WCGME-IRB PROTOCOL SUBMISSION FORM (Rev 04/27/12)

Reason for Submission: New Project [ ] Responding to Comment [ ] Reconsideration [ ] Disapproval Resubmission: [ ] Modification [ ] Renewal [ ] Adverse Event Report [ ] Date of Submission:	Protocol #:	**IRB Use Only:**

PART A – PROTOCOL/INVESTIGATOR/COORDINATOR INFORMATION

Title of Study:

Principal Investigator:

Title of Principal Investigator:

Address of Principal Investigator:

Phone number: FAX number:

e-mail address:

FAX NUMBER(s) WHERE THE APPROVAL LETTER SHOULD BE SENT:
NOTE: HARD COPIES ARE NOT SENT UNLESS THERE IS NO FAX NUMBER LISTED

Co-Investigators:

Coordinator's Name:
Address:

Phone number: FAX number:
e-mail address:

PART B – LEVEL OF RISK/TYPE OF REVIEW REQUESTED

Level of Risk: [ ] Minimal [ ] Moderate [ ] High

Type of Review Requested: [ ] Full Board [ ] Expedite

Note: For studies requiring Full Board Review the Principal Investigator must attend the meeting to present the study and respond to any questions posed by the IRB.

PART C – RECRUITMENT INFORMATION

Number of subjects to be enrolled:
Please note: the IRB considers a subject to be enrolled if s/he signs an informed consent document. If a higher number of subjects must be enrolled for screening in order to hit a targeted number of subjects completing the study, please indicate the higher number.

Gender: [ ] Male [ ] Female **Age Range all Subjects:**

Duration of Study Per Subject: **Duration of Study (entire study):**

Site(s) where research procedures will be performed:

PART D – SOURCE OF SUPPORT

Indicate all applicable sources of support and the sponsor:

[ ] Federal* – Sponsor:

[ ] Commercial** – Sponsor:

[ ] Foundation – Sponsor:

[ ] Other (specify) – Sponsor

[ ] No support

PART E: CONFLICT OF INTEREST

Does the principal investigator or any co-investigator or research coordinator involved in this study (or in aggregate with his/her spouse, dependents or members of his/her household):

a. Possess an equity interest in the entity that sponsors this research or the technology being evaluated that exceeds 5% ownership interest or a current value of $10,000? [ ] Yes [ ] No

b. Receive salary, royalty or other payments from the entity that sponsors this research or the technology being evaluated that is expected to exceed $10,000 per year? [ ] Yes [ ] No

c. Possess a license agreement with an external entity that would entitle sharing the current or future commercial proceeds of the technology being evaluated? [ ] Yes [ ] No

If yes, please attach detailed information to permit the IRB to determine if such involvement should be disclosed to potential research subjects.

PART F: ADDITIONAL APPROVALS REQUIRED

1. Has this protocol been reviewed by a prior scientific review committee?
   [ ] Yes, If this study was reviewed by a nationally recognized scientific review committee please list the committee name here:
   If this is a locally developed protocol please attach a copy of the approval letter to this form.
   [ ] No (Indicate the reason)

2. Does this research involve the administration, for research purposes, of a drug (investigational or FDA approved)? [ ] Yes* [ ] No
   *(Please attach written notification of receipt/review from the Investigational Drug Service)

3. Does this protocol involve the exposure of human subjects to ionizing radiation (excluding the use of standard diagnostic or treatment procedures, performed in a routine clinical manner and frequency)?
   [ ] Yes (Attach approval letter) [ ] No (Indicate the reason)

PART G: MISCALLANEOUS INFORMATION:

Please provide any additional comments that you feel are necessary for the review of this protocol.

Printed Name and Signature of Principal Investigator: Date

CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES

By signing below I agree/certify that:

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.

2. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
   - I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
   - I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.

3. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements; and (f) the current IRB approval status of the research study.

4. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.

5. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.

6. I will submit the research study in a timely manner for IRB renewal approval.

7. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).

   - I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.

8. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.

9. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.

10. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.

11. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

12. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.

Principal Investigator Name (typed)	Principal Investigator signature	Date