Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: XII.D.2
Section: RDRC Committee
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: November 14, 2003
Revision Dates: November 16, 2005; March 7, 2008; December 1, 2009; April 28, 2015; July 1, 2015

Subject: Procedure for Reporting of Adverse Events and/or Unanticipated Problems Involving Risk to Participants or Others to the Radioactive Drug Research Committee

Procedure:

This procedure outlines the process for reporting adverse events and/or unanticipated problems to participants or others involved in human subjects research in which a radioactive drug was involved.

I. Investigator Responsibilities.
A. It is the responsibility of the Investigator to report all adverse events and unanticipated problems involving risk to participants or others receiving ionizing radiation under an RDRC application according to HRPP Policy III.L.
B. It is the responsibility of the Investigator to report all adverse events and/or unanticipated problems involving risks to participants or others determined to be “probably attributable” to the use of the radioactive drug in a research study to the RDRC as soon as possible, but no later than 7 calendar days after the Investigator first learns of the event or problem.
C. Prior to and at the time of RDRC quarterly review of an approved research study, it is the Investigator’s responsibility to keep the RDRC informed for the accurate documentation, investigation, and follow-up of all possible study-related adverse events and/or unanticipated problems involving risks to participants or others.
D. Investigators are responsible for informing all sponsors of any adverse events and/or unanticipated problems involving risks to participants or others in accordance with the Federal regulations and Institutional policies and procedures including the IRB.
E. Investigators are responsible for informing the appropriate Institutional Committees (e.g., Institutional Biosafety Committee) of any adverse events and/or unanticipated problems involving risk to participants or others in accordance with the federal regulations and Institutional policies and procedures including the IRB.

II. RDRC Committee Responsibilities.
A. All reported adverse effects and/or unanticipated problem involving risk to participants or others associated with the use of a radioactive drug in a research study will be reviewed by the full RDRC Committee at the earliest convened meeting. The RDRC will evaluate the following factors for determining its recommendation:
   1. The seriousness of the event;
   2. The relationship of the event to study participation;
   3. The relationship of the event to the use of the radioactive drug; and
   4. Whether the Investigator is responsible for the reporting of adverse events and/or unanticipated problems involving risk to participants or others to a regulatory agency.
B. All serious and unanticipated adverse events or unanticipated problems involving risk to participants or others will be submitted to the Chairperson or his/her designee for an expedited or referral to the full RDRC/IRB for a determination.
C. The RDRC may render the following determinations:
1. Accept the adverse event or unanticipated problem involving risk to participants or others without revision to the study application or related documents;
2. Accept the adverse event or unanticipated problem involving risk to participants or others, but make recommendations to minimize reoccurrence and revisions of related documents;
3. Accept the adverse event or unanticipated problem involving risk to participants or others, with revision and re-consenting of current participants and/or notification of participants that might be affected that have ended participation; or
4. Suspend the study.
5. The RDRC may recommend termination of the study to the IRB, providing a rationale to the IRB and the Investigator (See HRPP Policy II.B).

C. The RDRC must immediately report all adverse events and unanticipated problems involving risks to participants or others determined by the RDRC to be “probably attributable” to the use of a radioactive drug in a research study to the FDA and any other appropriate federal agencies.