

**ICTS - SRC REVIEW FORM**

ICTS Protocol #	
IRB Protocol Name:	
Principal Investigator:	Date:
<b><u>Department:</u></b>	
<b>Submission – Administrative Review</b>	
Documents Received:	
ICTS on-line application form	<input type="checkbox"/> Yes <input type="checkbox"/> No
IRB Application form & appendices	<input type="checkbox"/> Yes <input type="checkbox"/> No
IRB Protocol Narrative	<input type="checkbox"/> Yes <input type="checkbox"/> No
IRB Informed Consent(s)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Master Protocol (Sponsor Protocol)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Investigator's Brochure	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Grant Application	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Comments:	
Type of study: <input type="checkbox"/> Phase I <input type="checkbox"/> Phase I/II <input type="checkbox"/> Pilot Study <input type="checkbox"/> Investigator Initiated - unfunded <input type="checkbox"/> Industry Sponsored (single site) <input type="checkbox"/> Investigator Initiated – funded (federal, state, private) <input type="checkbox"/> Industry Sponsored (multi-center) <input type="checkbox"/> Other:	
Drug Study: <input type="checkbox"/> Yes <input type="checkbox"/> No Comments: Drug name:	Device Study: <input type="checkbox"/> Yes <input type="checkbox"/> No Comments: Device name:
Study procedure(s) include: <input type="checkbox"/> Blood samples <input type="checkbox"/> Tissue samples <input type="checkbox"/> rDNA <input type="checkbox"/> Radiation (other than routine diagnostic): <input type="checkbox"/> Radiological Imaging <input type="checkbox"/> Diagnostic Evaluation <input type="checkbox"/> Medical Treatment <input type="checkbox"/> Questionnaires/Surveys <input type="checkbox"/> Human Performance <input type="checkbox"/> Other: (Explain)	
Services Requested from ICTS:	
Research Category:  <input type="checkbox"/> Research Patients (Category A) – inpatient or outpatient visits utilized solely for research purposes.  <input type="checkbox"/> Research / Service (Category B) – research procedures combined with standard of care  <input type="checkbox"/> Industry-Initiated Research (Category D) – research visits for an industry-initiated study	

<b>Reviewer Comments</b>	
<b>Background</b>	
Has a relevant reference to the background been presented? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Hypothesis/Specific Aims</b>	
Is the hypothesis/ses clearly identified in the protocol narrative? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the specific aim (purpose) of the research justified by the hypothesis? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Methodology/Study Design</b>	
Are the methodology and study design appropriate to validate the hypothesis/ses and the aims? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the research use procedures consistent with sound study design? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Test Articles/Procedures Information</b>	
Is justification for the proposed dosage and administration of the test article, or device application, appropriately defined and sustained by the research plan? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>Subject Enrollment</b>	
Are eligibility criteria, subject population and sample size clearly defined and appropriate? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the randomization process clarified in the body of the protocol? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does the study satisfactorily address inclusion of minorities/women/children? Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**Measures and Outcomes**

Are the measures and outcomes clearly identified in the application?

Are the endpoints and expected knowledge clearly and appropriately defined?

Yes  No

Comments:

**Statistical Consideration**

Is the power/sample size given and defended?

Yes  No  N/A

Comments:

Is adequate justification provided to support the proposed accrual rate and duration of the study?

Comments:

Yes  No  N/A

Is the follow-up duration clearly stated?

Yes  No  N/A

Comments:

Are plans for interim analyses satisfactorily provided for in the event of early termination?

Yes  No  N/A

Comments:

**Data and Safety Monitoring Plan**

Is the data and safety monitoring plan complete and appropriate for the level of risk involved in the research?

Comments:

Yes  No  N/A

Are outcome measures sufficient to validate the relevant data

Yes  No  N/A

Comments:

**Clinical Research Training Opportunity**

Does the proposal provide an opportunity for clinical research training activities that could be an integral part of this project?

Yes  No

Comments:

### Enhanced Research Experience

Does the proposal provide opportunities to enhance the research experience of the participant?

Yes  No

Comments:

### Summary Paragraph (to be added to the IRB Memo)

Summarize the scientific review concerns that must be addressed by the Investigator to achieve SRC approval (Please note that these comments will be incorporated into the IRB pre-review memo that is sent to investigators prior to the convened IRB meeting at which the proposal is reviewed):

Summary Concerns:

### Recommendation:

- Approved** as presented, procedures are consistent with sound scientific study design (*Protocol is complete as submitted with no revisions, restrictions, or contingencies required by the Committee*)
- Modification(s) Required** (*Protocol requires minor modifications that, when resubmitted, may be approved after an expedited review by the Chair and/or designated Committee members*)
- Tabled** (Protocol requires significant modifications or has major deficiencies that, when resubmitted, requires re-review by the convened committee)

\_\_\_\_\_  
Reviewer's signature

\_\_\_\_\_  
Date

### Resource Allocation Approval

Resources Approved by the ICTS: