

Graduate and Professional Schools Institutional Review Board (GPS IRB)
Human Subjects Research Compliance (AHSRC) Office

Mission and Duties

The GPS IRB Human Subjects Research Compliance Office has been formed to audit expedited and full review protocols to ensure adherence to the approved protocol procedures and to identify to improve the quality of research being conducted at Pepperdine University or by members of the Pepperdine University community. Specifically, the Office is responsible for conducting routine and directed reviews of GPS IRB approved human subject research protocols to:

1. Assess adherence to the IRB approved study protocol, good clinical practices (GCP) guidelines, and state and federal regulations;
2. Determine that the rights and welfare of human research subjects are being or have been adequately protected by the investigator and his/her research staff; and
3. Assess the integrity of the study data.

The AHSRC Office serves as an institutional liaison with GPS IRB and other regulatory agencies visiting the university for inspections.

The AHSRC Office performs human subject research compliance reviews as a component of the GPS IRB Human Research Protection Program and submits these review summaries to the IRB and other institutional officials. These compliance reviews serve as a confidential quality assurance measure internal to the institution.

Staff

Andrea Quintero, MBA, MA; Principal AHSRC Compliance Officer, AHSRC Reviewer
Kevin Collins, IRB Manager, AHSRC Advisor, AHSRC Reviewer
Judy Ho, Ph. D., ABPP; GPS IRB Chair, AHSRC Development and Oversight, AHSRC Reviewer
Keisha Lee, MA; AHSRC Reviewer, IRB GA
Kamil Lewis, BA; AHSRC Reviewer, IRB GA

Routine and Directed Reviews

A certain number of routine reviews are selected each term (fall, spring, and summer) based on a risk metrics developed by AAHSRC. A directed review is a review that has been requested by a department, the IRB, or is the result of a subject or anonymous complaint. Both types of reviews are conducted according to the procedures devised for a human subject research compliance review.

How Routine Protocol Selections Are Made

The AHSRC selects protocols by mining the IRB database for protocols involving the following risk factors. Active studies that have 2 or more of these risk factors will be filtered into an AHSRC database, and a random lottery system will be utilized each month by an AHSRC reviewer to select a minimum of 2 protocols for review. In addition, studies that have 5 or more of these risk factors may be prioritized for the review process (reviewed before other protocols in the database) at the discretion and direction of the Seaver and IRB Chairpersons, the IRB Manager/Director, and/or the Principal Research Compliance Officer.

1. Current phase of study (e.g., Pre-data collection, data collection and data analysis), with studies in active data collection phase prioritized for review process
2. Federally funded study status
3. Protocol recruits vulnerable populations
4. Protocol involves HIPAA protected information
5. Protocol involves collection of sensitive information (e.g., mental health diagnoses, student grades, treatment status, employment information, other information that is easily linked or identifiable to specific subjects)
6. Number of subjects planned and/or actually enrolled (with studies with over 50 prioritized for review process)
7. Number of safety events and protocol deviations filed with the IRB (2 or more)
8. New research investigator (i.e., first research implementation without prior substantive experience)
9. Study in educational settings (e.g., elementary and secondary schools, colleges and universities, and other alternative educational settings)
10. Study involves youth under age 18
11. Study exceeds minimal risk
12. Study involve quasi-vulnerable populations (e.g., Undocumented immigrants, non-English speaking subjects, subjects with physical limitations, subjects with disability status).
13. High risk for breach of confidentiality (e.g., multiple copies of data stored in more than one medium [electronic, hard copy]; data accessed by multiple people) Sensitive data (electronic, hard copy, student records, HIPPA
14. Protocols in which Principal Investigators (PIs) are required to use a data protection plan, confidentiality agreement or the equivalent
15. The study has been amended multiple times (3 or more).
16. The study involves researchers outside Pepperdine University community.
17. The study involves faculty members and multiple research assistants (3 or more).
18. The study is a multi-site study.
19. The study is part of a cooperative agreement.
20. Study involves animals and deemed higher risk by IRB reviewers with expertise in animal research

How Principal Investigators Are Notified

The AHSRC sends a Letter of Intent to Review via email to the Principal Investigator (PI) of the selected protocol, along with a description of the review proceedings, a copy of the *AHSRC Overview of Procedures*, the *AHSRC Review Process Flow*, an invitation to submit

preferred dates and locations for the Opening Meeting, materials to prepare for the review, and requests that the PI complete and return the attached *Internal Review Study Personnel Questionnaire* along with preferred dates for the review meeting within 14 days.

Prior to the review, the Principal Investigator and study team will be required to prepare the following items, along with other additional items that may be requested in the materials to prepare for the review list:

1. Compile all records for each of the studies subjects including contact information
2. Compile all Signed Consent Forms
3. Provide a copy of all material provided to subjects including but not limited: recruitment forms, follow-up emails, etc.

What does AHSRC review?
AHSRC will require full access to all source documentation, all subject information (such as Case Report Forms, electronic or paper and screening logs), personnel certification records (such as IRB certification, clinical certification, and Occupational and Environmental Safety Office certification), regulatory documentation and site activity areas (such as file storage, drug/device storage, subject examination areas). The reviewer will determine whether the requested subject information is available and will then assess the following protocol elements:

1. Protocol specific regulatory binder and IRB documentation
2. Review of the contract or grant for consistency with practice
3. Case Report Forms
4. Signed Informed Consents (AHSRC will review a minimum of 20% of the consents)
5. Research article accountability and storage
6. Record retention and storage (including hard copy storage systems and electronic systems/databases)
7. Overall data quality

The Opening Meeting
The AHSRC reviewers will prepare for the Opening Meeting by reviewing all documentation in IRB and becoming extremely familiar with the requirements of the protocol. This extensive review can generate questions and the Opening Meeting is an opportunity for those questions to be answered prior to beginning the on-site portion of the review. The Opening Meeting is also an opportunity for the study team to meet with the assigned reviewer and answer any questions that the study team may have about the review. A typical Opening Meeting should take no more than 45 minutes. The meeting should be attended by the PI and study coordinator and these individuals may invite anyone else they feel would benefit from meeting the reviewer.

On-site Review
The on-site portion of the human subjects audit will take between 1 to 3 days, and generally involve only one reviewer unless there are a large number of subject and/ or consents to be reviewed or there is a new individual training in AHSRC human subjects

reviews. Occasionally AHSRC will also be accompanied by someone wanting to learn about our process by way of shadowing a review.

During the audit, the AHSRC Reviewer will compare the research files to the protocol document and submitted forms to verify compliance and accurate data collection. Throughout the audit, the PI and the study team will be given the option to be available to assist the Reviewer as needed. The Auditor completes the Quality Assurance form to verify accurate consent has been obtained, that data collection and protection procedures have been followed, and assess the overall degree of protocol compliance. The Auditor may additionally interview the PI and members of the study team. Any additional materials requested during the On-site Review needs to be returned to the AHSRC within five business days.

Draft Closing Summary
The Reviewer will draft the Closing Summary within 14 days of the final on-site review date. The Closing Summary report may include some or all of the following information: the dates of the audit, institutional sites, study team members, AHSRC review findings, a detailed list of major and minor violations, pending questions and requests for additional materials for review, request for corrective action, and recommendations.

Closing Meeting (if needed)
The Closing Meeting will be scheduled between two to three weeks following the final on-site review date if there are some additional items needing clarification or recommended action steps. The PI and study coordinator must attend the Closing Meeting. Any additional attendees are at the discretion of the study team. At the closing meeting the reviewer(s) will present the Draft Closing Summary of the noted observations. This is a working meeting and is a time to clarify issues and discuss the observations prior to the final compliance review summary being issued. After the Closing Meeting, the study team has 5 business days to clarify any human subject issues with the reviewer prior to the final summary being issued.

Final Compliance Review Summary
The Final Compliance Review Summary will be issued by email within 14 days of the Closing Meeting or within 21 days of the On-site review if no closing meeting is required. As a part of the review, the PI will receive a Final Compliance Review Summary for the human subject portion of the study. The summaries will contain observations and action plans that will need to be completed within the required time frame, usually 25-30 business days. The PI may also receive a Recommendations List which may contain items the AHSRC reviewer feels would benefit the study team going forward as best practices.
The Final Compliance Review Summary is distributed to the PI, study coordinator and the following institutional officials: Vice Provost of Research and Strategic Initiatives; GPS IRB Chair, Seaver IRB Chair, IRB Manager/Director, Associate Officer, Human Subject Research Compliance; and Deans and Associate Deans of the relevant school from which the protocol was generated.

Observations include but are not limited to the following types of issues:

1. Violation of federal or state law or regulation that could lead to a government enforcement action, penalty, exclusion action or debarment
2. Violation of good clinical practices
3. Violations of the Common Rule
4. Violation of institutional policies or procedures
5. Any observation warranting a deviation report to IRB. These deviations are evaluated by the IRB for an independent determination of whether it constitutes serious or continuing noncompliance Unintended problem for subject or others that should be reported to IRB to determine if it should be reported as potential Unintended Problem Involving Research Subjects or Others
6. Subject eligibility issues (inclusion/ exclusion / waiver from sponsor/ IRB)
7. Substantive consent issues (wrong version of ICF if difference is material, unauthorized consenters)
8. Any indicia of subject coercion
9. Any indicia of falsification/ fabrication or plagiarism (referred over to Research Integrity Office for investigation)
10. HIPAA breaches or lack of HIPAA Authorization, lack of appropriate waivers, transmission of PHI unencrypted. Violations of HIPAA Privacy or Security rule
11. Broken blinds
12. Research prior to consent
13. Material discrepancies in research records (dates not matching in various documents, subject and consenter not signing on same day, etc.
14. Failure to fulfill corrective actions from AHSRC Reviewer
15. Minor observations that are significant in number

The most common findings are:
1. Protocol deviations that need to be filed
2. Informed consent /consent process issues
3. HIPAA violations
4. Missing data
5. Protocol not being followed as written/IRB approved
6. Subject eligibility (inclusion/ exclusion criteria
7. Missing original consent forms

PI's Formal Response

The PI may be requested to respond in writing to the Research Auditor regarding the overall findings of the audit using the criteria specified below. No formal written response will be required if the audit of the protocol is deemed as "Exceptional" (evidence of superior source documentation) or "Satisfactory" (few minor deviations noted). However, a formal written response by the PI is required if the audited protocol is evaluated as "Acceptable," "Needs follow-up", or "Unacceptable". If a formal written response is required of the PI, a maximum of thirty business days will be allotted unless a request for an extension is made in writing and approved by AHSRC on a case-by-case basis.

Length of Time Before Another Routine Review

If a study is selected for a routine review it will be a minimum of two years before that protocol would be selected for another routine review. However, a directed review can occur at any time and may cover multiple protocols belonging to the same PI.
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