

Policies and Procedures:

1	General Information
	OHRP General Information and HAC Policies and Procedures, Section 1, General Information (PDF)
2	Human Assurance Committee (HAC) Meeting Information
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) and Initial Submission Table
3	HAC Submission Instructions
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) and Initial Submission Table
4	Review Levels and Criteria
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) – Levels of Review and Initial Submission Table
	4A Exempt From Full Review
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) – Levels of Review and Initial Submission Table
	4B Expedited Review
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) – Levels of Review and Initial Submission Table
	4C Full Committee Review
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) – Levels of Review and Initial Submission Table
	4D Emergency Use Review
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF) – Levels of Review and Initial Submission Table
	4E Case Studies
	OHRP General Information
5	Veterans Affairs Medical Center (VAMC) Submission Instructions

	HAC Policies and Procedures, Section 5, Augusta Veterans Administration Medical Center (VAMC) Information (PDF)
6	Investigator Responsibilities
	OHRP General Information and Clinical Research SOPs
7	Additional Information for VAMC Investigator Responsibilities
	HAC Policies and Procedures, Section 5, Augusta Veterans Administration Medical Center (VAMC) Information (PDF)
8	Description of Research Proposal
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
	Description of Research Proposal Template
	Research Templates available at http://www.mcg.edu/research/ohrp/irb/hac/desresproptemp.asp
9	Informed Consent Process
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
	9A Research Notes Templates
	HAC Research Templates available at http://www.mcg.edu/research/ohrp/irb/hac/rnt.asp
10	Informed Consent and Children's Assent Documents
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
11	Informed Consent Document (ICD) and/or Children's Assent Document (CAD) Checklist
	HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
12	Sample Children's Assent Document(s) (CAD)
	Informed Consent Document Templates, available at http://www.mcg.edu/research/ohrp/irb/hac/icd.asp
13	Sample Minimal Risk Informed Consent Document (ICD)
	Informed Consent Document Templates, available at http://www.mcg.edu/research/ohrp/irb/hac/icd.asp
14	Protocol Amendments
	HAC Policies and Procedures, Section 3, HAC Policies for Ongoing Research Activities (PDF)

15	Addendum to ICD and/or CAD HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
16	Continuation Requests/Report (Clinical Study Status Report, HAC Form 107) HAC Policies and Procedures, Section 3, HAC Policies for Ongoing Research Activities (PDF)
17	Protocol Termination or Completion HAC Policies and Procedures, Section 4 HAC Polices for Termination/ Closure of A Study (PDF)
18	Protocol Deviations/Violations HAC Policies and Procedures, Section 3, HAC Policies for Ongoing Research Activities (PDF)
19	Adverse Events HAC Policies and Procedures, Section 3, HAC Policies for Ongoing Research Activities (PDF)
20	Genetic Research HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
21	Sample Genetic Informed Consent Document (ICD) Informed Consent Document Templates, available at http://www.mcg.edu/research/ohrp/irb/hac/icd.asp
22	Food and Drug Administration (FDA) Form 1572 "Statement of Investigator" HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF))
23	Certificate of Confidentiality HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
24	Cooperative Studies HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
25	Vulnerable Subjects HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF))
26	Investigational Drug Service/Clinical Research Pharmacy HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
27	Research Subject Advertising HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)

28	Submission Fee HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
29	Changes in Research Team HAC Policies and Procedures, Section 3, HAC Policies for Ongoing Research Activities (PDF)
30	Remote Informed Consent HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
31	Medical College of Georgia (MCG) Health, Inc. OHRP General Information, General Information (PDF)
32	Data and Safety Monitoring Plans (DSMP) and Boards (DSMB) HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
33	Clinical Research Education OHRP Policies and Procedures, General Information (PDF)
34	Subject Injury Policy and Language HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
35	Committee Membership HAC Policies and Procedures, Section 7, HAC Membership Policies and Procedures (PDF)
36	Students and Residents HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
37	Frequently Asked Questions These have been incorporated into each section
38	HAC Forms HAC Forms page at http://www.mcg.edu/research/ohrp/irb/hac/forms.asp
39	Research Non-Compliance HAC Policies and Procedures, Section 6, Research Non-Compliance
40	Biological Specimen Shipping Regulations OHRP Training Requirements Checklist for Human Subjects Research available at http://www.mcg.edu/research/ohrp/training/forms/TrainingChecklist2006.pdf Further information/guidance is available from the Biological Safety Office at http://www.mcg.edu/Services/EHS/biosafe/biosafe.htm
41	Emergency Use Sample Informed Consent Document Informed Consent Document Templates, available at http://www.mcg.edu/research/ohrp/irb/hac/icd.asp

- 42 Waiver of Written Informed Consent
HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
- 43 HIPAA and Databases, Medical Records Review and Collection of PHI
HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
- 44 Non-Member Attendance at the HAC Meetings
HAC Policies and Procedures, Section 7, HAC Membership Policies and Procedures (PDF)
- 45 Appeal to the Decisions of the Committee
HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
- 46 Privacy Board
HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
- 47 Medical Device Research
HAC Policies and Procedures, Section 2, HAC Policies for Initial Submission of Protocols (PDF)
- 48 HAC Record Storage
HAC Policies and Procedures, Section 4, HAC Policies for Termination/ Closure of A Study (PDF)

Research Related Appendices (in A-Z order) including:

Acronym List

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

The Belmont Report

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Belmont Report Historical Archive

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Cooperative Protocol Research Program (CPRP) Agreement

Replaced with Individual Investigator Agreement available at

Decision Making Charts

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Declaration of Helsinki

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Federal Wide Assurance

Federalwide assurance page available at
<http://www.mcg.edu/research/ohrp/irb/hac/fwa.asp>

Glossary

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

HAC Reviewer's Checklist

Forms page at <http://www.mcg.edu/research/ohrp/irb/hac/forms.asp>

HAC Submission Checklist

Forms page at <http://www.mcg.edu/research/ohrp/irb/hac/forms.asp>

The Nuremberg Code

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Radiation Dosimetry

OHRP Resources, available at <http://www.mcg.edu/research/ohrp/OHRPlinks.asp>

Research Self-Assessment Checklist / Sample

Forms page at <http://www.mcg.edu/research/ohrp/irb/hac/forms.asp>

Revised 04/28/05

Version Date: 4/19/07