

**PRINCIPAL INVESTIGATOR RESPONSIBILITIES
FOR CONDUCTING HUMAN SUBJECTS RESEARCH**

- *Provide documentation that you and your project staff have completed Human Subjects Training before initiating work involving human subjects.*
- *Comply with Federal, State and Institutional Human Subjects Research policies.*
- *Provide Client with notification of PNNL IRB approval(s).*
- *Notify the IRB when the project is authorized and when work involving human subjects begins.*
- *Secure approval from the IRB for any changes to the protocol, informed consent, or previously approved forms before initiating work that includes those changes.*

REPORT TO THE IRB - IMMEDIATELY:

- **ANY INJURY, ADVERSE EVENT, UNANTICIPATED PROBLEM, OR NONCOMPLIANCE WITH THE APPROVED PROTOCOL OR CONSENT, INCLUDING THOSE THAT OCCUR AT COLLABORATING INSTITUTIONS.**
- **ANY CHANGES OR NEW INFORMATION THAT MAY AFFECT THE RISK/BENEFIT ASSESSMENT OF THIS WORK.**
- **ANY SIGNIFICANT NEW FINDINGS THAT MAY AFFECT, OR RELATE TO A SUBJECT'S WILLINGNESS TO CONTINUE THEIR PARTICIPATION IN THE RESEARCH.**
- *Protect and maintain signed consent forms and all related research records.*
- *Provide yearly input to the DOE Human Subjects Database as requested by the IRB.*
- *Submit a Continuing Review Application once a year, or as otherwise required by the IRB.*
- *Participate in project conformance reviews as required by the IRB.*
- *Submit a Final Report at conclusion of the project.*

REQUIRED PROCEDURES AND FORMS ARE AVAILABLE IN SBMS UNDER HUMAN SUBJECTS

QUESTIONS? CALL SHERRY DAVIS AT 375-3610