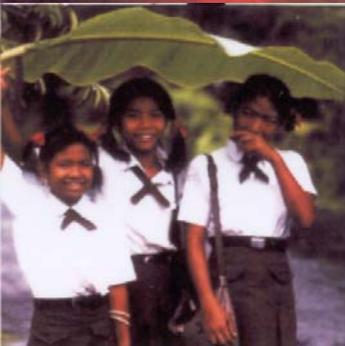
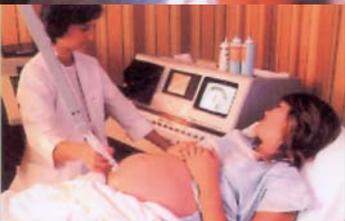


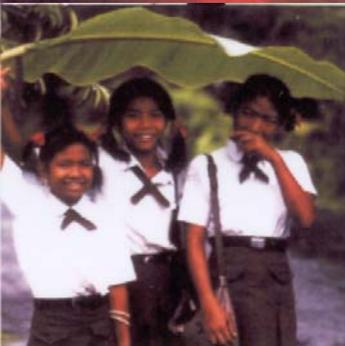
Roles and Responsibilities



Institutional Official

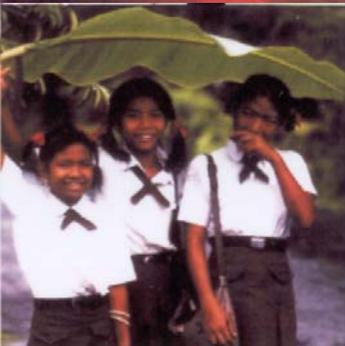
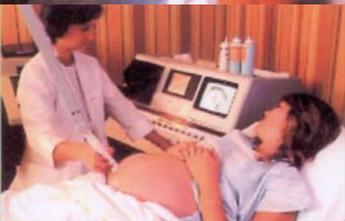
“The Buck Stops Here”

- Assumes obligations and is authorized to act for the institution
- Sets the “tone” for an institutional culture of respect for human subjects
- Knowledgeable point of contact for Office of Human Research Protection



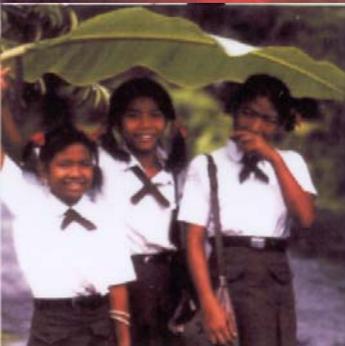
Institutional Review Board (IRB)

- Reviews and approves, requires modification in, or disapproves all research activities, including proposed changes in previously approved human subject research.
- Conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.



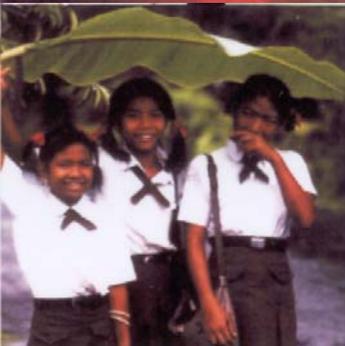
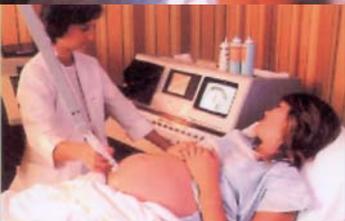
IRB

- Has the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.



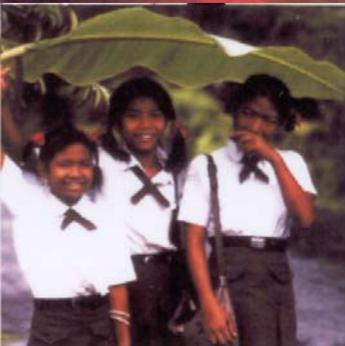
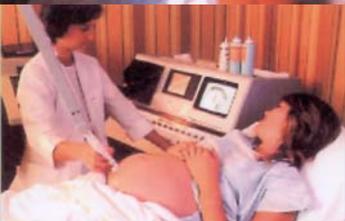
IRB

- Must be familiar with:
 - ethical principles of human subject research,
 - requirements of Federal regulations,
 - applicable state law,
 - the Institution's Assurance, and
 - institutional policies and procedures for the protection of human subjects.



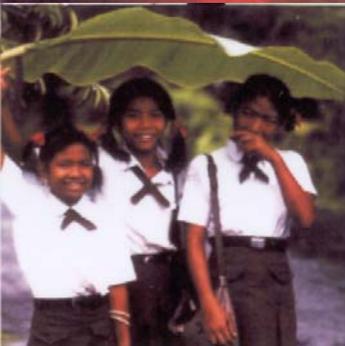
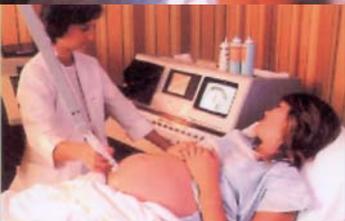
IRB

- Must have effective knowledge of
 - subject populations,
 - institutional constraints,
 - differing legal requirements, and
 - other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent.



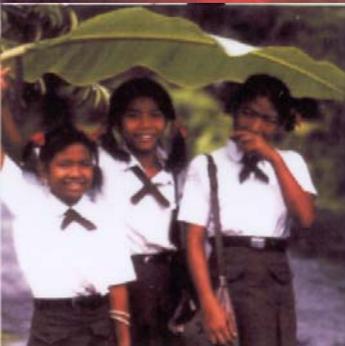
IRB Chair

- Ensures IRB carries out its responsibility
- Conducts expedited review or delegates to other IRB members
- Keeps Institutional Official informed
- Educates IRB members and investigators



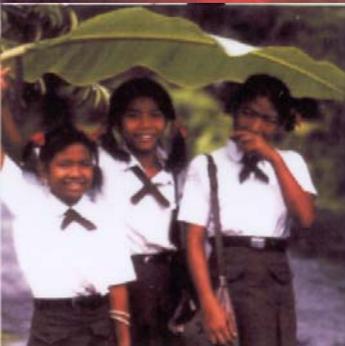
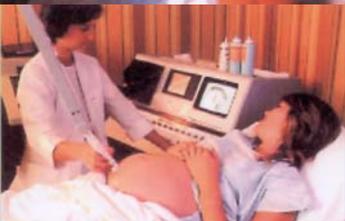
IRB Program Manager

- Subject Matter Expert and laboratory contact for human subject activities.
- Maintains Laboratory compliance with current Institutional, Federal, and State human subject policies.
- Manages Human Subjects Program.
- Develops/implements human subjects education program.
- Responds to internal/external audits.



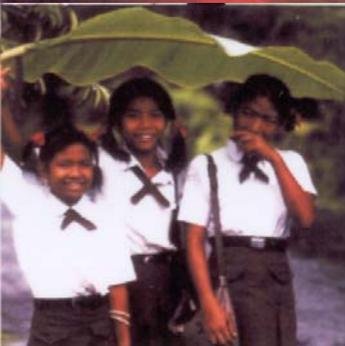
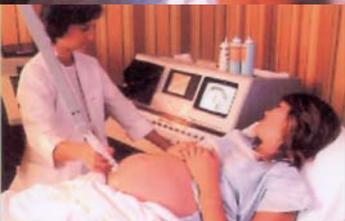
IRB Program Manager

- Receives research protocols, makes preliminary determination regarding exemptions/eligibility for expedited review.
- Facilitates constructive communication between the IRB, research and support staff, management, DOE, sponsors, and collaborative institutions.
- Advises and assists investigators throughout life of the project.
- Institutional contact for human subjects on all informed consents.



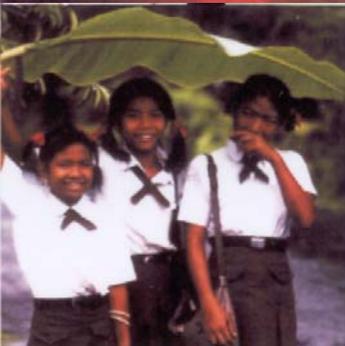
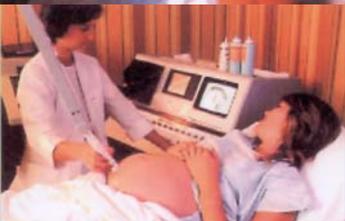
IRB Program Manager

- Reports promptly to Institutional Official, management, and sponsoring Federal department or agency head:
 - unanticipated injuries or problems involving risks to subjects or others,
 - a serious or continuing noncompliance with the regulations or requirements of the IRB,
 - suspension or termination of IRB approval for research.



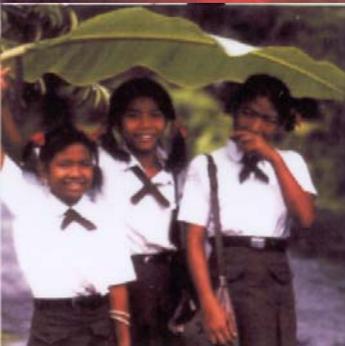
Research Management

- Aware of human subject activities and requirements.
- Sets the tone for a culture of respect for subjects and for the process.
- Assures scientific peer review of proposed research
 - Signs Application for Review



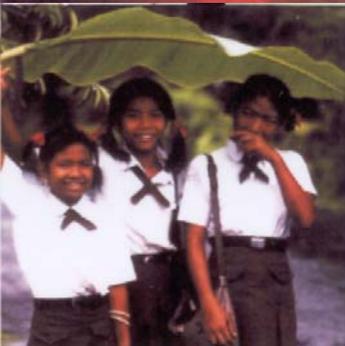
Investigator

- Has primary responsibility for protecting the rights and welfare of human research subjects and for complying with IRB requirements of approval.
- Is responsible for documenting human subjects education for all staff personnel.
- Is responsible for documentation of scientific peer review by line management.



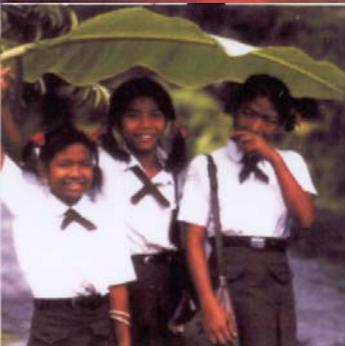
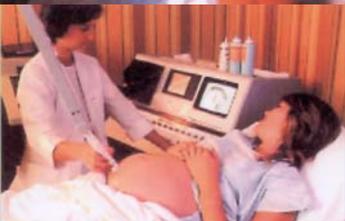
Investigator

- Must be familiar with:
 - the ethical principles of human subject research,
 - the requirements of the Federal regulations,
 - applicable state law,
 - the Institution's Assurance, and
 - institutional policies and procedures for the protection of human subjects.



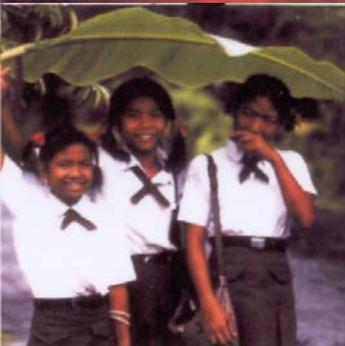
Investigator

- Conducts all research according to the IRB approved protocol and complies with all IRB determinations.
- Ensures that each potential subject understands the nature of the research and of the subject's participation and takes whatever steps are necessary to gain that comprehension.



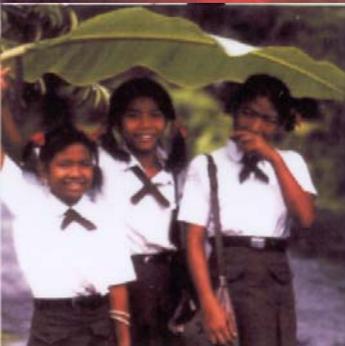
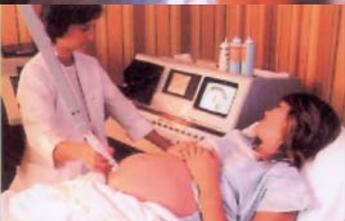
Investigator

- Provides an IRB-approved informed consent and Research Subjects Bill of Rights to each subject, unless these requirements are waived by the IRB.
- Retains all signed consent documents according to institutional policies, but at least three years beyond the completion of the research.



Investigator

- Promptly reports proposed changes in previously approved human subject research activities to the IRB.
- Does not initiate changes without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.



Investigator

- Reports progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once per year.
- Promptly reports to the IRB any unanticipated injuries or problems involving risks to subjects or others.