Registrant Statistics and IRB Changes

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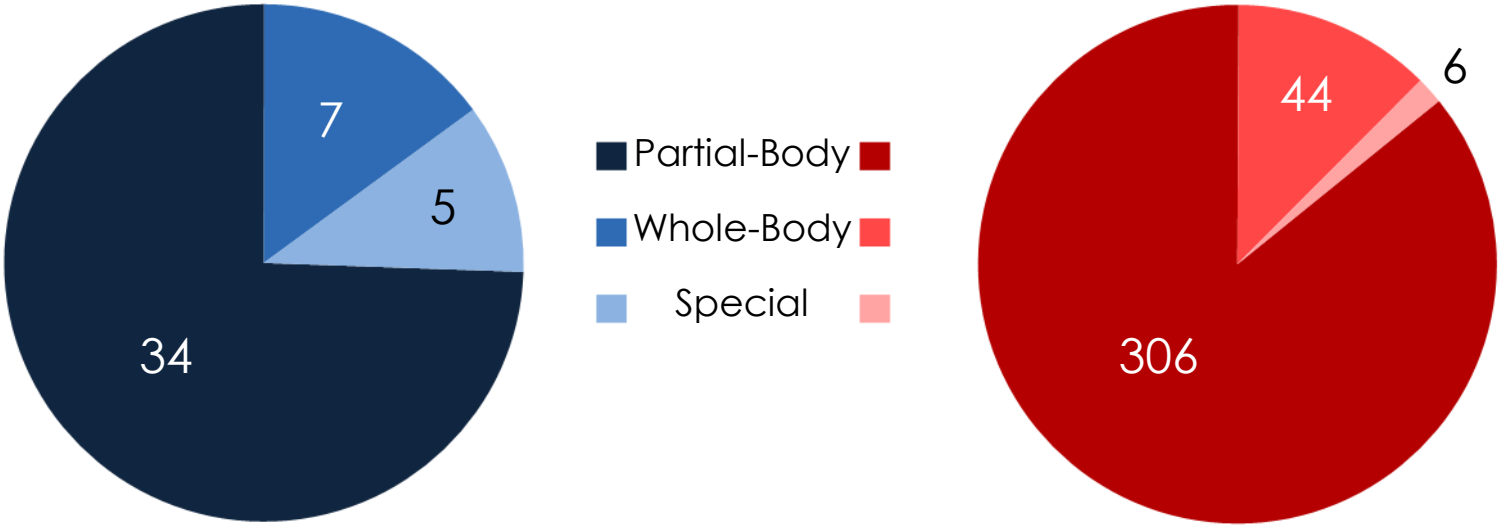
"Learning from Plutonium and Uranium Workers"

Number of Registrants

As of August 22, 2016

Living (46) + Deceased (356) = 402

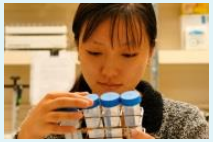


Inactive Registrants: 477

Since our last Annual Meeting...

4 Registrant Deaths reported

4 Autopsies Performed



Partial-Body – Colorado

- Numerous contamination incidents and minor wound injuries
  - ✓ None followed by positive bioassay measurements
- One skin laceration: 0.23 nCi Pu-239
- In-vivo chest counts indicated minor plutonium deposition in the lungs
- One Np-237 urinalysis was above the MDA

Whole-Body – Alaska

- Inhalation of Pu-239 oxide
- 'Faulty' respirator
- Lung burden
  - ✓ 20 nCi (initial)
  - ✓ 7 nCi (9 months post accident)
- Treated with Ca-DTPA (five 1-g i.v. injections)

Partial-Body – Alabama

- Inhalation of Pu-238
- Three possible acute inhalation incidents
- But worksite personnel assumed chronic intake over the course of 9 years
  - ✓ Mixture of soluble and insoluble
  - ✓ 260 nCi (76 pCi/d)

Partial-Body – Washington

- Acute inhalation of Pu-239
- Type S material
- Worksite intake estimate: 12.6 nCi

Institutional Review Board (IRB)

- Protects the rights and welfare of the human subjects who participate in research (our Registrants)
- We are in the process of changing our IRB of record from WSU to the Central DOE IRB

Why the Central DOE IRB?

- HIPAA considerations
- We will only report to CDOEIRB
  - ✓ Previously we reported to both WSU and CDOEIRB

What have we completed?

- WSU signed an Institutional Authorization Agreement, which says that WSU may rely on CDOEIRB for review and oversight of the USTUR
- USTUR submitted a full IRB to CDOEIRB
- CDOEIRB has approved our submission for a period of 3 months
- The Board would like to see additional consideration given to the process of re-consenting Registrants (renewals)

Re-consenting Registrants

- Currently, Registrants sign new paperwork every 5 years.
- "While the Board appreciates the consideration the project is trying to give to the participants, it is problematic to have them re-consent every five years due to the aging population that is likely to have diminished capacity over time for health reasons, i.e. dementia, Alzheimer disease"

Average Age of Living Registrants: 83 ± 11 years

Range: 46-96 years

Two alternatives suggested by CDOEIRB

1. Send periodic reminders of the participant's previous commitment to the program with information about the program. No additional information from the participant is requested. No additional consent would be required.

2. At the time of re-consent, provide tools to allow a participant and/or their family member to establish an individual who is authorized to complete the periodic medial history and sign the re-consent form should the participant become unable to complete the forms themselves. Consideration will need to be given to the laws of each state in which participants are resident to determine if this person needs to hold a legal power of attorney or if they can simply be a designated family care giver.

The proposed path forward

1. Send periodic reminders of the participant's previous commitment to the program with information about the program. ~~No additional information from the participant is requested.~~ No additional consent would be required.

We propose that:

- ✓ A periodic reminder of the participant's previous commitment be sent every year
- ✓ A periodic medical history questionnaire be sent every five years
- ✓ The consent form will be very clear that they will be re-contacted for the medical history questionnaire
- ✓ An information sheet will be included with the questionnaire with details provided in the consent form

Questions?