• General workflow
• Ohio State overview
• Required forms for submission
• Questions
General Submission Workflow

Sponsor provides information → PI creates Buck-IRB submission

ORRP review/ancillary review → Authorization provided to PI

PI submits to WIRB
• Study is written and designed entirely by the sponsor
  • *No scientific contribution by Ohio State faculty*
  • *Sponsor must be for-profit entity/company*

• No funding from federal or non-profit agency sources

• No planned emergency research

• No xenotransplantation, human gene transfer, or embryonic stem cell research (e.g., IBC-reviewed research)

• PI must meet Ohio State PI eligibility criteria

• Complete CITI training and COI disclosure
• Research protocol
• Informed consent form(s)
• WIRB Initial Review submission form
• Dose calculation worksheet (if research-related radiation included)
• Clinical Scientific Review Committee (CSRC) approval letter (if cancer-related research)
Sponsor liability – Not template language, but Ohio State requires for greater than minimal risk research

Suggested language:

SPONSOR LIABILITY: [Suggested language below.]
If the injury was caused by the product or procedures used in this study, then the study sponsor, ______________________ [Insert the sponsor’s name.], will pay the reasonable costs for necessary medical treatment that is not covered by your medical insurance provided you have followed the directions of the study doctor. This commitment for free medical treatment does not include treatment for any other complications or illness that you may experience during this study, which do not result from your participation in the study.

By signing this consent form, you will not be waiving any of the legal rights which you otherwise would have as a subject in a research study.

WIRB reference template (review required sections)
Following “Review Ceded” notification, future submissions, including adverse events, must be sent directly to WIRB and not through Buck-IRB.

**EXCEPTIONS:**

- **Submit to Buck-IRB:**
  1. Personnel changes, including PI
  2. Addition of research-related radiation procedures
  3. New or revised research locations

- **Email WIRBinfo@osu.edu:**
  4. Changes to Ohio State-required language in ICF
  5. Addition of new funding source
Sponsors submitting on PI’s behalf

- Not permitted for initial “ceded” submission
- Acceptable for amendments with approval by PI/study team
Questions?

WIRBInfo@osu.edu

http://orrp.osu.edu/irb/osuirbpolicies/wirb/

Jessica Mayercin-Johnson: 688-1059
Sarah Hersch: 688-1253
Updates at WIRB

The Ohio State University

By: Christopher Gennai, CIP

April 2, 2019
Disclosure

• WIRB employee since 2010

• Information in this presentation is generalized

• Analysis of a specific situation must be conducted to apply the following information
Agenda and Objectives

• Introductions
• Winning Together
• Submission Forms Updates
• Processing Updates
• 2018 Revised Rule
• Reminders
• Questions/Answers Open Forum
The OSU Stats at WIRB

• First Approval at WIRB
  – April 2002
  – 17 years of partnership
• 2834 Studies submitted
  – 166 per year average
  – 245 in 2018
The Ohio State University

- WIRB Working Days (does not include holds and clarifications)
  - Initial Review
    - 7.5 days average
  - Change in Research
    - 3 days average
- Working Days (all days IRB is open, regardless of submission status)
  - Initial Review
    - 16 working days
  - Change in Research
    - 5.5 working days
Ethics, Compliance History and Experience

- Over 50 years of Regulatory Experience
- Senior Advisors to: FDA, OHRP, AAHRPP
- Longest AAHRPP Accreditation History
- ISO-Certified IRB
- 20 Successful FDA Audits
- Over 500 Successful Sponsor/CRO Audits
- 200+ Experienced IRB Panel Members
- 35 Certified IRB Professionals (CIPs) on Staff
- IRB of Record for:
  - 95% of All North American Protocols
  - 96 of 110 FDA Approvals (2017)
Form Updates

• Removed HUD and Single patient information to separate form
• Add IND, IDE, and SR/NSR questions
• Updated Federal Funding section
• Updated minimal risk section
Form Updates

• Redesigned layout of form based on client feedback
• Consent processing section aligned to recent changes
• Consolidated questions regarding research locations
• Updated PI, Research Personnel, and History sections
IB Process Update

• December 12, 2018 the IRB will Approve Investigator Brochures
• Previously IB was only acknowledged
• If you submit an IB
  – IRB will approved newer versions
  – IRB will file older versions without action
• Updates to the IB are processed for all regardless of the source
DSMB Process Update

• August 20, 2018 the IRB will acknowledge DSMB submissions
• Previously DSMB information was only acknowledged on file by staff
• If you submit a DSMB
  – IRB will approved newer versions
  – IRB will file older versions without action
• DSMBs are processed for all regardless of the source
Consent Process Update

• July 3, 2018 started requiring the use of IRB-approved informed consent to track (redline) your site’s changes

• Decreases emails between you and WIRB staff

• Prevents errors
Translations Process Update

• May 2018 Translations Request Submission Form released
• New requests for translations required the form
• New form helps ensure we capture the exact intent of the request
• Update reduces delays
Board Action Update

• November 2017- NEW Certificate of Action
• One-stop shop for all Board determinations
• Approved Action for Doctor to Doctor Letters
• Approved Action for Press Releases
• Shared WIRB and CGIRB Panel with WIRB-Copernicus Group branding
Implementation of the revised Common Rule

• Issued on January 19, 2017
• Implementation on January 21, 2019
• Applicable to federally funded research
• FDA intends to harmonize
Implementation of the revised Common Rule

- Sponsors of FDA-regulated are not following revised common rule
- IRB will not require consent provisions in FDA-regulated research, at this time
Informed Consent and the revised Common Rule

• If the consent is longer than 4 pages, the form must start with a concise summary.

• The summary should not exceed 3 pages or 1/3 of the length of the remaining document (exclusive of face page and signature blocks), whichever is shorter.
Informed Consent and the revised Common Rule

• The consent summary has the following disclosures.
  – Participation involves research
  – Duration of participation
  – Purpose of research
  – Procedures
  – Risks
  – Benefits
  – Alternatives
  – Participation is voluntary
Informed Consent and the revised Common Rule

• The consent will also include
  – information that a reasonable person would want to have in order to make an informed decision about whether to participate
  – opportunity to discuss the information
  – the reasons why one might or might not want to participate
  – presented in a way that facilitates comprehension
  – not merely provide lists of isolated facts
Informed Consent and the revised Common Rule

• The consent will also include one of
  – De-identified information or biospecimens could be used for future research studies without additional consent
  – Subject’s information or biospecimens collected as part of the research, will not be used or distributed for future research studies
  – Research does NOT involve the collection of subject’s information or biospecimens
Informed Consent and the revised Common Rule

• The consent will also include
  – A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
  – A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
  – For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing
Additional resource and detail

- Elements of consent required under the 2018 Revised Common Rule are detailed in 45 CFR 46.116(a)(5)(i), 45 CFR 46.116(b)(9) and 45 CFR 46.116(c)(7), (8), and (9).

- These requirements can be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=P ART&ty=HTML#se45.1.46_1116.

- This document contains helpful information regarding writing the summary and additional elements. You can find detailed guidance and instructions on how to write the concise summary on pages 1 through 3.
Revised Common Rule and Minimal Risk Research

• The new rule allows for most minimal risk research to be conducted without IRB continuing review.
  – IRB will not require continuing review for applicable minimal risk research that is federally-funded or neither federally-funded nor FDA-regulated.
  – IRB will require continuing review for research that is under FDA jurisdiction as required by FDA regulations.
Revised Common Rule and Minimal Risk Research

• Regardless of the continuing review category, changes in research and new information that may constitute serious or continuing noncompliance or an unanticipated problem involving risks to subject or others must be submitted to the IRB.
Just a friendly reminder...
Helpful Resources

• Most of what you need is available on WIRB’s website: www.wirb.com
  • Submission Forms
  • WIRB’s Model Consent Form
• “Guide for Researchers:” an aid to WIRB’s perspective on developing, submitting, and conducting research.
Financial Conflicts of Interest

– Reporting new or changes in

• Use the Financial Interest Disclosure Form.

• Select the appropriate option from the form

• Include any management plan already in place (i.e. institution directed plan)
Continuing Review

– WIRB sends sites the first notice requesting completion of the Site Progress Report about 75 days prior to the expiration date of the study.

– Site Progress Report is due about 60 days prior to the expiration date of the study.

– Even if the site has not started enrolling subjects, the site must complete the report and return it to WIRB before the due date printed on it to inform the Board of the study’s status at the site.
Continuing Review

– About 50 days and 40 days prior to the expiration of the study, WIRB staff prepare a “past due” notification to all study contacts

– About 30 days prior to the expiration date, the delinquency is reported to the Board

  • Failure to provide the Site Progress Report can result in Suspension or Termination of the study site.
Continuing Review

– Board Review

• Board may conduct the study renewal review up to 30 days prior to the expiration date listed on the Certificate of Action

• Review is carried out unless WIRB receives a study closure notice prior to the Board’s renewal review

• If the Board approves renewal for an additional review period, a Certificate of Action is forwarded to the investigator and other study contacts as applicable
Planned Protocol Deviations

– Requesting changes before they take place

• Submit a **Change in Research Submission Form.**

• Anything that needs board approval before the event takes place.
  – Examples: Inclusion / Exclusion criteria, out of window visit.

• It usually takes about 3-4 business days for approval of the deviation.

• For urgent requests, contact me with the submission ID
Promptly Reportable Information

– Reporting events that have already taken place

• Use the **Promptly Reportable Information Submission Form**.

• Select the appropriate option from the form, and include the following information:
  – Date of occurrence and discovery
  – Brief description or outline of the topic/process/problem being documented
  – Cause of issue or actions taken leading to issue
  – Actions needed to correct issue
  – Changes proposed to prevent recurrence
  – Method of implementation
Questions?
Thank You!