Institutional Review Board

IRB REVIEWER CHECKLIST

Principal Investigator: _____ IRB # _____

Brief Application Title: _____ Date: _____

THE COVER SHEET – All appropriate information must be provided on the cover sheet. Reviewers should pay particular attention to the following questions:			
	Yes	No	Does Not Apply
Is an IND / IDE number provided for investigational drugs/devices (if applicable)?			
Did the principal investigator sign the Investigator's Certification?			
Is the risk level indicated by the investigators consistent with the risks that the study actually poses to the subjects?			
Is there a SGU Fiscal approval letter, if appropriate?			
If the research involves the administration of a drug, is there an investigational drug review needed?			
If radiation exposure that is not part of standard or accepted clinical care is involved, does the protocol need radiation safety review?			
THE PROTOCOL			
	Yes	No	Does Not Apply
Introduction And Brief Background			
Does the protocol contain sufficient background data concerning results of previous animal and/or clinical studies?			
Specific Aims			
Are the specific aims of the study clearly stated and achievable based on the proposed study methodology?			
Methods			
Is the study population appropriate for the goals of the study? (consider both the nature and size of the sample)			
Are the criteria for inclusion of subjects appropriate?			
Are the criteria for exclusion of subjects appropriate?			
Are appropriate rationale and criteria provided for the use of proxy consent in the event that direct consent cannot be obtained from the subject?			
Have appropriate statements regarding reproductive risks and birth control been included?			
Are methods of subject recruitment legal, ethical and free from coercion or undue influence? Has cold-calling been avoided?			

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Has justification been provided for the use of placebo?			
For placebo-controlled studies wherein an effective treatment exists for the study disease/condition:	Yes	No	Does Not Apply
1) has justification been provided for the placebo arm?			
2) is the duration of the study drug intervention limited appropriately to that which is minimally necessary to evaluate efficacy?			
3) are the subjects being evaluated at intervals that are sufficiently frequent so as to identify and prevent untreated problems?			
4) does the protocol mandate the identification of a contact person to ensure appropriate vigilance of the subject?			
Are there defined endpoints for study drug discontinuation in the event of a worsening condition?			
Is there a statistical justification for the sample size?			
Is the proposed statistical treatment of the data appropriate for the design of the study?			
Special Populations			
If children are being enrolled into the study, did the investigator include the appropriate justification for inclusion of children information?			
If prisoners are being enrolled into the study, did the investigator include the appropriate information for inclusion of prisoners in research?			
If the study involves the recruitment and/or study of decisionally impaired subjects, has the investigator included all elements required?			
If the study involves the recruitment and/or study of pregnant women, fetuses or in vitro fertilization, has the investigator provided appropriate justification?			
Waivers			
If a waiver of consent is being requested, has the investigator addressed the four required criteria?			
If a waiver to document informed consent is being requested, has the investigator addressed the two required criteria?			
Non-Local / International Sites			
If the study involves international sites, has the investigator included all applicable information (e.g., FWAs for federally funded studies, local IRB approval, translated consent forms as well as a back-translation)?			
If the study involves non-local sites (i.e., outside of the Grenada regional area) has a local IRB approval been obtained?			
Significance			
Does the research design carry enough likelihood of yielding data sufficient to warrant the risks to the subject?			

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Risk/Benefit Ratio	Yes	No	Does Not Apply
Are the risks (including known incidence) clearly described?			
Have adequate safeguards been adopted to reduce risk exposure as much as possible?			
Have adequate measures been taken to ensure that the occurrence of illness or injury will be detected and treated?			
Is there description of study design safeguards (e.g., data and safety oversight committee) such that if the research protocol needs to be modified, or changes in the risk level occur, they will be appropriately and timely brought to the attention of the IRB for review and approval?			
Where appropriate, have alternative procedures that might be advantageous to the potential research subjects been described?			
Does the protocol outline specific steps that will be taken (i.e., during study participation, after study participation, and with the publication of study results) to ensure that the subject's participation in the research study and respective data will be confidential?			
Are the potential benefits to the subject (if any) clearly described?			
Do the potential benefits to the subject and/or society outweigh the risks being incurred?			
Costs And Payments			
Are the financial obligations of the subject, the sponsor and the institution clearly described?			
Are costs/availability of the experimental drug/device following study completion addressed?			
Do any payments seem sufficient yet not large enough to be coercive?			
Qualifications Of Investigators			
Do the principal investigator and co-investigators or student advisor have the appropriate academic and clinical credentials and experience for this study?			
If the principal investigator is a staff member, graduate student or trainee of the St. George's University, have appropriate faculty support and supervision been guaranteed?			

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THE CONSENT FORM			
	Yes	No	Does Not Apply
General Considerations:			
Is the length of the form appropriate for the complexity of the study?			
Is clear, concise, non-technical language used throughout?			
Are appropriate subheadings and sequence used throughout?			
Is the first page printed on departmental/institutional letterhead?			
Is a blank line for subject initials included in the lower right corner of each page (except the signature page)?			
Is the use of person consistent throughout?			
Are all pages numbered sequentially?			
Title			
Is the general title "Consent to Participate in Research (or Clinical) Study included?			
Is the study title identical to that listed on the protocol? If no, has justification been provided for the use of a different title?			
Investigators			
Is the name, address, and phone number of each investigator listed?			
Source Of Support			
Is the source of financial support for the study listed and consistent with the cover sheet?			
Study Description			
Is there a clear statement of the purpose of the study?			
Is there a clear explanation of the reason a particular subject was invited to participate?			
Is it clearly stated that the subject is participating in a research study?			
If important to the decision to participate, is the approximate number of subjects to be studied noted (including gender and age range)? Is there a statement as to why this information is important?			
Is the duration and length of each subject's participation included?			
Is the description of all experimental treatments and procedures complete?			
Is there a description of all tests or diagnostic procedures being done for research purposes?			
Is the dose, route, and frequency of drug(s) to be given noted?			
Is the FDA approval status of the drugs to be given indicated?			
If the study involves the use of questionnaires, is there a description of the general content and time required to complete them?			
Is the total volume of blood to be drawn (if any) described in tablespoons or teaspoons?			

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Risks And Benefits Section	Yes	No	Does Not Apply
Is there a complete and clear description of the potential risks (i.e., is quantitative information on the expected frequency of the listed side effects provided)?			
Are reproductive risks adequately described and is appropriate birth control language included?			
Is there a clear description of the precautions taken to minimize risks?			
Are the potential benefits to the subjects (if any) clearly described?			
Alternative Treatments			
If applicable, have all alternative treatments been satisfactorily described?			
New Information			
Has the standard statement been included, if appropriate?			
Costs And Payments			
Is the language included in this section the same as that included in the protocol?			
Confidentiality			
Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy?			
Is the assurance of confidentiality clear and complete?			
Does the section sufficiently state who will have access to subject records (e.g., the FDA, study sponsor, Research Office, and Academic Department, if applicable)?			
Does this section indicate that all research records must be kept for a period of at least five years?			
Right To Withdraw			
Is this section clearly worded and non-coercive?			
Are the risks of subject withdrawal stated (if applicable)?			
Are reasons why a subject might be withdrawn from the study by investigators clearly defined?			
Are procedures for ensuring continued care of the withdrawn subject adequately addressed?			
If the investigator is recruiting from his/her own patient population, is the standard wording included to explain the conflict of interest inherent in the dual role of clinician/investigator?			
Compensation For Injury			
Is the standard statement or other satisfactory wording included?			
Voluntary Consent			
Is there an offer by the investigator(s) to answer questions?			
Is the statement regarding the availability of the IRB Office, to answer questions and the phone number (473-444-4175, Extension 2221) included?			
Are there appropriate lines for the date and signatures of the subject, surrogate/proxy, and witness?			

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Is there an Investigator's Certification section?			
Is the Verification of Explanation section included if children ages 6-13 are included in the study?			
Are there appropriate signature spaces included if children 14-17 are included in the study?			
If the protocol provides a justification for the use of proxy consent, are there appropriate signature spaces included?			

Level of Risk: ☐ *None* ☐ *Minimal* ☐ *Greater than minimal*

I have reviewed the proposed project in accordance with the University's policies related to the protection of human subjects and the institutional assurance to U.S. federal Department Health and Human Services. My comments and recommendations are furnished for use in arriving at the IRB consensus and writing the minutes. I have no conflict of interest or involvement with this investigation.

I recommend:

- ☐ *Full approval – no comments*
- ☐ *Approved subject to the modifications noted below*
- ☐ *Reconsideration*
- ☐ *Disapproval*

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Reviewer Name: _____ Review signature: _____

Date: _____