

HAC Policies and Procedures

What Do I Submit to the HAC for Initial Review and Approval?

This section provides guidance regarding the HAC forms and support documentation required for HAC submission. Research teams must maintain a copy of all submitted items.

Initial Review and Approval Table

	Emergency	Exempt	Expedited	Full
Required HAC Forms				
HAC Form 100, Clinical Study Document Cover Sheet	X	X	X	X
HAC Form 101, Protocol Information Sheet, including all required signatures	N/A	X	X	X
HAC Form 101EMG, Emergency Use	X	N/A	N/A	N/A
HAC Form 103, Human Biological Specimens for Genetic Research, if applicable	N/A	X	X	X
HAC Form 104, Research Medication Data Sheet, if applicable	N/A	N/A	N/A	X
HAC Form 105, Investigational Device Information Sheet, if applicable	N/A	N/A	N/A	X
HAC Form 112P, Request for Sponsor/CRO	N/A	X	X	X
Required Support Materials				
Description of Research Proposal (DRP)	N/A	X	X	X
The complete DHHS-approved protocol (if applicable)	N/A	X	X	X
Sponsor-provided protocol, if applicable	N/A	X	X	X
Protocol submitted to external sponsor (if applicable)	N/A	X	X	X
Data Collection Form	N/A	X	X	X

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(DCF) or Data Collection Tools, if applicable and investigator-initiated				
CV or résumé, if not on file in the HAC Administrative Office		X	X	X
Informed Consent Document and/or Children's Assent Document, if applicable	N/A	N/A	X	X
The DHHS-approved sample consent document (if applicable)				
Questionnaires, surveys, interviews, if applicable	N/A	X	X	X
Recruitment materials to include ads, postings (hard copy and electronic), etc., if applicable	N/A	X	X	X
Certificate of Confidentiality, if applicable	N/A	X	X	X
Approval letters from other sites and/or IRBs, if applicable	N/A	X	X	X
Information such as letters or memo for all committee members, if applicable	N/A	X	X	X
Drug Studies – Additional Required Documentation				
Investigational Drug Brochure and/or Package Insert	N/A	N/A	N/A	X
Form FDA 1572	N/A	N/A	N/A	X
IND Letter from the FDA, if applicable	N/A	N/A	N/A	
Device Studies - Additional Required Documentation				
Signed Investigators Agreement for Device Studies	N/A	N/A	N/A	X
Manufacturer's	N/A	N/A	N/A	X

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Information for Device Studies				
Copies for Distribution				
	Original only	Original plus two (2) copies of all forms and support materials, collated into sets	Original plus two (2) copies of all forms and support materials, collated into sets	Original plus four (4) copies of all forms and support materials AND Thirty (30) copies, collated into sets, of: <ul style="list-style-type: none"> • HAC Form 100 • DRP • ICD and/or CAD • Any letters or memoranda for all committee members to review • All recruitment material
Education Required?	No	Yes	Yes	Yes
Can the HAC Administrative Office Staff pre-review my submission?	Yes	Yes	Yes	Yes
Submission Deadline?	None	None	None	Must be submitted by 4 p.m. on the second Monday of each month

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OCIS HSRO review required if using MCG Health Inc resources (patients, records, buildings, supplies, staff, and equipment) and/or School of Medicine faculty, staff or student?	No	Yes	Yes	Yes
ITSS		Yes	Yes	Yes
IBC				
ICC				
RSC				