Unanticipated Problems/Adverse Events

Under 45 CFR 46 “unanticipated problems” involving risk to subjects or others must be reported to the IRB, institutional officials, study sponsor and OHRP. In addition, under 21 CFR parts 56, 312 and 812, adverse drug events and unanticipated adverse device effects that are “unanticipated problems” must be reported to the IRB, study sponsor, and FDA.

All deaths in interventional studies that occur within 30 days of the intervention must be reported to the IRB within 24 hours of discovery whether or not considered study-related when Rutgers is the IRB of record.

Incidents, experiences, outcomes and adverse events which meet all the criteria below also must be reported to the Rutgers IRB:

- unexpected in terms of nature, severity or frequency, given the research protocol, investigator's brochure, IRB-approved informed consent document, product labeling and other sources of information, and given the characteristics of the subject population being studied (expected natural progression of subjects' disease, disorder or condition or predisposing risk factor profiles)?
- related or possibly related to participation in the research, i.e., is there a definite or reasonable possibility that the incident, experience or outcome may have been caused by the research drug/device or research procedures?
- potentially place the research subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized?

Unanticipated problems which are serious adverse events must be reported within one week of discovery. All other unanticipated problems must be reported to the IRB within two weeks of discovery.

The following must be included in the submission of an Unanticipated Problems / Adverse Events in Human Subjects Research Report:

- 1 original and 2 copies of the Unanticipated Problems/Adverse Events in Human Subjects Research Report

If changes are to be made in the approved study protocol or documents in response to the event, then the following must also be included with the submission:

- 1 original and 2 copies of the Modification Request Form outlining what changes have been made and where.
- 1 original and 2 copies of all revised documents with proposed changes highlighted.
- 1 original of any revised documents with no highlighting for approval stamping.

Following review, the Unanticipated Problem/Serious Adverse Event will receive one of the following status determinations: Accepted or Not Accepted. This determination will be provided to the principal investigator, outlining follow-up steps as deemed necessary by the committee.