UH IBC

Policy for Tracking Research Protocol Approvals

I. Policy Statement

The purpose of this policy is to help ensure Institutional Biosafety Committee (IBC) registrations are submitted and approved before work begins with biological materials. In addition, registrations must be reviewed and renewed triennially to remain in compliance.

The IBC is responsible for reviewing all research, clinical and instructional-use activities involving recombinant or synthetic nucleic acid molecules, biological materials, biological derived toxins (toxins), dual use research of concern (DURC), select agents, other biological materials and human gene transfer projects, as well as developing institutional policies to ensure proper biosafety and biosecurity throughout the UH System. This review shall include, but is not limited to, the assessment of (i) containment levels required by the NIH Guidelines for the proposed research; (ii) facilities, procedures, practices, and training and expertise of personnel involved in the proposed research; and (iii) compliance with all surveillance, data reporting, and adverse event reporting requirements.

1. Much of the research at the University of Hawaii (UH) is funded by the National Institutes of Health (NIH). As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions must ensure that such research conducted at or sponsored by the institution, regardless of funding, shall comply with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines)*, particularly as they relate to the review and approval of research protocols.
2. Penalties imposed by NIH for non-compliance may include suspension, limitation, or termination of financial assistance for the non-compliant project and may also impact other NIH funding for recombinant DNA research at UH.
3. Non-compliance with NIH Guidelines can potentially affect all funding at UH, not just the funding for the specific lab in non-compliance.
4. Serious incidents of non-compliance have the potential to impact the health and safety of the University community and may impact the community as a whole.
5. The UH IBC may impose internal penalties for non-compliance with this policy, including but not limited to suspension, limitation, or termination of IBC registration, and notification of non-compliance to the applicable Chair and Dean/Director and upper leadership (i.e. Chancellor/Provost) of the researcher's school/college/reporting unit for further action as may be necessary.

II. Guidance and Procedures

1. Department Chairs are responsible for providing guidance to new faculty and staff as well as introducing them to research support offices where they can learn about the requirements for teaching and doing research at the University of Hawaii.
2. Department Chairs and new staff should contact the Office of Research Compliance (ORC) for specific information relating to their use of biological materials in such areas as research, teaching, training, permits, IBC registrations, laboratory inspections and other related requirements.

3. The IBC Coordinator utilizes Topaz Elements, an electronic protocol management system, to generate lists of approved registrations and their renewal dates and deadlines.
4. The IBC Coordinator emails courtesy reminders at least one month in advance to Principal Investigators (PI) when registrations are due for renewal.
5. The PI may request an extension, if needed, and must provide justification for the request in Topaz. Typically, the extension would be approved for 30 days, but the IBC may consider a longer time frame if the request is appropriately justified.
6. Work with biological materials under a new IBC registration or involving revised proposed procedures may not be initiated before approval from the UH IBC is granted. All work with biological materials relating to a previously approved project must stop until the requirements of a renewal are met and approval is granted. Notification from the IBC/Topaz of a "not approved" or "deferred" registration is sent to the PI and Department Chair and includes requirements needed for approval. The notification states that a response to the notification is required within 3 business days of receipt. The ORC Post Approval Monitoring Coordinator (PAM) will follow-up after 3 days to confirm that work was stopped.
7. If work is found to have started or continued after a notification to stop, an incident report is generated and the IBC will work with the Department Chair and/or Dean/Chancellor to secure all biological materials until the situation is resolved. Some situations may require an incident report be sent to NIH.
8. All facilities with active IBC registration are inspected by the IBC on an annual basis. Inspection reports include any observed issues of non-compliance. Some issues may require that work with biological materials stops until the issue is resolved. These are clearly noted in the inspection reports. Some require incident reports, with possibility of reporting to NIH.
9. The Post Approval Monitoring (PAM) Coordinator will work with the Biosafety Officer to conduct monthly audits of inspection deficiencies, not approved, and deferred protocols as a follow up to help ensure correction of the issues that were noted. Written reports are provided to the IBC and the PI.
10. The PAM Coordinator conducts random audits and visits in addition to annual IBC inspections for those projects that utilize higher risk biological materials. Written reports are provided to the IBC and the PI.
11. For extramural funding reporting purposes, the Office of Research Services (ORS) is provided with IBC approval letters for approved registrations upon request. Approval letters include the IBC protocol title, PI name, and triennial expiration renewal deadlines.

Reference:
NIH Guidelines: https://osp.od.nih.gov/biotechnology/nih-guidelines/

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