



Duke University  
Animal Care & Use Program  
Policy



**CONDUCTING IACUC BUSINESS IN THE EVENT OF  
A PANDEMIC OR OTHER SIGNIFICANT EXTENDED EMERGENCY**  
(Extraordinary IACUC Management Processes)

**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) that could jeopardize the health and wellbeing 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 institutions plan for absenteeism of ~40% if a contagion such as the H1:N1 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 a pandemic or other significant disaster. The modified process shall be called the Extraordinary IACUC Management Process. This policy established the process based in part upon the follow facts:

- A. The IACUC must conduct business to assure expectations of federal law, regulation, and policy.
- B. The IACUC must maintain proper constituency for all official actions.
- C. Full committee review (FCR) can only occur at a convened meeting with a quorum present.
- D. FCR, with a quorum present, is required to conduct the following:
  - 1) Suspension of a protocol
  - 2) Full committee review of protocol or amendmentAll other IACUC functions may be performed by the Designated Member Review (DMR) process.
- E. 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.

- F. The minimum number of meetings required of an IACUC, are 2 meetings a year, 6 months apart.
- G. 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.
- H. A telephone conference (audio only) is permissible for IACUC meetings in unusual or difficult circumstances.
- I. FCR is required when an IACUC member requests FCR.
- J. Every protocol involving USDA regulated species must be reviewed annually.
- K. Every protocol involving PHS funded activity requires a complete new review (de novo review) every three years.
- L. Amendments (modifications to the approved protocol) must be reviewed and approved prior to conducting the modified procedures on the current protocol.
- M. The Duke IAUCUC has an established practice for review of significant changes to approved protocols by the DMR process – the ‘Significant Change Subcommittee.’
- N. 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.
- O. Every location in which animal activity that is PHS funded, and where animals are housed for more than 24 hours, must be inspected every 6 months. Agents of the IACUC can conduct facility inspections.
- P. All vehicles used for transport of animals must be inspected twice a year, 6 months apart. Agents of the IACUC can conduct vehicular inspections.

#### **ROLES:**

- The IACUC Chairman must continue to perform the duties of Chairman during any disaster situation.
- The OAWA must continue providing necessary IACUC support for the performance of the required IACUC duties.
- 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:**

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

**Pandemic:** An epidemic of infectious disease that is spreading through human populations across a large region; for instance a continent, or even worldwide. Health professionals may require cessation of routine business practices in such a situation.

**PROTECTION POSTURES REQUIRED:** Protective postures will be dictated by other authorities, determined by the extent of the disaster at hand.

## POLICY EXPECTATIONS:

### 1. Engaging the Extraordinary IACUC Management Process:

- a. In the event a disaster situation compromises the IACUC's ability to convene a meeting of a quorum of the IACUC (pandemic or disaster situation) for the purpose of performing animal care and use oversight, the IACUC Chairman (or designee of the IACUC Chairman is unavailable) shall request the Institution Official authorize the use of the Extraordinary IACUC Management Process.
- b. When the Institutional Official designates the use of the Extraordinary IACUC Management Process, 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 Extraordinary IACUC Management Process, if the IACUC Chairman is unavailable for a period of greater than 3 calendar days, then the IACUC Vice Chair shall serve as the IACUC Chairman. If the IACUC Chair and Vice Chair are both unavailable for a period greater than 3 business days, then the Director, OAWA shall serve as the IACUC Chairman.

### 2. The Extraordinary IACUC Management Process is as follows:

- a. 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.
- b. **Protocol/Amendment Review:** A revised protocol/amendment review policy utilizing the Designated Member Review (DMR) method will be used:
  - i. **New Protocols involving non-USDA species:** Protocols which include only non-USDA covered species shall be reviewed and approved according to the IACUC's existing Minor with Veterinary Review procedures.
  - ii. **New Protocols involving USDA species:** Protocols which include USDA covered species shall be reviewed and approved by a telephone conference of a quorum of the IACUC.
  - iii. **'MINOR' Amendments:** Those amendments which qualify as a minor amendment shall be reviewed by the current process for Minor procedures.
  - iv. **Other than 'MINOR' Amendments involving non-USDA species:**
    1. Amendments involving non-USDA species and which qualify for Minor with Veterinary Review or which qualify for Significant Change Subcommittee shall be reviewed by the existing Minor with Veterinary Review process (or clarification, this activity will be distinguished from routine procedures and will be referred to as the Amendment Requiring Veterinary Review process).
    2. Actions which qualify as a significant change shall require email advisement (to allow members to call for FCR) prior to processing as Amendment Requiring Veterinary Review. All IACUC members will be notified via their Duke email account of applications eligible

for the Amendment Requiring Veterinary Review process; members are provided 3 business days to call for FCR prior to initiating the modified review/approval process. All actions completed via the modified procedures will be reported to the IACUC at the next FCR.

3. A review by OESO and EOHW 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 considered during this time. The IACUC Chairman or his designee shall have the authority to release the approval letter with agreement from the PI that:
  - a. No biohazardous components of the approved study will be conducted until 'CLEARED' by the OESO.
  - b. Any OESO or EOHW issues (if any) will be resolved as soon as practical.

v. **Amendments involving USDA species:**

1. Amendments involving USDA species and which qualify for Minor with Veterinary Review or which qualify for Significant Change Subcommittee shall be reviewed by the existing Minor with Veterinary Review process.
2. Actions which qualify as a significant change shall be reviewed by telephonic meeting process (details below).

c. **Semiannual IACUC Actions:**

- i. **Program Review:** While the review shall be announced and input requested from Committee members, the IACUC Chairman (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 Chairman 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. Agents of the IACUC are defined as DLAR Operations Managers, DLAR Veterinary Technicians, or OAWA Compliance Liaisons.
- d. **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.edu' email account is considered an electronic signature for the purpose of signing this report. When a majority of the IACUC's membership (a quorum) have replied by email with agreement of the proposed Semiannual Report, the Report shall be considered approved by the IACUC. Minority opinion may be provided by email from the member's Duke.edu email account.

- e. **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. Telephone Meeting Processes:

- a. The OAWA has established a contract with Premier Conferencing to serve as host for telephone conferencing in the event of a pandemic or other extraordinary emergency.
  - i. See attachment (ReadyCast Quick Source Guide) for process details of setting-up a telephone conference.
  - ii. See attachment (ReadyCast Audio Only Tip Sheet) for process details on joining a telephone conference.
- b. The OAWA shall arrange for a telephone conference at a time and a date appointed by the IACUC Chairman (or designee).
- c. The meeting shall occur with a published pdf agenda, provided by whalemail to the members Duke.edu email account, and following the agenda (meeting procedures are the same as the current IACUC meeting procedures).
- d. 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.
- e. A roll-call vote will be taken of actions which occur via a telephone conference to assure a majority of the quorum have determined a specified action is approved.

## Premiere Global Services:

- Customer Service Representative at 1-877-807-0970 or 1-719-389-0133.
- Ready Conference Plus
  - Account Name: Ron Banks
  - Client ID: 918756
  - Company Name: Duke University-Office of Animal Welfare Assurance
  - Web Password: m3t321
  - Hub URL: <https://www.myrcplus.com>
  - Host link: <https://www.premiereglobal.com>
  - US Toll Free: 800.201.2375
  - US Toll: 469.759.7753
  - Host Passcode: 3390912
  - Participant Passcode: 399860
- Meeting Conference Controls:
  - \*0 to reach an operator
  - \*6 to mute or "un-mute" a line.
  - \*4/\*7 to increase or decrease conference volume
  - \*5/\*8 to increase or decrease your voice volume
- Moderator Controls
  - \*93 to disconnect all participant lines
  - \*94 to lock or unlock conference
  - \*95 to dial out to participants
  - \*96 to mute all participants
  - \*97 to unmute all participant lines
  - \*21 to activate Subconferencing.
  - \*22 to initiate record and playback (\*22 again to pause/stop the recording)
  - \*31 to turn Conference Security Code on/off.
  - \*32 to record your Conference Introduction.
- To Start Using Your Conference Today...
  - Distribute the dial-in number and participant passcode to IACUC members.
  - Host call the dial-in number and enter unique host passcode.
  - Participants call the dial-in number and enter unique participant passcode.
  - Begin your conference

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