

Office of Regulatory Affairs and Research Compliance Required Documents Checklist for Animal Subjects

The following documents must be on file at HJF before funding is released for any research involving animals (this includes the purchasing of animals):

- Initial local Institutional Animal Care and Use Committee (IACUC) approval letter.
- Second-level/Third Level review approval letter. (A second-level review or third-level review/approval may be required depending on funding source and where the PI or AIs are billeted.)
- Protocol application form and final approved version of protocol **with signature(s)** (electronically signed is acceptable) **where indicated**. Application should reflect funding source.
- Data collection forms used in protocol (as applicable).
- Current copies of CVs for PI, AIs and all personnel listed on the protocol.
- Current assurances from rDNA, radiation, biosafety committees, and/or relevant impact statements (Directorate of Information Management, laboratory, and personnel) as required.
- If protocol is DoD funded, protocol must be in DoD format.
- Animal lab assurances:
 - The Office of Laboratory Animal Welfare (OLAW)
 - Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
 - Current USDA Registration Certificate
 - Most current USDA Animal and Plant Health Inspection Service (APHIS) report.

Documents Required Until Study Closure

- Continuing review/annual progress reporting:
 - Copies of continuing review/annual progress report (**with signature(s) if applicable**) (electronically signed is acceptable) submitted to the IACUC.
 - IACUC approval letter for continuing review
- Triennial Review (Animal protocols expire 3 years after the original approval date):
 - Copies of triennial review report (**with signature(s) if applicable**) (electronically signed is acceptable) submitted to the IACUC.
 - IACUC approval letter for triennial review
- Amendment documents:
 - Copies of protocol amendment requests **with signature(s)** (electronically signed is acceptable) and all supporting documents submitted to the IACUC.
 - IACUC approval letter **with signature(s)** (electronically signed is acceptable) and any approved forms for amended protocols.
- Final report submitted to IACUC with signature(s) (electronically signed is acceptable) and the IACUC approval letter of study closure with signature(s) (electronically signed is acceptable).**