Medical College of Georgia (MCG)
Human Assurance Committee (HAC)
Clinical Study Document Cover Sheet

Section A.	***Research Team Information***
Principal Investigator (PI)	
Name	
Institution:	
E-Mail:	
School *(if applicable):*	
Department *(if applicable)***:**	
Section *(if applicable)***:**	
Address:	
(Address should be campus mailing address (for example, CJ-3301), if applicable)	
Phone #:	**Fax#:**
Study Coordinators (SC)	
Name:	
Institution:	
E-Mail:	
School *(if applicable):*	
Department *(if applicable):*	
Section *(if applicable):*	
Address:	
(Address should be campus mailing address (for example, CJ-3301), if applicable)	
Phone #:	**Fax#:**

Administrative Contact (AC)	
Name:	
Institution:	
E-mail:	
School *(if applicable):*	
Department *(if applicable):*	
Section *(if applicable):*	
Address:	
(Address should be campus mailing address (for example, CJ-3301), if applicable)	
Phone #:	**Fax#:**

Section B. Study Title

Study Title *(Titles on protocols, informed consent documents and all other forms must match this title according to federal regulations. Please take the time now to double-check this title against the NIH submission or the externally funded protocol to prevent delays in grant or contract approval/release):*

Comments:

Section C. Mail Preference (Check one):

☐ Send HAC response via campus or US mail ☐ I will arrange response pick-up from HAC office

Section D. Determining Whether a Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions Screening Tool

Please contact the HAC Administrative Office (HAC@mcg.edu) for additional guidance if you are uncertain if this project is research.

Please complete Sections 1 and 2 for Section D and then proceed to Section E:
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Section 1.

a.) Is the activity a systematic investigation as defined in the MCG OHRP policy "What is Research?"

☐ Yes ☐ No

b.) Is the activity designed to develop or contribute to generalizable knowledge as defined in the MCG OHRP policy "What is Research?"

☐ Yes ☐ No

c.) The investigator will obtain data about living individuals. ☐ Yes ☐ No

If yes, complete the following questions. If no, skip to section 2.

The investigator will obtain that data through intervention as defined in the MCG OHRP Policy "What is a Human Subject?"	Yes ☐	No ☐

The investigator will obtain that data through interaction as defined in the MCG OHRP Policy "What is a Human Subject?"	Yes ☐	No ☐

The information obtained is private because the:

Information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place

Yes		No	

Individual has provided the information for specific purposes and can reasonably expect that the information will not be made public *(for example, a medical record)*

Yes		No	

The information obtained is individually identifiable, because the identity of the participant is, or may readily be ascertained by the investigator or associated with the information

Yes		No	

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Section 2.

a.) Does the activity involve the use of a drug[2] that is being used in the study for obtaining FDA approval?

Yes		No	

Is it a:

	A new drug
	An additional, or new, indication than what it was approved by the FDA for previously

b.) Does the activity involve the use of a device[3] to evaluate safety or effectiveness of that device?

Yes		No	

c.) Will data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product[4]?

Yes		No	

d.) Will the test article be used on one or more humans?

Yes		No	

e.) Will data obtained from controls will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product[4]?

Yes		No	

f.) Data from the use of a device[3] on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product[4].

Yes		No	

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[1]Activities that meet this definition are subject to DHHS regulations when a federalwide assurance is in effect indicating that the institution applies the protections of 45 CFR 46 to all research regardless of support, or when the research is conducted or funded by DHHS, or is otherwise subject to regulation by DHHS.

[2]The term "drug" means articles:

(A) recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

[3]The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[4]Includes foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

Section E. Check all that apply for the attached submission

I. HAC Forms

All studies require the following forms:

☐	HAC Form 100, Clinical Study Document Cover Sheet
☐	HAC Form 101, Protocol Information
☐	HAC Form 101C, Sub-Investigator Continuation Sheet, as applicable

Studies that will use drugs (investigational or approved) must complete the following document(s) in addition to the appropriate documents as noted above:

☐	Investigational Drug Brochure/Package Insert
☐	FDA Form 1572, as applicable
☐	IND Verification, as applicable

Studies that will use investigational devices must complete the following document(s) in addition to the appropriate documents as noted above:

☐	Investigator's Agreement
☐	Manufacturer's Information
☐	IDE, HUD HDE Verification

II. Support Documents

All studies require the following support documents:

☐	Description of Research Proposal (DRP)	Version Date(s):

Must be formatted according to current HAC Policies and Procedures – Please refer to the website for all current policies and procedures as these change over time.

☐	Original Protocol	Version Date(s):

This includes the full protocol submitted to any funding source or the protocol provided by the industry sponsor or cooperative group (e.g., NIH PHS 398, external sponsors such as American Heart, March of Dimes, etc.). *For example, if the NIH protocol is 500+ pages in length, the entire document should be submitted.*

☐	Protocol Amendment(s), if applicable	Version Date(s):

NOTE: These are usually only associated with industry or cooperative group sponsored studies.

☐	Curriculum Vitae (CV)/Résumé for research team members (**Note:** CV's and resumes must be dated.)

If the project will include informed consent, the following documents must be submitted in addition to the appropriate documents as noted above ***unless the request to waive informed consent or the documentation of informed consent is included in the DRP***

Informed Consent Document (ICD), if applicable

Must be formatted according to HAC Policies and Procedures – Please refer to the website for all current policies and procedures as these change over time.

☐	Subject	Version Date(s):
☐	Parent	Version Date(s):
☐	Partner	Version Date(s):
☐	Legally Authorized Representative	Version Date(s):
☐	Other	Version Date(s):

If the project will include children (please refer to the OHRP Policy for the legal age of consent in Georgia) the following documents must be submitted in addition to the appropriate documents as noted above ***unless the request to waive informed consent or the documentation of informed consent is included in the DRP***:

Childrens' Assent Document (CAD), if applicable

Must be formatted according to HAC Policies and Procedures – Please refer to the website for all current policies and procedures as these change over time.

☐	7 – 12 years old	Version Date(s):
☐	13 - 17 years old	Version Date(s):

If the project will recruit subjects the following documents must be submitted in addition to the appropriate documents as noted above:

Recruitment Tools, if applicable

Must be formatted according to HAC Policies and Procedures – Please refer to the website for all current policies and procedures as these change over time.

☐	Ads (newspaper, bulletin boards, etc.)	Version Date(s):
☐	Web site postings	Version Date(s):
☐	Social networking postings	Version Date(s):
☐	Scripts for radio or T.V.	Version Date(s):

If the project will use surveys, etc., they must be submitted in addition to the appropriate documents as noted above:

☐	Surveys, Questionnaires, etc., if applicable	Version Date(s):

If the project is investigator initiated, the following document(s) must be submitted in addition to the appropriate documents as noted above:

Data Collection Tools or Data Capture Forms or Case Report Forms, if applicable

Studies that will use drugs (investigational or approved) must submit the following document(s) in addition to the appropriate documents as noted above:

☐ Drug Brochure/Package Insert	Version Date(s):
☐ FDA Form 1572, if applicable	Date of PI Signature:
☐ Verification of IND Status, *if applicable*	

Studies that will use investigational devices must submit the following document(s) in addition to the appropriate documents as noted above:

☐ Investigator's Agreement	Date of PI Signature:
☐ Manufacturer's Brochure/Technical Information	Version Date(s):
☐ Verification of IDE, HDE, or HUD Status, *if applicable*	

III. Required Education

☐ Collaborative Institutional Training Initiative (CITI)
Completion of the appropriate learner group is required for ***all*** individuals listed on the protocol. The research team members must provide documentation detailing what group and the date CITI was completed for each member of the research staff. OHRP recommends maintaining a copy of the CITI certificate and submitting this for verification. This is an investigator responsibility. Review the OHRP web site at http://www.mcg.edu/research/ohrp/training/citi.html for more information.

☐ HIPAA
Completion is required. Please contact the MCG HIPAA Privacy Officer at 706-721-5631 for additional information or guidance. This is an investigator responsibility.

☐ Other required education or training may be required by different departments/sections.
Please see the OHRP Training Requirements for Conducting Human Research Checklist at http://www.mcg.edu/research/ohrp/training/documents/2009TrainingChecklist.pdf This is an investigator responsibility.

IV. Other Required Approvals (as applicable):

It is the responsibility of the investigator to submit to the appropriate institutional approval with the exception of MCG IT and Graphics Standards Committee. HAC maintains the responsibility to submit to MCG IT and Graphics Standards Committee only.

HAC cannot release any HAC approvals until the following appropriate approval has been submitted to the HAC by the investigator (with the exception of MCG IT). Please follow up with each approver /committee promptly to ensure that the research project is not delayed.

MCG IT

Will MCG research records be stored or shared electronically during the course of this research?

Yes	☐	No	☐

MCG Graphics Standards Committee

Will this protocol use advertisements and/or recruitment materials?

Yes	☐	No	☐

Office of Clinical Investigative Services (OCIS)
Are personnel on this project in the School of Medicine?

Yes		No	

- If yes, the HAC application and support documents must be submitted to the OCIS HSRO for review and release prior to HAC submission.
- HAC must have OCIS HSRO release prior to HAC submission if School of Medicine faculty, staff or students.
- Provide a single copy of the OCIS HSRO email with this submission.

Will MCG HI resources (patients, equipment, buildings, staff, supplies or electronic medical records) be used during the conduct of this research?

Yes		No	

- If yes, the HAC application and support documents must be submitted to the OCIS HSRO for review and release prior to HAC submission. HAC must have OCIS HSRO release prior to HAC submission if the project will use MCGHI resources (patients, equipment, buildings, staff, supplies or electronic medical records). NOTE: If the research will not use MCGHI resources, OCIS HSRO is not required unless the research team members are in the School of Medicine.
- Provide a single copy of the OCIS HSRO email with this submission packet. NOTE: It is an investigator responsibility to seek IBC approval and provide documentation of that approval to HAC.
- HAC must have MCGHI approval prior to releasing the HAC approval if the project will use MCGHI resources (patients, equipment, buildings, staff, supplies or electronic medical records). NOTE: If not using MCGHI resources, MCGHI approval is not required.

Institutional Biosafety Committee (IBC) – MCG or Charlie Norwood VA Medical Center

Will the project involves the use of biological materials including blood and blood components such as serum plasma, tissues, urine, sputum, respiratory exudates, buccal samples, organs, vaginal swabs and others?

Yes		No	

If yes, HAC must have written documentation of the IBC approval prior to releasing the HAC approval if the project involves the use of biological materials.

Will this research obtain, use, ship, or store any of the materials listed above?

Yes		No	

If yes, then the investigator must have an approval as issued by the IBC of the appropriate institution.

Institutional Chemical Committee (ICC) – MCG or Charlie Norwood VA Medical Center

Will this research involve the use of chemicals in the conduct of the research?

Yes		No	

If yes, HAC must have written documentation of the ICC approval prior to releasing the HAC approval if the project involves the use of chemicals.

Radiation Safety Committee (RSC) – MCG or Charlie Norwood VA Medical Center

Will this research involve the use of the use of ionizing radiation for either diagnostic or therapeutic use in the conduct of the research?

Yes		No	

If yes, HAC must have written documentation of the RSC approval prior to releasing the HAC approval if the project involves the use of the use of ionizing radiation for either diagnostic or therapeutic use.

Other performance site(s) under the direction of this Investigator

- HAC must have a signed agreement prior to releasing the HAC approval such as an Individual Authorization Agreement (IIA) or an IRB Authorization Agreement.
- HAC must also have written documentation prior to releasing the HAC approval of the other site's IRB approval letter or letter of support from the other performance site(s).