Non-Human Research

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Background:

Some types of research may be undertaken without definite plans to include human subjects (as defined in 45 CFR 46.102(f)); Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”.

In the event that the research does not include human subjects, federal regulations (The Common Rule) do not apply and IRB review may not be required. However, per UF policy, this determination may only be made by the IRB.

Q: What are some examples of non-human research?

Some examples of non-human subject research may include:

- tissue and/or data obtained from another source (not directly from the patient) that is either:
  - totally anonymous (i.e. None of the HIPAA 18 identifiers) and un-linkable to the person from whom it was obtained, or

- is coded such that the researcher obtaining the sample has no access to the key to the code, and does not know to whom the tissue\data belongs, AND a confidentiality agreement assures the researcher cannot learn the identity. data or tissue obtained directly from individuals who are deceased prior to their involvement in the study (see guidance on Decedent Research).

Q: How do I know if my study meets non-human research?

The principal investigator will submit the study through myIRB and select Non-Human. IRB Administrative Reviewers (IRB Chair, Vice Chair or designated IRB Administrative Staff) are responsible for reviewing the preliminary determinations of non-human made by investigators. Only the IRB may make the final determination that proposed research meets the regulatory criteria for non-human. If the Administrative Reviewer finds that the submissions meets the criteria, the PI will receive an approval letter from the IRB with the determination of “non-human” status.

For VA research, the IRB will defer to the requirements for Exempt research as outlined in VHA Handbook 1200.05 handbook.

If the IRB Administrative Reviewer determines that the protocol does not meet the definition of non-human research and should be reviewed as exempt or under expedited or Full Board procedures, the investigator will be notified by the IRB via correspondence within myIRB. Any status change will be reflected in the history log for the study.
Q: Are continuing reviews required for non-human studies?

No, projects approved as non-human research do not require continuing review by the IRB.

Q: Are revisions required for Non-Human research projects?

Yes, changes in non-human research activities must be reported to the IRB prior to initiation. The IRB Administrative Reviewer may, however, depending upon information submitted, change the protocol status if it no longer qualifies as non-human.