REGULATORY REQUIREMENTS

OLAW

The Institutional Animal Care and Use committee (IACUC) prepares an annual report submitted to the Office of Laboratory Animal Welfare (OLAW) through the Institutional Official (IO). The report describes any changes in the institution's animal care and use program, AAALAC accreditation status, IO and IACUC membership, dates for the IACUC's semiannual program and facilities evaluations, and any committee minority views.

The IACUC/IO is required to report all serious adverse events and serious and/or continuing incidents of protocol noncompliance to OLAW.

To receive PHS funds for animal activities, the university must maintain a valid Animal Welfare Assurance D16-00168 (A3261-01), renewed every four years.

USDA

The Ohio State University is registered with the United States Department of Agriculture (USDA) (31-R-0014) and is required by the Animal Welfare Act Regulations (AWAR) to submit an annual report that documents the number of animals used for research, testing, teaching and/or experimentation by specific pain category. The IACUC is also required to report a change of operations, protocol suspension, and uncorrected significant deficiencies from a semiannual inspection to the USDA Animal and Plant Health Inspection Service (APHIS).

The USDA conducts unannounced inspections at least once a year at each registered location (Columbus and Wooster).

OHRP

Ohio State holds Federalwide Assurance (FWA) (00006378) from the Office for Human Research Protections in the Department of Health and Human Services. This FWA is an agreement between DHHS and Ohio State to review and approve federally-sponsored research involving human subjects in accordance with the ethical principles outlined in the Belmont Report and the DHHS regulations 45 CFR Part 46. The FWA is renewed every five years.

OHRP provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by DHHS.

FDA

The Food and Drug Administration (FDA) is charged with ensuring the protection of the rights, safety, and welfare of human subjects who participate in clinical investigations subject to the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA (including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products).

Institutional Review Boards (IRBs) reviewing clinical investigations involving FDA-regulated products are required to register with the FDA. Registration is renewed every three years, or sooner if contact information changes.

NIH

The Institutional Biosafety Committee (IBC) is required to report its membership roster annually to the National Institutes of Health (NIH) Office of Science Policy (OSP).

The Ohio State University is responsible for reporting to NIH any significant problems, violations of the NIH Guidelines, or any significant research related accidents and illnesses involving recombinant or synthetic nucleic acid molecules.

Animal Assurances/Registrations

OLAW Expires: **02.28.2023**

USDA Expires: **08.01.2020**

Human Assurances/Registrations

FWA Expires: **04.25.2021**

IRBs Registered: **3**

Data as of March 29, 2019.