

HAC Policies and Procedures

Augusta VAMC Additional Information

The HAC serves as the Institutional Review Board (IRB) and the Privacy Board for the Augusta Veterans Affairs Medical Center. Due to current regulations, commercial IRBs may not be used. Investigators and research team members are responsible for meeting all requirements of the MCG and MCGHI as well as any additional requirements of the Augusta VAMC when conducting human subject research with or at the Augusta VAMC.

The Augusta VAMC has a separate FWA and list the HAC as their IRB of record. Note: All research that will be conducted with or at the Augusta VAMC, must receive HAC approval prior to the Augusta VAMC Research & Development (R&D) committee approval. No research may be initiated at the Augusta VAMC without these approvals.

What If I Want To Add The Augusta VAMC As A Performance Site After My Protocol Is Approved By The HAC?

Submit an amendment to your protocol to the HAC and submit the protocol to the R&D for review.

Does The HAC Stamp Each Page Of The ICD And/Or CAD With An Approval Stamp?

Yes. Each page of the ICD and/or CAD must display the HAC stamp of approval that indicates the approval and expiration dates of the study. This is for all sites (MCG, MCGHI and Augusta VAMC to include the VA Form 10-1086.)

The approval date is from the initial period of review. This will change as amendments are submitted and approved as well as at the time of continuing review.

Do All Augusta VAMC Investigators Have an MCG Appointment?

No. These are granted by MCG on an individual basis.

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Additional Responsibilities For Augusta VAMC Investigators

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Are There Additional Responsibilities For Augusta VAMC Investigators?

All Augusta VAMC employees conducting research on VA time, and/or with VA research subjects (either patients or staff), and/or using VA resources (e.g., equipment, space, dollars) must have their research reviewed and approved in writing by the Human Assurance Committee (HAC) and the Research and Development (R&D) Committee. VA employees must conform to the Standards of Ethical Conduct for Employees of the Executive Branch. These employees should refer to the Standards of Ethical Conduct for Employees of the Executive Branch with attention directed to 5 CFR 2635.801 et, seq., when performing outside activities which might not require the approval of HAC. These VA employees are encouraged to seek ethical guidance from the VA Office of Regional Counsel in determining whether research is an outside activity not requiring approval of HAC and to seek guidance on conflict of interest. All research that involves use of human subjects, regardless of where the research is conducted, must always have written IRB approval prior to conducting such research.

Each Veterans Affairs Medical Center (VAMC) investigator has a prime obligation to be personally certain that each subject is adequately informed and freely consents to participate in the investigator's research. In other words, the researcher has an obligation to fully discuss the research protocol, risks, benefits, etc., with the subject. Each investigator must personally assure that every reasonable precaution is taken to reduce to a minimum any risk to the subject. Compliance with all applicable required procedures provides evidence that the investigator is protecting the subject's rights and safety. Compliance, however, cannot replace conscientious practice, as discussed in the [Belmont Report](#) (1979).

A research subject must be competent to give informed consent. For incompetent subjects, a surrogate whose *primary* interest is the subject's welfare may give informed consent if conditions outlined in Augusta VAMC Policy Memorandum 509-07-24/05 are met. This policy states that the investigator will ensure the prospective subject, or the legally authorized representative, is given sufficient opportunity to consider whether or not to participate in the study.

What Is A Legally Authorized Representative for the VAMC?

A Legally Authorized Representative (LAR) is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involve in the research. In accordance with VHA Handbook 1200.5, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

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What Happens When Competency Is Unclear at the VAMC?

When the question of competency is unclear, competency is commonly judged by subjects evidencing a choice in regard to research participation, by factual understanding of issues, by rational manipulation of information, and by appreciation of the nature of the research project. If competency is an issue, it must be acknowledged in the research proposal and the procedures used to evaluate competency must be described in detail.

The subject or his/her legally authorized representative must sign a copy of the VA Form 10-1086 (VA Research Consent Form dated January 1990). Each page of the narrative Informed Consent Document (ICD) must be initialed and dated by the subject or his/her legally authorized representative. The investigator must provide the subject with a copy of the ICD. When the legally authorized representative signs the narrative ICD, the incompetent subject as well as the representative should be given a copy.

Consent should be limited to a legally authorized representative where the prospective participant is incompetent or has impaired decision-making capacity as determined and documented in the person's medical record in a signed and dated progress note.

If the determination has been made that a participant is incompetent or has an impaired decision-making capacity by a legal determination or by the practitioner consulting with the chief of service and appropriate medical evaluation indicates that the prospective participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.

Consultation with a psychiatrist or licensed psychologist has to be obtained if the determination that the prospective participant lacked decision-making capacity is based on a diagnosis of mental illness.

Can Augusta VAMC Research Subjects Be Paid?

VHA 1200.5 prohibits paying participants in research when the research is integrated with a patient's medical care and when it makes no special demands on the participant beyond those of usual medical care. PIs should limit paying VA participants to situations when one of the following is true:

- The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant is being treated, and when the standard of practice in affiliated non-VA institutions is to pay participants in this situation.
- The research is a multi-institutional study and participants at collaborating non-VA institutions are paid for the same participation in the same study at the same rate proposed.
- In the opinion of the HAC, payment of participants would be appropriate in other comparable situations.
- The participant will incur new transportation expenses that would not have been incurred in the normal course of receiving treatment and will not be reimbursed by another mechanism.

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Can Research Related to In Vitro Fertilization Be Conducted at the Augusta VAMC or by VA Investigators While on Official Duty?

Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities. In Vitro Fertilization in any fertilization of human ova, which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

Pregnant Women

Can Pregnant Women Participate In Research Conducted By VA Investigators While On Official Duty, Or At VA Facilities, Or At Approved Off-Site Facilities?

Federal regulations [45 CFR 46.207] stipulate that any research involving pregnant women in any manner must have specific approval for their participation. Research involving pregnant women at the Augusta VAMC cannot be approved by the HAC unless:

- The research includes adequate provisions to monitor the risks to the participant and the fetus.
- Adequate consideration is given to the manner in which prospective participants are going to be selected.
- Adequate provision is made to monitor the actual consent process by procedures such as:
 - Overseeing the process by which individual consents are secured either by:
 - Approving enrollment of each individual
 - Verifying, perhaps through sampling, that procedures for enrollment of individuals into the activity were followed
 - Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

Can Research Related to When the Subject is a Fetus, In-Utero or Ex-Utero (including human fetal tissue) In Vitro Fertilization Be Conducted at the Augusta VAMC or by VA Investigators While on Official Duty?

Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue) must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.

What about Research Involving Children?

Research involving children as participants cannot be approved unless:

- A waiver is granted by the Chief Research and Development Officer.
- The study presents no greater than minimal risk.
- The study meets all requirements of Subpart D of the DHHS or FDA regulations.

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- The Medical Center Director certifies that the facility is able to respond to pediatric emergencies.
- If a contractor or a non-VA employee conducts the research, the individual or entity performing the research has appropriate liability insurance.

What about Research-Related Injuries?

In the event of research-related injury, the VA has to provide necessary medical treatment to a participant injured by participation. The necessary care will be provided in VA medical facilities except:

- Situations where VA facilities are not capable of furnishing economical care.
- Situations where VA facilities are not capable of furnishing the care or services required.
- Situations involving a non-veteran participant.
- An explanation of the VA's authority to provide medical treatment to participants injured by participation in a VA research project.

Can Non-Veterans Be Entered into a Research Study at the Augusta VAMC?

Non-veterans can only be entered into a research study at the Augusta VAMC when there are insufficient veterans available to complete the study.

VA Form 10-1086 Research Informed Consent

For additional formatting and guidance, please see the Augusta VAMC Forms section.

As An Augusta VAMC Investigator, Am I Required To Use The VA Form 10-1086 As My Consent Document?

Yes. All VA Informed Consent Forms should utilize VA Form 10-1086, which has a distinct first page and a continuation page. Use as many continuation pages as necessary. NOTE: If the protocol will recruit subjects from the Augusta VAMC and MCG or MCGHI, then both informed consent documents should be used as applicable. For example, if the MCGHI study will recruit VAMC subjects, then both the MCGHI and VAMC informed consent documents must be used.

Does The Augusta VAMC Have Any Additional Formatting Requirements For The VA Form 10-1086?

- Text must be in compliance with current HAC Policies and Procedures as well as VAMC Policies and Procedures.
- Readability must be at the eighth grade reading level. Most word processing software allows a check for readability scale. HAC highly recommends giving the draft document to a non-medical person for their review. Often having another medical

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professional review the draft does not allow for true comprehension by a layperson.

- The Informed Consent Form (VA Form 10-1086) should be written following the guidelines on the VHA 1200.5 web site.
- If applicable, a copy of Investigational Drug VA Form 10-9012 must be placed in the patient's medical record. The subject's medical record will periodically be audited to make sure that the investigator is complying with the regulations set forth by the Department of Veterans Affairs.

Can A Subject Be Forced To Give Up Their Property Rights To Their Body Fluids, Substances Or Tissues?

No. If the investigator believes that body fluids, substances or tissues of a research subject could be part of or lead to the development of a commercially valuable product, the consent document should contain the language as specified for Augusta VAMC subjects.

Is There A Guide For Preparing The VA Form 10-1086 For The Augusta VAMC?

1. Formatting
 - a. Must use VA Form 10-1086.
 - b. Must state "Research Informed Consent Document"
 - c. Must have a bottom margin of at least 1.25" on each page (to allow adequate room for HAC approval stamp)
 - d. Do not use a font size smaller than 12 pt (Times New Roman or Arial is recommended). NOTE: If the primary subject pool is visually impaired, this size may be altered to accommodate their needs.
 - e. Version date of document must appear in lower left corner as follows: Version date: 10/01/1999. The Footer feature in most word processing software is useful for this item.
 - f. Study title (MUST be word for word identical to the title on protocol, investigator's brochure, [Form FDA 1572](#), all HAC forms and the Augusta Biomedical Research Corporation (ABRC) or Division of Sponsored Programs Administration (DSPA) paperwork).
 - g. Name of Principal Investigator (PI): State the PI's name here.
 - h. Name(s) of Sub-investigators (sub-I): State the name(s) of the Sub-I's here. NOTE: Only list those sub-I that are proposed to the HAC to obtain informed consent.
 - i. Name of Sponsor: State the name of the external sponsor here.
2. Invitation to Participate

Invitation to participate in the research study [45 CFR 46.116(a)]: "You are invited to participate in a research study of..."

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3. State why the subject was invited to participate [45 CFR 46.116(a)], e.g.:

“You are asked to participate because...”

4. State if the study drug or device is investigational.

“The study medication is an investigational medication” or “The study device is an investigational device”

5. Clearly explain in language understandable to the subject the study design of the research which [45 CFR 46.116(a)]. NOTE: Although the information is similar to the Description of Research Proposal, please do not simply cut and paste the information here as these two documents are for two different target audiences.

Use lay terms whenever possible, e.g.:

“This study is designed to . . . “

6. Give the approximate number of subjects involved in the study at the Augusta VAMC or other local locations, e.g.:

“You are one of _____ subjects to participate at VAMC”

If a multi-center study, indicate how many subjects overall will be enrolled, e.g. [45 CFR 46.116(a)]

“You are one of _____ subjects to participate in this study throughout the United States (US).”

7. Give a clear, concise description of the protocol to be followed, and procedures to be performed, **in language understandable to the subject**. [45 CFR 46.116(a)]

This section should explain exactly what the subject’s participation would involve, with particular attention to the way it will be experienced by the subject. The language should be clear about: the frequency and length of hospitalization, clinic follow-up, types of medications, questionnaires, videotapes, photographs, diets, withholding of standard treatment, types and numbers of tests, amount of exercise, stress to be experienced, amount of blood to be withdrawn (in lay terms, e.g. ounces, teaspoons, number of small tubes), amount of radiation to be received (similar to a chest x-ray, GI series, etc.), size of scar to be expected after biopsy, etc.

8. Indicate the duration of the subject’s participation, and be specific about the number of visits and how long each will take.

[45 CFR 46.116(a)] e.g.:

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“You will continue the treatment for ____ months or until _____, after which...” or

“Visit one will take approximately two hours while visit two will only take about 30 minutes.

9. Identify any procedures or devices, which are experimental, e.g.:

“...your catheterization must be done as part of the evaluation of your heart disease, and is not experimental. Several new measurements are performed during the heart catheterization and they are considered experimental. They involve...”

10. State whether a placebo(s) and/or randomization will be used, e.g.:

“In order to test the effectiveness of _____ you will be selected by lot (like the flip of a coin) to take either _____ or a placebo (inactive compound) which will look the same as the drug.”

11. If the study design is double-blind, state the following:

“Neither you nor your doctor will know which you are taking until after the study is complete, although this information will be available in an emergency.”

12. Study Payment

State whether the subject will be paid or not for participation or reimbursement of expenses, if applicable. If subjects will be paid or reimbursed, indicate how much and when. Indicate whether the payment or reimbursement will be prorated and paid at each visit or paid upon completion of the study. State if the subjects will be paid in cash or via check, e.g.:

“You will/will not (as appropriate) be paid for your participation in this project.”

“You will not receive any payment nor will you be required to pay any money for your participation in this research study.”

13. A veteran-participant will not be required to pay for care received as a participant in a VA research projects except in accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g) certain veterans are required to pay co-payments for medical care and services provided by the VA.

“If the VA determines as based upon their policy that you are supposed to pay a certain portion of the costs of the outpatient visits, you will be responsible for these payments.”

14. Compensation For Injury

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In the event of research-related injury, the VA has to provide necessary medical treatment to a participant injured by participation. The necessary care will be provided in VA medical facilities.

15. If there is a possibility of products of commercial value coming from the research, e.g., a cell line of commercial use, the following statement must be included:

“By your consent to participate in this research study, you give up any property rights you may have to your body fluids, tissues or substances.”

16. Authorization for Release of Protected Health Information for Research Purposes

"By signing this document, you authorize the Veterans Health Administration (VHA) to provide (insert name of Principal Investigator) and his or her research team to access the following information about you:

(Insert here a description of the data to be used, “in a specific and meaningful fashion.”)

If you do not sign this authorization, you may not participate in the study.

This authorization to use your information will expire at the end of the research study.

OR

This authorization has no expiration date.

OR

(Describe dates or circumstances under which the authorization will expire)

You can revoke this authorization at any time. To revoke your authorization, you can write to (insert name of Principal Investigator) or you can ask a member of the research team to give you a form to revoke the authorization. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient.

If you revoke this authorization, (insert name of Principal Investigator) and his or her research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

17. Insert the following if the study has a sponsor outside the VHA (i.e., pharmaceutical company):

“As part of the study, we may disclose your information to (insert name of sponsor), the sponsoring company for this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for

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the purposes related to the study. Any information shared with the sponsor may no longer be protected under federal law.

18. Insert the following if the study includes the creation of a database or tissue repository):

"This study includes the creation of a database of information or specimens such as blood, tissue, or other bodily fluids that will be used in future research. By signing this authorization, you agree to allow the information collected in this study to be added to that database."

19. Notice of Privacy Practices

"The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all of other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you."

20. Signature Block

"You have read this form that serves as an informed consent document and an authorization and have been given the opportunity to ask questions. If you have questions later, you can contact (insert contact person name). You will be given a signed copy of this document for your records. You authorize the use of your identifiable information as described in this form.

The risks and benefits to you if you participate in this study have been explained. You are encouraged to and will have the chance to ask questions and these questions will be answered. You voluntarily agree to participate and to authorize the use of your protected health information in this study."

Subject's Name (print)

Subject's Signature

Date

Legally Authorized Representative or Parent/Guardian's Name (print) *(if applicable only)*

Legally Authorized Representative or Parent/Guardian's Signature

Date

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Witness' name (print)

Signature of Witness

Date

to the informed consent process and the signature of the subject and/or subject's legally authorized representative or parent and/or legal guardian

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the subject's medical record source documents and/or research chart source documents, as applicable. A copy of this signed document will be placed in the subject's medical record and/or research chart, as applicable. A copy of this document will be given to the subject or the subject's legally authorized representative.

Printed name of investigator obtaining consent

Signature of investigator obtaining consent

Date

Does The Informed Consent Process Have To Occur At Each Visit Or Interaction for the Augusta VAMC Research Subjects?

Yes. Remember that the informed consent process should take place at each protocol visit to ensure that the subject is aware of the research and that they want to continue. This verbal confirmation of continuation of consent should be documented in the research chart and medical record.

How Do We Document That The Initial Informed Consent Was Obtained Prior To Participation In The Study for the Augusta VAMC Research Subjects?

All studies must include a statement in the case history or medical record if the subject is an Augusta VAMC patient that informed consent was obtained prior to participation in the study. The investigator must sign and date the statement. No screening procedures or answers to study specific questions may be obtained prior to the subject signing the informed consent document. The Joint Commission [TJC; previously known as The Joint Committee on Accreditation of Healthcare Organizations (JCAHO)] requires the information to be placed in the subject's chart or medical record also.

Are We Required To Notify the Augusta VAMC Research Subjects Of Any New Significant Findings During The Course Of The Study?

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Subjects must be informed of any significant new findings that develop during the course of the study, which may relate to their continued willingness to participate. This may require revisions to the VA Form 10-1086 and may also require re-consent of previously enrolled subjects.

NOTE: If a subject is unable to read or write, it must be documented on the informed consent document and in the medical record or visit note.

Documentation of the ongoing informed consent process must also be documented on the research notes.

Does The Investigator Keep A Signed Original VA Form 10-1086 In Their Site Records For the Augusta VAMC Research Subjects?

Yes. The investigator must also make a notation in the healthy subject's source document that informed consent was obtained prior to participation in the study. [21CFR 312.62(b)].

How Should We Document the Informed Consent Process for the Augusta VAMC Research Subjects?

Augusta VAMC VA Form 10-1086 (ICD) copies and distribution:

- A copy of the original signed VA Form 10-1086/ICD must be scanned into the subject's electronic medical record and attached to the informed consent progress note template in the Computerized Patient Record System (CPRS) and the standard operating procedure on the MCG OHRP website
- The original signed VA Form 10-1086/ICD must be kept in a secure location in the principal investigator's area
- The subject and/or subject's representative must be given a copy of the signed VA Form 10-1086/ICD

Are There Any Additional Forms Required for Recruiting or Enrolling Augusta VAMC Research Subjects if We Will Record and/or Use Their Image (Photograph or Video) or Record Their Voice?

Yes. VA Form 10-3203, Consent for Use of Picture and/or Voice, must also be completed, when applicable.

Are There Any Additional Forms Required for Recruiting or Enrolling Augusta VAMC Research Subjects if The Augusta VAMC Subject has a History of Alcoholism, Drug Abuse, Sickle Cell Anemia or Infection with HIV?

Yes. VA Form 10-5345, Subjects with a History of Alcoholism, Drug Abuse, Sickle Cell Anemias, Infection with HIV, must also be completed, when applicable.

What Is A Progress Report for the Augusta VAMC?

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At least once a year, the investigator will be responsible for furnishing a progress report to the Research and Development (R&D) Committee and the HAC. The [HAC Form 107](#), Clinical Study Status Report, must be completed and submitted to the HAC. However, the HAC Form 107 does not replace the R&D Progress Report. It is the investigator's responsibility to file these reports on time. If the study has not been approved for continuation by the approval expiration date, all activity must cease immediately. Subjects receiving research medication should be withdrawn in an orderly manner appropriate to the medication. Quarterly, the investigator must furnish to the VAMC Research Service a list of names and Social Security numbers of all new VA research subjects enrolled in the study. This information will be used to audit records for compliance with regulations. The investigator will also be responsible for providing a final report to the HAC and the Research and Development Committee when a study is completed or terminated.

Who Will Be Notified Of Non-Compliance For The Augusta VAMC?

The ACOS R&D is notified if an investigator is found to be in serious or continuing non-compliance of the requirements of VHA Handbook 1200.5. The ACOS R&D will be responsible for notifying the following of serious or continuing non-compliance sent to:

- Office of Research and Development.
- Regional VA Office of Research Oversight.
- VA Privacy Officer, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
- VHA Information Security Officer when the report involves violations of VA information security requirements.

Who Will Be Notified Of Unanticipated Problems Involving Risks To Research Participants Or Others at the Augusta VAMC?

The ACOS R&D is notified of unanticipated problems involving risks to research participants or others in compliance with the requirements of VHA Handbook 1200.5. The ACOS R&D will be responsible for notifying the following of serious or continuing non-compliance sent to:

- Office of Research and Development.
- Regional VA Office of Research Oversight.
- VA Privacy Officer, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
- VHA Information Security Officer when the report involves violations of VA information security requirements.

Does The Augusta VAMC Have Any Specific Requirements for Record Retention?

For the Augusta VAMC investigators, VHA Handbook 1200.5 page 18 states:

- j. Record Retention. The required records, including the investigator's research records, must be retained for a minimum of 5 years after the completion of the study and in

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accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors.

- (1) All records must be accessible for inspection and copying by authorized representatives of VHA, DHHS OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.
- (2) Records are the property and the responsibility of the local research office. The medical center must designate where the records will be maintained and/or stored.

Augusta VAMC Representation on the HAC

Are There Individuals Affiliated With The Augusta VAMC Who Cannot Discuss Or Vote On Any Protocols That Will Be Conducted At Their Respective Institution?

Yes. Individuals in the following positions **who** serve on the Committee are **required to recuse themselves from discussing and voting on any** protocols that will be conducted at their respective institution:

The Associate Chief of Staff for Research (ACOS/R) and/or the Administrative Officer for Research (A/O) at the Augusta Veterans Affairs Medical Center (VAMC).

Who is the Augusta VAMC Privacy Officer?

The Augusta VAMC Privacy Officer is Shirley Padgett, 706-733-0188 x 3168, e-mail address of shirley.padgett@va.gov.

Who is the Augusta VAMC Security Officer?

The Augusta VAMC Information Security Officer is Debbie Wiggins, phone: (706)481-6743, e-mail address of Debbie.wiggins@va.gov.

The Augusta VAMC and Investigational Medication or Devices

What About Investigational Medication and The Augusta VAMC?

All medications provided to patients at the Augusta Veterans Affairs Medical Center (VAMC) will be dispensed through the Augusta VAMC Pharmacy. The investigator is responsible for submitted a completed VA Form 10-1223 to the Augusta VAMC Pharmacy to ensure that HAC and R&D Committee approvals have been obtained.

The investigator must also submit a signed copy of the VA Form 10-1086 to the VAMC Hospital Pharmacy to document each participant's consent to participate in the study.

The investigator must also notify the Chief, Pharmacy Service and the R&D Committee when a study involving investigational drugs has been terminated. The HAC provides a copy of the HAC minutes to the AO and ACOS R&D which includes a listing of protocols whose protocol approvals have expired or terminated.

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What Is The Correct Address For Drug Shipment If At the Augusta VAMC?

All drug shipments must be mailed to:

The Augusta VA Medical Center

Pharmacy (14) – Room 1C109

950 15th St., Augusta GA 30901

Phone: 706-733-0188 ext. 3093

Do Augusta VAMC Studies Require Approval By The MCG Graphics Standards Committee?

No.

What Information Is Required To Change A Study Title for an Augusta VAMC Protocol?

Submit a completed [HAC Form 113](#), Amendment Submission Form and indicate protocol title change. Provide a reason for requesting the title change. If the study is actively recruiting subjects, a revised ICD and/or CAD may be required as well as a revised [Form FDA 1572](#). If funded, the contract may also require revision. Please contact the Augusta Biomedical Research Center for Augusta VAMC protocols for additional guidance.

Does The VA Have Any Specific Requirements for Tissue Banks?

Only VA approved tissue banks may obtain and store tissue.

Does The VA Have Any Specific Requirements for Data Warehousing?

Only VAMC approved investigators may obtain data from the VHA data warehouse.

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