Stratton VA Medical Center
IRB Standard Operating Procedure: Research Related Complaints, Allegations of Non-Compliance & Allegations of Undue Influence on the IRB

POLICY

The goal of this policy is to provide a reporting mechanism for research related complaints, allegations of non-compliance, and allegations of undue influence on the IRB, and to ensure compliance with VAMC policies and procedures and applicable federal and state laws, regulations, and guidance.

PURPOSE

This policy describes the processes available for receiving, responding to, and reporting research related complaints, allegations of non-compliance and allegations of undue influence on the IRB.

RESPONSIBILITIES

Institutional Official: The Institutional Official is responsible for the overall assurance of protections for human participants and the independence of the IRB from undue influence within the VAMC.

Associate Chief of Staff/R&D (ACOS/R&D): The ACOS/R&D is responsible for the implementation, conceptual oversight, and administrative leadership with regard to ensuring compliance and quality improvement for the HRPP.

Research Compliance Officer (RCO): The RCO is responsible for the day-to-day monitoring of the HRPP, including the ongoing Quality Improvement activities, the implementation of needed improvements, and the follow-up of corrective actions. The RCO also is responsible for the review and evaluation of reports, audits, compliance assessments, and quality improvement activities as related to human research protections.

Administrative Officer/R&D (AO/R&D): The AO/R&D is responsible for the organizational support and deployment of resources that are required to maintain compliance with HRPP activities, including compliance audits.

Institutional Review Board (IRB): The IRB is responsible for reviewing the reports of the RCO and making a determination of serious or continuing non-compliance. The IRB develops a corrective plan of action for the involved investigator(s) and/or research staff.

IRB staff and IRB members are responsible for reporting allegations of undue influence on IRB actions or processes.

DEFINITIONS

- Non-compliance is the failure to follow the federal regulations or VA guidance or the requirements and determinations of the IRB.
- Serious non-compliance is non-compliance that adversely affects the rights and welfare of participants or places participants at increased risk of harm
- Continuing non-compliance is a pattern of non-compliance that indicates an unwillingness to comply or a lack of knowledge that may lead to an adverse effect on the rights and welfare of participants or may place participants at an increased risk of harm,. Examples of continuing non-compliance include: repeated instances of allowing a study to expire before it is re-approved; repeated failure to respond to Stratton VAMC Research Office inquiries or requests for documentation; repeated failure to respond to and resolve any study contingencies.

PROCEDURES

PROCEDURES FOR REPORTING AND RESPONDING TO ALLEGATIONS OF NON-COMPLIANCE WITH HRPP REQUIREMENTS: Any allegation of noncompliance which arises will receive responsive examination as follows:

Any employee of the Stratton VA Medical Center, research investigator or member of a research team (including Without Compensation Employees) who becomes aware of an incident(s) of non-compliance of HRPP regulations, requirements, or determinations is required to provide a prompt report to the RCO or to other senior institutional officials (i.e., ACOS/R&D, Chief of Staff, Patient Advocate, Hospital Director) at the VAMC. In addition, participants in human research studies, their designated representatives, or members of their community are also encouraged to report any activities or behaviors that they believe may be non-compliant or inappropriate. The RCO will be responsible for providing immediate notification to the ACOS/R&D and the IRB Chair.

The research informed consent form provides the subject with the telephone number of the Patient Advocate in addition to the Research Office (ACOS/R, IRB Chair) and the Principal Investigator. The Investigator or research staff will respond to participant complaints or requests for information. The Patient Advocate identifies the ACOS/R, AO and the RCO as the Point-of-Service contacts for patient complaints and allegations of non-compliance.

All complaints or allegations of non-compliance pertaining to the HRPP will receive a prompt response, and the person submitting the complaint or allegation will receive appropriate feedback.

Initial Investigation and Action: The ACOS/R&D, the Chair of the IRB, the Chair of R&D or the RCO will obtain as much information as possible from the individual reporting the event. If the incident can not be resolved immediately, a meeting will be arranged by the ACOS/R&D. The attendees will be determined by the ACOS/R&D and is

dependent on the circumstances and severity of the complaint or allegation of non-compliance. The process will include:

i. Description of the incident and the facts presented to date.

ii. List of attendees required for the meeting, to be held within 72 hours of the report, whenever feasible.

The IRB chair will review all complaints and allegations and determine the need for full IRB Committee review. A primary reviewer system is not used. The documents that will be distributed to the Chair and the IRB members may include: a summary of the incident, a copy of the protocol for the relevant study or any data or information gathered during the investigation of the incident. If the complaint or allegation goes to the full IRB committee, then the convened IRB will review the report to determine if the facts substantiate the allegation of serious or continuing non-compliance, or whether there was an unanticipated problem involving risks to participants or others.

If an allegation of non-compliance is substantiated, but the facts do not support a finding of serious or continuing non-compliance or unanticipated problems involving risks to participants or others, the IRB will take corrective actions as required to remedy the non-compliance. If required remedial actions for non-compliance with the HRPP will take into consideration the rights and welfare of current research participants. Relatively minor or one-time non-compliance that does not pose an immediate risk to human participants will be promptly addressed through local administrative mechanisms.

If more than minor modifications to previously reviewed research id made in response to serious or continuing non-compliance, they will be reviewed by the convened IRB.

If the facts support a finding of serious or continuing non-compliance or unanticipated problems involving risks to participants or others, the IRB will take corrective actions which may include:

- Temporary suspension of the protocol
- Termination of the protocol
- Restrictions on privileges to conduct research
- Disciplinary actions against perpetrators of violations
- Modification of the protocol
- Modification of the information disclosed during the consent process
- Providing additional information to past participants
- Notification of current participants when such information may relate to participants' willingness to continue to take part in the research
- Requiring current participants to re-consent to participation
- Modification of the continuing review schedule
- Monitoring of the research
- Monitoring of the consent process

IRB decisions to suspend or terminate research, substantiated allegations of serious or continuing non-compliance, or findings of unanticipated problems involving risks to subjects or others will be reported to the appropriate authorities per VHA Handbook

1058.01, VHA Memorandum "What to Report to the Office of Research Oversight" dated September 8, 2005 and other appropriate agencies such as OHRP (if the study is subject to DHHS regulations) and the FDA (if the study is subject to FDA regulations).

In the event that the incident appears to be isolated and of a non-serious and non-continuing nature or was not an unanticipated problem that involved risks to participant or others, it will be handled internally by the convened IRB.

The responsible investigator(s) and appropriate department heads and agencies are notified of the decision by the ACOS/R&D. Correspondence will be sent to the complainant by the ACOS/R&D acknowledging receipt of the complaint or allegation of non-compliance and indicating that the issue is being investigated.

The Institutional Official is notified immediately after these initial decisions are made. Institutional Officials will determine whether an administrative investigation is required in cases of possible research misconduct. VHA Handbook 1058.2 entitled "Research Misconduct" establishes the procedures and requirements for handling allegations of research misconduct in Department of Veterans Affairs (VA) research.

Institutional Review Board (IRB) Review Process: The convened IRB is notified of the incidents and action taken at the next scheduled meeting.

The IRB will determine if outstanding issues exist and what actions should be taken. The IRB will determine if any further action should be taken such as protocol suspension, placing hold on accrual, or no action. Such action must take into consideration any potential effects on current research subjects' safety and well-being. Any suspensions or closures of approved studies shall include a statement of reasons for the IRB's action. A vote to continue, to suspend, or terminate approval will be reported immediately to the investigator(s), Institutional Officials, ORO, OHRP, the FDA if the research is regulated by the FDA and to sponsor(s) and other applicable agencies. All communications will be documented in the IRB minutes.

PROCEDURES FOR REPORTING AND RESPONDING TO ALLEGATIONS OF UNDUE INFLUENCE ON IRB

Any employee of the Stratton VA Medical Center, research investigator or member of the IRB (including Without Compensation Employees) who becomes aware of an allegation of undue influence or perceives himself or herself subject to undue influence regarding IRB policies and/or procedures must report the incident(s) immediately. The report should be made to the RCO or to other senior institutional officials (i.e., ACOS/R&D, Chief of Staff, Patient Advocate, or Hospital Director) If the allegation involves ACOS R &D or the RCO, then the Chief of Staff or Director should be notified. If the Chief of Staff or Director is involved, the report should be made immediately to the VISN 2 Network Compliance officer. If the allegation involves network level staff, the report must be made to the Regional Office of Research Oversight (ORO).

All allegations of undue influence on IRB staff or members will receive a prompt response, and there will be notification of the response activity to the reporter.

Investigations of allegations of undue influence will be initiated by the ACOS R & D or official to whom it is originally reported or an appropriate (same or greater administrative responsibility) designee.

Investigations will be initiated by fact finding, including interviews as needed with reporter(s) and the individual(s) about whom the allegation is made

Reporters shall be held anonymous.

After fact finding a report will be made to the Institutional Official (director) or the Network Compliance officer.

Findings shall be: undue influence exerted or attempted or no undue influence exerted or attempted.

If there is a finding of undue influence exerted or attempted, a report shall be made to the IRB Chair, R&D Chair and the RCO. Actions to be taken against the individual(s) found to have attempted or exerted undue influence will be determined by a committee composed of the IRB Chair, R & D Chair, ACOS/R&D and the Director. If one of the individuals so tasked is named in the allegations, he or she will be excluded from the considerations. Actions against the individual will be determined based on the level of undue influence based on considerations of patient risk, privacy and other issues appropriate to IRB considerations.

REPORTING REQUIREMENTS PROCEDURES

HRPP coordinator and/or RCO in consultation with the IRB Chair prepares a letter that contains the following information:

- The nature of the event
- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator on the project
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (i.e., grant, contract, or cooperative agreement)
- A detailed description of the problem including the findings of the IRB and the reasons for the IRB decision
- Actions the institution is taking or plans to take to address the problem (e.g., suspend subject enrollment, terminate the research, revise the protocol and/or informed consent, inform enrolled subjects, increase monitoring, etc.)
- Plans, if any, to send a follow-up or final report.

The IRB Chair and IO review the letter and modify as needed. The final letter is signed by the IO and returned to the HRPP Coordinator for distribution and follow up.

The HRPP Coordinator and/or RCO, or designee, sends copies of the letter to the following as appropriate:

- The Chair of the R&D Committee

- The IRB, by including the letter in the next agenda packet as an information item
- The VISN Director
- Office of Research and Development
- The Regional VA Office of Research Oversight
- FDA, if the study is subject to FDA regulations
- OHRP, if the study is subject to DHHS regulations
- Principal investigator
- Sponsor, if the study is sponsored
- Contract research organization (CRO), if the study is overseen by a CRO
- The VA Privacy Officer if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information
- The VHA Information Security Officer if the event involved violations of information security requirements