



# FINAL REPORT IACUC PROCESS IMPROVEMENT WORKING GROUP

August 5, 2022

## Committee Membership:

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## CHARGE AND PROCESS

The IACUC Process Improvement Working Group was formed by Dr. Norton in February 2022 in response to recurring concerns raised by investigators and senior administrators regarding efficiency and culture of regulatory affairs surrounding research involving animals at the University of Florida. The committee was charged with determining needs and providing a list of actionable items for improving processes related to animal research. The committee met weekly from February-July, conducted approximately 25 focus groups inclusive of more than 100 investigators from across the University, Animal Care Services veterinarians and technicians, members of the IACUC staff and committee, and individuals from multiple divisions of Environmental Health & Safety. The work of the committee confirmed meritorious concerns, expressed by all groups surveyed, in the existing processes surrounding animal care and compliance that would benefit from immediate action. The recommendations below are offered in response to the most critical concerns raised and with the sole intent of improving processes and climate surrounding UF animal care and research. In addition to this summary, the committee has submitted several Addendums that provide more detail on the process, as well as additional specifics from different stakeholder groups that may not be fully captured in the summary recommendations.

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**1. IACUC COMMITTEE.** Investigators expressed a desire for the IACUC committee to incorporate a greater breadth of scientific expertise, and for more transparency and investigator input with respect to member selection and accountability. Some concerns raised by investigators indicated additional clarity in the charge and process of the IACUC would be helpful (examples can be found in the Investigator Questions Addendum which collates questions that arose during the investigator focus groups). Actionable items:

1.1 Incorporate greater investigator input into the membership selection process and create a structure to elevate the prominence of IACUC committee to encourage service. Specific suggestions include implementing:

- A consistent incentive structure to attract new membership to the committee and to reward service.
- Greater recognition of IACUC service within the promotion and tenure process.
- A process for soliciting self- and peer-nominations for committee service.
- A process for regularly soliciting investigator feedback regarding potential gaps in scientific expertise on the committee. Incorporate this feedback when filling committee vacancies, or address by adding to committee membership.

1.2 Educate investigators regarding the performance metrics whereby the committee members are evaluated; and how accountability is accomplished.

1.3 Develop new, and/or enhance the visibility of existing, mechanisms for investigator feedback regarding IACUC committee performance and establish ways to communicate back to investigators actions arising from their feedback.

**2. ONBOARDING.** Specific concerns were raised by “new-to-UF” investigators regarding lack of direction for efficient onboarding. Actionable item:

2.1 Develop a comprehensive onboarding process for all new investigators involved in animal research that is integrated across IACUC, EH&S, and ACS offices and includes in-person introductions to key staff who can address their questions.

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## **3. GoIACUC TRANSITION.** Investigators and IACUC staff raised concerns regarding inadequate support for making the GoIACUC transition as seamless as possible. Actionable items:

- 3.1 Develop and quickly implement a comprehensive strategy to assist in the transition to the GoIACUC platform. Specific suggestions include:
  - Expedite hiring of additional staff to support investigators in transitioning into GoIACUC.
  - Develop a communication and education strategy regarding GoIACUC for investigators, IACUC, and ACS staff, including informational and instructional videos.
  - Hold regularly-scheduled informational workshops wherein investigators can learn how to use GoIACUC.

## **4. PROCESS.** Major investigator concerns regarding process included 1) a continual escalation in the administrative burden resultant from maintaining protocols and laboratory compliance; 2) consistency of protocol review between reviewers and from one submission to the next; and 3) expediency of protocol review. With respect to expediency, investigators specifically cited a need to reduce back-and-forth during protocol review, and a desire to increase speed of review for simple amendments. IACUC committee members noted that revising the structure of veterinary protocol review could expediate the process. Actionable items:

- 4.1 Expediate hiring of Research Regulatory Liaisons to work with investigators as colleagues, assisting with the GoIACUC transition, protocol submissions, and modifications, and serving as a key source of information regarding new guidelines and regulations.
- 4.2 Develop and/or share the strategy for monitoring and continually improving consistency in review.
- 4.3 Overhaul the process for adding new personnel to IACUC protocols. This includes creating a new process for health/safety screening which is integrated with the IACUC office from start to finish.
- 4.4 Evaluate the current protocol review processes to determine opportunities for more efficient review
- 4.5 Expand the list of universal SOPs in GoIACUC that include veterinary input and approval for procedures that are common across many investigators.
- 4.6 Enable sharing of protocols/procedures/SOPs among investigators conducting similar work.

## **5. STAFFING.** Investigators, ACS veterinarians and staff all expressed concern regarding ACS understaffing. Actionable items:

- 5.1 Increase resources to enhance recruitment and improve retention of ACS Veterinarian and staff. Additional feedback should also be solicited from ACS staff regarding ways to increase recruitment and retention efforts.
- 5.2 Re-evaluate the laboratory animal medicine Veterinary residency program, which provided an important connection to the laboratory animal medicine community and is valuable for retaining and attracting skilled faculty to the University of Florida.

## **6. COMMUNICATION AND CULTURE.** Feedback across focus groups indicated that bi-directional distrust and negativity are pervasive across the animal research community. A need for improved communication was also recognized across groups. Actionable items:

- 6.1 Invest in a comprehensive communications strategy to improve bi-directional information flow between investigators and all offices involved in animal research. Specific suggestions include creating:

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- A one-stop website that merges policies, guidelines, and resources across institutional offices.
- A network of liaisons to improve information dissemination.
- Step-by-step guides and video tutorials for new procedures.
- A 'living document' of FAQs to aid investigator understanding of federal, state, and institutional policies and procedures.

6.2 Develop a shared code of conduct for all members of the research community that involves expectations of collegiality from all. This should include clear expectations for behavior that exemplify values of trust, transparency, and efficiency.

6.3 Consider ways to promote teamwork and build trust among ACS, EH&S, IACUC, and investigators. Ideas include:

- Expanding opportunities for in-person "meet and greets" for new faculty and staff and increasing the number of informal interactions that promote the building of relationships (e.g., regularly scheduled appreciation breakfasts, lunches at different facilities).
- Holding weekly "office hours" with representation from all regulatory offices to enable collaborative problem-solving with investigators.
- Creating more opportunities for bringing ACS staff, veterinary faculty, and animal users into discussions about ongoing research projects to promote collaboration and shared investment across these entities. ACS staff and veterinary faculty should be recognized as not only providing a service, but as valued colleagues with unique expertise within the UF research community.
- Enhancing the visibility of existing mechanisms for feedback to ACS to EH&S, and promote ways to communicate about how such feedback is being used.
- Creating campaigns which promote a "we are in this together" mentality to increase comradery.

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## NEXT STEPS

As the breadth of the recommendations illustrate, there are numerous areas where improvements can be made to enhance our animal research community. Successful implementation of these recommendations will require further elaboration, development of specific action plans, and accountability metrics to monitor success. External consultants are needed to provide objectivity and the benefit of experience from other institutions, as well as for establishing a comprehensive implementation plan to maximize the positive impact of actions taken. The committee encourages open communication with the community regarding subsequent action plans, including the timeline. Making the implementation strategy highly visible to the research community and engaging investigator and staff feedback throughout the process is viewed as essential for improving the culture across the research community.

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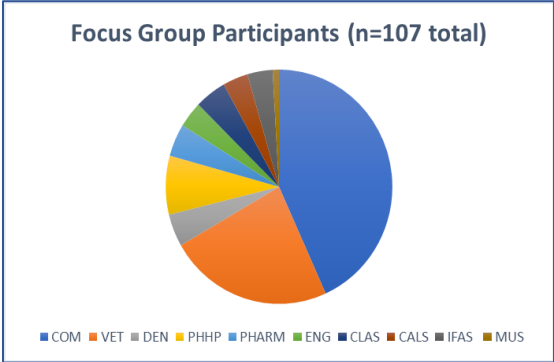
## Addendum 1. Details of Process

The IPIWG Committee sought feedback from different members of our research community through facilitated focus groups. Specifically, over 25 focus groups were held in April-May which included the following stakeholders: (1) Investigators; (2) IACUC staff; (3) IACUC committee; (4) ACS veterinarians; (5) ACS veterinary technicians; (6) ACS husbandry staff; (7) EH&S; and (8) Occupational Medicine. To encourage frank and honest feedback, focus group facilitators were recruited from across the community and care was taken to ensure there were no supervisory relationships among focus group members and facilitators. Each facilitator received slides and instructions from the committee to assist in guiding discussions towards desired outcomes and potential solutions for perceived challenges in our research community. The committee is grateful for the following individuals, each of whom served as facilitators for 2-6 focus groups. Deidentified summaries from these focus groups is available upon request.

### Facilitators:

- Joseph Besesi, PhD** Asst. Professor, Dept. of Environmental and Global Health, College of Veterinary Medicine
- Sara Burke, PhD** Assoc. Professor, Dept. of Neuroscience, College of Medicine
- Karyn Esser, PhD** Professor, Dept. of Physiology, College of Medicine
- Ryan Mulligan, MRA, MS, CRA**, Research Administration Manager, College of Medicine
- Sobha Jaishanker**, Asst. Vice President, Office of Research
- Joanna Peris, PhD** Assoc. Professor, Dept. of Pharmacodynamics, College of Pharmacy
- Leah Resnikov, PhD** Assoc. Professor, Dept. of Physiological Science, College of Veterinary Medicine
- Barry Setlow, PhD** Professor, Dept. of Psychiatry, College of Medicine

**Investigator Subgroup Participation.** For Investigators, n=18 focus groups were held at different times extending over a two-week period in April. To promote free exchange of ideas, the size of each group was capped at n=6 per group, plus one facilitator. Focus groups were advertised through the IACUC and ACS listservs, and emails to Chairs. In total, 107 investigators participated; these participants were distributed across the university (see pie chart on the right) and generally reflected the distribution of IACUC protocols across the UF campus (see pie charts below).



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**Addendum 2. Questions arising from Investigator Subgroups.** These questions were raised during the focus groups and the Investigators on the committee felt that providing answers could be a start in resolving some communication barriers across the research community. Per Recommendation 6.1 in the Executive Summary, the committee felt a “living” Q and A document could be of benefit for clarifying current policies and promoting education and communication among stakeholders.

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1. At UF we have an IACUC committee, an IACUC office, ACS, EH&S, and so many more entities involved in animal research. Could you please explain their organization and who I should go to for what when I need help?
2. I am a funded investigator who is maintaining multiple grants and several subprojects at University of Florida. I was told that I must have a separate protocol for each of my awards. Others in my department do not have this arrangement. Please clarify the current policy and why it exists. Is this a federal, state or institutional policy?
3. I would like to serve on the IACUC committee. Can I self-nominate and how? What qualifications do you look for in members? Who will evaluate my nomination and when will I hear? Can you describe the training for new IACUC members? How long is the term? What are the expectations of serving as an IACUC member?
4. The experimental design of my protocol is being questioned by an IACUC member. The grant that funds the work in my protocol was peer-reviewed and the animal numbers and justification were deemed acceptable. Nevertheless, this is not sufficient for the IACUC committee. In as much detail as possible, please explain the purview of the committee with respect to experimental design and provide the reference for these regulations to assist with my understanding.
5. An IACUC committee member requested a better justification for my animal numbers. Where can I find resources for exactly what the committee requires in terms of justifying animal numbers? Are these based on federal, state, or institutional policies?
6. I have received a very unprofessional comment from a member of the IACUC committee. Where can I provide feedback? What will be done with my feedback? Can I request a different member handle my protocol? If yes, to whom do I make this request? If not, why not?
7. I have been going back and forth with a reviewer of my IACUC protocol for weeks and I simply don't understand what they want. Who do I contact and what can I do to help resolve this situation?
8. I have four protocols, all with the same procedure. Revisions required at the request of committee members during the protocol review has resulted in different post-operative care procedures for each protocol. I see this is a barrier for my ability to maintain compliance. Moreover, I don't understand at this point which represents best standard of care. What can I do about this and how can I prevent this from happening in the future?
9. I submitted a simple request weeks ago and it is still pending review. This procedure is critical to collect preliminary data for an upcoming grant proposal. What can I do to move my protocol along? How are decisions made about which things can be approved through administrative review and which things go to full committee review? Are these decisions based on federal, state or institutional guidance?
10. I am a new investigator to University of Florida setting up a lab. Who do I contact to receive assistance for my onboarding?

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11. Despite starting my protocol three months ago, I have a grant for which the funding is being held because the IACUC protocol is not yet approved. The funding agency is indicating the money must be released soon or the funding will be withdrawn. Who should I contact for help?
12. I submitted an administrative request to add a new summer student to my protocol three weeks ago but I have not received any word on the status of this amendment. The summer student is only here for 10 weeks and is rapidly running out of time to have a meaningful research experience. Who can I contact to move this forward and how can I prevent such a delay in the future?
13. I understand that investigators are provided a checklist regarding lab inspections and post-approval monitoring visits but I am not receiving these. Who do I contact?
14. I have worked closely with an ACS staff member for a long time and they have become a partner in ensuring animal care in my research program. This individual has just told me they are being transferred to another facility. Is there anything I can do? Who can I contact to discuss? Can you explain why the staff is regularly rotated?
15. Why do we need to renew our IACUC protocols triennially? Why can't the protocol last for the duration of a longer (e.g., 5yr) term if my grant is for longer?
16. I submitted a modification to my approved protocol and I received back requests for modifications from the veterinarian and IACUC member on aspects of my protocol that were already approved and not changed in this modification. Why is this? Can I speak with someone about this and who?
17. Despite my best efforts for the past three months, with the new GoIACUC transition, my new protocol is not going to be approved before my old one expires. Can you please detail what needs to be done with my federal grants until my new protocol is approved? Does NIH need to be notified? Can my lab staff still be paid?
18. I have just started to transition to the GoIACUC and I'm completely lost. Who can I contact for assistance? Are there training modules?



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**Addendum 3. Detailed EH&S Feedback and Recommendations.** This addendum was prepared based on feedback from the EH&S focus groups. Numbering corresponds to the Executive Summary and elaborates recommendations as they pertain to EH&S.

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**3. ONBOARDING.** Specific concerns were raised by EH&S and Occupational Medicine (OccMed) staff regarding lack of direction for efficient onboarding. There is too much reliance on online training during onboarding and orientation of PIs/research staff resulting in lack of understanding of expectations and consequences. Furthermore, delays in OccMed approvals are primarily due to researchers submitting incomplete forms and/or lack of payment from the departments. Actionable items:

3.1 As reflected in the primary document, develop a comprehensive onboarding process for new investigators involved in animal research that is integrated across IACUC, EH&S, and ACS offices and includes in-person introductions to key staff who can address their questions. Additionally, expectations are communicated using an onboarding checklist or interactive online onboarding tool.

3.2 Develop training for departmental HR staff on expectations and requirements for OccMed programs including information on why these programs exist. Departmental HR liaisons should be responsible for:

- Ensuring occupational medicine forms are properly filled out
- Submitting payment to the Occupational Medicine Clinic in a timely manner

**4. PROCESS.** The following concerns were raised regarding processes: 1) the lack of integration between different regulatory registration processes (IACUC, IBC, Radiation Control Committee) causing multiple rounds of bureaucracy for the Investigator and discrepancies between submissions (between IACUC and IBC protocols); 2) there is no method in place for an applicant to track OccMed submissions and for OccMed personnel to provide feedback to departments and applicants. Actionable items:

4.1 Implement an integrated system for the submission of IACUC, IBC, and IRB protocols to allow easy transfer of information from one registration process to another.

4.2 Implement a software system to support the submission, review, and approval of OccMed clearances. The software would allow applicants to view application status and would provide a mechanism for the OccMed clinic or EH&S to provide updates or next steps to the applicant and department liaisons. Additionally, the system could notify users when clearances are up for renewal.

**5. STAFFING.** Concerns regarding staffing include: 1) the lack of dedicated animal research safety staff to support the needs of the animal research program - animal research safety is a small part of the overall duties of EH&S staff and existing staff do not have sufficient expertise or the bandwidth to support the current demands from the animal research program; 2) the absence of an OccMed physician to support the Occupational Medicine program. Actionable items:

3.1 Hire dedicated animal research safety personnel to work collaboratively with the IACUC and ACS and provide the necessary expertise needed to support animal research.

3.2 Develop a dedicated OccMed clinic (outside of the Student Health Care Center) appropriately staffed with an OccMed physician. Additionally, the creation of an OccMed residency program within the COM could assist with servicing UF's OccMed programs.

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**4. COMMUNICATION AND CULTURE.** Feedback across focus groups indicated that bi-directional distrust and negativity are pervasive across the animal research community. Specific to EH&S and OccMed, the following issues were identified: 1) The absence of uniform communications and messaging was the single theme that was repeatedly mentioned during the Biosafety focus group. Updates in requirements for one committee are not effectively communicated across the different committees involved in overseeing animal research. Staff supporting other committees generally find out about changes or expectations while assisting faculty. There is lack of communication between Investigators and their lab/research staff and a significant gap in knowledge of protocol among users from the same lab leading to altered procedures and non-compliance issues. 2) The OccMed program is siloed with minimal communication between the departments, EH&S, and the OccMed providers leading to confusion between entities.

4.1 As identified in the main document, invest in a comprehensive communications strategy to improve bi-directional information flow between investigators and all offices involved in animal research.

4.2 As identified in the main document, consider ways to promote teamwork and build trust among ACS, EH&S, IACUC, and investigator

4.3 Create an OccMed committee comprised of stakeholders which include EH&S, OccMed providers, Departmental HR liaisons and IACUC staff that will meet on a regular basis and work to troubleshoot and continually improve the process regarding Animal Contact Forms.

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**Addendum 4. Detailed ACS Feedback and Recommendations.** This addendum was prepared based on feedback from the ACS focus groups.

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- 1. SUPPORT.** ACS veterinarians feel the financial support allocated to ACS does not match the quality of care and service that is expected and provided. All groups suggested that additional financial support is needed for recruitment, training and retention of staff and additional support space (not housing or procedure room space) was needed. Actionable items:
  - 1.1 Evaluate budgetary needs to include financial support for staff recruitment, training and retention.
  - 1.2 Evaluate current space allocations with consideration to areas required for staff support and operational function, not just research need.
- 2. PROCESS.** Consistency was identified as problematic within ACS focus groups, specifically related to EH&S function and support, and the implementation of the animal care program between various facilities (veterinary and husbandry care). Actionable items:
  - 2.1 Identify a dedicated contact person for EH&S that is experienced in the issues involved with animal care and use.
  - 2.2 Identify areas to improve consistency in implementation of veterinary care and the animal care program between different facilities covered by ACS.
  - 2.3 Develop training and onboarding programs for ACS staff to improve consistency in care and support
- 3. STAFFING.** Several concerns regarding staffing were identified by ACS focus groups including: 1) Difficulty in recruitment and retention of staff, especially those in a more senior position within ACS and with the clinical veterinarian positions. All groups identified staffing concerns as a primary issue that impedes ability to provide service to the research community. 2) Confusion around job roles within ACS and lack of clearly defined job scope. Actionable items:
  - 3.1 Identify areas to open up pipeline to hiring operations staff, veterinary technicians and veterinarians with interest and experience in laboratory animal science and animal research.
  - 3.2 Develop and explore options for retention to address employee needs for work-life balance, competitive salaries and professional development
  - 3.3 Evaluate management infrastructure within ACS to clearly identify job roles and reporting
- 4. COMMUNICATION AND CULTURE.** Feedback across focus groups indicated that bi-directional distrust and negativity are pervasive across the animal research community. Specific to ACS, the following issues were identified: 1) operations and veterinary staff feel that the culture has shifted away from animal welfare and compliance, and towards a prioritization of getting research approved. This may result in confusion and inconsistency in monitoring animal welfare and safety concerns associated with the use of hazards. 2) ACS personnel feel disconnected from research outcomes and their role in the scientific and academic process, especially when time/resources are limited and prevent relationship building with investigators and internally. 3) Several ACS focus group participants discussed the impression or reputation that they were “policing” animal research instead of advocating for and promoting animal welfare and quality research outcomes
  - 4.1 As identified in the main document, invest in a comprehensive communications strategy to improve bi-directional information flow between investigators and all offices involved in animal research.

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- 4.2 As identified in the main document, consider ways to promote teamwork and build trust among ACS, EH&S, IACUC, and investigator
  - 4.3 Address staffing and resource issues to allow for additional time/opportunity to build relationships with investigative and other support (EH&S, IACUC) teams
-