

**HAC Policies and Procedures**

**Prisoner Research**

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### **Prisoner Research**

Federal regulations [45CFR 46 Subpart C .301-.306] stipulate that any research involving prisoners in any manner must have specific approval for their participation.

#### **What is a Prisoner?**

A prisoner is considered to be an individual involuntarily confined or detained in a penal institution. These individuals may be:

- 1) Sentenced under a criminal or civil statute.
- 2) Detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution; and/or
- 3) Detained pending arraignment, trial or sentencing.

#### **What's the composition of the HAC when reviewing prisoner research?**

The majority of the HAC shall have no association with the prison except for the one voting member. This voting member shall be a prisoner representative with appropriate background and experience to speak on behalf of prisoners.

#### **What must the HAC document?**

The HAC must document that the research protocol meets one of the categories of research that is allowed under the regulations and that the additional duties of the HAC as required under 46.305(2-7) are met.

#### **Does anyone else have to review the research?**

Yes. Under 45 CFR 46.305(c), the institution responsible for conducting research involving prisoners that is supported by Department of Health and Human Services (DHHS) shall certify to the Secretary (through DHHS OHRP) that the HAC has made the seven findings required under 45 CFR 46.305(a). The HAC must send to DHHS OHRP a certification letter to this effect, which should also include the name and address of the institution and specifically identify the research protocol in question and any relevant DHHS grant application or protocol. DHHS conducted or supported research involving prisoners as subjects may not proceed until DHHS OHRP issues its approval in writing to the institution on behalf of the Secretary under 45 CFR 46.306(a)(2).

Under its authority at 45 CFR 46.115(b), DHHS OHRP requires that the institution responsible for the conduct of the proposed research also submit to DHHS OHRP a copy of the research proposal so that DHHS OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)

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(2), and if so, which one. The term "research proposal" includes the HAC-approved protocol, any relevant DHHS grant application or proposal, any HAC application forms required by the HAC, and any other information requested or required by the HAC to be considered during initial HAC review.

Prisoner research certification letters should be mailed to:

Attention: OHRP Prisoner Research Contact Person  
Office for Human Research Protections  
Department of Health and Human Services  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

### **Can we start the study before DHHS OHRP Prisoner Research Contact Person approves the study?**

No.

### **Does the Augusta VAMC Have Any Additional Requirements for Using Prisoners in Their Research?**

Yes. Research involving prisoners as participants cannot be approved unless a waiver has been granted by the Chief Research and Development Officer.

### **Who Do I Contact if I Have Any Questions?**

For additional guidance, 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 PI 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.