Study Start-Up
SS-201.03

STANDARD OPERATING PROCEDURE FOR
Assessing Protocol Feasibility

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24 May 2017
(Signature and Date)

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            Chief Medical Officer

30 May 2017
(Signature and Date)

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Primary Author:  Anita Clavier, BSN, MPH
Previous Reviewer:  Alice S. Kerber, MN, APRN (March 2014)
I. INTRODUCTION AND PURPOSE

A clinical protocol that meets scientific and ethical standards is a fundamental requirement of clinical investigations. Georgia CORE must determine the scientific, ethical and financial merits of participating in any proposed research. Additionally, Georgia CORE considers the potential benefits of proposed studies to cancer control in Georgia and development of the state’s research portfolio. Compensation, research infrastructure and clinical sites must be available to support the performance of all study-related procedures according to the requirements of good clinical practice (GCP). This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within the Georgia CORE research network.

2. SCOPE

This SOP applies to the activities involved in assessing protocols for studies subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

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<th>Version</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.2017</td>
<td>NCCN Guidelines</td>
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<tr>
<td>21 CFR 56.109</td>
<td>IRB review of research</td>
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<td>21 CFR 56.111</td>
<td>Criteria for IRB approval of research</td>
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<td>21 CFR 312.21</td>
<td>Phases of an investigation</td>
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<td>21 CFR 312.23</td>
<td>IND content and format</td>
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<tr>
<td>21 CFR 312.60</td>
<td>General responsibilities of investigators</td>
</tr>
<tr>
<td>May 1997</td>
<td>International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline</td>
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4. REFERENCES TO OTHER APPLICABLE SOPs

| SM-301 | Communication |

5. ATTACHMENTS

A. Georgia CORE Clinical Trial Development Process
B. Georgia CORE Research Concept Proposal (RCP) Form
C. Georgia CORE Scientific Review and Monitoring Committee (SRMC) Evaluation Form
D. Site Solicitation Summary Report

6. RESPONSIBILITY
This SOP applies to Georgia CORE leadership, staff members and consultants involved in clinical trials. This includes the following:

- President and CEO
- Chief Medical Officer
- Scientific Review and Monitoring Committee
- Georgia CORE staff and consultants

7. DEFINITIONS

The following definitions from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline apply to this SOP.

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**Investigational Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Well-being (of the trial subjects):** The physical and mental integrity of the subjects participating in a clinical trial.

8. PROCESS OVERVIEW

A. Based upon the established review process, evaluate the feasibility of carrying out the protocol.

9. PROCEDURES

A. Evaluate the Research Concept Proposal (RCP) and/or the protocol, assess the scientific, ethical and financial merits of the research and its potential impact upon subjects, cancer control and Georgia’s research portfolio.
Based upon the established review process (Attachment A), determine the scientific, ethical, financial and practical merits of conducting the study within the Georgia CORE Research Network.

- Review RCP form (Attachment B) submitted electronically via the Investigators’ Exchange on www.GeorgiaCORE.org. Review protocols submitted by Investigator to Georgia CORE.
- Distribute the RCP form and/or protocol electronically to the Scientific Review and Monitoring Committee members
- Review the RCP form and/or protocol within one week.
- Complete the Scientific Review and Monitoring Committee (SRMC) Evaluation Form (Attachment C) which is available on the Investigators’ Exchange on www.GeorgiaCORE.org. Web completion of the SRC Evaluation Form will populate the database fields for future report queries.
- Create the SRMC Summary Report which is a compilation of individual evaluations.
- Distribute the SRMC Summary Report to the Investigator, Chief Medical Officer and key research team members for their review and comment.

Compile comments from Investigator, Chief Medical Officer and research team and forward to the Investigator. Once the Investigator returns the revised RCP/protocol, send the RCP/protocol to the Chief Medical Officer. Determine the feasibility of advancing to the next phase of study development based on review of the revised RCP/protocol and discussions with the Investigator.

Upon CMO approval to proceed, work with the Investigator and Research Development Committee (RDC) to identify and complete outstanding study documents (e.g. protocol summary, study budget, pharmaceutical plan and budget, data management and statistical plan). (Research Development Committee includes representatives from areas such as finance, operations, pharmaceutical, data management and statistics)

Forward completed documents to the President and CEO and Chief Medical Officer.

Review documents and provide approval to proceed to next phase or provide direction to the Designee and Investigator as to what changes need to be made.

Once documents are approved by the President and CEO and Chief Medical Officer, distribute the protocol and budget to Research Network sites electronically for review. Collect feedback via the Site Solicitation Summary Report (Attachment D).

Assess feasibility of activating protocol. Notify Investigator, research team and site representatives regarding next steps.
10. HISTORY OF CHANGES

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<th>Section Number</th>
<th>Modification</th>
<th>Approval Date</th>
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<td>All</td>
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<tr>
<td>201.01</td>
<td>9</td>
<td>Updated the procedure to be consistent with new attachment A</td>
<td>17 May 2010</td>
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<td>201.01</td>
<td>Attachment A</td>
<td>New process flow chart</td>
<td>17 May 2010</td>
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<tr>
<td>201.01</td>
<td>Attachment B, C, D</td>
<td>Updated the lettering and Title of each attachment</td>
<td>17 May 2010</td>
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<td>201.02</td>
<td>Attachment B</td>
<td>Added PK sampling considerations</td>
<td>09 March 2012</td>
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<tr>
<td>201.02</td>
<td>Attachment B</td>
<td>Medical College of Georgia changed to Georgia Regents University</td>
<td>01 June 2014</td>
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<td>201.03</td>
<td>3</td>
<td>Included additional guideline</td>
<td>03 March 2017</td>
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Attachment A
PHASE I RESEARCH CONCEPT REVIEW AND CRITIQUE

PI submits RCP\(^1\) form or protocol via www.GeorgiaCORE.org

SRMC completes the evaluation form in Investigator's Exchange on www.GeorgiaCORE.org

PI, CMO and key research team members review SRMC summary report and comment

PI returns revised RCP/protocol. CMO determines next steps.

Refine RCP/protocol further – repeat steps as necessary

Decide not to proceed

Proceed with next phase of development

Georgia CORE reviews and distributes document to the SRMC\(^2\)

Georgia CORE compiles SRMC summary report

Georgia CORE compiles comments; distributes to PI for potential revisions

PI returns revised RCP/protocol. CMO determines next steps.

Decide not to proceed

Proceed with next phase of development

Phase II CLINICAL TRIAL DEVELOPMENT

Georgia CORE submits RCP/protocol to RDC\(^3\) for review and input

CMO and President and Financial Advisor review documents.

Refine RCP/protocol further – repeat steps as necessary

Distribute approved RCP/protocol and related documents to Research Network sites for review.

Research Network sites submit Site Solicitation feedback forms.

Georgina CORE completes Site Solicitation Summary Report

Final feasibility decision made by Georgia CORE; PI notified of next steps.

\(^1\)RCP=Research Concept Proposal

\(^2\)SRMC =Scientific Review and Monitoring Committee (includes other investigators and scientific experts)

\(^3\)RDC =Research Development Committee (includes areas such as finance, operations, pharmaceutical, data management and statistics)
GEORGIA CORE RESEARCH CONCEPT PROPOSAL (RCP) FORM

Introduction

The Georgia CORE Research Concept Proposal (RCP) Form is designed to guide investigators interested in submitting research ideas to Georgia CORE for consideration of protocol development or initiation of a study through the Georgia CORE research network. Information requested will assist the Georgia CORE Clinical Research Committee to evaluate your idea relative to support of the goals of Georgia CORE; scientific merit; compatibility with network resources; resource requirements; and potential funding sources. Please answer each section as completely as possible in the space provided.

Georgia CORE Tracking number:
Schema layout = (year) – (disease) – (sponsor/PI initials – 3 letters) – sequential numbering 001
(Disease – M= melanoma, B=breast L=lung, C=colon, P=prostate)
Example – Dr. Bordoni’s melanoma protocol
05-M-RAB-001

Date of Proposal Concept submission:

Study Title:

Please provide a brief two paragraph description for each question and attach additional background in a word document.

Study Description

Statement of Need/Rationale

Primary Objective/Outcome:

Secondary Objectives/Outcome:

Study End Points:
(Please include relevant terminology for NCI research database inclusion - Safety, efficacy, safety and efficacy, bioequivalency, bio-availability, pharmacokinetics, pharmacodynamics.)

Expected Benefits to Cancer Control in Georgia:

Potential Risks:
Research Design/Methods/Schema:

IND Protocol  ____yes ____no

IND Number

Phase I  ____Phase II  ____Phase III  ____  Phase IV  ____

Randomized:  ____  Yes  ____  No

Interventional:  ____  Yes  ____  No

Intervention type  ____drug  ____biologic  ____gene transfer  ____vaccine  ____behavior  ____device

____procedure  ____other(specify)

Biological markers/tissue sampling  ____yes  ____no

(If yes describe)

Pharmacokinetics:  ____Yes  ____No

Observational:  ____  Yes  ____  No

Masking:  ____Open Label  ____Single blind  ____  Double blind  ____Other(specify)____

Control:  ____Placebo  ____Active  ____Dose Comparison  ____Uncontrolled  ____Historical  ____Other (specify)

Assignment  ____Single group  ____Parallel  ____Crossover  ____Factorial  ____Other(specify)____

Purpose  ____Prevention  ____Diagnostic  ____Treatment  ____Palliative Care  ____

____Educational/counseling/training  ____Other(specify)____

Study size and timetable

Estimated Study Sample Size____

Number of patients YOU would expect to enroll to the study in 12 months: ______

Projected Study start date: ______

Projected enrollment period: ______

Estimated First patient in: ______

Estimated Last patient in: ______

Estimated Last patient out: ______

Estimated Study Completion: ______

Long term follow-up:  ____yes  ____no

(If yes how long)

Target Population/Key Clinical Considerations/Inclusion/Exclusion Eligibility Criteria:

Highlight patient Conditions, disease characteristics and medical criteria

Age – Minimum  ____ Maximum____

Gender  ____male  ____female  ____both

Performance status – ECOG ____
Life expectancy in months_____

Patient metabolic ranges for study inclusion/exclusion
Hematopoietic_____
Hepatic_____
Renal_____
Cardiovascular _____
Pulmonary _____
Other (i.e., child bearing, post menopausal)

Prior/Concurrent Therapy: (required or prohibited i.e., >3 weeks since prior chemotherapy)
  Biological
  Chemotherapy
  Endocrine
  Radiotherapy
  Surgery
  Other

Financial/funding aspects
Potential Funding Sources

Sponsor/Collaborators Name, contact information (phone, email, fax address)

Unique personnel/equipment/resources required for study participation:
Estimated cost/per-patient:
Estimated total Costs:
Estimated out-of-pocket costs to patients:

Study Development Needs requested of Georgia CORE:

Estimated number of participating sites_______
Potential Site participation sought for this study: Emory ____ Georgia Regents University ____ Mercer ____
Morehouse _____ Community Oncologists__________
Any specific sites requested_______

Yes/No for service request:
Financial support negotiations ____
Protocol writing ______
Statistical design ____
Central IRB filing _____
Data management ______
Data Safety Monitoring Board formation____
Interim analysis ______
Final analysis ______
Publication ______
Other_______

Contact Information:

Study Chair or Principal Investigator Name:
Preferred Contact: _____ Work _____ Home _____ Cell _____ Pager

Work Phone: ( )_________________ Cell Phone: (____) -___________

Home Phone: (____) - ___________________ Pager: (____) -________
Preferred E-mail: ___________ Fax (____) _______________

Organization/Institution: ______
Preferred Address: ____ Work ____ Home (Check One)

____________________________________________________
City: ________ State: __GA__ Zip Code: ______ - ________

Best times/way to contact you: _____________________

This form is available via the Investigators’ Exchange on the web site and is designed to be completed electronically.
Attachment C

GEORGIA CORE SCIENTIFIC REVIEW AND MONITORING COMMITTEE (SRMC) RESEARCH CONCEPT PROPOSAL EVALUATION

Concept:

Submitting investigator:

Date:

Georgia CORE Tracking Number:

1. Define the proposed study population, Phase and number of patients:
   Breast _______________________
   Lung ________________________
   Colon _______________________
   Prostate_____________________
   Other (name) ______________________

2. How does the proposed study contribute to the prevention, diagnosis, treatment or quality of life for Georgia cancer patients?
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

3. Does the investigator present a robust scientific rationale in the proposed protocol?
   _____Yes _____No (explain) ___________

4. Does the data presented supply reliable, valid measures and study end points for the study population?
   ______Yes _____No (if no, delineate) ___________
   __________________________________________________________________________

5. Do the outcome measures place an unacceptable burden on the patient (time, effort, risk, and cost)?
   ____Yes (delineate why) ____No
   __________________________________________________________________________

6. Are potential benefits and risks of study participation clearly specified?
   _____Yes __No_____ (specify) ____________

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7. Does the investigator present justification for the sample size? ___Yes ___No (explain)________

8. Does the statistical design and/or analysis plan correlate to the study endpoints? ___Yes ___No (delineate)________

9. Does the protocol correlate to reasonable enrollment time frames and associated study costs? ____Yes ____No (explain) _________

10. Does the study include collection of tumor tissue for banking purposes? ____Yes ___No (explain) ______________

11. Is the study schema complete – agents, doses, rout, frequency, administration cycle, etc? ____Yes ____No (why) __________

12. What is the estimated budget per patient? ____________

13. How does this study design benefit the patients of Georgia?

________________________________________________________________________
________________________________________________________________________

14. Study accepted for Georgia CORE implementation? ____Yes ____No
    If no, provide rationale

15. Was a Scientific Review and Monitoring Committee Review Meeting held to discuss this research concept? ____Yes ____No (reason) ____________

This form is available via the Investigators’ Exchange on the web site and is designed to be completed electronically.
Attachment D

GEORGIA CORE SITE SOLICITATION FEEDBACK FORM

Date

(These variables would be populated from the Research Concept Design Form)
Study Name:
GA-CORE Protocol #
Study Phase
Site, Stage, Study endpoint

Investigator Name

Institution/practice

Contact information – address, email, phone, fax, etc.

Study participation level:

__Very interested ___Have competing protocols for this patient population

___Lukewarm ___No interest

___would serve as investigator and enter patients on the trial. Our practice sees ___# of patients per month who would qualify for the study trial

___would screen patients to the trial

___would refer patients to the trial

___would not recommend patients for the trial

Benefits of the trial (1-2 sentences)

Concerns/issues about the trial (1-2 sentences)

This form is available via the Investigators’ Exchange on the web site and is designed to be completed electronically.