USE OF RADIATION IN RESEARCH STUDIES INVOLVING HUMAN SUBJECTS

ANNUAL REPORT

Principal Investigator: _____

IRB Protocol Title: _____

_____

_____

IRB No.: _____ **JRSC No.:** _____

Calendar year to which this Report relates: _____

Total number of subjects approved by the IRB and the JRSC to date: _____

Total number of subjects recruited to date: _____

Please provide the following information with respect to the calendar year noted above. If you provide a positive answer to any of the questions, please elaborate in the space following the questions. Number your responses to match the question. Use additional sheets as necessary.

1. Have there been any modifications of the protocol that relate to the following?

	Yes	No	Date*
(a) Change in number of subjects	☐	☐	_____
(b) Change in study population	☐	☐	_____
(c) Change in type, number and/or frequency of radiographic or nuclear medicine studies	☐	☐	_____
(d) Change in Principal Investigator	☐	☐	_____
(e) Change in Clinical Authorized User	☐	☐	_____
(f) Change in Physician Liaison	☐	☐	_____

2. Have there been any protocol deviations/violations relating to the use of radiation?

☐ Yes ☐ No Date* _____

3. Have any unanticipated problems relating to the use of radiation been reported to the IRB?

☐ Yes ☐ No Date* _____

4. Have any adverse events relating to the use of radiation been reported to the FDA or a study sponsor?

☐ Yes ☐ No Date* _____

5. Has any subject participated in any other study conducted by you involving exposure to radiation during the past year?

☐ Yes ☐ No Date* _____

If yes, what is the total effective dose received by the subject from all studies? _____

6. Do you plan to accrue any additional subjects?

☐ Yes ☐ No Date* _____

Please elaborate on any Yes answers above: _____

_____

_____

_____

_____

Name of Principal Investigator: _____

Principal Investigator Signature: _____ **Date:** _____

Phone: _____ **Email:** _____

Name of Clinical Authorized User: _____

Clinical Authorized User Signature: _____ **Date:** _____

Phone: _____ **Email:** _____

Name of Physician Liaison: _____

Physician Liaison Signature: _____ **Date:** _____

Phone: _____ **Email:** _____

Submit by Email