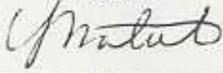


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: IRB Review of Research		DOCUMENT NUMBER: IRB-016	
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IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature 	Signature 	Signature 
Name Fishman	Name Donald Pasqualetti	Name Yvonne N. Tate
Date 4/20/04	Date 4-6-04	Date 4/8/04

1 POLICY

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

2 FORMS

None

3 PROCEDURE

- 3.1 The IRB will review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the Stratton VA Medical Center OHRP Federal Wide Assurance (FWA #00002073).
- 3.2 The IRB will require that information given to subjects as part of informed consent is in accordance with "Informed Consent, IRB - 010". The IRB may require that information, in addition to that specifically mentioned in "Informed Consent, IRB - 010" be given to the subjects when in the IRB's judgment the information would add to the protection of the rights and welfare of subjects.
- 3.3 The IRB will require documentation of informed consent or may waive documentation in accordance with "Informed Consent, IRB - 010".
- 3.4 The IRB will notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity as per "Initial Review of Research, IRB - 001", "Continuing Review of Research, IRB - 002", and "Revisions to Previously Approved Research, IRB - 006". If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond as per "Initial Review of Research, IRB - 001", "Continuing Review of Research, IRB - 002", and "Revisions to Previously Approved Research, IRB - 006".

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- 3.5 The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and will have authority to observe or have a third party observe the consent process and the research.
- 3.6 The IRB will monitor changes in VA and other Federal regulations and policies that relate to Human Research Protections.
- 3.7 Research is considered exempt from the regulations if:
- 3.7.1 The research does not involve the use of an FDA regulated test article; and
- 3.7.2 The only involvement of human subjects will be in one or more of the following categories:
- 3.7.2.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
- 3.7.2.1.1 Research on regular and special education instructional strategies, or
- 3.7.2.1.2 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 3.7.2.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
- 3.7.2.2.1 Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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- 3.7.2.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous section, if:
- 3.7.2.3.1 The human subjects are elected or appointed public officials or candidates for public office; or
 - 3.7.2.3.2 Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 3.7.2.4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 3.7.2.5 Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- 3.7.2.5.1 Public benefit or service programs;
 - 3.7.2.5.2 Procedures for obtaining benefits or services under those programs;
 - 3.7.2.5.3 Possible changes in or alternatives to those programs or procedures; or
 - 3.7.2.5.4 Possible changes in methods or levels of payment for benefits or services under those programs.
- 3.7.2.6 Taste and food quality evaluation and consumer acceptance studies:
- 3.7.2.6.1 If wholesome foods without additives are consumed; or

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3.7.2.6.2

If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- 3.8 An IRB may use the Expedited Review procedure to review either or both of the following:
- 3.8.1 Some or all of the research published in the Federal Register, 63 FR 60364-60367 "Protection of Human Subjects: Categories of Research That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited" (dated November 9, 1998), and found by the IRB Chair or designee to involve no more than minimal risk and/or
 - 3.8.2 Minor changes in previously approved research during the period (of 365 days or less) for which approval is authorized.
- 3.9 In order to approve research the IRB will determine that the research is exempt from the regulations or that all of the following requirements are satisfied:
- 3.9.1 Risks to subjects are minimized:
 - 3.9.1.1 By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - 3.9.1.2 Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - 3.9.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
 - 3.9.2.1 In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.)

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- 3.9.2.2 The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- 3.9.3 Selection of subjects is equitable. In making this assessment the IRB should take into account the purpose of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable subjects.
- 3.9.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, "Informed Consent, IRB – 010."
- 3.9.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by, "Informed Consent, IRB – 010."
- 3.9.6 When appropriate, the research plan will make adequate provisions for monitoring the data collected to ensure the safety of subjects.
- 3.9.7 When appropriate, there will be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 3.9.8 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, the research includes additional safeguards to protect the rights and welfare of these subjects.
- 3.9.8.1 If the research involves adults who do not have the capacity to consent for themselves, the IRB will also follow "Research Involving Adults who Lack Capacity to Provide Informed Consent, IRB –005."
- 3.9.9 The amount and method of payment to subjects neither presents problems of coercion or undue influence on the trial subjects. When appropriate, payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.
- 3.10 **Research Involving Investigational Devices:** When some or all of the research involves an investigational device, the research includes the following additional safeguards to protect the rights and welfare of the subjects:
- 3.10.1 The sponsor makes a determination that the device is either significant risk or non-significant risk.

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- 3.10.2 If the sponsor has an IDE number the device is automatically designated as a significant risk device. The IDE number will be documented in the minutes.

- 3.10.3 If the sponsor does not have an IDE number and determines that the device is non-significant risk, the IRB must determine that the device is non-significant risk and document that finding in the minutes to approve the research.
 - 3.10.3.1 The IRB will determine that a device is non-significant risk if there is no indication that the use of the proposed device:
 - 3.10.3.1.1 is intended as an implant.
 - 3.10.3.1.2 is used in supporting or sustaining human life.
 - 3.10.3.1.3 is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health.
 - 3.10.3.1.4 presents a potential for serious risk to the health, safety, or welfare of a subject.
 - 3.10.3.2 If the IRB determines that the device is significant risk, the IRB staff will notify the sponsor and investigator of the significant risk decision.

- 3.10.4 The Stratton VA Medical Center Pharmacy must have procedures in place for receipt, control, custody, and dispensing of investigational devices.

- 3.11 Nothing in this SOP is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.