Welcome!

Welcome!
Today's session will begin shortly.
There will be no audio sound until the session begins.

Zoom Meeting Reminders

- Zoom technical support at 1-888-799-9666, option 2
- Audio can be connected through your computer or through a call-in number
- Submit questions at any time in the Q&A box at the bottom of your screen
- Webinar slides and session summaries posted shortly after the event at **thefdp.org**. (Note: This session will not be recorded at the request of the Presenters.)

FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Animal Subcommittee Updates

CUSP (Compliance Unit Standard Procedures)

Universal Protocol Template

Revision of the Guide for the Care and Use of Laboratory Animals

Dr. Aubrey Schoenleben, University of Washington
Mr. Bill Greer, University of Michigan
Dr. Teresa Sylvina, National Academies of Sciences, Engineering, and Medicine

FDP Meeting – May 2020

Agenda

- CUSP Project Update
- Universal Protocol Template Update
- The Guide: A Listening Session

FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

CUSP Project Update

Aubrey Schoenleben, University of Washington

Animal Subjects Subcommittee– May 26, 2020

CUSP SHARING SITE

<u>Goal</u>:
Develop an online venue where participating institutions can share standard procedures used in animal care protocols.

CUSP = **C**ompliance **U**nit **S**tandard **P**rocedure

Current Project Status

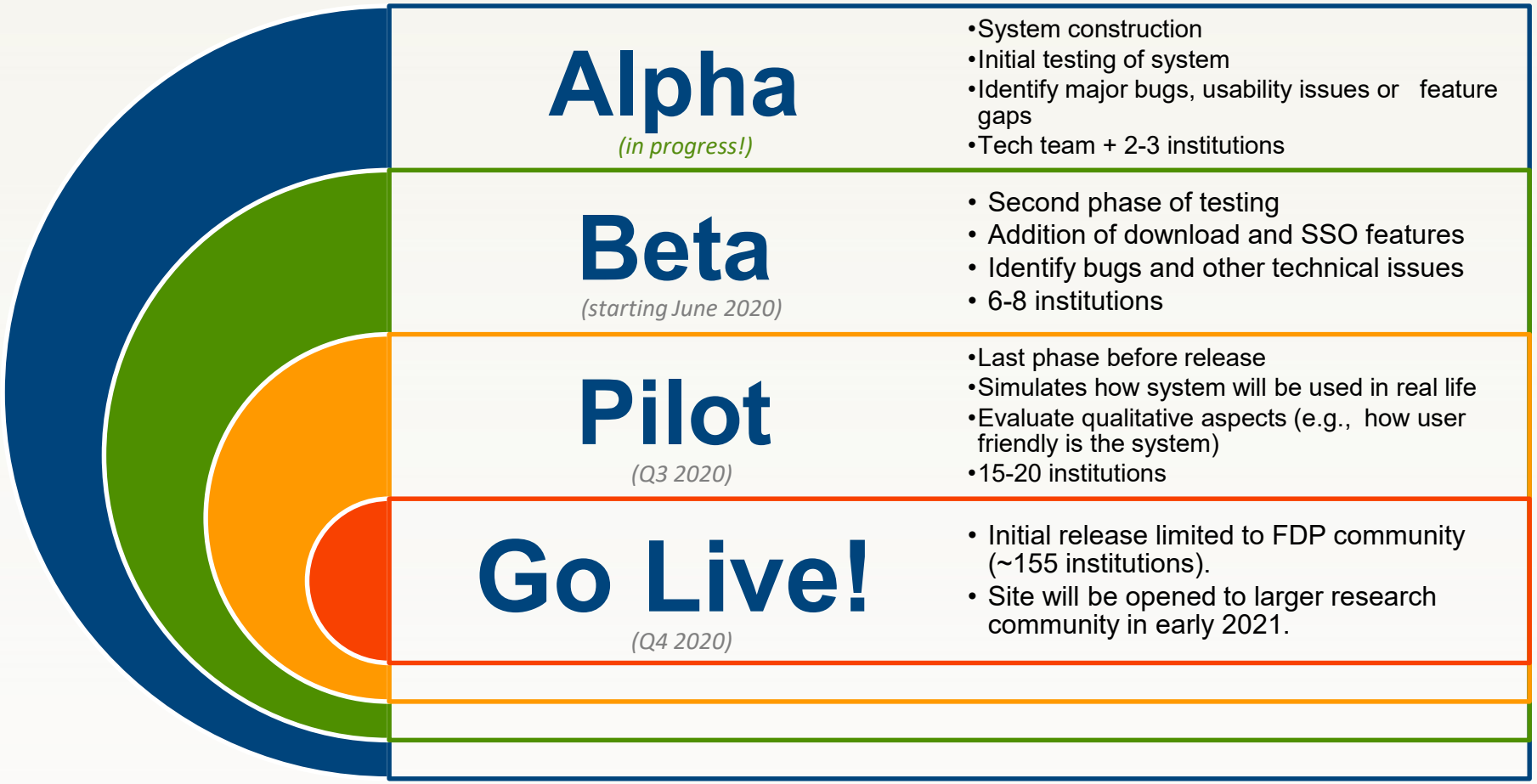
Alpha Testing

- Initial testing of system.
- Identify major bugs, usability issues or feature gaps.
- Largely performed by tech team
- 2-3 institutions

Dev Team:
Jaret Langston
David Wright

Testers:
Scott Bury
Elaine Kim
Ellen Ladenheim
Eva McGhee

Development: Next Steps



Steering Committee & New Teams

CUSP Working Group

Aubrey Schoenleben, Sally Thompson-Iritani
Federal Representative: Axel Wolff

Education & Outreach

Scott Bury, Michelle Brot

Help Desk

Elaine Kim, April Ripka

Quality Control

Eva McGhee, Cyndi Rosenblatt

Technical Systems

Jaret Langston

Upcoming Presentations

1. ***NABR Webinar***
   Moving Forward with the 21CCA
   May 20, 2020
   Recording available soon!

2. ***PRIM&R Virtual Meeting***
   Harmonization without Compromising Welfare
   June 17, 2020, 11:30 – 1pm ET

3. ***September FDP Meeting – details TBD***

4. ***AALAS National Meeting***
   On the CUSP: A New Option for Addressing Administrative Burden (live demo!)
   October 26, 2020, 8 – 10:15am ET

FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

Universal Protocol Template Update

Bill Greer, University of Michigan
Ron Banks, University of Oklahoma Health Sciences

Animal Subjects Subcommittee– May 26, 2020

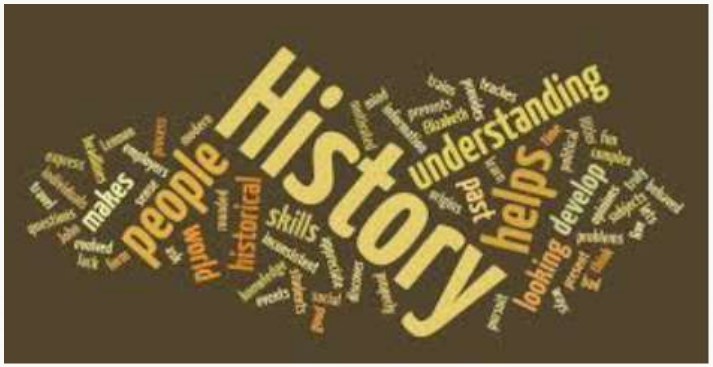
Session Goals

1. The Regulatory Reform Initiative
2. Summary of Project Initiation
3. Target Product (UPT)
4. Working Group Activities
5. Project status
6. Anticipated Timelines

IACUC Administrator Association

History Lesson

1. Regulatory Reform: the push, impact and opportunity
2. IACUC Administrators Association engagement and projects
3. FDP, IAA, USDA, OLAW, DoD and VA partnership



IACUC Administrator Association

The Push for Regulatory Reform

Reducing Regulatory Burden for Scientists

1. 2005 Federal Demonstration Partnership survey of investigator (42%)
2. 2009 National Research Council (NRC) report stated that the problem of excessive regulatory burdens on university research programs could cost "billions of dollars over the next decade."
3. A 2012 survey of FDP faculty members (seven years after the first survey) found that the average time that PIs of federally sponsored research projects spend on associated administrative tasks remained at 42 percent.
4. A 2013 review by the Council on Governmental Relations' (COGR) November, demonstrated there continues to be an ongoing increase in regulations affecting PIs and research institutions.
5. 2014 National Science Board Report - Reducing Investigators Administrative Workload for Federally Funded Research (AKA – Reducing Regulatory Burden) – average remained 42%
6. A 2018 survey of FDP faculty members (six years after the first survey) found that the average time that PIs of federally sponsored research projects spend on associated administrative tasks remained at 44 percent.

IACUC Administrator Association

Impact - 21st Century Cures Act

1. The 21st Century Cures Act, Section 2034 (d) was signed into law on December 13, 2016, which requires regulating agencies (e.g., OLAW and the USDA) to review animal research regulations and make revisions that would result in reduce administrative burden for investigators.

2. On February 24, 2017, President Trump issued an Executive order: (**139 - Executive Order 13777)** to enforce the Regulatory Reform Agenda**.** http://www.presidency.ucsb.edu/ws/index.php?pid=123412

3. Upon completing their assessment of the animal research regulations; on March 14, 2018, federal regulators offered ideas for proposed changes through the Federal Register (https://www.federalregister.gov/d/2018-05173/page-11221).

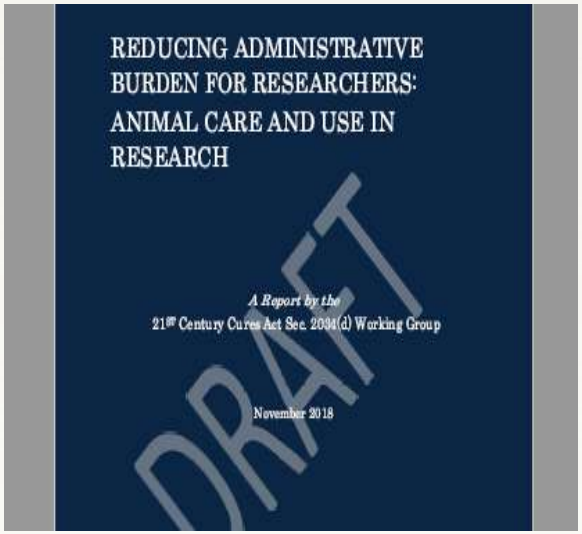
4. Through the federal register (Federal Register / Vol. 83, No. 50 / Wednesday, March 14, 2018) (83 FR 11221) information from the animal research community was requested.

IACUC Administrator Association

Regulatory Reform – An Opportunity

Example highlights:

- Propose to align USDA and PHS protocol re-review requirements
- Update guidance on the use of non-pharmaceutical drugs and agents.



Develop a resource that defines what is exempt from IACUC review

IACUC Administrator Association

Universal Protocol Template

Where/When did we start?

1. A discussion topic at an IACUC Administrators Best Practice Meeting around 10 years ago.

2. Opinions changes as discussions around regulatory reform started.

3. Three years ago, through the IAA, Ron Banks and I started to develop an universal protocol template, which would be made available to the community.

IACUC Administrator Association

IAA Starting Point

OLAW Protocol Sample Template

- Based on a form used by the intramural NIH investigators

- Supplemented with information gathered from templates used by many different other institutions

Resource: (https://olaw.nih.gov/resources/documents/animal-study-prop.htm)

IACUC Administrator Association

IAA and FDP Partnership

1. IAA developed a draft protocol template (2017- 2018)

2. Formalized a project with FDP (May, October, 2019)

3. Established an FDP Working Group involving FDA members
   a. OLAW and USDA
   b. DoD and VA
   c. IAA, and
   d. The IACUC Administrative Community

IACUC Administrator Association

What should the UPT look like?

1. Tailored to species most commonly used (i.e., mice and rats);
2. Only include information needed by the IACUC to conduct the review;
3. Provide as much information as possible to the PI (use check boxes); and
4. Keep it user friendly for all.

IACUC Administrator Association

Action Plan (1/2)

1. Think about every question
   a. Is every question in the template clearly written from a PI's prospective
   b. Is the information needed by the IACUC to review the proposed animal activities
   c. Is the information related to compliance, but not necessarily the animal activities
   d. Is gathered information managed under another section of the program (e.g., Vet Care)

2. Break the UPT into sections
   a. Administrative Information
   b. Research Objectives and Animal Use
   c. Procedures
   d. Departures
   e. Hazardous Materials Use

IACUC Administrator Association

Action Plan (2/2)

1. Question Reviews
   a. Regulatory – OLAW and the USDA
   b. VA and DoD
   c. Principal Investigator
   d. IACUC Member

2. Final Document User Testing
   a. PIs
   b. IACUC Members
   c. Compliance Directors and Veterinarians

IACUC Administrator Association

FDP Subcommittee Work thus far

1. Administrative Section
2. Justification Section
3. Animal Use and Departures/Exceptions Section
4. Experimental Design Section
5. Procedures, Part 1 Section

IACUC Administrator Association

Administrative Questions (1/2)

Section 1

Administrative Information

1. Project Title:
2. PI Name (First, Last):
3. Status (Faculty):
4. Department:
5. Primary Laboratory Location
6. Cell Phone Number:
7. Email:

Section 2

Project Funding Source(s)

1. Please check "Yes" to provide assurance that adequate funds are available for the procurement and care of the animals associated with this protocol for the project duration.

   [ ] Yes [ ] No

2. Please provide below the following information for each source of funding that will be used to support this project.

   a. Source of the funding (e.g., NIH or Internal):

   b. Reference Number (e.g., grant number):

   c. Period of Support (e.g., when does the grant start and when does it end):

   d. Granting agencies require institutions to verify that proposed animal activities are approved by an IACUC prior to funds being received by the institution. Please check "Yes" to provide assurance that the animal activities supported by these funds are describe in an IACUC protocol(s). [ ] Yes [ ] No

IACUC Administrator Association

Administrative Questions (2/2)

Section 7

Activity locations and the movement of animals between locations

1. Please check "Yes" to provide assurance that all animal activities (i.e., housing and procedures) will occur in the central facilities (i.e., areas directly managed by the Attending Veterinarian).

   [ ] Yes, continue to Q2 [ ] No, please provide the following information

   Please provide the following information about locations where animal activities will occur outside the central facilities.

   a. Building <Text Box>
   b. Room Number <Text Box>

   Please check all animal activities that will occur in this location

   ☐ Behavior studies

   ☐ Euthanasia

   ☐ Housing (i.e., Animals are maintained greater than 12 consecutive hours)

IACUC Administrator Association

Justification for Animal Use

2. Briefly provide the goal(s) and a general description of this project in language that can easily be understood by a layperson. **Note: The specific and related details (e.g., drug doses, routes of injection, and steps in a surgical procedure) of the associated procedures will be provided in later questions.** <Text Box>

3. Please describe the importance of this project as it relates to human or animal health, the advancement of knowledge, or the good of society. <Text Box>

4. Explain your rationale for animal use, and indicate why you cannot use non-animal models (e.g., cell or tissue culture, isolated organ preparations, computer simulations, etc.). <Text Box>

~~5. Please check "Yes" to provide assurance that the animal activities conducted under this protocol do not unnecessarily duplicate previously conducted activities.~~

~~[ ] Yes [ ] No, please provide your rationale <Text Box>~~

IACUC Administrator Association

Animal Information

Section 4

Animal Subjects Information (to be completed for each species used under this protocol)

Please provide the following information for the animals that will be used in the activities proposed under this protocol. If multiple species, the information will need to be provided for each species.

1. Species (Could be a drop down box for e-forms):

2. Source(s)

   - ☐ Another approved protocol
   - ☐ Captured Wildlife
   - ☐ Commercial Vendor (Animal Resource Program Approved Vendor)
   - ☐ Other <Text Box>

3. Explain why this species was selected to conduct the activities describe in this protocol.

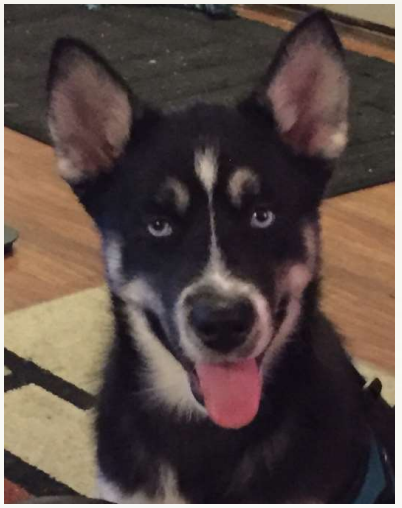
   ○ <Text Box>

4. Please check "Yes" to provide assurance that the species selected is the lowest on the phylogenetic scale that can be used to satisfy the study requirements (e.g., rabbits were not selected if the activities can be successfully conducted in mice).

   [ ] Yes [ ] No, please provide your rationale <Text Box>

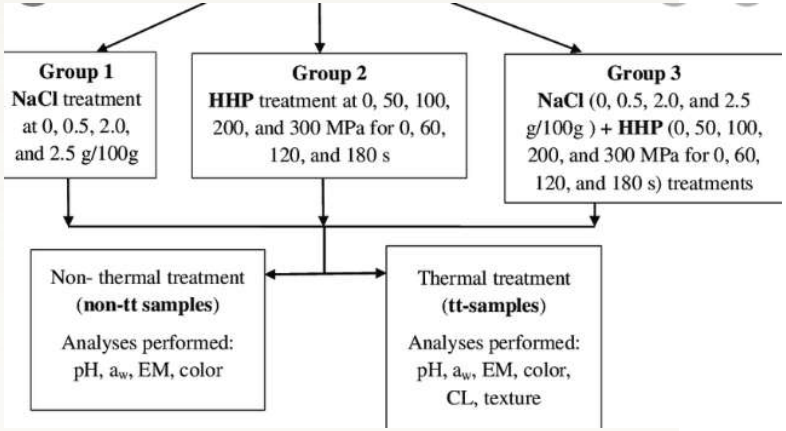
5. Please indicate the final disposition of the animals (Check all that apply).

   - ☐ The animal will be euthanatized according to the process described in this protocol
   - ☐ The animal will be transferred to another approved protocol
   - ☐ The animal will be release back to the wild
   - ☐ Other (please describe) <Text Box>



IACUC Administrator Association

Experimental Design Section



Section 5

Experimental Design

1. The goals of this protocol are achieved through animal activities. Comparisons are typically made by using numerous cohorts of animals with each having a different variable.

   a. Experiment Title or Number (i.e., the comparison to be made): <Text Box>

   b. Species: <Text Box>

   c. Please provide a clear and concise, sequential description of the procedures involving the use of animals in a manner that is easily understood by the IACUC. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment through the endpoint of the study. Note: Please do not provide the specific details (e.g., drug doses, routes of injection, and steps in a surgical procedure) of the animal procedures you will conduct since those details will be provided as part of subsequent questions.

   d. Please indicate the estimated total number of animals needed for this protocol

   e. The number of animals used for each experiment should be the minimum required to achieve the scientific aim(s) and produce statistically valid results. Please check "Yes" to provide assurance that the number of animals used in this experiment is minimum needed to produce statistically valid results.

      [ ] Yes [ ] No, please provide your rationale <Text Box>

IACUC Administrator Association

Procedure Questions

1. Blood Collection
2. Euthanasia
3. Behavior Studies
4. Etc.

☐ **Euthanasia**

Please identify the method(s) that will be used (check all that apply)

☐ ***(Only appears if the species is mice or rats)*** Adult mice or rats will be euthanized by gas (i.e., carbon dioxide or isoflurane) inhalation followed by one of the listed secondary physical methods (i.e., decapitation, bilateral pneumothorax, removal of a vital organ, cervical dislocation) of euthanasia

☐ Lethal injection with or without subsequent tissue harvest

☐ **Blood Collection**

1. Please check all that apply

   ☐ Up to 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) may be collected in 14 days or less.

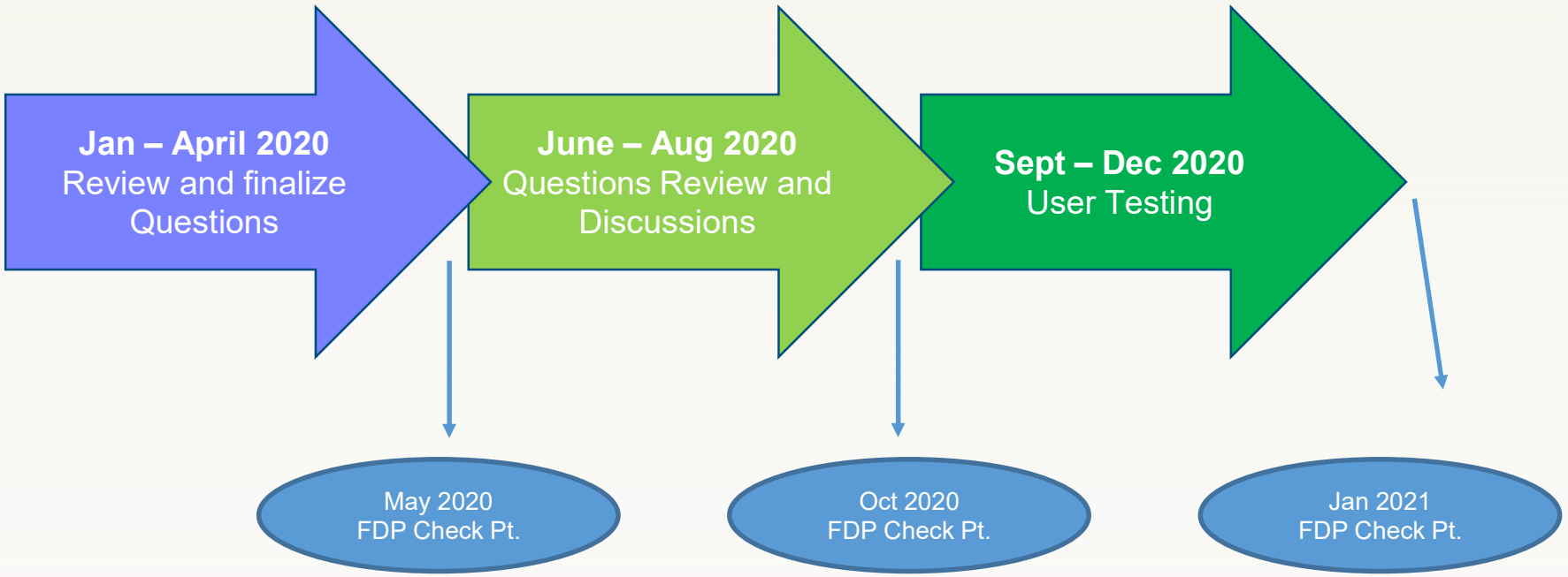
   ☐ Other, please describe <Text Box>

2. Please identify the route of blood collection

   ☐ The lateral tail and/or saphenous vein, and/or by tail incision ***(Only appears if the species is mouse or rat)***

IACUC Administrator Association

Timeline



IACUC Administrator Association

Questions/Thoughts

IACUC Administrator Association

Contact Info

- **Bill Greer**
  University of Michigan
  wggreer@med.umich.edu
- **Aubrey Schoenleben**
  University of Washington
  aubreys@uw.edu
- **Teresa Sylvina**
  National Academies of Sciences
  tsylvina@nas.edu
- **Axel Wolff**
  NIH/OLAW
  wolffa@od.nih.gov

FDP May Meeting Remaining Sessions

- **Faculty Forum and Meeting** (Tuesday, May 26, 2020 from 2-3:30pm EDT)
- **Subawards Subcommittee Webinar** (Tuesday, May 26, 2020 from 4-5:15pm EDT)
- **Plenary - COVID Federal Panel** (Wednesday, May 27, 2020 from 1-3pm EDT)
- **Supporting COVID-19 related Data Transfer and Use Agreement needs** (Wednesday, May 27, 2020 from 4-5pm EDT)
- **The Impacts of COVID-19 on Research Activities: The University Perspective** (Thursday, May 28, 2020 from 1-2:30pm EDT)

(thefdp.org/)