

HAC Policies and Procedures

What is Covered in this Section?

This section covers the following topics:

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What Are the Types of Research?

There are unlimited types of research. The information provided is a guide. For additional information, please contact the HAC Administrative Office.

Case Studies

A single case study does not require HAC approval. However, please note that many journals follow the requirements of the “Vancouver Convention for Publications” requiring HAC approval prior to publication. If there is intent to publish in a journal that subscribes to the Vancouver Convention, please submit for HAC review prior to submission to the journal. If it appears that several cases may be similar during the course of a case study, then a protocol must be approved by the HAC prior to any data gathering. If additional guidance is needed, please contact the HAC Administrative Office.

Educational Activities that May Involve Human Subjects Research

Student research is considered to be human subjects’ research, even if the activity is not designed to develop or contribute to generalizable knowledge if it involves obtaining data in a systematic investigation as defined above either through intervention or interaction with the individual

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outside the class, or identifiable private information. Such research must meet all of the requirements of the applicable HAC policy. If additional guidance is needed, please contact the HAC Administrative Office.

Pilot or Feasibility Research

Pilot studies and feasibility studies must have prospective HAC approval and require the same level of review. These types of studies should be identified as such and informed consent must be obtained from subjects.

Development Only Protocols

Federal funding opportunities may involve human subjects or human derived materials at some point during the research but may not be fully defined at the onset of the grant. The PI may create a development only protocol that outlines the future plans of the research as known at the current time. This protocol should be submitted for HAC approval. The PI should check with the funding source to determine what level of documentation they require as some agencies or institutes may require prospective HAC approval.

Research Using Data, Documents, Records and Biological Specimens

Research that uses data about human subjects obtained under an earlier research protocol or for other reasons (standard of care, quality assurance projects, etc.) may require HAC approval. This type of research involves the secondary use of data that was collected in an earlier approved research project or other approved method. These protocols must be submitted for review prior to initiating the research.

Some research may use data that may appear to be publicly available data for a secondary analysis. These types of data sets are not always truly publicly available and the HAC must make the final decision on if the protocol is exempt from full review.

People who have legitimate access to information that individuals would reasonably expect to remain confidential and not disclosed to others without their consent or permission (e.g., medical records, grades, test results, etc.) may provide “masked” or “blind” data to an investigator only after the HAC approves the research. Legitimate access may be someone such as a person’s primary physician or dentist, other health care workers, employer or school officials. This may require an informed consent waiver or specific de-identification procedures. Masked or blind data means that the investigator cannot link this information back to a specific person.

Secondary use of data that can be linked to an individual will require HAC approval prior to the use of the data. At times, it may be impracticable to obtain informed consent from the individuals and the HAC may approve a waiver of informed consent. All requests for waiver of informed consent require full committee review.

Waste or Extra Biological or Diagnostic Specimens

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Research may involve the use of “waste” or “extra” biological or diagnostic specimens (human tissue or fluids). “Waste” materials would be those obtained during a clinical or diagnostic procedure but is no longer needed and would normally be discarded (e.g., left over blood or tissue samples). These types of studies may require an informed consent document but the HAC may also decide to waive the informed consent requirement. The decision to waive informed consent is determined by the HAC and not by the PI. This type of research must be approved by the HAC prior to its initiation.

“Extra” materials are those collected above and beyond what was needed for a clinical or diagnostic procedure. It is collected during the same procedure or process but solely for the purpose of the research (e.g., blood draw for lab value for clinical care and an extra tube for the research, or obtaining 2 more centimeters of tissue than is actually required for clinical care). This type of research must be approved by the HAC prior to its initiation and requires written informed consent.

Specimens Obtained From “Banks”

The HAC does not require approval of research involving only commercially available cell lines.

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What is a Performance Site?

A performance site is considered to be the site where the research is being conducted using a MCG, MCGHI or Augusta VAMC initiated research protocol or grant and/or using personnel employed by these sites.

MCG should be checked as the performance site if the protocol will be conducted by an MCG faculty, staff or student or if MCG resources will be used.

MCGHI should be checked as the performance site if the protocol will be conducted by an MCGHI staff member or if MCGHI resources will be used.

The VAMC should be checked as the performance site if the protocol will be conducted by an Augusta VAMC staff member or if Augusta VAMC resources will be used.

MCG and MCGHI should be checked as performance sites if the protocol will be conducted by an MCG faculty, staff or student and the subjects or human derived materials will be recruited from MCGHI.

MCG and the VAMC should be checked as performance sites if the protocol will be conducted by an MCG faculty, staff or student and the subjects or human derived materials will be recruited from the Augusta VAMC.

MCG and MCGHI should be checked as performance sites if the protocol will be conducted by an MCG faculty, staff or student and the subjects or human derived materials will be recruited from MCGHI.

MCG, MCGHI, and the Augusta VAMC should be checked as performance sites if the protocol will be conducted by an MCG faculty, staff or student and the subjects or human derived materials will be recruited from MCGHI and the Augusta VAMC.

If the protocol will be conducted by MCG faculty, staff or student and the subjects or human derived materials will be recruited from sites other than MCGHI or the Augusta VAMC, then both MCG and the other site should be checked as performance sites.

What If We Are Using An External Site?

External sites must show written support of the site. Some sites may have their own IRB and their approval must be obtained. Some situations may require the use of an additional agreement.

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What Is the Life Cycle of Typical Protocol?

The life cycle of a typical protocol is initial approval, amendments, protocol deviations/violations, unanticipated problems, adverse events, serious adverse events, IND safety reports, continuing review and completion of the protocol and data analysis. These events must be reported to the HAC by the PI as they occur. Each part of the protocol life cycle is covered in this next section.

