

HAC Policies and Procedures for Research at the Charlie Norwood VA Medical Center

The purpose of this section is to provide specific guidance to the investigators and research team members who conduct research at the Charlie Norwood VA Medical Center. It should be noted that these investigators must meet the requirements located at HAC Policies and Procedures for Investigators and Research Team Members Revised December 2007 in addition to the items described in this section.

The items described in this section are:

- Charlie Norwood VA Medical Center Additional Information
- Legally Authorized Representatives and Competency
- Payment of Research Subjects, Non-Veterans in VA Research, Tissue Banks, Data Warehousing and Other Approvals
- In Vitro Fertilization, Pregnant Women, Fetuses, Children
- Research Informed Consent at the VA – Process and Documentation
- Amendments, Modifications, Progress Reports, Non-Compliance, Unanticipated Problems and Record Retention and Access
- Charlie Norwood VA Medical Center Representation on the HAC
- Charlie Norwood VA Medical Center and Investigational Medication or Devices

Charlie Norwood VA Medical Center Additional Information

The HAC serves as the Institutional Review Board (IRB) and the Privacy Board for the Charlie Norwood VA 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 Charlie Norwood VA Medical Center when conducting human subject research with or at the Charlie Norwood VA Medical Center.

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

Do All Charlie Norwood VA Medical Center Investigators Have an MCG Appointment?

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

Are There Additional Responsibilities For Charlie Norwood VA Medical Center Investigators?

All Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center 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.

Legally Authorized Representatives and Competency

What Is A Legally Authorized Representative for the Charlie Norwood VA Medical Center?

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) involved 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.

What Happens When Competency Is Unclear at the Charlie Norwood VA Medical Center?

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 determination must be made in accordance with the following requirements:

- (a) The practitioner, in consultation with the chief of service, or COS, may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
- (b) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.
- (c) Disclosures required to be made to the subject by the investigator must be made to the subject's surrogate.
- (d) If feasible, the practitioner must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

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 then the subject must be considered incompetent and additional protections apply.

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.

Payment of Research Subjects, Non-Veterans in VA Research, Tissue Banks, Data Warehousing and Other Approvals

Do Charlie Norwood VA Medical Center Studies Require Approval by the MCG Graphics Standards Committee?

No.

Can Charlie Norwood VA Medical Center 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.

Can Non-Veterans Be Entered into a Research Study at the Charlie Norwood VA Medical Center?

Non-veterans can only be entered into a research study at the Charlie Norwood VA Medical Center when there are insufficient veterans available to complete the study. All regulations pertaining to the participation of veterans as participants including requirements for indemnification in case of research-related injury pertain to non-veteran participants enrolled in VA-approved research.

Does The VA Have Any Specific Requirements for Tissue Banks?

Only VA approved tissue banks may obtain and store tissue. A listing of these approved tissue banks is available from the VAMC Administrative Office.

Does The VA Have Any Specific Requirements for Data Warehousing?

Only VAMC approved investigators may obtain data from the VHA data warehouse. There is an application process that must be reviewed and approved by the VISN7 Compliance Officer. Contact the VAMC Administration Office for further instructions.

In Vitro Fertilization, Pregnant Women, Fetuses, Children

Can Research Related to In Vitro Fertilization Be Conducted at the Charlie Norwood VA Medical Center 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 is 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.

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 Charlie Norwood VA Medical Center 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.

NOTE: These determinations must be documented in the IRB minutes. There are also general limitations that apply:

(1) Activities related to pregnant women must not be undertaken unless:

(a) Except if appropriate studies on animals and non-pregnant individuals have been completed, and data for assessing potential risks to pregnant women and fetuses is provided.

(b) The purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal, and, in all cases, is the least possible risk for achieving the objectives of the activity.

(c) Individuals engaged in the activity will have no part in:

1. Any decisions as to the timing, method, and procedures used to terminate the pregnancy; or
2. Determining the viability of the fetus at the termination of the pregnancy.
3. Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

(2) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of research activity

(3) No pregnant woman may be involved as a subject in a research activity unless:

- (a) The purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or
- (b) The risk to the fetus is minimal.
- (c) The mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:
 - 1. The purpose of the activity is to meet the health needs of the mother,
 - 2. His identity or whereabouts cannot reasonably be ascertained,
 - 3. He is not reasonably available, or
 - 4. The pregnancy resulted from rape.

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 Charlie Norwood VA Medical Center 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.
- 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.

Research Informed Consent at the VA– Process and Documentation

As an Investigator at the Charlie Norwood VA Medical Center, 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 Charlie Norwood VA Medical Center and MCG or MCGHI, then both informed consent documents should be used as applicable. For example, if the MCGHI study will recruit Charlie Norwood VA Medical Center subjects, then both the MCGHI and Charlie Norwood VA Medical Center informed consent documents must be used. For additional formatting and guidance, please see the Charlie Norwood VA Medical Center Forms section for the VA Form 10-1086 Research Informed Consent.

Does the Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center 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 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.

Is There a Guide for Preparing the VA Form 10-1086 for the Charlie Norwood VA Medical Center?

Yes. The VA Form 10-1086 and template are on the OHRP web site and provides all elements and required wording for the document.

Are there Specific Formatting Instructions for the VA Form 10-1086?

Yes. Please follow the formatting instructions below:

- 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.

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 Charlie Norwood VA Medical Center subjects.

What about Research-Related Injuries?

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

- Situations where Charlie Norwood VA Medical Center facilities are not capable of furnishing economical care.
- Situations where Charlie Norwood VA Medical Center facilities are not capable of furnishing the care or services required.
- Situations involving a non-veteran participant.

The informed consent form needs to include language explaining Charlie Norwood VA Medical Center authority to provide medical treatment to research subjects injured by participation in a Charlie Norwood VA Medical Center research project.

Does The Informed Consent Process Have To Occur At Each Visit Or Interaction for the Charlie Norwood VA Medical Center 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 electronic patient medical record.

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 Charlie Norwood VA Medical Center 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. The expiration date is the last date of HAC approval.

Who can Consent a Charlie Norwood VA Medical Center Subject?

Only an HAC approved investigator is allowed to conduct the interview and obtained informed consent for Charlie Norwood VA Medical Center subjects.

How Should We Document the Informed Consent Process for the Charlie Norwood VA Medical Center Research Subjects?

Please refer to the Charlie Norwood VA Medical Center Policy Memorandum 509-07-24/05 available on the OHRP web site at <http://www.mcg.edu/research/ohrp/va/policies/inf-consent.pdf> for complete instructions on documenting the informed consent process at the Charlie Norwood VA Medical Center.

How Do We Document That the Initial Informed Consent Was Obtained Prior To Participation in the Study for the Charlie Norwood VA Medical Center Research Subjects?

All studies must include a statement in the case history or electronic medical record if the subject is a Charlie Norwood VA Medical Center 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 electronic medical record also. The PI 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)].

Does The Investigator Keep A Signed Original VA Form 10-1086 In Their Site Records For the Charlie Norwood VA Medical Center Research Subjects?

Yes. The investigator must keep a signed original VA Form 10-1085 in their site records. 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)].

Are There Any Additional Forms Required for Recruiting or Enrolling Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center Research Subjects if the Charlie Norwood VA Medical Center 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.

Are We Required To Notify the Charlie Norwood VA Medical Center Research Subjects Of Any New Significant Findings During The Course Of The Study?

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 HAC Determine if a Patient's Medical Record (Electronic or Paper) Must be Flagged to Protect the Subject's Safety?

The HAC must determine if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study by using the HAC Reviewers Checklist for Research at the Charlie Norwood VA Medical Center. The HAC may not want to require the medical record to be flagged if:

(1) The subject's participation in the study involves:

(a) Only one encounter, (b) Only the use of a questionnaire, or (c) The use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

Amendments, Modifications, Progress Reports, Non-Compliance, Unanticipated Problems and Record Retention and Access

Will the HAC Approve an Amendment that Requires Other Appropriate Committee or Subcommittee Approval?

The HAC will approve an amendment that relates to biosafety or radiation safety at the VA only if the appropriate committee or subcommittee first approved the amendment.

What Information Is Required To Change A Study Title for a Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center protocols for additional guidance.

What If I Want to Add the Charlie Norwood VA Medical Center 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.

What Is A Progress Report for the Charlie Norwood VA Medical Center?

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 Charlie Norwood VA Medical Center Research Service a list of names and Social Security numbers of all new Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center?

The ACOS R&D is notified if an investigator is found to be in serious or continuing noncompliance 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:

- Office of Research and Development.
- Regional VA Office of Research Oversight.
- Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center?

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 Charlie Norwood VA Medical Center Have Any Specific Requirements for Record Retention?

For the Charlie Norwood VA Medical Center 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 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.

Charlie Norwood VA Medical Center Representation on the HAC

Are There Individuals Affiliated With the Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center.

Are There Requirements for Charlie Norwood VA Medical Center Representation on the HAC for Discussion and Votes of the Research Projects that take Place at the Charlie Norwood VA Medical Center?

At least two of the three Charlie Norwood VA Medical Center representatives must be present at the HAC meeting if the HAC will discuss research projects that will be conducted at the Charlie Norwood VA Medical Center. At least of these representatives must be a physician. VA projects cannot be voted on if one of the VA appointed members is not at the meeting.

Who is the Charlie Norwood VA Medical Center Privacy Officer?

The Charlie Norwood VA Medical Center Acting Privacy Officer is Shawana Burch, 706-733-0188 x 3553, e-mail address of shawana.burch@va.gov .

Who is the Charlie Norwood VA Medical Center Security Officer?

The Charlie Norwood VA Medical Center Information Security Officer is Nikki Glover, phone: (706) 823-3910, email address of nikki.glover@va.gov .

Charlie Norwood VA Medical Center and Investigational Medication or Devices

What about Investigational Medication and the Charlie Norwood VA Medical Center?

All medications provided to patients at the Charlie Norwood VA Medical Center will be dispensed through the Charlie Norwood VA Medical Center Pharmacy. The investigator is responsible for submitting a completed VA Form 10-1223 to the Charlie Norwood VA Medical Center 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 Charlie Norwood VA Medical Center 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.

What Is The Correct Address For Drug Shipment If At the Charlie Norwood VA Medical Center?

All drug shipments must be mailed to:
The Charlie Norwood VA Medical Center
Pharmacy (14) – Room 1C109
950 15th St., Augusta GA 30901
Phone: 706-733-0188 ext. 3093