

## HAC Policies and Procedures

### HAC Administrative Office Staff

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

The HAC Administrative Office staff 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 her 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	Internal Routing Form	Color	Publicly Available	Web address/Shared File
New protocols	HAC Submission Checklist	White	Yes	<a href="http://www.mcg.edu/research/OHRP/hac/HAC%20Submission%20Checklist%2008.02.05doc.doc">http://www.mcg.edu/research/OHRP/hac/HAC%20Submission%20Checklist%2008.02.05doc.doc</a>
Exempt Protocols	Exempt Routing Form	Salmon	No	L drive
Expedited Protocols	Expedited Routing Form	Dark turquoise blue	No	L drive
Full Review Protocols	HAC Submission Checklist	White	Yes	<a href="http://www.mcg.edu/research/OHRP/hac/HAC%20Submission%20Checklist%2008.02.05doc.doc">http://www.mcg.edu/research/OHRP/hac/HAC%20Submission%20Checklist%2008.02.05doc.doc</a>
Stipulation Responses	Action Item	Dark Rose	No	L drive

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Action	Internal Routing Form	Color	Publicly Available	Web address/Shared File
Continuing Review	HAC Staff & Reviewers Checklist Internal Routing Form	Yellow	No	L drive
Protocol Deviations/ Violations	Protocol Deviation/Violation Internal Routing Form	Purple	No	L drive
Adverse Events or Serious Adverse Events	Local Adverse Event and/or Serious Adverse Event Notification Internal Routing Form	Red	No	L drive
IND Safety Reports	IND Internal Routing Form	Light green	No	L drive
Final Protocol Approvals	Final Protocol Approval	White	No	L drive

### 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.

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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 ORHP 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
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 by generally includes the following:

Initial submission:

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- 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, educational requirements met, 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

**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 auditing or accreditation purposes.