

## Delinquent IBC Registration Procedure

In conjunction with NIH rDNA guidelines, it is the policy of the National Cancer Institute at Frederick (NCI-F) that all work with recombinant DNA, pathogens, other potentially infectious materials, as well as transgenic or genetically modified animals be registered with the IBC prior to the initiation of work. NCI-F Policy and Procedure #604, approved April 2007, clearly defines the requirement to register the research of “all laboratories handling non-clinical and clinical research scale work at the NCI-F with known or suspected pathogens, toxins, recombinant DNA, Select Agents and other biological materials, and other potentially infectious material (OPIM).” In accordance with the IBC Charter, approved May 2007 “the IBC reserves the right to recommend that management suspend research activities in laboratories which are non-compliant with the NIH rDNA guidelines and/or have not successfully satisfied the IBC registration requirement for research involving rDNA, pathogens, oncogenes, human material or other potentially infectious materials, and toxins, as well as transgenic or genetically modified animals.”

If a Principal Investigator (PI) has failed to respond to the IBC’s request to register his/her research or to clarify the research/safety practices of the laboratory, the following procedure will be enforced:

- **If no response after 30 days from initial submission:** The PI will be sent a reminder to respond to the IBC’s inquiry and notified of the subsequent enforcement actions.
- **If no response after 45 days from initial submission:** The PI and immediate supervisor will be sent a second notification. At this time, the PI has 15 days to fulfill the committee’s request for additional information in an effort to obtain IBC approval to proceed with the proposed research; or withdraw the registration because the scope of the work is no longer necessary or active.
- **If no response after 60 days from initial submission:** The PI, immediate supervisor and the NCI Management will be notified of the lack of response and compliance. The proposed registration will be withdrawn from the IBC record. Should the PI want to register the work after this time, the registration process will need to be re-initiated by the PI by submitting a new registration document. NCI-Frederick management has the authority to take additional disciplinary action.