

## HAC Policies and Procedures for HAC Members and OHRP Staff

### HAC Administrative Office Staff

#### Who Provides Funding For The HAC Administrative Office Staff?

The staff members of the HAC Administrative Office are employees of the MCG Office of Human Research Protection and therefore, MCG OHRP funds their positions.

#### Who Receives The HAC Mail Each Day?

The MCG OHRP Office Assistant receives and date stamps all HAC mail each day. In case of an absence, the duties are assumed by the HAC Administrative Office Staff or the MCG OHRP Assistant Director.

#### Are All HAC Submissions Logged In?

Yes. All HAC submissions from new protocols, amendments, continuing review, adverse event reports, serious adverse reports, IND safety reports, protocol deviations/violations, data safety monitoring reports, Research Self-Assessment Checklists, terminations, general information and letters to the HAC are logged in on a daily basis by the MCG OHRP Office Assistant.

#### What Internal Tools Does the HAC Administrative Office Staff Use To Route Paperwork Through The Process?

Action	Intake/Internal Routing Forms	Color	Publicly Available
New protocols	HAC Submission Checklist	White	Yes
Exempt Protocols	Exempt Routing Form	Salmon	No
Expedited Protocols	Expedited Routing Form	Dark turquoise blue	No
Full Review Protocols	HAC Submission Checklist	White	Yes
Stipulation Response	Action Item	Dark Rose	No
Continuing Review	HAC Staff & Reviewers Checklist Internal Routing Form	Yellow	No
Protocol Deviations/ Violations	Protocol Deviation/Violation Internal Routing Form	Purple	No
Unanticipated Problems, Related	Unanticipated Problems, Related and Unexpected Adverse Event and/or	Red	No

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and Unexpected Adverse Events or Serious Adverse Events	Serious Adverse Event Notification Internal Routing Form		
Final Protocol Approvals	Final Protocol Approval	White	No
HAC Approval Expiration, Suspension or Termination	HAC Approval Expiration, Suspension or Termination Internal Routing Form	White	No

### **When are the HAC Members Packets Distributed?**

The Reviewer's Packets are generally mailed or hand-delivered by the Friday following the second Monday. This allows roughly 10 days for the reviewers to review their packets since the HAC meetings are held on the fourth Monday unless that day is a holiday.

### **How Is Quality Assurance/Quality Improvement Measured?**

The MCG OHRP auditors conduct an internal audit of each HAC file in preparation for the site audit. For more information on the MCG OHRP auditing program, please view their web site. These findings are communicated to the MCG OHRP Assistant Director who assigns these to the appropriate staff member for correction. Education and training or re-training may be necessary and is implemented.

### **How Is The Workload Distributed?**

The workload is currently distributed by the last name of the PI. Each of the three HAC Administrative Office Specialists is assigned a specific letter group (A-G, H-P, and R-Z) as their primary responsibility, although they are cross-trained and share information.

The Office Specialists use a calendar to keep track of meeting assignments, agenda and minutes preparation as well as continuing review report generation. All OHRP office staff assist with meeting set-up/take down. Catering needs are coordinated by the OHRP Office Assistant.

### **Is There A Database?**

Yes. The current database uses an Access front end on Sequel Server with Visual Basic Program and is not web-enabled at this time. The new system, eProtocol, is web-enabled and should be implemented soon.

### **How Much Space Does The HAC Have?**

The HAC is administratively supported by the MCG OHRP whose total square footage is 1782 square feet. Dedicated HAC space occupies the following:

HAC Administrative Office	258.10
HAC Chairperson/Vice-Chairperson office	73.64
HAC Active File Room #1	114.22

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HAC Active File Room #2	73.64
HAC Terminated File Room	146.75
Total square footage	666.35

Meeting space is a shared conference room with wireless internet access and is approximately 500 square feet.

### **What Is The Hard Copy Filing System?**

Active files are stored in Lektriever filing systems to facilitate easy identification and ergonomics. Files are assembled and are created as needed. For more information, please see the HAC Administrative Office Staff Operations Manual.

Routine study closures files are placed alphabetically by year in standard vertical filing cabinets. Files that have been closed for more than one year are archived off-site with a local storage provider. A log is kept on site for easy retrieval.

### **What is in the Hard Copy HAC file?**

The hard copy HAC file is the definitive record for each study. The contents of the file will vary based on the type of research conducted but generally includes the following:

- The original protocol and Description of Research Proposal
- Draft Informed Consent Document (ICD)/Children's Assent Document (CAD)
- Questionnaire/Surveys (if applicable)
- All applicable HAC Forms
- Stipulation Response from PI
- Amendments
- Clinical Study Status Reports (Continuations)
- Research materials (advertisements, brochures, pamphlets, newsletters, etc.)
- HAC approval letters
- The original HAC approved ICD/CAD and Questionnaire (if applicable)
- All correspondence regarding the study (emails, memos, letters, etc.)
- Audit reports of the HAC file
- All other institutional approvals (MCGHI, IBC, RSC, Charlie Norwood VA Medical Center IBC, Charlie Norwood VA Medical Center RSC, educational requirements met, MCG IT, MCGHI IT, other sites, etc.)
- FDA Form 1572, package inserts, investigational drug brochure
- Investigator's agreement, device manual, technical information
- Unanticipated problems
- Adverse Events/Serious Adverse Events
- Data safety monitoring reports, interim analyses, etc.
- Intake forms/internal checklist
- Protocol Deviations/Violations
- HAC Reviewer's Checklist and comments

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**NOTE:** Minutes of each meeting where an action took place regarding this protocol are maintained in separate files that may be retrieved upon request for purposes related to auditing or accreditation.

### **What about Communication?**

The HAC Administrative Officer serves as the primary contact points for both the investigator and the HAC members.