University of Pittsburgh
Radioactive Drug Research Committee (RDRC)

Reporting Form for Adverse Events (AEs)

All Adverse Events (regardless of severity) associated with research subject participation in a RDRC-approved study must be reported to the RDRC within 24 hours of notification to the PI/study group. Please complete and submit this form to the RDRC (N. Scott Mason, Ph.D. masonns@upmc.edu or Courtney Wilkes crw29@pitt.edu)

CLEAR FORM

Principal Investigator:

RDRC/HUSC #:

IRB #:

Protocol Title:

Date of Report:

Research Subject ID#:

1. Date of occurrence of the Adverse Event:

2. What was the severity of the Adverse Event?

   Mild ◯ Moderate ◯ Severe ◯ Life-threatening ◯ Death ◯

3. Describe the Adverse Event. For the research subject in question, include details regarding the nature of the Adverse Event and how it was managed, including the outcome and any planned follow-up.

(*If necessary, response continues on Page 3)*

4. Was this Adverse Event:

   Unanticipated* ◯ Anticipated ◯

   *i.e. - The Adverse Event was **not** described as a potential risk in the study protocol/PittPRO application or disclosed in the informed consent document.

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5. Does this study remain open to enrollment of new subjects?

   No ◯ Yes ◯

6. Was this Adverse Event reported to the University of Pittsburgh IRB? Yes ◯ No ◯

7. It is felt (i.e., by the physician P.I., if applicable, or Authorized User for this study) that this Adverse Event is:

   ◯ not related to the administration of the radioactive drug(s) used in this study.

   ◯ possibly related to the administration of the radioactive drug(s) used in this study.

   ◯ probably or definitely related to the administration of the radioactive drug(s) used in this study (i.e., there is a reasonable possibility that the adverse event was or may have been caused by the radioactive drug)

Signed/dated by the physician PI, if applicable, or Authorized User for the research study listed above, and who was responsible for the review of this Adverse Event:

SIGNATURE (May be signed electronically)

Date:

INFORMATION BELOW TO BE COMPLETED BY RADIATION SAFETY OFFICER OR RDRC CHAIR

_____

Date: Received by RDRC office:

1. Does this event require reporting to the FDA by the University of Pittsburgh RDRC?
   Yes ◯ No ◯

Date Reviewed by RDRC Chair or Radiation Safety Officer :

SIGNATURE (May be signed electronically)
(RDRC CHAIR or RADIATION SAFETY OFFICER)

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3. (*continued from page 1)* Describe the Adverse Event. For the research subject in question, include details regarding the nature of the Adverse Event and how it was managed, including the outcome and any planned follow-up.