Your Study Is Approved

NOW WHAT?
WHAT ARE MY RESPONSIBILITIES AS A PRINCIPAL INVESTIGATOR?

1. Agree to maintain current contact information, education, compliance related education/certification and applicable experience;

2. Accurately identifies research site and team members. Assures all Investigators and study personnel complete initial and continuing education in human research protections to remain up-to-date on Federal regulations, ETSU policies and procedures, and compliance expectations.

3. Adheres to Federal regulations, state and local laws, Institutional policies, IRB policies and procedures regarding the safety and protection of human participants and Good Clinical Practice (GCP) guidelines (if applicable to the type of research).

4. Adheres to all Federal and ETSU policies regarding the responsible conduct of research as presented at [http://www.etsu.edu/research/researchethics.htm](http://www.etsu.edu/research/researchethics.htm).

5. Ensure that the ETSU IRB and ETSU/VA IRB (registered and holding OHRP approved Federalwide Assurances (FWA) in compliance with the requirements of 45 CFR 46, 38 CFR 17, and 21 CFR Part 56) will be responsible for the initial and continuing review and approval of the research.

6. Reports adverse events and unanticipated problems involving risk to participants and others to the IRB according to IRB policies and procedures, sponsors and appropriate Federal agencies as required.

7. Assures continuing review applications are submitted in a timely manner so that their review occurs prior to their expiration date. The Investigator acknowledges that the Federal regulations do not allow a grace period. The Investigator is responsible for being aware of the current literature in his/her field of study to assure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven. The Investigator should build off previously conducted research to decrease the potential for participants to be needlessly placed at risk.

8. Acts as a liaison between the IRB and the sponsor.

9. Supervises the research process, ensuring that research is conducted in a manner which will minimize risks to subjects. Takes responsibility for assuring study personnel are properly trained, qualified and have appropriate facilities and resources to conduct the research. Agrees to ensure that all students, faculty, associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments. Assures adherence to the study protocol. Monitors the informed consent process. Communicates regularly and effectively with their research staff. Responsible for protection of the safety and welfare of research participants.
10. Oversees external performance sites, assuring adequate staff, resources, pharmacy practices and Federal assurances with appropriate IRB approvals.

11. Assures the IRB protocol is reflected in the grant proposal for extramural or intramural support, informs the IRB of any updates or modifications to the protocol prior to their implementation and in compliance with Federal and institutional regulations.

12. Assures proper performance of the informed consent process. Retains a copy of the signed and dated informed consent document in the study file and provides a copy to the research participant.

13. Promotes compliance and maintains documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants. Agrees to make those records available for inspection in accordance with 21 CFR 312.68.

14. Agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, to not make any changes in the research without written IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

15. Reviews and approves IRB applications, amendments and adverse events prior to their submission to the IRB, as documented by their signature on the IRB application. Submits applicable reports in a timely manner or according to published deadlines;

16. If applicable, read and understand the information in the investigator’s brochure, including the potential risks and side effects of the drug.

17. Assures participant privacy (relates to person) and confidentiality (relates to data) according to HIPAA guidelines, Institutional and IRB policies and procedures.

18. Agrees to conduct the study in accordance with the relevant, current protocol and to only make changes in a protocol after notifying the IRB, and if funded, the sponsor, except when necessary to protect the immediate safety of subjects.

19. Agrees to inform the OPHRS, VA R&D, the ETSU or ETSU/VA IRB (as appropriate) at the time of research site or records audits conducted by study sponsor, monitor or other internal, external or regulatory entity, whether announced or unannounced, for-cause or not for-cause. The initial notification (auditors on site) will be followed by a copy of the written audit findings forwarded by the auditing body to the PI, within 30 days of the PI receiving the report. The audit report must bear a stamped date indicating the receipt of the report at the local site. As available, a copy of the PI response, along with any corrective actions plans must additionally be forwarded.
20. Agrees to inform and identify to any subject, or any persons used as controls, those procedures or other interventions being used for research purposes and ensure that the requirements related to obtaining informed consent and IRB review and approval found in 45 CFR 46 are met.

21. Be responsive to IRB request for information

22. Notify IRB in writing of completed study (form 107)

Additionally, for studies with investigational drugs or devices,

23. (for investigational drug studies) Agree to inform any subject, patients, or any persons used as controls, that the drugs are being used for investigational purposes and ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met. Agree to protect the rights, safety and welfare of the participants under their care.

24. Administer the drug or device only to participants under their personal supervision or the supervision of a sub-investigator

25. Supply investigational drug or devices only to persons authorized to receive it under 21 CFR 312.61; 21 CFR 812.110

26. Maintain adequate records of the disposition of the drug, including dates, quantity and use by participants. Device records must include records of receipt, use or disposition of a device including the type and quantity of a device, the receipt date, the batch number or code mark, names of all persons who received, used, or disposed of each device, records of returns, repairs or disposals.

27. Return unused supplies of the drug to the sponsor or otherwise provide for disposition of the unused drug according to regulations at 21 CFR 312.59; 21 CFR 312.62; 21 CFR 812.110

28. Maintain adequate and accurate records recording all pertinent data including the obtaining of informed consent prior to study participation. Allow authorized persons to have access to, and copy and verify records or reports (21 CFR 312.62 and 21 CFR 812.145)

29. Maintain records to meet the standards of all applicable regulations, including federal guidance, institutional standards and sponsor requirements. FDA requires record retention for drug studies to be maintained for a period of 2 years following the date a marketing application is approved for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified (21 CFR 312.62). FDA requires record retention for device studies to be maintained for 2 years after the latter of the following two dates: termination of completion or when records are no
longer required (21 CFR 812.140). ETSU policy requires retention of records for five years after the study has been closed. Sponsor requirements may vary.

30. Furnish reports to the sponsor of the drug, including report shortly after completion of their participation

31. Promptly report to the sponsor any adverse effect that may reasonably be regarded as

32. Provide sponsor with accurate disclosure statements as required at 21 CFR 312.64; 21 CFR 812.110; 21 CFR 54.4(b)

33. Assure that an IRB meeting the requirements of part 56 is responsible for initial and continuing approvals

34. For investigational drug subject to the Controlled Substances Act, take all required security precautions

VA Investigators have additional responsibilities

Please see both IRB and VA policies for additional information
WHAT IS A CONTINUING REVIEW?

A Continuing review is a periodic IRB review of ongoing research activities to ensure that the rights and welfare of human subjects are protected. It includes analysis of risk/benefit ratio, with special attention to whether new information or unanticipated risks have been discovered since the previous IRB review, and whether any new information regarding the risks and benefits should be provided to participants.

HOW OFTEN MUST A CONTINUING REVIEW BE DONE?

The Department of Health and Human Services (DHHS), the Food and Drug Administration, East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center, under the DHHS Regulations, Title 45 Code of Federal Regulations Part 46 (45 CFR 46), require at 46.109(e), that “an IRB shall conduct continuing review covered by this policy at intervals appropriate to the degree of risk, but not less than once per year...” of all non-exempt projects involving human subjects. The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Affairs Institutional Review Board (ETSU/VA IRB) is to conduct continuing review of all research proposals at intervals appropriate to the degree of risk, but not less than once per year [21 CFR 56.108(a)(1), 56.109(f) and 45 CFR 46.109(e)].

WHAT TYPES OF STUDIES MUST UNDERGO CONTINUING REVIEW?

Only those studies previously approved determined to be an expedited or full study must undergo a continuing review. Studies that have been determined to meet exempt status do not undergo continuing review unless a change in the study renders it ineligible for exempt status per federal guidelines. Investigators are informed in the exempt status letter to inform the IRB of any change in the project prior to its implementation, and recategorization under expedited or full review would be determined at that time by the IRB Chair. Please note that a status of Closed to Accrual of New Subjects Still Requires Continuing Review.

WILL I BE NOTIFIED ABOUT THE CONTINUING REVIEW AND WHAT MUST I SUBMIT WHEN NOTIFIED?

As a courtesy, the IRB Coordinator will forward a letter to the Principal Investigator (PI) and his/her advisor named on question 4 of the Form 103 requesting submission of a completed Application for Continuing Review (Completed Form 107). The template letter will clearly state the protocol number, Study title, current approval date, the date of expiration of approval, scheduled meeting date, the version date of latest approved informed consent, and the deadline for submission of completed packet. It will also state what needs to be submitted to the IRB. The letter will be forwarded approximately 4 weeks prior to the submission deadline, which will be approximately 8 weeks prior to the project expiration deadline. The same procedure as an initial review is followed after the completed form 107 has been received. It is the responsibility of the PI to be aware of the expiration date of the study. As stated above, a completed form 107 must be submitted. If continuing the study, a
clean copy of the approved, stamped ICD or Letter to participants must also be submitted along with
any other appropriate documents, if any.

WHAT IS THE BASIS ON WHICH MY RESEARCH IS REVIEWED?

The same approval criteria used to review and approve the initial submission are used to review and
approve continuing reviews. Continuing review is substantive and meaningful, and of sufficient depth
and frequency to ensure the continued protection of the rights and welfare of research participants.

WHAT ARE OTHER FACTORS BEING REVIEWED DURING THE CONTINUING REVIEW?

- When conducting continuing review, the IRB is responsible for determining which studies need
  verification from sources other than the investigator that no material changes in the research have
  occurred since the previous IRB review [21 CFR 56.108(a)(2)]. The need for additional verification
  will be determined by the IRB on a case-by-case basis according to the following criteria. Source
  verification will be required when:
    o Investigator is providing inconsistent information that cannot be resolved
    o The IRB doubts the investigator's veracity
    o IRB doubts that the investigator has sufficient relevant knowledge
    o IRB perceives that investigator is intentionally not providing necessary information.

  If a reviewer determines the need for source verification for an expedited study, the continuing
  review must be referred to the full board.

  If the IRB determines that a need for source verification exists, the IRB may request an
  independent assessment. This scope and extent of this assessment will be determined by the IRB
  on a case-by-case basis. Sources for information could include site visits conducted by authorized
  personnel, literature searches, or a directed audit. The IRB has the authority to observe or have a
  third party observe the consent process and the research [45CFR46.109(e)].

- The IRB is also responsible for ensuring that changes in approved research are promptly reported
to, and approved by, the IRB [21 CFR 56.108(a)(3-4)]. Continuing review will include an IRB
determination of whether new information or unanticipated risks have been discovered since the
previous IRB review. Based on new information or unanticipated risk, the IRB has the authority to
reconsider its approval, require modifications to the study, and/or revise the continuing review
timetable. Any significant new findings which may relate to the subject's willingness to continue
participation should be provided to the subjects in accordance with 21 CFR 50.25.

- The IRB is also responsible for suspending or terminating approval of research that is not being
  conducted in accordance with the IRB's requirements [21 CFR 56.108(b)(2) and 56.113]. The IRB,
  by regulation, has not only the authority but also the responsibility for taking appropriate steps
  including termination or suspension of approval of research that is not being conducted in
  accordance with the IRB's requirements.
• Routine IRB continuing review will include IRB review of a written progress report from the principal investigator. The written progress report will consist of a summary of project activities that have occurred since previous IRB review, including the following information:
  
  o Enrollment update
  o Adverse events
  o Data and Safety Monitoring Reports
  o Any unanticipated problems involving risk to participants or others
  o Audits
  o Any protocol changes (amendments or modifications)
  o Any change in risk/benefit ratio
  o Any complaints received from participants
  o Any participant withdrawals and reasons for withdrawals
  o Any interim findings
  o Any progress reports
  o Any multi-center reports, if applicable
  o Any recent relevant literature
  o Any protocol violations and/or deviations
  o Any other relevant information, especially information about risk associated with the research

• IRB continuing review will also include evaluation of the informed consent document currently in use. The currently approved informed consent, as well as any proposed informed consent document, will be reviewed to determine if the information provided continues to be accurate and complete, and to determine if any new information needs to be added.

• The informed consent document will also be reviewed to ensure that any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with DHHS regulations at 45 CFR 46.116(b)(5). Review of the informed consent document will take place not only at continuing review, but at other times when new information becomes available that needs to be communicated to participants.

• Amendments or revisions to a research protocol may be submitted at the time of continuing review. A Request for Modification Form and all appropriate documentation, accompany the Continuing Review Application (IRB Form 107) upon its submission. The modification is not implemented by an Investigator prior to review and approval by the IRB. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 10 working days) on Form 109 (www.etsu.edu/irb).
WHAT HAPPENS IF I DO NOT RESPOND TO THE CONTINUATION LETTER?

If a completed form 107 is not received by the deadline stipulated on the letter, a warning letter will be mailed to the PI and his/her advisor requesting that a completed form 107 be submitted along with a deadline to submit this document. If the IRB Office does not receive the completed form 107, an Expiration letter is faxed and mailed the day before the study is due to expire. This expiration notice is sent to the PI and his/her advisor. If the completed form is not received by the deadline indicated on the Expiration letter, a determination of non-compliance will be made by the Chair and/or full IRB committee. Serious and/or continuing non-compliance will be reported to the appropriate officials and may prevent you from being able to do future research.

NOTE: If continuing review and re-approval fails to occur by the expiration date specified by the IRB, all research activities must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

DO I HAVE A GRACE PERIOD?

Per regulations, there is no grace period that allows the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. If any activity occurs or continues after the expiration date, the investigator is deemed to be out of compliance with both federal regulations and ETSU/VA policies.

If the study is approved pending requested changes, IRB approval is not given until the requested changes are received and approved. The approval period is not extended.

The IRB may restrict, require modifications, or terminate a research project based on continuing review by the IRB Committee. All studies in which the IRB requests changes to current documents are assigned a pending status.

If the IRB does not re-approve the research by the expiration date, the IRB approval expires. The PI, upon receipt of an expiration letter, must immediately submit to the Chair a list of participants that could be harmfully affected by the expiration of the research.

The IRB Chair, with appropriate consultation with (for VA) either the Chief of Staff (COS), or in his/her absence, the ACOS/R, or (for ETSU), the Vice Provost for Research (VPR), will determine if the subject(s) may continue in the research. If the ACOS/R or VPR is not a physician, they will designate a physician as a consultant. If the study is an FDA regulated study, the COS, ACOS/R or VPR and the IRB Chair will follow FDA requirements in 21 CFR56.108(b)(2) and (3) in making their decision. The sponsoring agency or private sponsor will additionally be informed. In addition, the IRB Coordinator faxes a copy of expiration letter pertaining to VA Studies to the VA Administrative Officer (AO) on the date the letter is mailed/faxed to the PI.
DO I HAVE TO WAIT FOR THE CONTINUING REVIEW LETTER TO CLOSE MY STUDY?

When your study has been completed, you should not have to wait until you receive the continuing review letter to notify the IRB Office of the completion. You must notify the IRB Office of the completion by submitting a completed Form 107 (Available on our website). No emails or memos will be accepted. If the office is not notified in a timely fashion, then your study will expire.
REPORTING CHANGES

WHAT IS A MODIFICATION?

A modification is a proposed change in a research activity during the period for which IRB approval has already been given. **A complete description of the modification must be received prior to review and approved by the IRB prior to implementation of that modification.** The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108(a)(4)]. In such a case, the IRB will be promptly informed of the change following its implementation (within 10 working days) and will review the change to determine that it is consistent with ensuring the subject’s continued welfare.

WHAT ARE EXAMPLES OF MODIFICATIONS THAT MUST BE REPORTED?

Modifications may include, but are not limited to,

- protocol amendments,
- changes in the number of subjects,
- changes in the informed consent, etc.

WHAT ARE THE PATH DETERMINATIONS THAT A CHAIR CAN MAKE?

Current regulations distinguish two categories in which a modification can be approved. Each category is determined based on the risk imposed by the change. The initial request as to whether a modification alters risks to the participants is made by the Principal Investigator. The modification is received by the Coordinator and presented to the Chair for his/her review. The Chair is responsible for evaluating the change in procedures and risks, and determining whether the modification can be approved through the expedited pathway or whether full board review is required.

Minor Modifications

If the proposed changes for previously approved research is classified as a minor modification, it may be reviewed and approved in an expedited manner by the IRB Chair or, in the case of the Chair’s absence or conflict of interest, his/her Designee. The designee should be one or more experienced reviewers designated by the chairperson from among the IRB membership.

Examples of Minor Modifications

Examples of minor modifications may include, but are not limited to, the following:

- Administrative changes, such as correction of typographical error(s)
- Revision of phone number(s)

Non-Minor Modifications

If the modification is determined to be non-minor, the Chair or his/her designee serves as a primary reviewer. The IRB Committee receives a synopsis of the primary reviewer’s findings at the convened meeting. The IRB must review and approve changes at a convened meeting* before changes can be
implemented when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)].

In such a case, the IRB must be promptly informed of the change following its implementation (within 10 working days) on Form 109 (www.etsu.edu/irb). (*meeting at which a majority of the members are present, including at least one member whose primary concerns are non-scientific).

At the Chair’s discretion, the Principal Investigator may be required to present the non-minor modification to the convened board.

**Examples of a Non-Minor Modifications**
Examples of non-minor modifications may include, but are not limited to, the following:

- Change in protocol procedures, such as increasing the number of times a test is performed or adding additional procedures
- Deletion or decrease in tests performed as part of safety evaluations
- The addition of serious unexpected adverse events or other significant risks to the ICD
- Changes, which, in the opinion of the IRB Chair or his/her Designee, do not meet the definition of a minor modification
- Any change that increases the risk of the study

**DO I HAVE TO SUBMIT MODIFICATIONS FOR STUDIES APPROVED AS EXEMPT?**

Any changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The IRB Chair will determine if the modification renders the study ineligible for continuing exempt status; and if so, the modification will not be approved. The investigator will be notified in writing that he may withdraw the modification request and continue the study as previously determined to qualify under exemption guidelines or submit the study for appropriate review and approval through an expedited or full board review.

**WHAT IS REQUIRED IF CHANGING THE PRINCIPAL INVESTIGATOR?**

In the case of a change in the principal investigator, if at all possible, the Modification Request should be signed by the investigator who holds the approval. The newly assigned investigator of a full review study however, must show proof of having obtained required education and submit a current CV for the purpose of assessment of qualifications. If the PI is unknown to the IRB, the PI must also attend a convened IRB meeting.

**WHAT HAPPENED IF CHANGES ARE MADE ON THE INFORMED CONSENT DOCUMENT?**

If the modification warrants changes to the informed consent document, the investigator must address whether the information needs to be communicated to currently or previously enrolled participants, and if so, how it will be communicated. This may be accomplished by using an addendum to the initial
ICD or by re-consenting the subject using the modified ICD. While the investigator is responsible for making the initial decision regarding any necessary document changes, the IRB will make the final determination. The IRB will also make the final determination of the necessity of re-consenting of currently enrolled participants or notification of participants who have completed research interventions.
REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRTSO)

WHAT IS AN UNANTICIPATED PROBLEM OR A UPIRTSO?

Unanticipated problems /events are those that are NOT already described as potential risks in the consent form, NOT listed in the Investigator Brochure, or NOT part of an underlying disease.

An Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) includes those events that:
1. are not expected given the nature of the research procedures and the subject population being studied
2. suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

WHAT IS THE REPORTING REQUIREMENT?

Federal regulations require the organization to ensure promptly reporting of “any unanticipated problems involving risk to subjects or others” to the IRB, regulatory agencies, and institutional officials. The ETSU/VA and ETSU IRB require investigators to promptly submit any problem or event that meets the following criteria to the IRB within 10 working days.

WHAT MUST I SUBMIT?

IRB policies require that you submit a completed Form 109 (unanticipated problem report) signed by the PI.

Note: VA reporting requirements require immediate reporting of the loss or theft of VA research data/information or portable media such as laptops, or personal computers (see IRB Policy 18 for more information)

WHAT MUST BE REPORTED WITHIN 10 WORKING DAYS?

Events to be reported include:

a. Any serious event, including on-site and off-site adverse events, injuries, side effects, deaths, or other problems, which in the opinion of the local PI, was unanticipated, involved risk to participants or others, and was possibly, probably or definitely related to the research.

b. Any accidental or unintentional change to the IRB-approved protocol that involves risks or has the potential to recur.

c. Any deviation from the protocol taken without IRB approval to eliminate apparent immediate hazard to a research participant.

d. Any publication in the literature, safety monitoring report, (including Data and Safety Monitoring Reports), interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
e. Any breach in confidentiality that may involve risk to the participant or others.

f. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff.

g. Any local death, whether anticipated or not.

h. Incarceration of a participant.

i. Any other possibly related event which in the opinion of the investigator constitutes an unanticipated risk.

j. Addition of a black box warning on any drug used in your research (for VA studies, this also includes VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to a VA research study.

k. Interruptions of subject enrollment or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

l. Any work-related injury to personnel involved in human research, or any research-related injury to any other person, requiring more than minor medical intervention or that leads to serious complication or death.

m. Any Data Monitoring Committee (DMC) report or any sponsor analysis describing a safety problem.

n. For VA studies, any local Serious Adverse Event (see definition).

o. For VA studies, any problem that involves or suggests risks to VA research subjects or anyone else in VA research.

Reports of off-site events occurring in studies that are completed and closed at the local site should be reported if the event meets the IRB definition as detailed above AND the local PI judges that this event may affect risk to participants who have completed the study.

All problems/events that do not meet these criteria should be reported to the IRB in summary form (table or spreadsheet) at the time of continuing review.

Follow-up reports of an off-site event may be submitted on a tracking log without an accompanying Form 109 if the following are true:

- the initial report of the event was submitted as a UPIRTSO on a Form 109
- the local PI has determined that the follow-up information does not contribute meaningful new information

**WHAT IS THE REPORTING REQUIREMENT FOR VA STUDIES?**

*VA Reporting of Loss or Theft of VA research data/information*

The loss or theft of VA research data/information or portable media such as laptops or personal computers must be immediately reported (as soon as it is discovered that there has been a loss) as follows:

1. Report the loss to security/police officers IMMEDIATELY. If within a VA health care facility, notify the VA police. If the loss or theft occurs while on travel or at another institution, notify
the security police officers at the institution (such as hotel security, university security, etc.) as well as the police in the jurisdiction where the event occurred.

2. Obtain the case number and the name and badge number of the investigating officer. If possible, a copy of the case report should be obtained.

3. Report the incident IMMEDIATELY to your immediate supervisor*
   - VA Privacy Officer at your facility *
   - VA Information Security Officer at your facility* ACOS at your facility*

4. Report the incident to the IRB using a Form 109 (Unanticipated Problem Involving Risks to Subjects or Others).

* The name and contact information should always be readily available. Wallet cards that list the contact name and number of the James H. Quillen VA ACOS, the VAMC Privacy Officer and the VAMC Information Security Officer are available through the VA R&D office and the IRB Office.
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