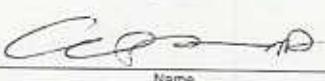
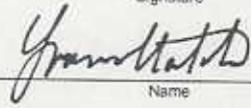


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: IRB Membership and Management		DOCUMENT NUMBER: IRB-012	
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: <i>March 4, 2004</i>	PAGE 1 OF 5

IRB CHAIR OR DESIGNEE: <small>Signature</small>	ACOS R&D: <small>Signature</small>	COMPLIANCE: <small>Signature</small>
		
<small>Name</small> <i>Erica Fishman</i>	<small>Name</small> <i>Donald Pasquale</i>	<small>Name</small> <i>Yvonne Natale</i>
<small>Date</small> <i>2/27/04</i>	<small>Date</small> <i>3/1/04</i>	<small>Date</small> <i>3/4/04</i>

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state and federal regulations in the conduct of clinical research studies. Written procedures are required to detail the membership and management of the IRB for review of research.

2 FORMS

Not Applicable

3 PROCEDURE

- 3.1 All CV's of potential IRB Chairs, Vice-Chairs, or members are reviewed by the ACOS R&D to ascertain the background and qualifications of the potential member.
- 3.2 The Medical Center Director appoints the Chair and Vice-Chair of the IRB in writing.
 - 3.2.1 The appointments are for one year and may be re-appointed indefinitely in writing.
- 3.3 The Medical Center Director appoints IRB members in writing.
 - 3.3.1 Recommendations for IRB membership are made by IRB members and R&D Committee members according to the needs of the IRB. Members are selected based on background, qualifications, and the diverse needs of the IRB. Potential conflicts of interest are taken into consideration in the selection of new members.
 - 3.3.2 Other VA personnel may submit names to the IRB or R&D Committee to be forwarded to the Medical Center Director for consideration.

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- 3.3.3 Members of the VA IRB must be appointed by the Medical Center Director for a period of 3 years, and may be re-appointed indefinitely. Members may resign from the IRB at any time.
- 3.3.4 VA representatives to affiliate IRBs must be appointed by the Medical Center Director for a period of 3 years, and may be re-appointed indefinitely. Members may resign from the IRB at any time.
 - 3.3.4.1 Two or more VA employees must serve as voting members of the affiliate IRB that reviews VA research.
 - 3.3.4.2 At least one of these members must have scientific expertise.
 - 3.3.4.3 VA members must serve as full members of the IRB, which includes the review of non-VA research.
 - 3.3.4.4 At least one of these members must be present during the review of VA research.
- 3.3.5 IRB members are voting or non-voting members.
 - 3.3.5.1 The ACOS R&D, AO for R&D, and the Research Compliance Officer serve as ex-officio non-voting members of the IRB. R&D administration officials may not serve as voting members of the IRB.
 - 3.3.5.2 All other members are voting members.
- 3.4 The Medical Center Director appoints IRB members to ensure that:
 - 3.4.1 The IRB has at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
 - 3.4.2 The members of the IRB are qualified through expertise and diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, and promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.
 - 3.4.3 The IRB includes persons with the professional competence necessary to review research activities regularly reviewed by the IRB.

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- 3.4.4 The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice so as to be able to ascertain the acceptability of proposed research in terms of these issues.
- 3.4.5 The IRB includes one or more individuals who are knowledgeable about and experienced in working with categories of vulnerable subjects involved in research regularly reviewed by the IRB. Vulnerable categories of subjects may include children, prisoners, pregnant women, or handicapped or mentally disabled persons.
- 3.4.6 In a non-discriminatory manner, the IRB does not consist entirely of men or entirely of women, or consist entirely of individuals from one profession. No member will be selected to serve on the IRB merely on the basis of gender.
- 3.4.7 The IRB includes at least one member whose primary expertise is in scientific areas, and one member whose primary expertise is in non-scientific areas.
- 3.4.8 The IRB includes at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- 3.4.9 The IRB cannot have a member participate in the review of research in which the member has a Conflict of Interest, except to provide information requested by the IRB.
- 3.5 The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to that available on the IRB.
- 3.5.1 Consultants are not considered IRB members and do not vote.
- 3.5.2 Any IRB member may request a consultant by making a verbal or written request to the IRB Chair or designee.
- 3.6 IRB members review proposed research at convened meetings at which a majority of the voting members of the IRB are present, including at least one voting member whose primary expertise is in nonscientific areas.
- 3.6.1 In order for research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

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- 3.6.2 Conference calls or video-conference procedures may be used at a convened meeting, if a member has received copies of the documents that are to be reviewed at the meeting. The member may vote and be considered as part of the quorum.
- 3.6.3 IRB members may not participate in the review of any research in which the member has a conflict of interest, except to provide information requested by the IRB. The research will not be voted upon should quorum be lost due to the absence of the member(s) with a conflict of interest.
- 3.6.4 IRB members with a conflict of interest in the research are expected to declare the reasons for the conflict to the IRB.
- 3.6.5 The IRB may consider the comments of members who cannot attend the convened meeting. Absent members are not considered in the quorum or voting of IRB meetings.
- 3.7 The Stratton VA may use alternate members for the IRB.
 - 3.7.1 The Medical Center Director appoints alternate IRB members in writing.
 - 3.7.1.1 The term of appointment is the same as the term of the primary member.
 - 3.7.2 The IRB roster will identify the primary IRB member for whom the alternate member may substitute.
 - 3.7.3 The alternate member's qualifications must be comparable to those of the primary member to be replaced.
 - 3.7.4 When an alternate member replaces the primary member at a convened meeting, the primary member must assure the alternate member receives and reviews the meeting materials in advance of the meeting.
 - 3.7.4.1 The alternate member has the same privileges as the primary member, i.e. reviews and votes on protocols at a convened IRB meeting.
 - 3.7.5 The alternate member should receive the same IRB training as primary members.
 - 3.7.6 The alternate should attend as many IRB meetings as possible, even when not required to be present as a formal alternate.

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- 3.7.7 The alternate member is allowed to replace the primary member 3 times per year.
- 3.7.8 The IRB meeting may not be conducted if alternates constitute the majority of the members present.
- 3.7.9 The IRB minutes must document when an alternate member replaces a primary member.
- 3.8 All IRB members are required to attend at least 6 out of 12 IRB meetings per calendar year, with the exception of those members covered under a Memorandum of Understanding (MOU).
- 3.9 In the absence of the Chair, the Vice-Chair or designee is the acting Chair.
- 3.10 The Stratton VA liability Federal Tort Claims Act (FTCA) covers authorized actions of IRB members taken in their official capacity as IRB members.
- 3.11 The IRB staff maintains a file of the current curricula vitae of IRB members.
- 3.12 Any change in IRB membership is reported to Office of Human Research Protections (OHRP) and the Office of Research Oversight (ORO) by the Research Office.
- 3.13 The Medical Center Director, at his or her discretion, may remove IRB members, the Chair or Vice-Chair for cause only after an administrative investigation or other disciplinary action is completed.
- 3.14 A list of scheduled IRB meetings and the membership roster is available on the P drive (IRB folder).