# 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:** _____