Meeting Synopsis

1. Call to order
2. Review of the minutes from March 13, 2019
3. Discussion on “Foreign Influences on Research Integrity”
4. Discussion on concerns relating to the University of Washington’s Institutional Animal Care and Use Committee (IACUC) and development of Class C resolution
5. Discussion and vote on contract waiver request: APL-UW waiver request from Dr. Aubrey Espana
6. Good of the order
7. Adjourn

1. Call to order

The meeting was called to order at 9:05 a.m.

2. Review of the minutes from March 13, 2019

Due to a lack of quorum, Frevert, the chair, asked that the Council Analyst set up an electronic vote for the minutes to be approved.

3. Discussion on “Foreign Influences on Research Integrity”

The chair shared current concerns over potential foreign influences on research integrity (Exhibit 1, Slide 1).

A member asked if there are consequences if a person does not comply and fully report their conflict of interests. Carol Rhodes and Lynette Arias responded that the Office of Sponsored Programs does not have this oversight, but the Office of Research does have oversight of work outside the University and conflicts of interest.

The chair noted that the biggest concern are with contracts with the Department of Defense and Department of Energy, and the federal government has issued new guidance. The NSF and NIH have not yet disseminated new guidance, but the University will review the new regulations as they become available.

A member suggested that the council publicize these new regulations and possibly work with CoMotion on potential intellectual property issues. Another member commented that in a culture of hypervigilance, the University needs to be more aware of regulations and potential issues to protect any foreign researchers and students. Arias recommended that FCR ask Mary Lidstrom to share an update on CoMotion.

A member asked about standardized regulations around data management. Arias responded that NIH does have draft policies around this, but it is also confusing as institutions are promoting open access.

The chair summarized that the council should be aware of this topic.
4. Discussion on concerns relating to the University of Washington’s Institutional Animal Care and Use Committee (IACUC) and development of Class C resolution

Kim Stocking, Director of the UW Office of Animal Welfare, and Sally Thompson-Iritani, Director of Animal Welfare & Research Support, attended the council. The chair referenced two letters, from Cindy Pekow, Clinical Associate Professor and Veterinary Medical Officer, and Stocking (Exhibits 2 & 3). The chair further summarized discussion points relating to animal welfare (Exhibit 1, Slide 2).

A member asked to if Stocking could clarify a “designated member review” (DMR). Stocking responded that when a change is made every member is notified. The members have five business days to respond. If there are no responses the IACUC chair designates one member to conduct a review. The member then asked if the IACUC takes into account member’s background and expertise.

A member asked if the IACUC balances scientific review and harm/benefit analysis. Thompson-Iritani clarified that the IACUC review process aims to ensure that studies line up with what is intended, but that there are several pre-reviews that assess the harm/benefit analysis. She also noted a full committee review does not necessarily yield better assessments. The pre-review and veterinary review is often more thorough.

A member asked about the workload and compensation for IACUC members. Stocking responded that the workload varies, and IACUC members are not compensated. The chair shared that he directed a similar question to David Anderson, Executive Director of Health Sciences Administration. Anderson responded that compensation would be tough to accomplish based on the number of committees. The chair further commented that the council could include compensation as a recommendation. Another member agreed and offered that rather than relying on DMR, that the IACUC could use a study review which utilizes more than one member.

A member asked how the University is attempting to increase openness and transparency around animal housing, care, use, and care staff members. Thompson-Iritani responded that one attempt is to give tours and place cameras in all animal care facilities. She further noted that there is currently not buy in for this due to perceived criticism from outside organizations (e.g. PEETA). Thompson will share additional resources with the council.

The chair shared citations that the UW received from the USDA (Exhibit 1, Slide 3). Thompson-Iritani clarified that these are issues that the University identifies and notifies the USDA. The USDA issues citations against the Office of Animal Welfare (not the IACUC). She also commented that is important to understand the context around each citation, and she offered to share that with the council.

The chair suggested that the council set up a task force to look into improving the IACUC and animal welfare. The chair also noted that it will be important to hear from the AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) review before.

5. Discussion and vote on contract waiver request: APL-UW waiver request from Dr. Aubrey Espana

Due to a lack of quorum the chair asked the council analyst to set up an electronic vote for the restricted contract.

6. Good of the order

Nothing was stated.
7. Adjourn

The meeting was adjourned at 10:23 a.m.

Minutes by Lauren Hatchett, lehatch@uw.edu, council analyst

Present: Faculty: Chuck Frevert (chair), Michael Rosenfeld, Sara Kover, Mike Averkiou
Ex-officio reps: Larry Pierce, Stewart Tolnay
Guests: Susan Camber, Lynette Arias, Kim Stocking, Sally Thompson-Iritani, Kris Deibler, Lisa Jones-Engel

Absent: Faculty: Donald Chi, Paul Fishman, Benjamin Marwick, Francis Kim, Nicole Gibran
President’s designee: Mary Lidstrom
Ex-officio reps: JoAnn Taricani, Angelia Miranda, Laura De Vos, Jennifer Muilenburg,

Exhibits
Exhibit 1 – CWF Presentation -Final.pptx
Exhibit 2 – E-mail Cindy Pekow.pdf
Exhibit 3 – Letter to FCR 4-5-2019.pdf
Foreign Influence

1) Concerns regarding foreign influence
   a) Duke student taking IP to China
   b) Sharing of confidential information on grant applications by NIH peer reviewers
   c) Failure by some researchers working at NIH-funded institutions to disclose substantial resources from foreign governments.

2) NIH Letter from Francis Collins

3) E-mail from Carol Rhodes to UW Faculty
   a) Significant Financial Support: Approval for relationships with outside entities, including foreign entities and governments must be requested in advance as described in EO57
   b) Inventions must be promptly reported: To UW CoMotion and federal research sponsors as part of progress reporting.
   c) Mitigate risk to IP
   d) Protect the integrity of peer review.

4) Federal Agencies Involved
   a) NIH: NIH convenes ACD Working Group – August 2018, with report and recommendations issued – Dec 2018
   b) NSF: Has issued informal policy clarifications around other support
   c) DOD: New requirements issues around active and pending support

5) Working Groups
   a) Higher Ed and Scientific Associations: AAU, APLU, COGR, et al
   b) Congressional Hearings

6) Media and Journal Reports
   a) Nature Article, December 13th, 2018
   b) Washington Post Article of April 03, 2019
Discussion Items Relating to UW Animal Welfare

1) E-mail from Cindy Pekow
   a) Having ethicists available for consultation might be helpful to the IACUC in some instances.
   b) The idea that the UW should be a national leader in IACUC composition or protocol review is laudable. As pointed, metrics to evaluate the benefits of making changes are needed before embarking on change.
   c) It would be important to see if other IACUCC members at the UW feel that Designated Member Review (DMR) is being over-used.
   d) Additional voices that need to be added are the IACUC chair (and past chairs), the IO, and possible other IACUC members
   e) I think the key to public trust of animal research is not based on the IACUC, but rather in increased openness and transparency about animals housing, care, use, and animal care staff.

2) COGR Report: Of 94 responses, 66% of institutions indicated they use DMR as the default.

3) Review of the UW IACUC by outside sources
   1) USDA (March and November of 2018)
   2) NIH OLAW (2017).
   3) The UW IACUC will be reviewed by AAALAC in June 2019.

4) UW USDA Citations (2014 to 2018)
## USDA Citations

<table>
<thead>
<tr>
<th>Date</th>
<th>Species</th>
<th>Reason for Citation</th>
</tr>
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<tbody>
<tr>
<td>Feb-28-2014, 2.31</td>
<td>Rabbit</td>
<td>Significant change was made to protocol without IACUC approval</td>
</tr>
<tr>
<td>Feb-28-2014, 2.32</td>
<td>Guinea Pig</td>
<td>Significant change was made to protocol without IACUC approval</td>
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<td>Feb-11-2015</td>
<td>NHP</td>
<td>Animal Husbandry</td>
</tr>
<tr>
<td>Jul-14-2015</td>
<td>Wild Bat</td>
<td>Significant change was made to protocol without IACUC approval</td>
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<tr>
<td>25-JAN-2017</td>
<td>NHP</td>
<td>Animal Husbandry</td>
</tr>
<tr>
<td>04-APR-2017</td>
<td>NHP</td>
<td>Minor change was made to protocol without IACUC approval</td>
</tr>
<tr>
<td>15-NOV-2018</td>
<td>NHP</td>
<td>Animal Husbandry</td>
</tr>
</tbody>
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FCR Approval for Restricted Contract

- **Principal investigator**: Dr. Aubrey Espana
- **Task**: “Extracting, Explaining and Estimating Information in Sonar Data.”
- **Publications**: No publications in deliverables
- **Restrictions**: Publication of results of the research must be approved by the Office of Naval Research (ONR) before dissemination. There is a timely process for approval for open publication of results if not restricted by the security classification guides.
- No students will be involved in the project.
- No ‘foreign nationals’ will be working on this project
Hi Chuck and Thea,

I left the council meeting yesterday feeling unsettled. In reflecting on the discussion, what bothered me was that I felt as though countering some of Dr. J-E’s assertions came across as NOT advocating for animal welfare or good science, which we all know is not the position we hold. What I think I failed to convey adequately is that I agree with the concerns expressed about the heavy load of review work on the IACUC, and the public’s decreased support for animals as research subjects. I have not seen data to establish that public distrust is based on a general concern about IACUCs being stacked with researchers-- I suspect it’s rather a larger problem of public mistrust/lack of science understanding. The letter sent to the council in advance of the meeting identified primarily a concern with the appearance and the bias of a committee stacked with scientists and lacking ethicists, yet at the meeting the presentation additionally described the concern that there is not adequate scientific review by the committee. It would seem difficult to reconcile adding non-scientists to the committee with a desire to improve the scientific assessment of the protocols.

Would adding more non-affiliated personnel or ethicists to the IACUC change the outcome of committee deliberations? It will look better to the public. However, as is described in one of the articles (2012, Hansen) shared by Dr. J-E, even Swedish animal ethics committees with their mandated balance of non-scientists and scientists do not spend their discussion time focused on harm-benefit analysis. I agree that having ethicists available for committee consultation might be helpful to the committee in some instances. As far as finding metrics to measure what defines an effective or successful committee, I think the article I shared with you earlier (2013, Varga) provides the best discussion I’ve seen of the difficulties in making such assessments. The idea that the UW should be a national leader in IACUC composition or protocol review is laudable. As was pointed out during the discussion at the council meeting, some sort of metrics to evaluate the benefits of making any changes is needed before embarking on change.

A take-home message for me from my readings and from the various articles shared by Dr. J-E was that reproducibility of research and robustness of data are helped by the PI’s consulting with pathologists, statisticians, veterinarians, geneticists, or other pertinent specialists in the planning and writing stages of the protocol. So, facilitating access to these services is a big part of helping the committee to receive well-considered protocols; the UW may be doing this well already, or may want to step it up. It sounds like the pre-review process at the OAW is already quite extensive.

IACUC member workload is always a concern. Should another IACUC be added? Perhaps you would want to talk with Kathryn Bayne at AAALAC, Int’l, to ask her opinion on whether AAALAC sees problems vs benefits at institutions that have multiple IACUCs, and what the pitfalls might be for an institution if it should to decide to move that direction. I can think of lack of consistency between committees as a concern, but I have no experience with this situation so have no data to go on.

The suggestion that the research-community-service aspect of serving on the IACUC be in some way rewarded or compensated for the scientists who are on the IACUC is another avenue that might be explored. We need scientists to serve on the IACUC, but they are under pressure to be conducting their own work as well.
The use of Designated Member Review (DMR) of protocols requires that all committee members have a chance to request to see the full protocol and to hold the protocol for Full Committee Review (FCR) at a convened meeting. Are protocols sent for DMR ever held for FCR because of a committee member’s concern? Is the workload so great that protocols that should be considered by the full committee are being rushed into DMR? DMR can save a lot of committee time: many protocols (or changes to approved protocol) are of a sort that are routinely approved, and use of DMR for these reduces committee burden. It would be important to see if other committee members at the UW feel that DMR is being over-used.

Voices that need to be added to this discussion are the IACUC chair (and past chairs), and the IO. I also wonder what the other IACUC members think about the committee composition, effectiveness, and workload (and use of DMR). Before drafting any resolution to go to the faculty senate, the perspectives of these others are important to consider. Dr. J-E’s concerns should not be discounted; do the other committee members share the concerns she has raised?

I think the key to public trust of animal research is not based on the IACUC, but rather in increased openness and transparency about how animals are housed, cared for and used, and the people who work with them. I know that Sally Thompson-Iritani is one proponent of this transparency for the UW, but do not have any knowledge of what has been proposed or is happening for the UW program along these lines. Opening facilities to be seen with video, public outreach activities, and the like has helped buck negative public attitudes in Europe. (EARA [http://eara.eu/en/](http://eara.eu/en/)) There are groups such as Americans for Medical Progress that are working on campaigns in the US, as I’m sure you’re well aware.

I hope my thoughts are helpful.

Sincerely,
Cindy

Cynthia Pekow, DVM, DACLAM, CPIA
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Dear Dr. Frevert:

The IACUC Semi-annual report covering July-December 2017 was sent to IO on 1/29/18 and included a minority report expressing concerns around the ability to call for full committee review, regarding study design vs scientific merit, and expressed concern that the UW IACUC was not in compliance with regulations. The USDA conducted a routine inspection in March 2018 and the inspectors looked at that semi-annual report, our OLAW Assurance, IACUC meeting minutes, IACUC membership list and various other documents. They also interviewed the member who submitted the minority report and another IACUC members to investigate the concerns expressed in that report. That USDA inspection resulted in “No non-compliant items identified during this inspection.” So UW was not cited for any issues related to the function or composition of the IACUC. During a focused inspection in November 2018, the USDA again looked at our meeting minutes and January-June 2018 semi-annual report and did not cite any issues with the IACUC.

The OLAW Annual Report form includes a section about inclusion of “Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F....” and in our 2017 OLAW Annual Report, we included the minority view that was filed with our July-December 2017 semi-annual report. OLAW did not follow up with any questions or concerns related to the concerns expressed in the minority report.

UW will have an AAALAC site visit in early June 2019. AAALAC International is “a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.” Currently more than 1,000 organizations have AAALAC accreditation. AAALAC assesses programs every 3 years and as part of that assessment, they look at the institution’s policies, animal housing and management, veterinary care, and facilities. This includes whether the IACUC is properly functioning and constituted in accordance with regulations and best practices. At the conclusion of the site visit, AAALAC will give an initial assessment of what is working well, suggestions for improvement and any mandatory findings that must be addressed. While AAALAC is not a regulatory body, those institutions that meet or exceed AAALAC standards are awarded accreditation.

Please let me know if you need additional information.

Sincerely,

Kim Stocking, DVM, DACLAM

Attending Veterinarian
Director, Office of Animal Welfare