Clinical Radiation Safety Committee and Considerations for Research Involving Children

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Clinical Radiation Safety Committee
ex officio member of medical IRBs

• Evaluates protocols that deal with:
  - Radioactivity from isotopes or radiochemicals (e.g., P\textsubscript{32}, radioactive iodine)
  - Radiation from instruments (e.g., x-ray machines)
  - Nuclear Medicine, cancer studies involving CT scans, etc.

Radiation Safety Committee review is done in parallel with IRB review; no IRB approval is granted until Rad. Safety has approved the protocol.
Types of Radiation in the Electromagnetic Spectrum

We look here; includes CT, x-rays and radiologicals

http://www.epa.gov/radiation/understand/ionize_nonionize.html
Instructions:
- If you answer YES to Collaborating Institution, click the ADD button to enter the
details for one or more institutions.
- To remove an institution, check the box next to the name, and click DELETE.
- To view/modify details of previously entered institutions, click the link of the institution
name.

Reminder: If your study meets the ICMJE definition of a clinical trial, regardless of the
funding source, you must register your study at http://clinicaltrials.stanford.edu prior to
enrolling any research participants.

General Checklist
- Yes No Multi-site
  - Is this a multi-site study?

Equipment
- Yes No
  - Use of Patient related equipment? If Yes, equipment must meet the standards established by
    Hospital Instrumentation and Electrical Safety Committee (650-725-5000)
  - Medical equipment used for human patients/subjects also used on animals?
  - Radioisotopes/radiation-producing machines, even if standard of care?

Payment
- Yes No
  - Subjects will be paid for participation? See payment considerations.

Funding
- Yes No
  - Training Grant?
  - Program Project Grant?
  - Federally Sponsored Project?
  - Industry Sponsored Clinical Trial?
The Clinical Radiation Safety Committee’s Role in the IRB Review Process

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Alternate Radiation Safety Officer
Radiation Safety Committee Org Chart

APRS
Oversees entire radiation safety program for Stanford and the VA

NHRSC
Reviews laboratory use of radiation (radiochemicals and instrumentation)

CRSCo
Reviews procedures involving ionizing radiation in humans (research and clinical)

RDRC
Reviews research using radioactive drugs in humans w/o an IND and under specific conditions
IRB sends protocol to Health Physics for review

HP reviews protocol for:
Completeness
Accuracy
Estimation of dosage

HP asks questions (ergo, whole body versus organ specific scans, number of scans, etc.)

HP performs scientific and scholarly review of radiation portion of the protocol activity and estimation of dosage

HP submits dose and consent language to IRB

If ≤ 5 rem adult or ≤ .5 rem for minors protocol is reviewed/approved by HP

If > 5 rem adult or ≥ .5 rem for minors protocol is reviewed by Chairmen, RS Officer, and a physician faculty member
Suggested Consent Language

“You will be exposed to radiation during this research.”
“Your total effective dose will be about X millirems.”

If ≤ 5 rem:

“If there is any risk from this exposure, it is too small to be measured. The risk is low compared to other everyday risks. You receive about 300 millirems each year from natural sources. Radiation workers can receive 5000 millirems each year.”

If > 5 rem:

“This dose has an estimated risk of fatal cancer of about X percent. This is in addition to the natural fatal cancer risk of about 25 percent.”
Why delineate at 5 rem?

• There is substantial and convincing scientific evidence for health risks following high-dose exposures. However, below 5-10 rem health effects are too small to be observed.

Note: Risk estimates used to predict health effects in exposed individuals or populations are based on epidemiological studies of well-defined populations (e.g., Japanese atomic bomb survivors) exposed to high doses delivered at high dose rates.
Why does CRSCo review minors at 10% of adult dose?

• Children are at greater cancer risk than adults from given radiation exposure both because:
  – They are inherently more radiosensitive
  – They have more remaining years of life during which a radiation-induced cancer could develop
IRB Obligations for Radiation Exposure (general)

• The reviewer must:
  
  o weigh and consider risks and benefits
  o consider both long and short term risks
  o consider vulnerability and circumstances of all participants
  o check for consistency throughout the protocol application in the number of scans to be performed
Considerations for IRB Reviewers (Children)

- Is this procedure the best method of examination for the research?
- Can radiation exposure be lowered? (ergo, settings are set for children?)
- Can additional protections be provided? *For example, lead aprons, limited areas, only X number of tries, sedation for squirmy children*
- Are technicians and equipment certified (accredited)?