THE OHIO STATE UNIVERSITY

Office of Research

Office of Responsible Research Practices

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orrp.osu.edu

Additional Resources

General Resources for Clinical Investigations Involving Drugs

- From ORRP:
  - Investigator Guidance: https://orrp.osu.edu/irb/investigator-guidance/
  - HRPP Policy: Research Involving Investigational Drugs: http://orrp.osu.edu/files/2012/02/Research-Involving-Investigational-Drugs.pdf
  - Past ORRP Educational Sessions: http://orrp.osu.edu/irb/workshopsseminars/orrpeducation/
- From FDA:
  - Clinical Trials & Human Subject Protection: https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection
  - Drug Guidance Documents: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
  - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency
- Others:
  - ReGARDD: Regulatory Guidance for Academic Research of Drugs and Devices: http://www.regardd.org

Drug Information: Product labeling & classification

- Databases of approved drugs and biologics:
  - DailyMed drug label database: https://dailymed.nlm.nih.gov/dailymed/
  - FDA's Approved Drug Databases (includes link to Biologics database): https://www.fda.gov/drugs/drug-approvals-and-databases/resources-information-approved-drugs
- Drug classification & product jurisdiction
  - Biologics Product Jurisdiction: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-product-jurisdiction
  - Combination Products: https://www.fda.gov/combination-products
  - Draft guidance: Requesting FDA Feedback on Combination Products: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice
  - Guidance: Classification of Products as Drugs and Devices & Additional Product Classification Issues: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice

Investigational New Drug Applications (INDs) & IND Exemptions

- From FDA:
    - General IND page: https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application
    - Investigator Initiated IND Applications: https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications
    - FDA Guidance: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf
    - FDA Guidance: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ind-exemptions-studies-lawfully-marketed-drug-or-biological-products-treatment-cancer
- Ohio State Resources
    - Center for Clinical and Translational Science (CCTS) IND/IDE support: https://ccts.osu.edu/content/indide-support
- Other Resources
    - ReGARDD's Initial IND Submission information (templates, info, and video walk-through): http://regardd.org/drugs/initial-ind-submission
    - UNC/ReGARDD IND Workshop (3 hours): https://panopto-web.med.unc.edu/Panopto/Pages/Viewer.aspx?id=0d8208a7-e853-4d55-a5a7-ac1d8e80f2d3

IRB Application Resources

- General Buck-IRB information: http://orrp.osu.edu/irb/buck-irb
- Submissions to Western IRB (WIRB): http://orrp.osu.edu/irb/osuirbpolicies/wirb/
- Submissions to NCI Central IRB (CIRB): http://orrp.osu.edu/irb/osuirbpolicies/nci-central-irb/
- Recorded education sessions: http://orrp.osu.edu/irb/workshopsseminars/orrpeducation/
    - "Buck-IRB and Initial IRB Submissions – medical focus" (March 2019)
    - "Amendments and Buck-IRB" (December 2019)
    - "Event Reporting in Human Subjects Research" (June 2020)

FDA Inspections & Audits

- ORRP guidance for investigators/research staff: http://orrp.osu.edu/irb/investigator-guidance/fda-inspections/
- FDA's Biomonitoring Program (BIMO): https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/bioresearch-monitoring-program-bimo

FDA Divisions Relevant to Drug Research & Contact Information

- Center for Drug Evaluation and Research (CDER) Offices & Divisions: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-offices-and-divisions
- Center for Biologics Evaluation and Research (CBER): https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber
- IND/IDE Contacts (general): https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/indide-contacts