CONDUCTING IACUC BUSINESS
IN THE EVENT OF AN EMERGENCY
(IACUC Management Processes in Extraordinary Situations)

PERFORMANCE STANDARD: Institutional Animal Care & Use Committee (IACUC) business of oversight and program monitoring will continue unabated during disaster situations.

BACKGROUND: Institutions must adhere to provisions of the PHS Policy, the Guide, and the commitments detailed in their Animal Welfare Assurance with OLAW. This includes advance planning for conditions that could arise as a result of a disaster situation (e.g. human pandemic such as influenza or natural disaster) that could jeopardize the health and well-being of animals because of a lack of personnel to care for the animals and/or to conduct IACUC official business. The Centers for Disease Control and Prevention (CDC) has suggested that institutions plan for absenteeism of 40% if a contagion such as the H1N1 influenza virus should reach pandemic status. Regardless of external events, the United States Department of Agriculture (USDA) and the Office of Laboratory Animal Welfare at NIH (OLAW) expect each institution's IACUC to continue to conduct business according to requirements found in the PHS Policy, the Animal Welfare Act and Regulations, and the Guide.

Recognizing its obligation under federal law, regulation, and policy, the Duke IACUC has established the following business plan for the Duke animal care and use program in the event of an emergency. The modified process shall be called the IACUC Management Process in Extraordinary Situations. This policy establishes the process, based in part upon the follow facts:

1. The IACUC must conduct business to assure expectations of federal law, regulation, and policy.
2. The IACUC must maintain proper constituency for all official actions.
3. Full committee review (FCR) can only occur at a convened meeting with a quorum present. If possible, FCR for any given month should be conducted within that calendar month.
4. FCR with a quorum present is required to conduct the following:
   a. Suspension of a protocol; OR
   b. Review of protocol, amendment, or annual progress report that requires full committee review according to this or another Duke IACUC policy or has been specifically called for full committee review
   c. All other IACUC functions may be performed by the Designated Member Review (DMR) process.
5. The IACUC must ensure that protocol approvals are not allowed to expire due to failure of the IACUC to meet or review. If protocols do expire, then the IACUC must assure no further animal activities (e.g., data collection) are conducted under the expired protocol.
6. The minimum number of meetings required of an IACUC is two (2) meetings a year, six (6) months apart.
7. A subcommittee of at least 2 individuals is necessary to accomplish the review of the animal care and use program and inspection of the facilities.
8. A telephone conference (audio only) is permissible for IACUC meetings in unusual or difficult circumstances (e.g. when this disaster policy is activated by the IO).
9. FCR is required when an IACUC member requests FCR.
10. Every protocol involving USDA-regulated species must be reviewed annually.
11. Every protocol involving PHS-funded activity requires a complete new review (de novo review) every three years.
12. Amendments (modifications to the approved protocol) must be reviewed and approved prior to conducting the modified procedures on the current protocol.
13. The Duke IACUC has an established practice for review of significant changes to approved protocols by the DMR process-the 'Significant Change Subcommittee.'
14. Every facility in which USDA-regulated species are housed for more than 12 hours must be inspected every 6 months by at least 2 members of the IACUC. Agents are not acceptable for USDA-regulated activities.
15. Every location in which animal activity that is PHS-funded occurs or where animals are housed for more than 12 hours must be inspected every 6 months. Agents of the IACUC can conduct facility inspections.
16. All vehicles used for transport of animals must be inspected twice a year, 6 months apart. Agents of the IACUC can conduct vehicular inspections.
17. Agents of the IACUC are defined as DLAR/DLC Operations Managers, DLAR/DLC Veterinary Technicians, OAWA Compliance Liaisons, or as other individuals designated by IACUC leadership.

ROLES:
1. The IACUC Chair or designee must continue to perform the duties of Chair during any disaster situation.
2. The OAWA must continue providing necessary IACUC support for the performance of the required IACUC duties.
3. IACUC members shall be available by telephone or videoconference to serve on required committees or other bodies necessary for the functioning of the animal program.

DEFINITIONS:
1. **Disaster Situation:** Any large scale event, including a natural disaster or pandemic, wherein restriction of Duke campus activities is declared and personnel are not on-campus for animal oversight activities.
POLICY EXPECTATIONS:

1. Engaging the IACUC Management Process in Extraordinary Situations:

   a. In the event that a disaster situation compromises the IACUC's ability to convene a meeting of a quorum of the IACUC for the purpose of performing animal care and use oversight, the IACUC Chair (or designee if the IACUC Chair is unavailable) shall request the Institutional Official to authorize the use of the IACUC Management Process in Extraordinary Situations, as spelled out in this policy.

   b. When the Institutional Official designates the use of the IACUC Management Process in Extraordinary Situations, the OAWA shall initiate the steps necessary (e.g. arranging for telephone conferencing) to provide for the modified review and approval mechanisms.

   c. For purposes of the IACUC Management Process in Extraordinary Situations, the order of appointed leadership for IACUC activities shall be:
      i. IACUC Chair; if unavailable, then
      ii. IACUC Vice Chair (the program has 2); if unavailable, then
      iii. Director, OAWA; if unavailable, then
      iv. Associate Director, OAWA.

2. The Extraordinary IACUC Management Process is as follows: IACUC meetings will be minimized, but sufficient to accomplish the requirements of animal care or use oversight and meet the expectations of the federal and accreditation agencies.

   a. Protocols/Amendments/Annual Progress Reports: A review process utilizing the Designated Member Review (DMR) method will be used:
      i. New Protocols involving non-USDA species in USDA Use Categories B, C, or D; or Annual Progress Reports shall be reviewed and approved via Designated Member review of at least 2 IACUC members designated by the IACUC Chair (or designee).
      1. All IACUC members will be provided the complete list of protocols that are to be reviewed under section 2.i or 2.ii via their Duke Email account at least 24 hours prior to disposition.
2. Upon notification that the IACUC Management Process in Extraordinary Situations has been enacted, members have the opportunity to call any protocol to full committee review. All actions completed via the modified procedures will be reported to the IACUC at the next FCR.

ii. **New Protocols involving USDA species and all USDA Use Category E activities** shall be reviewed and approved by a quorum of the IACUC membership (see below).

iii. **Minor Amendments (Category IV)** shall be reviewed by the current process for Minor Amendments.

iv. **Amendments classified as Minor with Veterinary Review (Category III)** shall be reviewed by the current process for Minor with Veterinary Review Amendments.

v. **Significant Change Amendments (Category II)** shall be reviewed by the existing Minor with Veterinary Review process.

1. All IACUC members will be provided the complete list of protocols that are to be reviewed under section 2.v via their Duke Email account at least 24 hours prior to disposition. NOTE: Category II amendments that are automatically considered for FCR will be approved by the FCR process as described in the policy *IACUC Review and Approval Practices (Amendments to Approved Protocols)*

2. Upon notification that the IACUC Management Process in Extraordinary Situations has been enacted, members have the opportunity to call any SC amendment to full committee review. All actions completed via the modified procedures will be reported to the IACUC at the next FCR.

b. **Adverse Events (AE) or Non-compliant items (NCI):** The IACUC Chair (or designee) will review all adverse events or non-compliant items for that month’s review and place them in the following review categories

i. **AE/NCI that are determined by IACUC leadership to be not-reportable to OLAW, granting, or oversight bodies** shall be reviewed and recommendations determined via Designated Member Review by a subcommittee of at least 2 IACUC members designated by the IACUC Chair (or designee).

ii. **AE/NCI that are determined by IACUC leadership to be reportable to OLAW, granting, or oversight bodies** shall be
reviewed and approved by a quorum of the IACUC membership (see below).

c. Other Full Committee Review Items
   i. **Any item called by an individual member for Full Committee Review** shall be reviewed and approved by a quorum of the IACUC membership (see below).
   
   ii. **IACUC Minutes** shall be reviewed and approved by a quorum of the IACUC membership (see below).
   
   iii. **Any item described by policy as requiring Full Committee Review that is not explicitly mentioned in this policy** shall be reviewed and approved by a quorum of the IACUC membership (see below).

d. Clearance items
   i. A review by OESO and EOHW and other clearance items (an example is an MOU) will be requested, but failure to receive clearance during a declared disaster situation and post-disaster recovery period shall not delay the release of the approval letter for protocols/amendments/annual progress reports considered during this time. The IACUC Chair or designee shall have the authority to release the approval letter with agreement from the PI that:

      1. No biohazardous components of the approved study will be initiated until 'CLEARED' by the OESO.
      2. Any OESO or EOHW issues (if any) will be resolved as soon as practical.


e. Semiannual IACUC Actions:
   i. **Program Review:** While the review shall be announced and input requested from Committee members, the IACUC Chair (or designee) shall appoint a Subcommittee of at least 2 IACUC members to conduct the Semiannual Program Review within the required 6 month interval.

   ii. **Semi-annual Facility Inspections:** While the inspection schedule shall be announced and participation requested from Committee members, the IACUC Chair shall appoint at least two individuals to conduct the semiannual review of facilities within the required 6 month interval. In addition to IACUC members, appointed agents of the IACUC may also be used for these inspections.
f. **Approval of the Semiannual Report to the IO:** Committee members shall be provided with a copy of the proposed Semiannual Report to the IO by their Duke Email account. Replies from the IACUC member's Duke Email account is considered an electronic signature for the purpose of signing this report. When a majority of the IACUC's membership have replied by email with agreement of the proposed Semiannual Report, the Report shall be considered approved by the IACUC. Minority opinion(s) may be provided by email from the member's Duke Email account.

g. **Appointment of DMR:** The IACUC Chair (or designee) has standing authority to select and appoint IACUC members as DMR for specified purposes of review and approval.

3. **Full Committee Review Options:** One or a combination of the following options can be used to hold an IACUC Full Committee meeting. Regardless of the mechanism chosen, a quorum of IACUC members must be represented to conduct IACUC Full Committee Business. IACUC Full Committee meetings should fall within the month the IACUC business items should be discussed to ensure items are addressed prior to protocol renewal or annual progress report expiration.
   a. **Rescheduled in-person Full Committee meeting**

   b. **Video-conferencing. Examples:**
      ii. https://www.ciscojabbervideo.com/home
      iii. Skype
      iv. Join.me
      v. Other options as appropriate

   c. **Teleconferencing. Examples:**
      ii. Skype
      iii. Join.me
      iv. Other options as appropriate
4. Full Committee Review Scheduling

   a. The OAWA shall arrange for a rescheduled in-person meeting, video-conferencing or telephone/web-based conference at a time and a date appointed by the IACUC Chairman (or designee).

   b. Meetings held solely by video- or teleconferencing shall occur with a published agenda. Meeting procedures are the same as the current IACUC meeting procedures.

   c. Minutes of the meeting shall be recorded by OAWA staff and provided to the IACUC for approval at the next convened meeting of the Committee.

   d. A roll-call will be taken at the start of the meeting and when necessary during the meeting to ensure that quorum remains present. Actions which occur via a telephone conference and are not unanimous will include an additional roll-call of votes to assure a majority of the quorum have determined the outcome.

5. Miscellaneous Disasters that are Really, Really, Bad (e.g., internet, database, drive, or phone failure):

   a. In the event that any disaster impedes timely contact and dissemination of information to the IACUC members, the IACUC Leadership (IACUC Chair and/or IACUC Vice-Chair(s), OAWA Leadership (OAWA Director and/or OAWA Associate Director), and Attending Veterinarian and/or AV designee will craft a plan to address decisions on behalf of the institution. The Chair (or designee) is empowered to make decisions, or identify who will make decisions, on behalf of the Duke IACUC to ensure animal care is occurring and all IACUC functions are being conducted in accordance with the regulations.

      NOTE: This action will ensure that the minimum requirements of the regulations are being met; however, it allows exemptions from all institutional requirements (e.g., policies, guidelines, SOPs, etc.) as might be necessary to assure animal well-being and institutional integrity. All actions completed via the modified procedures will be reported to the IACUC at the next FCR.

Endorsed by the Program Institutional Official:

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