University of Colorado
Denver | Anschutz Medical Campus

# RDRC Adverse Event Reporting Form

The regulations require that the RDRC must report immediately, but no later than 7 calendar days, to FDA all adverse reactions probably attributable to the use of the radioactive drug in the research study.

In order to meet its obligation, the RDRC requires that the PI of the study must immediately, but no later than 7 calendar days, report to the RDRC all adverse effects associated with the use of the radioactive drug in the research study.

Please submit this report to the RDRC@ucdenver.edu.

Study Title:
PI:
Study ID:
Date of Incident:
Date of Submission:

1. Please summarize the event. Please include duration of the adverse event and the response time and action taken by the PI, study team or other health care provider. Describe below or attach additional documents as needed.

2. Is the event:

   ☐ possibly

   ☐ probably

   or

   ☐ definitely related to exposure to the radioactive drug used in the research
   (This means that there is a reasonable possibility that the incident, experience, or outcome may have been caused by the radioactive drug).

3. What is the current status of the research subject involved?

_____

Signed/dated by the PI or designee of the study listed above

Date: Received by RDRC office: _____

Date Reviewed by Radiation Safety Officer or RDRC Chair: _____

Requires reporting to the FDA? Yes ___ No ___