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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30 May 2017
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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

Version 1.2017	NCCN Guidelines
21 CFR 56.109	IRB review of research
21 CFR 56.111	Criteria for IRB approval of research
21 CFR 312.21	Phases of an investigation
21 CFR 312.23	IND content and format
21 CFR 312.60	General responsibilities of investigators
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline

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

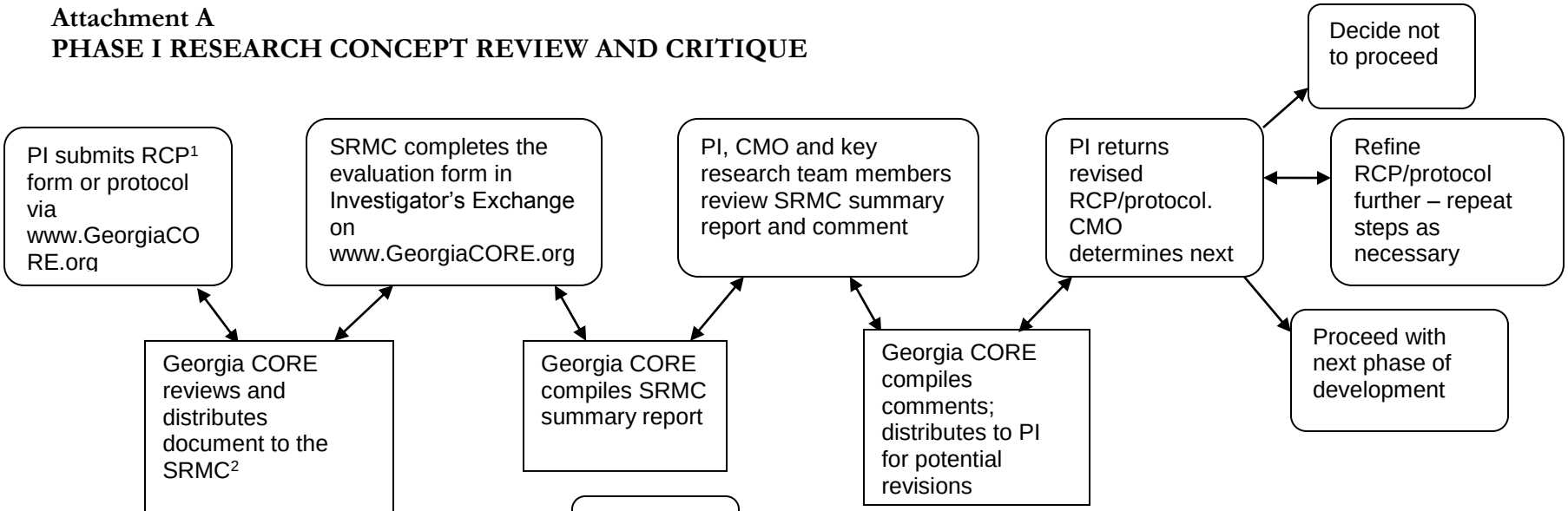
A. Evaluate the Research Concept Proposal (RCP) and/or the protocol, assess the scientific, ethical and financial merits of the research and its potential impact upon subjects, cancer control and Georgia's research portfolio.

• Designee • Scientific Review and Monitoring Committee members • Designee	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.
• Designee • Chief Medical Officer • Designee	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)
• Designee • President and CEO • Chief Medical Officer	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.
• Designee • President and CEO • Chief Medical Officer	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.

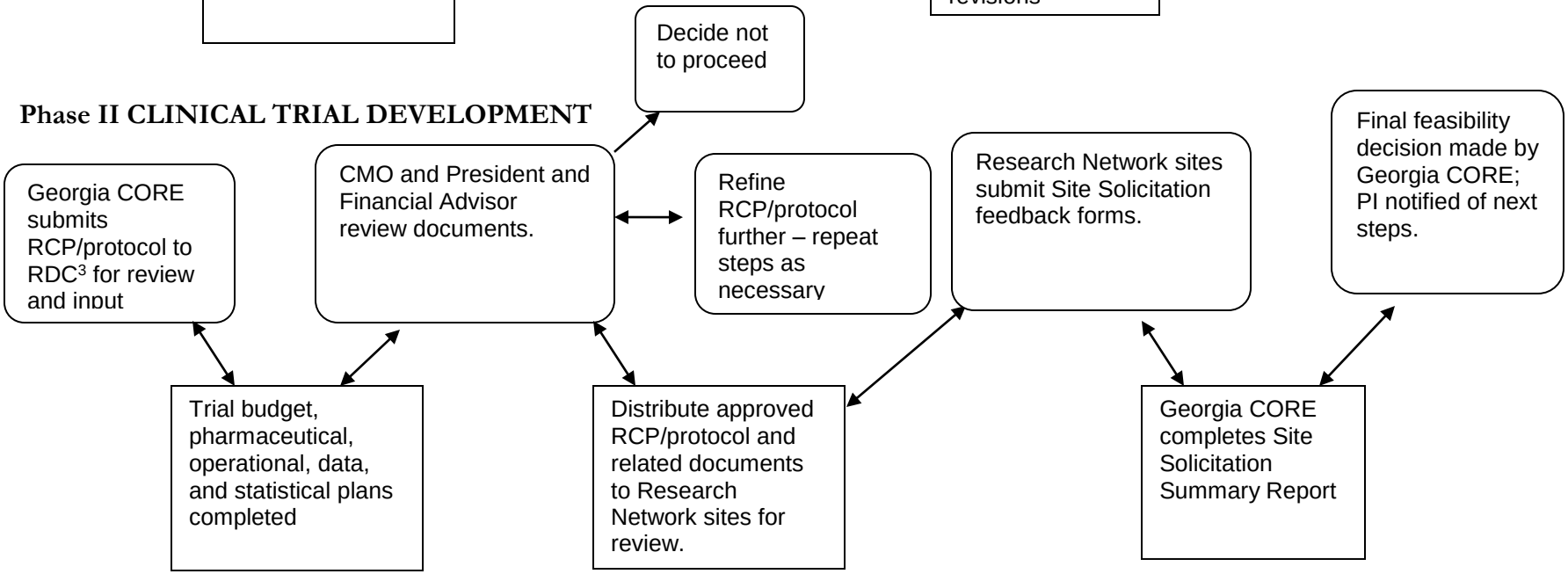
10. HISTORY OF CHANGES

Version Number	Section Number	Modification	Approval Date
201.00	All	Original Version	
201.01	9	Updated the procedure to be consistent with new attachment A	17 May 2010
201.01	Attachment A	New process flow chart	17 May 2010
201.01	Attachment B, C, D	Updated the lettering and Title of each attachment	17 May 2010
201.02	Attachment B	Added PK sampling considerations	09 March 2012
201.02	Attachment B	Medical College of Georgia changed to Georgia Regents University	01 June 2014
201.03	3	Included additional guideline	03 March 2017

Attachment A
PHASE I RESEARCH CONCEPT REVIEW AND CRITIQUE



Phase II CLINICAL TRIAL DEVELOPMENT



[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)

Attachment B

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, bio-equivalency, 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) _____

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

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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.