

United States Transuranium and Uranium Registries  
2021 Scientific Advisory Committee Meeting  
Teleconference, Richland, WA, April 8 – 9, 2021

## Registrant Statistics and IRB Changes

Stacey L. McComish  
[s.mccomish@wsu.edu](mailto:s.mccomish@wsu.edu)

Associate in Research  
College of Pharmacy and Pharmaceutical Sciences  
Washington State University

1845 Terminal Drive, Suite 201, Richland, WA 99354  
[www.ustur.wsu.edu](http://www.ustur.wsu.edu)

*“Learning from Plutonium and Uranium Workers”*



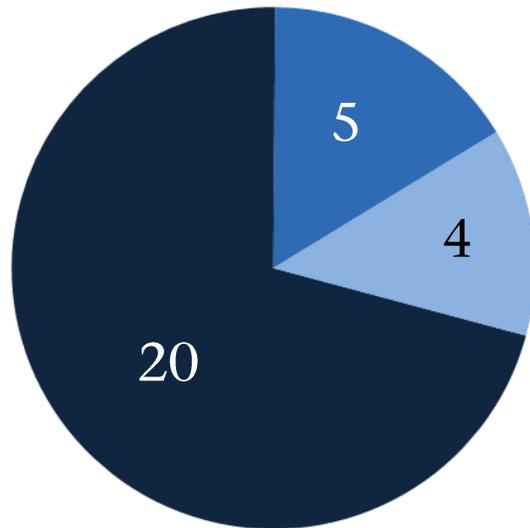
College of  
Pharmacy and  
Pharmaceutical Sciences  
WASHINGTON STATE UNIVERSITY



# Number of Registrants

As of March 31, 2021

Living (29)

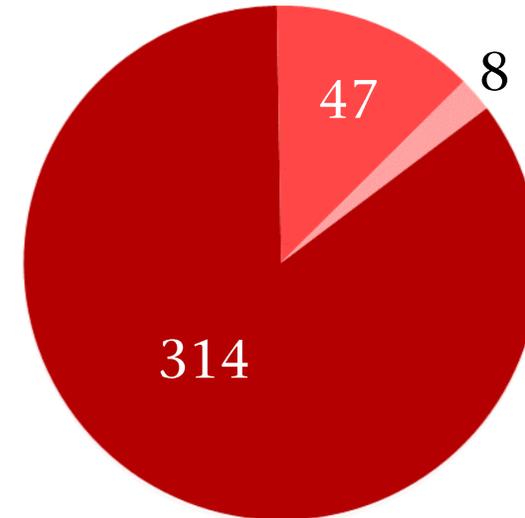


+

Deceased (369)

= 398

- Partial-Body
- Whole-Body
- Special



Inactive Registrants: 482





# Two Registrant Donations

Partial  
body

- 3 nCi plutonium “systemic deposition”
- Several minor wound incidents
  - 0.003  $\mu\text{g}$  plutonium, decontaminated to background
- 1 positive plutonium in urine
- 1 positive enriched uranium in urine

- No recorded intake incident
- 0.76 nCi “systemic burden” midway through employment
- No urine or external dosimetry data in file

Partial  
body



# Institutional Review Board

- Submissions to Central DOE IRB
  - ✓ September 2020: Continuing review + minor modifications
  - ✓ March 2021: Urine sample modification
  - ✓ September 2021: Continuing review + minor modifications



# Continuing Review and Minor Modifications

- Submitted: September 2020
- Publications policy (P107)
  - ✓ USTUR staff member must be a co-author if
    - Previously unpublished data, tissues, or other materials
    - Collaborative effort by Registries staff
  - ✓ Worksites referred to by category (e.g. defense nuclear facility, source manufacturing, uranium mine, medical)
- Approved through September 8, 2021

*Recommendation #8: SOPs should help assure appropriate acknowledgement of the role of USTUR and inclusion as appropriate as co-authors.*



# Updated Communication Policy (P103)

**F103b** **Data Request: Deceased Registrant**  
Created 09/19  
Revised n/a  
Approved by *S. Y. Tolmachev* Sergei Y. Tolmachev, Director  
September 2019

*To request information on behalf of a deceased individual, the requestor must be next of kin and provide a copy of the death certificate.*

*To protect our Registrants' information, we require proof of your identity. To request information by mail, your signature on this form must be notarized OR the person requesting information must provide a photocopy of two identifying documents bearing your name and signature, one of which shall bear your current home or business address and date of birth (e.g. driver's license). To request information in person, you must present one identifying document bearing your photograph and signature (i.e. driver's license or passport).*

**Part A: Individual for Whom Data is Requested**

Full Name \_\_\_\_\_

Most Recent Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Social Security Number \_\_\_\_\_ Date of Birth \_\_\_\_\_ Date of Death \_\_\_\_\_

**Part B: Individual Making Request**

*To request information on behalf of a deceased Registrant, the requestor must be next of kin.*

Full Name \_\_\_\_\_ Telephone Number \_\_\_\_\_

Mailing Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Relationship to individual in Part A \_\_\_\_\_

**Part C: Determine Registrant Status**

Did the above individual in Part A donate tissues to the USTUR?

Facilities where the individual worked with or around plutonium, americium, uranium, or other actinides \_\_\_\_\_

USTUR Policies and Procedure Manual

- Will submit with continuing review in September 2021
- Refers to new data request forms from 2019 (F103a, F103b)
  - ✓ Formal process for requesting information from a Registrant file
  - ✓ Address who can request records
  - ✓ Verify identity of requestor

*Recommendation #9: Periodically review and update Policy and Procedures to ensure access to Registrant information is provided to only legitimate representatives.*





# Regulated Data Environment (RDE)

- Recently set up by WSU to make it easier for recipients of federal grants to store data according applicable regulatory standards
- Hosted in Amazon and Microsoft cloud infrastructure
- Exploring this as an option for sharing files containing personally identifiable information with collaborators
  - ✓ E.g. exposure history, mortality data, with case numbers
  - ✓ Not names, SSNs, etc.





# Collection of Urine Samples from Living Registrants

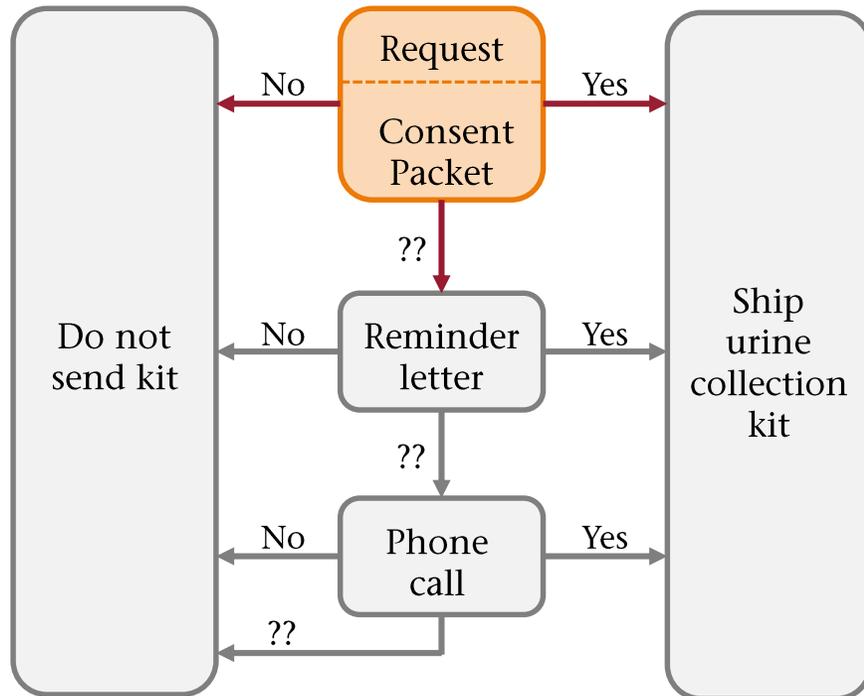
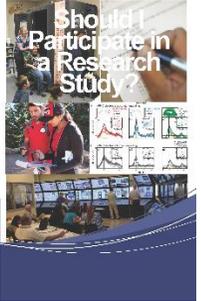
- The USTUR has urinalysis results from worksite
- But few, if any, measurements after employment ended
- Useful for biokinetic modeling of long-term retention
- Living USTUR Registrants will be asked to submit a urine sample
  - ✓ One-time
  - ✓ Yearly
- March 2021: Modification was submitted and approved

*Recommendation #5: Initiative to collect current bioassay monitoring data for all living Registrants should be completed as soon as possible.*





# Request to Participate and Consent Packet



Cover letter

- ✓ What we are doing and why



Informed consent form

- ✓ Does not impact Registrant status
- ✓ No cost to Registrant (or compensation)
- ✓ Risks



Additional information form

- ✓ Shipping address for collection kits
- ✓ Mailing address for results

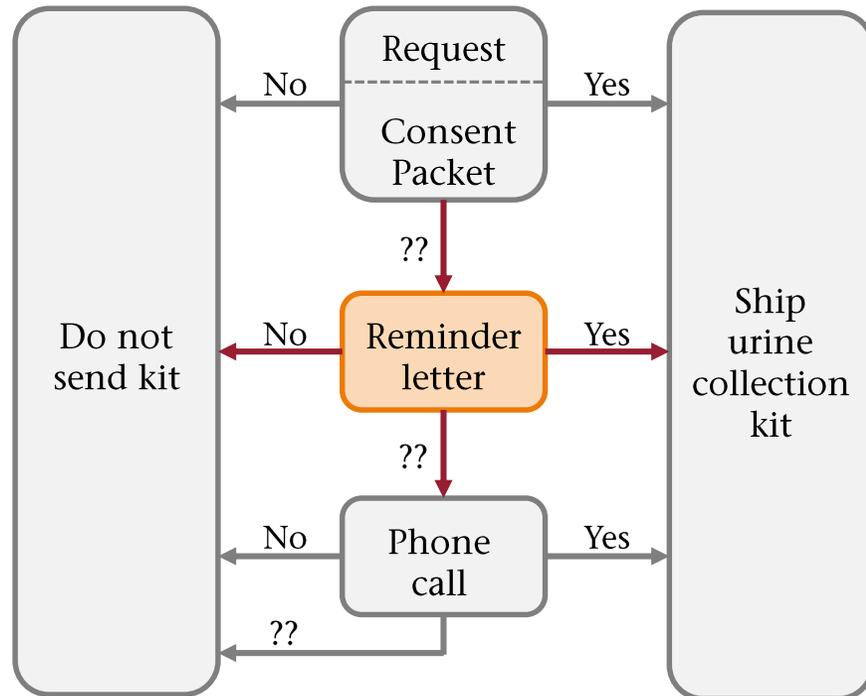


DOE Brochure – Should I take part in a research study?





# Reminder Letter



Reminder letter

- ✓ Sent after 3 weeks
- ✓ Can indicate if they have questions or do not want to participate



Cover letter



Informed consent form



Additional information form



DOE Brochure – Should I take part in a research study?

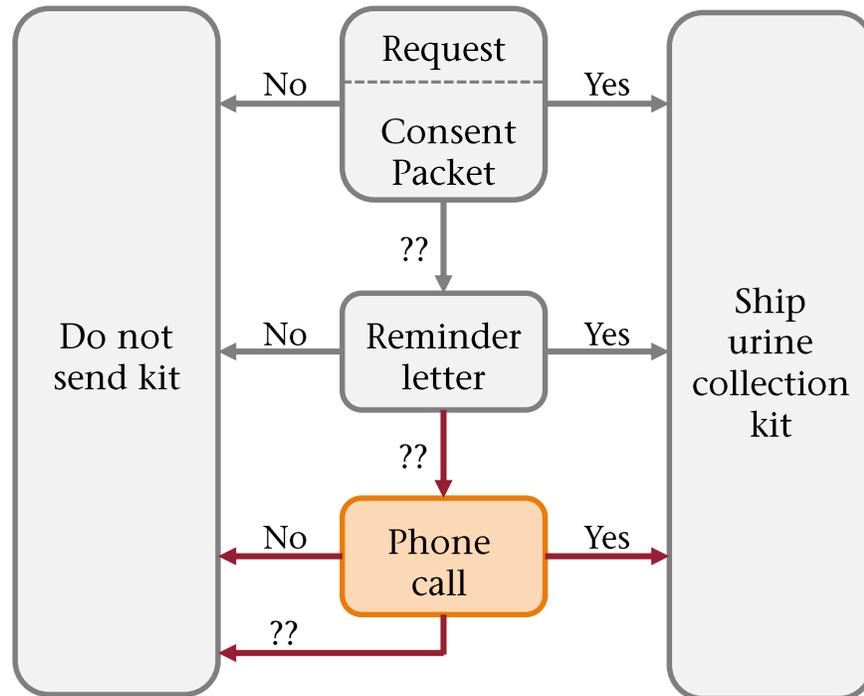


# Call Remaining Registrants



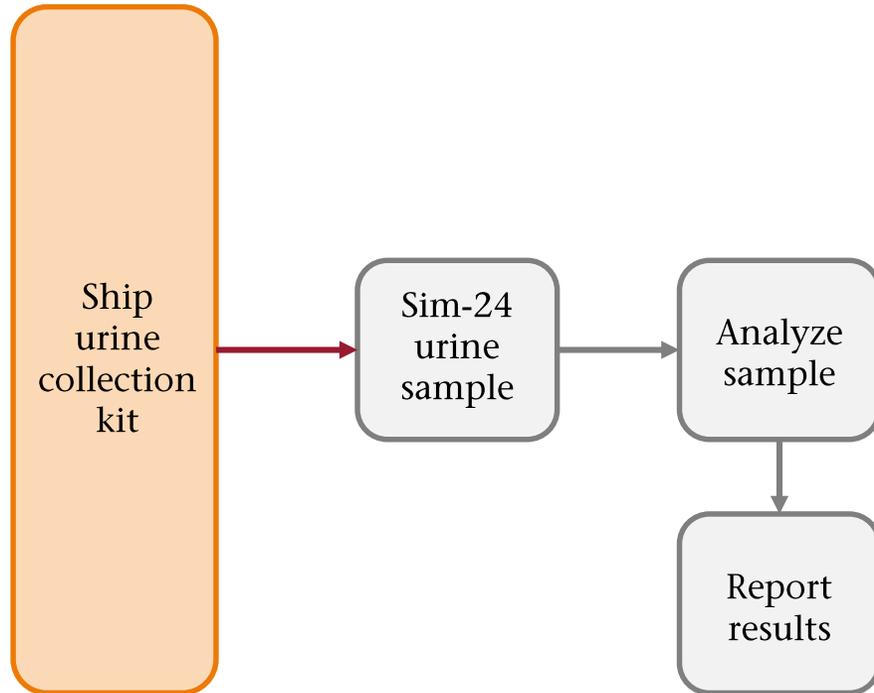
## Phone call

- ✓ After 3 weeks
- ✓ Do they have any questions?
- ✓ Do they want to participate?





# Ship Kits



Collection kit

- ✓ 3 – 1 liter bottles



Instruction sheet

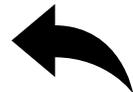
- ✓ Step-by-step instructions
- ✓ Collection and return of sample
- ✓ Based upon Hanford instructions



Another opportunity to request results



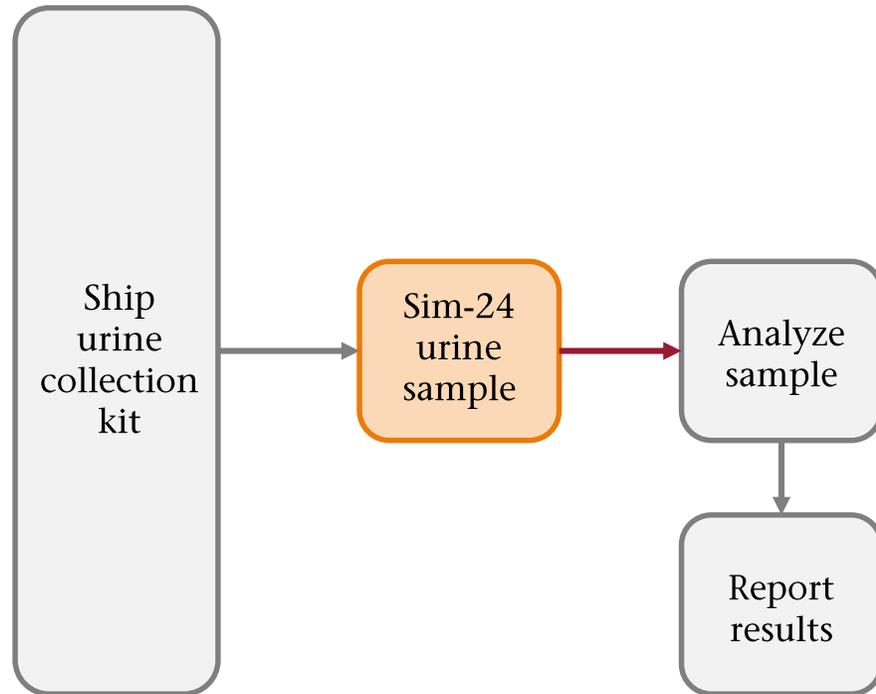
Packaging for return shipment



Prepaid return shipping label



# Sample Collection



## Simulated 24 hour urine sample

- ✓ All urine starting a half hour before going to bed
- ✓ All voids through the night
- ✓ A half hour after waking up
- ✓ Two consecutive nights

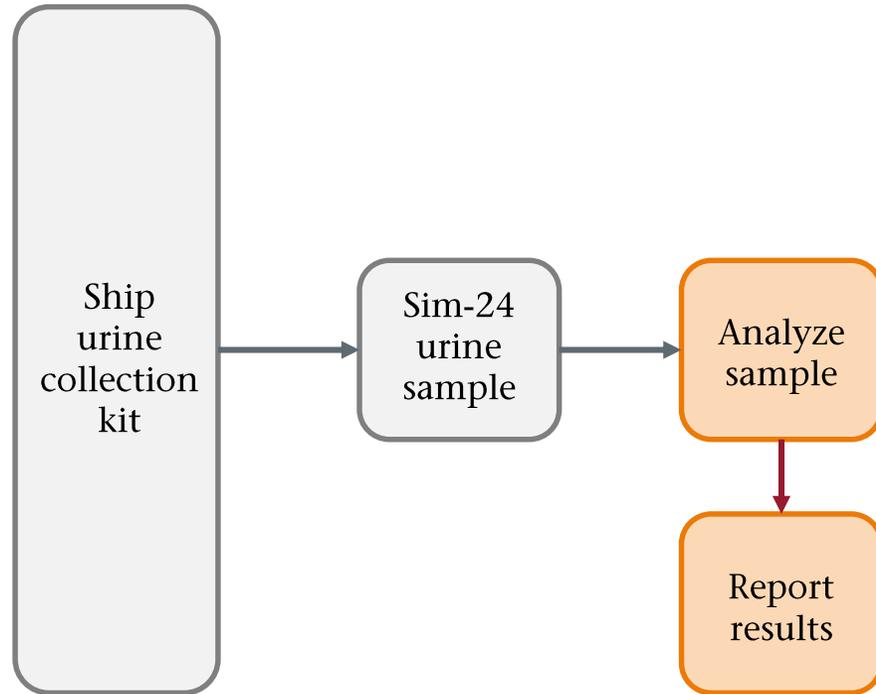


## Ship sample back to USTUR

- ✓ Call phone number for FedEx pickup
- ✓ Alternate arrangements if this is difficult



# Analyze Samples and Report Results



## Analyze samples

- ✓ Alpha spectrometry: Am, Pu, Cm
- ✓ ICP-MS: U, Np
- ✓ Based on exposure history
- ✓ Most likely will be analyzed by external laboratories



## Report results to Registrants

- ✓ If not requested at consent or sample collection, must complete F103a or F103b



# Questions?

