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# Registrant Statistics and IRB Changes

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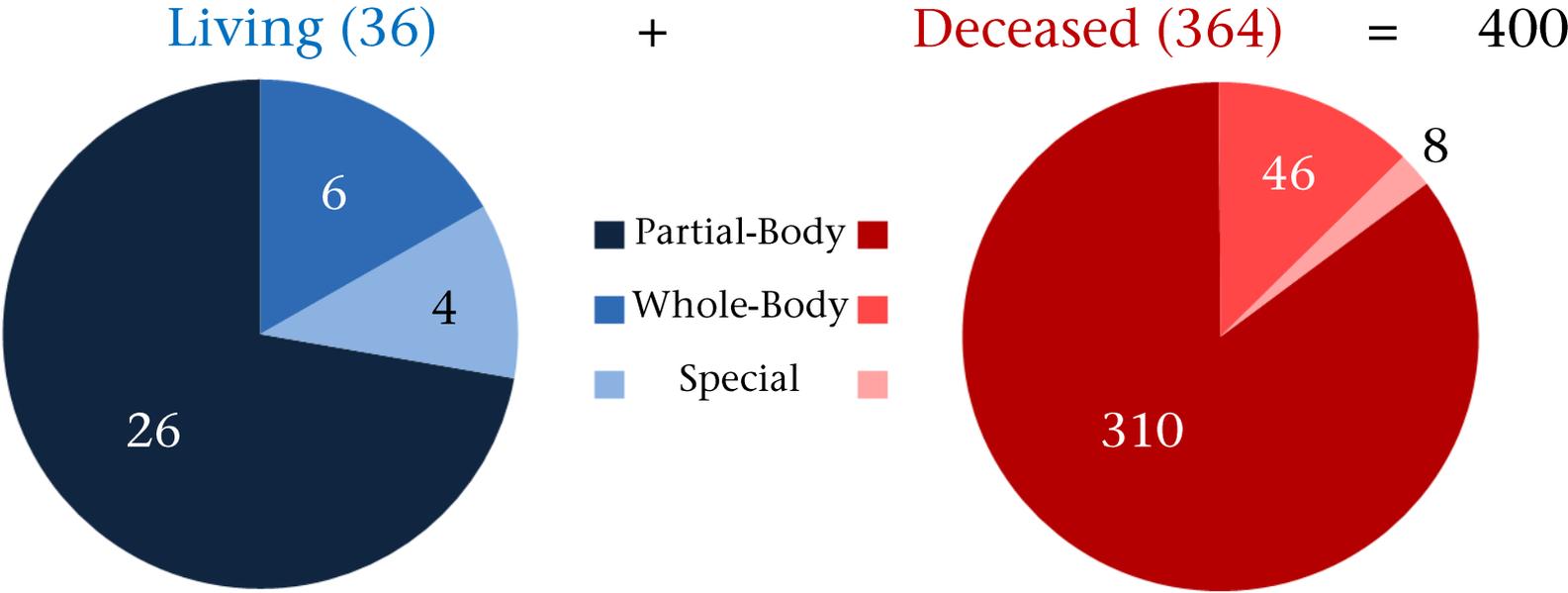
*“Learning from Plutonium  
and Uranium Workers”*





# Number of Registrants

As of March 31, 2019



Inactive Registrants: 479



# Two Registrant Donations

1 Whole-body  
1 Partial-body

## Partial-Body Donor

- Possible Cm-244 intake
- Extensive Pu contamination
  - ✓ Contaminated acid burns
  - ✓ Chelated (Ca-DTPA)
  - ✓ 8 nCi systemic 24 y post-intake

## Whole-Body Donor

- Single wound
  - ✓ Decontaminated to background with routine scrubbing
- Possible inhalation
  - ✓ Pu measured in a single urine sample prior to wound
- 2 nCi systemic activity at termination of employment



# Inquiries About Registrants

- Current Nuclear Worker
  - ✓ Have I ever been a Registrant?
  - ✓ Do you hold data on me?
  - ✓ How do I access this data?
- Worker Advocate (on behalf of the widow of a deceased worker)
  - ✓ Did the person donate tissues to the Registries?
  - ✓ Do you have medical and exposure records?
- Brings to light the need to have a form for
  - ✓ Asking if someone is a Registrant
  - ✓ Requesting a copy of records



# Types of Registrant Information

- Living, Deceased, or Inactive (879 cases)
  - ✓ Radiation exposure records
  - ✓ Worksite medical records
  - ✓ Autopsy report
  - ✓ Radiochemistry results
  - ✓ Correspondence
  - ✓ Consent forms
- Historical (566 cases – autopsy authority)
  - ✓ Full name - or last name and initials (100%)
  - ✓ SSN (95% of cases)
  - ✓ Worksite (25%)
  - ✓ Address (10%)
  - ✓ Birth date (4%)
  - ✓ Deceased date or Telephone (rare)





# Who Can Request Information?

- Living Registrant
  - ✓ Registrant
  - ✓ Power of Attorney (must provide signed POA)
- Deceased Registrant
  - ✓ Typically, close family members
  - ✓ Next of kin?



# What Personal Information About the Registrant Do We Need?

- Name
- Social Security Number
- Date of Birth
- Date of Death?

A work in progress: The new request form will require IRB approval before it can be used.



# Institutional Review Board

- The Central DOE IRB is the IRB of record
- WSU completely relies on the Central DOE IRB for review and oversight of the USTUR
- August 2018: continuing review submitted
- September 2018: IRB approved until September 11, 2019
- Added staff members and updated training



# Scientific Collaboration and Data Access

- Recommendation 8: Develop a written operating procedure for control, release, and potential return of data and tissues that lists responsibilities and authorizing individuals.
- Revised the USTUR Scientific Collaboration and Data Access policy (P106)
  - ✓ An internal policy
  - ✓ Something collaborators must read and agree to



## United States Transuranium and Uranium Registries Statement of Confidentiality

I have read the policies of the USTUR regarding collaborative research, data access, and confidentiality (Policies 106 and 107). I agree to abide by these policies and maintain the confidentiality of the USTUR Registrants and their next-of-kin unless legally required to do otherwise



# Policy Summary





## Potential Collaborators Must...

- Submit a written proposal
- Provide assurance that they can receive human samples
- Agree to follow USTUR policies on human subjects and privacy of Registrants
  - ✓ Old wording included informed consent and national security
  - ✓ Privacy is the element of the informed consent form that is relevant to collaboration



# Approval of Collaborative Project

- Requires director approval
- Director will grant access to data at one of three levels

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
	<i>Medical and Radiat. Protection Personnel<sup>†</sup></i>	<i>Collaborative Researchers</i>	<i>Collaborative Researchers</i>
Personal Identifiers (Direct)	Yes	No	No
Specific Dates	Yes	Yes	No
Site Descriptions	Specific sites of employment	General site description	General worksite information

<sup>†</sup>From the Registrant's current or former worksite



# Data Transfer



Redact direct  
personal identifiers



Encrypt  
file(s)



Save to DVD,  
USB drive, etc.



Ship, overnight,  
signature required



Send passwords  
separately



# Stewardship of Data and Tissues

- USTUR data and biological specimens are shared:
  - ✓ With approved collaborators
  - ✓ For specific research purposes
- Biological specimens and data may not be analyzed for purposes beyond the scope of research agreed upon prior to receipt of specimens
- Data may not be shared with other researchers without prior approval from the Registries
  - ✓ Read procedures
  - ✓ Sign statement of confidentiality



# Data Storage

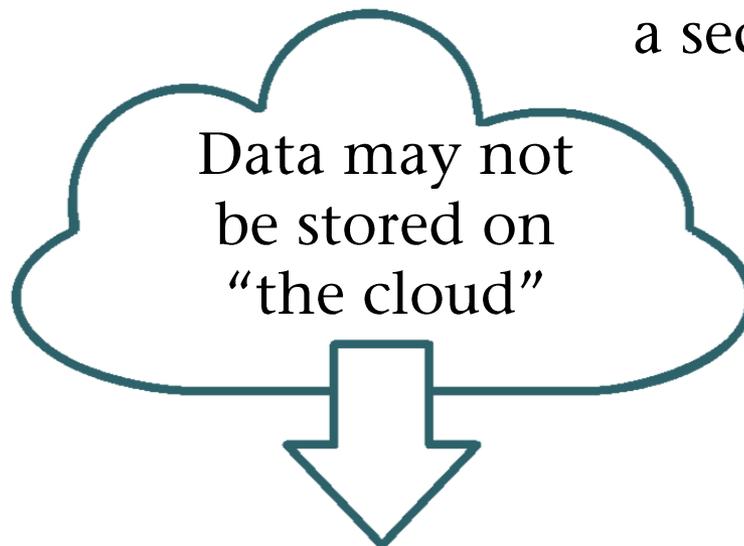


Computers must be Protected by

- ✓ Firewall
- ✓ Password



Electronic and paper files must be kept in a secure location





# Return or Disposal of Materials



Original Data

AND



Secondary Files



Destroy or Return within  
1 year of publication, or  
5 years of receipt



Tissue Materials

Not destroyed  
during analysis



Return within  
1 year of analysis, or  
3 years of receipt

1-year extensions may be granted



# Questions?