

## HAC Policies and Procedures

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#### Exempt from Full Review

Under current Department of Health and Human Services (DHHS) regulations, research activities in which the only involvement of human subjects will be in one or more of the categories listed below may be exempt from full HAC review. [45CFR 46.101(b)]. However, studies involving investigational drugs, devices or biologics (e.g. under FDA regulations) may not be approved under the exempt category.

#### Exempt Categories

#	Subpart A 46.101B	Subpart D 401B Children	FDA Regulated	Prisoners
1	<p>Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:</p> <ul style="list-style-type: none"> <li>(i) research on regular and special education instructional strategies, or</li> <li>(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</li> </ul>		<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>
2	<p>Research involving the use of <u>educational tests</u> (cognitive, diagnostic, aptitude, achievement), <u>survey procedures</u>, <u>interview procedures</u> or <u>observation of public behavior</u>, unless:</p> <ul style="list-style-type: none"> <li>(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and</li> <li>(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation.</li> </ul> <p>NOTE 1: The exemption for research involving survey or interview procedures or observations of public behavior of children does <u>not</u> apply to research covered by this subpart, <u>except</u> for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.</p>	Check NOTE 1	<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>
			If the data will be submitted to the FDA, then the project is likely FDA-regulated.	<b>NOT ALLOWED</b>
3	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:</p> <ul style="list-style-type: none"> <li>(i) the human subjects are elected or appointed public officials or candidates for public office; or</li> <li>(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.</li> </ul>		<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>

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4	Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.	<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>
5	<p>Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:</p> <ul style="list-style-type: none"> <li>(i) public benefit or service programs;</li> <li>(ii) procedures for obtaining benefits or services under those programs;</li> <li>(iii) possible changes in or alternatives to those programs or procedures; or</li> <li>(iv) possible changes in methods or levels of payment for benefits or services under those programs.</li> </ul> <p>NOTE: DHHS OHRP <i>must</i> be involved in all protocols under this criterion prior to HAC approval.</p>	<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>	<b>NOT ALLOWED</b>
6	<p>Taste and food quality evaluation and consumer acceptance studies:</p> <ul style="list-style-type: none"> <li>(i) if wholesome foods without additives are consumed or</li> <li>(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</li> </ul>			<b>NOT ALLOWED</b>

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### **Who Decides If The Protocol Is Exempt From Full Committee Review?**

The investigator may request exempt status but that decision lies with the HAC Chairperson or designee. If appropriate, the HAC Administrative Office will send the investigator a letter stating that the protocol was found to be exempt from full review. No studies may be conducted without this letter signed by the HAC Chairperson or his designee. Occasionally a protocol that is submitted for exempt review must be reviewed via the expedited review procedure. If this occurs, the PI and/or research team is notified via an email from the HAC Administrative Office.

### **When Are Exempt from Full Committee Review Protocols Reported To The Full HAC?**

Exempt from full Committee protocols are reported to the full Committee at the earliest regularly scheduled Committee meeting via the meeting agenda.

### **Does Exempt Review Include Preparatory to Review Requests?**

Yes. To obtain preparatory review approval, the protocol should be submitted to the HAC requesting exempt status. In the Description of Research Proposal (DRP) the investigator must:

- Clearly indicate that the purpose of the review is for preparing a research protocol.
- Identify the specific condition or population to be studied.
- Indicate the time frame for conducting the review. The time frame will be limited to a maximum of 6 months from the date of approval and is not renewable.
- Specifically identify the individual(s) who will conduct the review.
- Clearly justify any request for deviations from these requirements.
- Indicate that none of the 18 identifiers listed as protected health information (PHI) will be retained except for the numbers of potential subjects who may qualify for the study, age distribution of potential subjects, and gender of potential subjects.

After review and approval by the HAC, a letter will be provided identifying the project, the condition or population to be reviewed, the Principal Investigator, and the individual(s) authorized to have access to the protected health information. If a research protocol is subsequently submitted, the investigator must identify the specific protocol under which the initial preparatory review was conducted.

### **What Materials Are Required For Exempt from Full Committee Review?**

See the **Initial Review and Approval Table** for required forms, support documents, number of copies and deadlines that are required for submission to the HAC.

### **We Are Conducting A Study That Will Use Off-Site Investigators (That Is, Not MCG, VAMC, Etc). Do We Need To Submit A Copy Of Their CV and/or Résumé To The HAC?**

No. Only those investigators with MCG, MCGHI or Augusta VAMC affiliations must submit their dated and preferably signed CV/ résumé.

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### **I Submitted a Protocol Last Month for My Investigator with Five Copies of the CV and/or Résumé. Do I Have To Submit This Again This Month?**

No. The investigator's CV or résumé must be updated and forwarded to the HAC on an annual basis. Only one copy of the CV or résumé should be submitted. The CV or résumé must be dated and preferably signed by the individual. Contact the HAC Administrative Office staff as listed below.

### **Can the HAC Administrative Office Pre-Review My Submission for Exempt from Full Review?**

Yes. Contact the HAC Administrative Office staff as listed below.

### **What Should I Expect After I Submit My Protocol Packet to the HAC?**

#### **Communication Process**

Initially, you will receive an email from the HAC Administrative Office staff indicating the HAC file number for your protocol once the protocol is accepted for processing. You may then receive emails requesting additional information or clarification. And lastly, you will receive a letter with the HAC approval information if the protocol is approved.

#### **HAC File Number**

Each protocol is assigned a distinct HAC file number (year, month, the number of protocols received in the fiscal year). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the HAC file number and the last name of the PI.

### **What's the Average Turnaround Time for Exempt from Full Review Studies?**

The average turnaround time from HAC receipt to HAC approval for exempt from full review is approximately 10 business days. These times are dependent on the timely responses and actions of other others involved in the research process including, but not limited to, investigators and research team members, MCGHI, ITSS, RSC, ICC, IBC, or sponsors. If you do not hear from the HAC Administrative Office within 3 business days after your submission, contact the HAC Administrative Office staff as listed below.

### **Can I Start My Study Before I Receive HAC Approval?**

No. There may be other approvals necessary prior to initiating the study.

### **What Is the Contact Information for the HAC Administrative Office Staff?**

Contact the HAC Administrative Office at [HAC@mcg.edu](mailto:HAC@mcg.edu) or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.

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