

Occupational Health Disclosure and Medical Evaluation for Research Involving Animals

1. Purpose

- 1.1. All individuals working with animals in research or accessing animal facilities both in the Freimann Life Science Center (FLSC) and individual Satellite Animal Facilities at the University of Notre Dame shall participate in the Occupational Health Disclosure and Medical Evaluation program administered by FLSC, Notre Dame Research Administration and Compliance (NDRAC), and the Notre Dame Wellness Center (NDWC). Participation in this program is necessary for approval of Institutional Animal Care and Use Committee (IACUC) protocols and for personnel safety and well-being. The requirements for the program depend on the animals to be worked with and requires completion of an online form which permits the NDWC to review your occupational medical history. In some instances, the NDWC may recommend testing or vaccinations which are covered by the University of Notre Dame and which may be declined. Participation in the program is required in order to be granted access to FLSC.
- 1.2. This procedure describes the occupational medical evaluation program for the pre-placement/baseline evaluation of personnel who handle, maintain, or use animals for teaching or research and the procedure for periodic re-evaluation.
- 1.3. The purpose of this medical evaluation process is to provide researchers with recommendations to help prevent an occupational disease while conducting work as described in paragraphs 3.1 and 3.2 below at or for the University of Notre Dame.

2. Responsibilities

- 2.1. Freimann Life Science Center (FLSC) shall:
 - 2.1.1. Provide personnel key card access to the FLSC only if the requesting personnel have completed the requirements of working with Category A or B animal or species as outlined below.
 - 2.1.2. Provide training on occupational health issues including universal precautions, animal allergies, procedures to follow in event of an injury, etc., to all personnel who have been granted access to the FLSC
- 2.2. IACUC Committee shall approve IACUC protocols only if all personnel listed in the application have completed the requirements in this procedure.
- 2.3. Notre Dame Research Administration and Compliance (NDRAC) shall:
 - 2.3.1. Maintain this procedure to regulatory and national consensus standards.
 - 2.3.2. Conduct audits to verify compliance to this procedure.

- 2.4. Principal Investigator/manager/supervisor shall:
- 2.4.1. Require personnel working under the IACUC protocol to adhere to the requirements in this procedure.
 - 2.4.2. Not permit personnel that have not met the requirements of this procedure to perform activities as defined as Category A or B.
 - 2.4.3. Provide funding for charges associated with this program.
 - 2.4.4. If responsible for a Satellite Animal Facility, ensure that access is only allowed when animals are present to personnel who have met the requirements of this procedure.
- 2.5. All personnel (working at or for the University) conducting research involving animals under an approved IACUC protocol shall:
- 2.5.1. Provide a complete and accurate health history and description of research activities, when required.
 - 2.5.2. Respond to communications from NDWC during the medical evaluation process.
 - 2.5.3. Cooperate with RMS to ensure that any implemented safety practices are adhered to.
 - 2.5.4. Update form as needed.
- 2.6. Any individual who wishes to access animal facilities (FLSC or Satellite Animal Facilities) for purposes other than conducting animal research shall certify that the activities they conduct will not include any described in 3.1 below. Examples of activities requiring access might include facilities inspections, repairs, NDDP assistance with CS disposal, etc.
- 2.7. Notre Dame Wellness Center shall:
- 2.7.1. Evaluate Category A and B forms and provide personnel recommendations as necessary based on the Category A form information.
 - 2.7.2. Submit Category A and B forms to Occupational Health Management (OHM) system for future access.
 - 2.7.3. Provide medical evaluation or treatment as directed by the Wellness Center physician for personnel completing the Category A form.
3. Definitions
- 3.1. Category A – Those working with live or dead whole animals (except those working exclusively with aquatic species), animal tissue, fluids, and materials from potentially biohazardous animals. ND Medical and Occupational History Form for Animal Exposures – Category A shall be completed through OnBase.
- 3.2. Category B – Those working with only aquatic species, freshly harvested animal tissues/fluids from non-biohazardous animals (animals not infected with a biological agent), or requiring non-animal contact access to an animal facility.



Occupational History Form for Animal Exposures – Category B shall be completed through OnBase.

4. General Requirements

- 4.1. All personnel working in situations as defined as a Category A or Category B shall complete and submit the appropriate forms through OnBase.
- 4.2. Access to the FLSC in the Galvin Life Science building and Raclin-Carmichael Hall shall not be granted until personnel have taken the appropriate steps as outlined below.
- 4.3. Access to individual lab spaces outside of the FLSC vivarium with animals present in housing or being used in experimental procedures shall be limited to personnel who have completed the appropriate steps as outlined below.

5. Category A Process –Review Appendix A for Process Flow Chart

- 5.1. Category A Forms are required to be completed at least once every three years. Access to the FLSC will be denied or the IACUC Protocol approval may be withdrawn. The Category A Form shall be updated:
 - 5.1.1. In the event of significant medical changes, or
 - 5.1.2. A significant change in the type of research may occur or if a different animal species not indicated on the Category A Form is desired to be used, or
 - 5.1.3. There is a change of address for an individual who previous completed a Category A Form but is within the 3-year window.
- 5.2. The Principal Investigator (PI) or researcher submitting the IACUC Protocol shall identify personnel who conduct animal research work under the Protocol.
- 5.3. The PI or researcher shall notify all personnel that they must complete and submit a Category A Form through OnBase.
- 5.4. The PI or researcher shall not permit any individual to commence work without the completion of the Category A Process.
- 5.5. The Wellness Center shall review the Category A Form when received.
- 5.6. The Wellness Center physician shall review the completed Category A Form and determine if the researcher requires medical treatment or an exam and fills out the recommendations in OnBase.
- 5.7. The Wellness Center shall complete the Category A Medical and Occupational History Evaluation form in OnBase. OnBase sends notification to the

researcher of the recommendations.

- 5.8. If the researcher does not respond to specified recommendations or requirements the Wellness Center is not required to take any additional action.
- 5.9. The researcher is required to respond to the Wellness Center by:
 - 5.9.1. Completing a Declination Form through OnBase. The Declination Form communicates that the researcher understands the recommendation but chooses not to adhere to them; or
 - 5.9.2. Adhering to the Wellness Center recommendations.
- 5.10. If the researcher fails to respond to requests from the Wellness Center, a pending submission may be administratively withdrawn.
- 5.11. If the researcher responds and completes the required medical treatment or a Declination Form, FLSC and RMS will be informed through the OnBase system that the individual is cleared to work under the Category A guidelines.
- 5.12. The FLSC shall grant the cleared individual access to the FLSC facility.
- 5.13. OnBase will maintain a list of personnel meeting the requirements and NDRAC shall provide that information to the IACUC as requested by the Committee. NDRAC shall also use the information for auditing purposes.
6. Category B Process – Review Appendix B for process flow chart.
 - 6.1. Individual Category B Forms through OnBase are required to be completed only once. If the researcher’s work changes into Category A work, the Category A Form shall be completed prior to the start of the work.
 - 6.2. The Principal Investigator (PI) or researcher submitting the IACUC Protocol shall identify personnel who are required to work under the Protocol.
 - 6.3. The PI or researcher shall notify all personnel that they must complete and submit a Category B Form through OnBase.
 - 6.4. The PI, researcher, or supervisor shall not permit any individual to commence work in FLSC without the completion of the Category B Process.
 - 6.5. The Wellness Center shall maintain the Category B Forms in OHM for future access to medical record.
 - 6.6. Once the Category B form is signed electronically in OnBase, the system will

record that the individual is cleared to work under the Category B guidelines.

6.7. FLSC shall provide the individual with training and grant access to the FLSC facility.

6.8. The OnBase system will maintain a list of personnel meeting the requirements and NDRAC will provide that information to the IACUC as requested by the Committee. NDRAC shall also use the information for auditing purposes.

7. Category A Tracking, Vaccination and Testing Follow-up

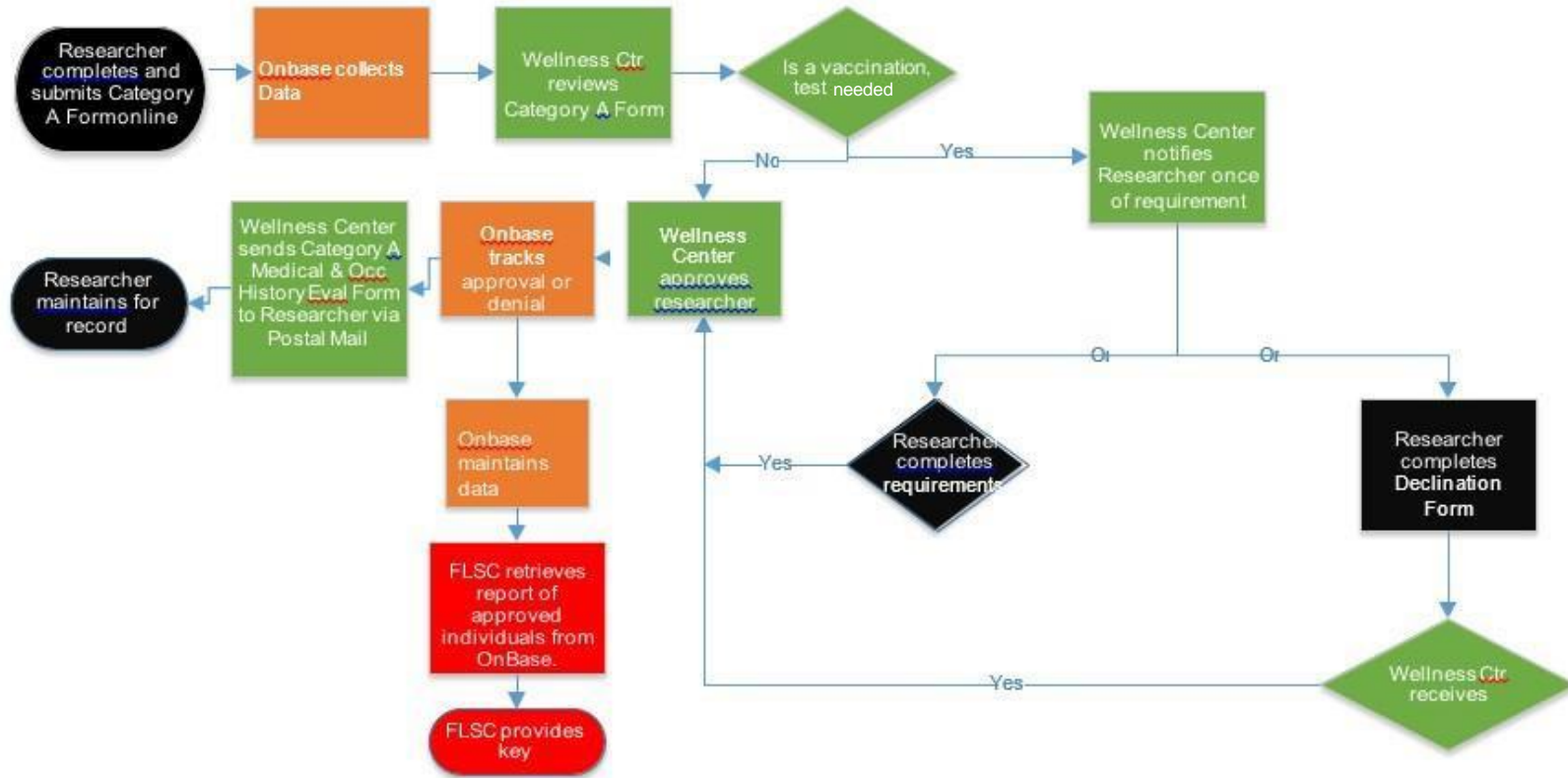
7.1. The OnBase system will send notification to the researcher every three years when Category A forms must be updated. The Category A process flow - Appendix A will be followed.

8. Record Retention – Category A and B forms shall be maintained by the Wellness Center as medical records for the submitter’s duration of employment plus 30 years.

Revision History Table

History	Effective Date
Added references to OnBase in sections: 4.1, 5.3, 5.9.1, 5.11, 5.13, 6.1, 6.3, 6.6, 6.8, 7.1 Changed from “tracking” to “submitting to OHM” Category A&B forms	November 2016
Section 1.1 added	January 2017
Updated footer to match other procedures	July 2017
Updated management of procedures to NDRAC from RMS	September 2023

Appendix A



Appendix B

