Guidance for Investigators: Exempt & Non-Human Subjects Research

Chart 1: Projects Regulated by the U.S. Food & Drug Administration (FDA)

Is the project regulated by the FDA? If unsure, reference the FDA Navigation Guide for help in contacting the appropriate FDA office with questions.

- **Yes**
  - Does the project include people, either healthy or patients, who become a participant in research, either as a recipient of a test article or as a control (i.e. human subjects per 21 CFR 50.3(g))?
    - **No**
      - The project may not be classified as human subjects research according to FDA regulations. Proceed with OSF application for non-human subjects research.
    - **Yes**
      - Does the project involve any experiment that involves a test article and one or more human subjects (i.e. clinical investigation of a test article per 21 CFR 50.3(c) & (j))?
        - **No**
          - The project may be exempt from IRB review according to FDA regulations. Proceed with OSF application for exempt research.
        - **Yes**
          - Is the project a taste and food quality evaluation or consumer acceptance study (21 CFR 56.104(d))?
            - **Yes**
              - The project is likely human subjects research that requires IRB review and approval prior to initiation. Proceed with OSF application for human subjects research requiring IRB review.
            - **No**
              - Go to Chart 2 for projects that are not subject to FDA regulation.
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Chart 2: Projects that are NOT Regulated by the U.S. FDA

Does the project involve a systematic investigation designed to develop or contribute to generalizable knowledge (i.e. research per 45 CFR 46.102(d))?  

Yes  

No  

The project may not be classified as human subjects research according to HHS regulations. Proceed with OSF application for non-human subjects research.

Does the project include a living individual about whom an investigator conducting research obtains either data or identifiable private information through interaction or intervention with the individual (i.e. human subject per 45 CFR 46.102(f))?  

Yes  

No  

Will the research be conducted in established or commonly accepted educational settings, involving normal educational practices (45 CFR 46.101(b)(1))? Review OHRP Decision Chart 3 for additional assistance.

Yes  

No  

Will the research involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior (45 CFR 46.101(b)(2) and (3))? Review OHRP Decision Chart 4 for additional assistance.

Yes  

No  

Will the research involve the collection or study of existing data, documents, records, or pathological or diagnostic specimens (45 CFR 46.101(b)(4))? Review OHRP Decision Chart 5 for additional assistance.

Yes  

No  

Will the research study, evaluate or examine public benefit or service programs (45 CFR 46.101(b)(5))? Review OHRP Decision Chart 6 for additional assistance.

Yes  

No  

Will the research involve taste and food quality evaluation or consumer acceptance studies (45 CFR 46.101(b)(6))? Review OHRP Decision Chart 7 for additional assistance.

Yes  

No  

The project is likely human subjects research that requires IRB review and approval prior to initiation. Proceed with OSF application for human subjects research requiring IRB review.