



RAOR – IRB and DASH Update

January 2026



THE UNIVERSITY OF
TENNESSEE
KNOXVILLE

Who is the HRPP?



Rob Withrow

- Arts and Sciences
- Engineering
- Law
- University-Wide Units



Becca Massey

- Nutrition
- Public Health
- KRSS
- Nursing



Kadie Rome

- Business
- Public Policy
- Agriculture
- UTIA
- CCI
- RHTM
- Social Work
- Veterinary Medicine



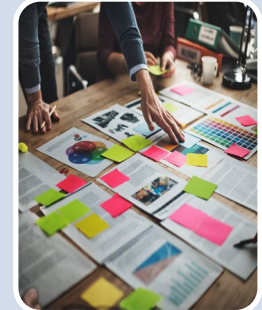
Linda Zerby

- CEHHS
- CHDFS
- ELPS
- TPTE



Tammy Loy

- Quality Assurance Specialist



Karen Walker

- Administrative Assistant

What is the IRB and what does it do?



Reviews research that involves human subjects



Comprised of roughly 20 individuals including, medical professionals, faculty from many colleges/departments in the University, non-scientific reviewers, and persons not affiliated with the University.



The Full Board meets once a month to review research that is greater than minimal risk, including new protocols, changes to research, continuing reviews of existing research, and reportable new information.

IRB Team



Eboni Winford
Interim IRB Chair



Renee Smith
Vice-Chair



Graciela Cabana
Vice-Chair

Dr. Tami Wyatt

Institutional Official

The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance



What Requires IRB Review?

Human Subjects Research: Activities must meet the definitions of "research" and "human subjects" under DHHS

Research: A systematic investigation₁ to develop or contribute to generalizable knowledge₂

1

Systematic Investigation

Planned data collection and analysis to answer a question.

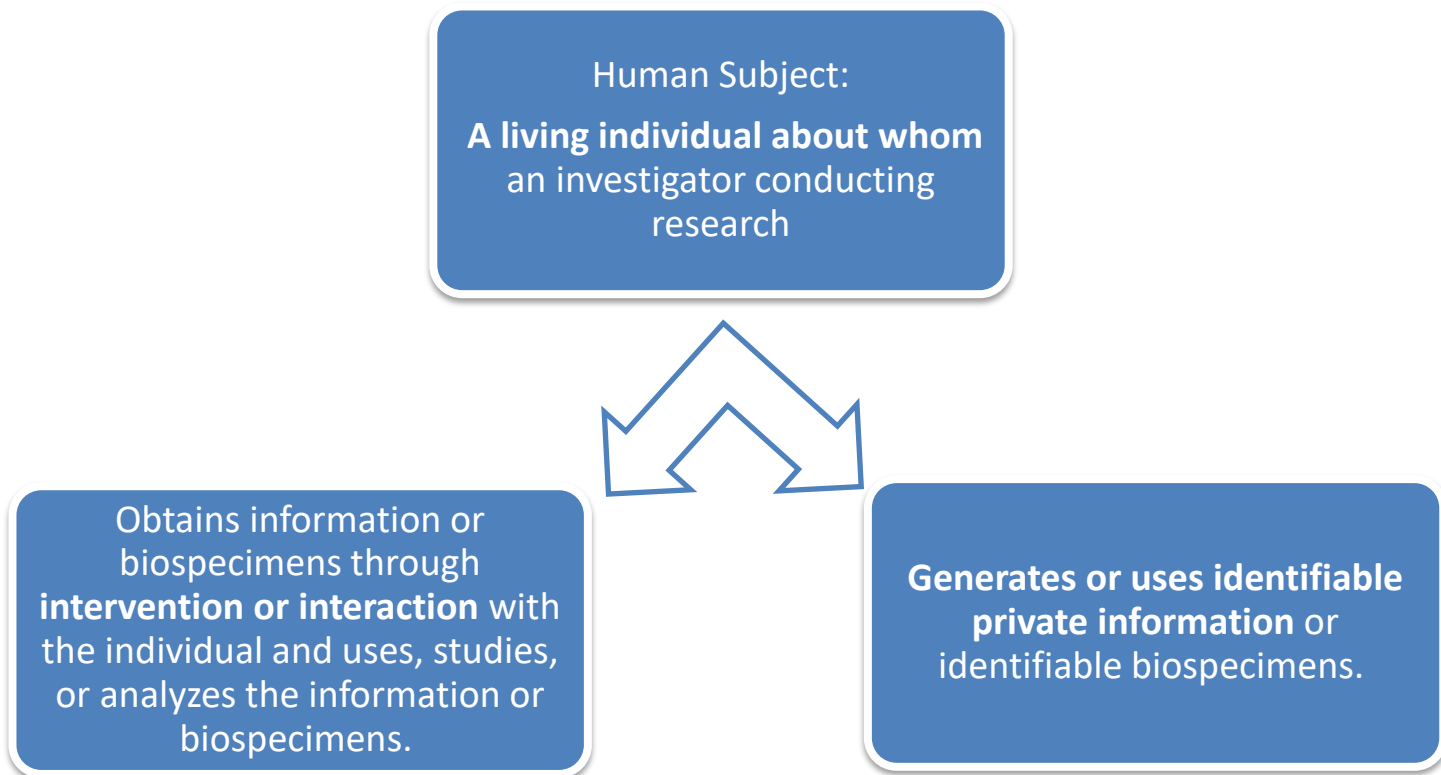
- Examples: Surveys, interviews, data analyses, cognitive experiments, chart reviews.

2

Generalizable Knowledge

- Information where the intended use of the research findings can be applied to populations or situations beyond that studied.
- **Examples:** Knowledge contributing to an established theoretical framework.
- Results are intended to inform other researchers, scholars, or practitioners.
- Results expected to be generalized to larger populations or replicated in other settings.

DHHS Definition Human Subjects



Activities Not Considered HSR

Quality Improvement (QI) Projects:

- **Focus:** Systematic efforts to improve program quality, healthcare delivery, or organizational performance.
- **Key Point:** Aimed at specific improvements within an organization, not at making generalizable claims outside of the scope of the organization.
- **Distinction:** QI projects improve performance at a specific site (e.g., healthcare system). Research projects add new knowledge through scientific testing.

Scholarly and Journalistic Activities

- Includes activities such as oral history, journalism, biography, literary criticism, legal research, and historical scholarship.
- **Key Point:** These activities focus directly on specific individuals or events and there is no intent to test a hypothesis or produce generalizable knowledge.

Course Related Activities

- Data collected from students during standard classroom exercises or assignments, used **strictly for educational purposes** and not intended for publication or presentation outside of the classroom.
- IRB approval might be necessary if wish to explore pedagogical methods within the classroom setting, with the aim of generating widely applicable insights into educational strategies

When is Personnel Considered Engaged in HSR?



UTK considers personnel engaged in Human Subjects Research (HSR) if they are **named in the grant or contract** or **responsible for any of the following activities**:



Collecting Data: Gathering information or biological specimens from participants for research purposes.



Obtaining Informed Consent: Engaging with participants to explain the research, its risks, and benefits, and securing their consent to participate.



Analyzing Identifiable Data: Working with data that can be linked to individual participants, whether directly or indirectly.



Answering Research Questions: Responding to inquiries from potential, current, or past participants about the research, or otherwise acting as an extension of the Principal Investigator (PI).

Need Help Determining if Your Project is HSR?

Complete the Worksheet

Unsure if your project requires IRB review? Start by completing the [Human Subjects Research Determination Worksheet](#). This tool helps clarify your project's status based on regulatory definitions.

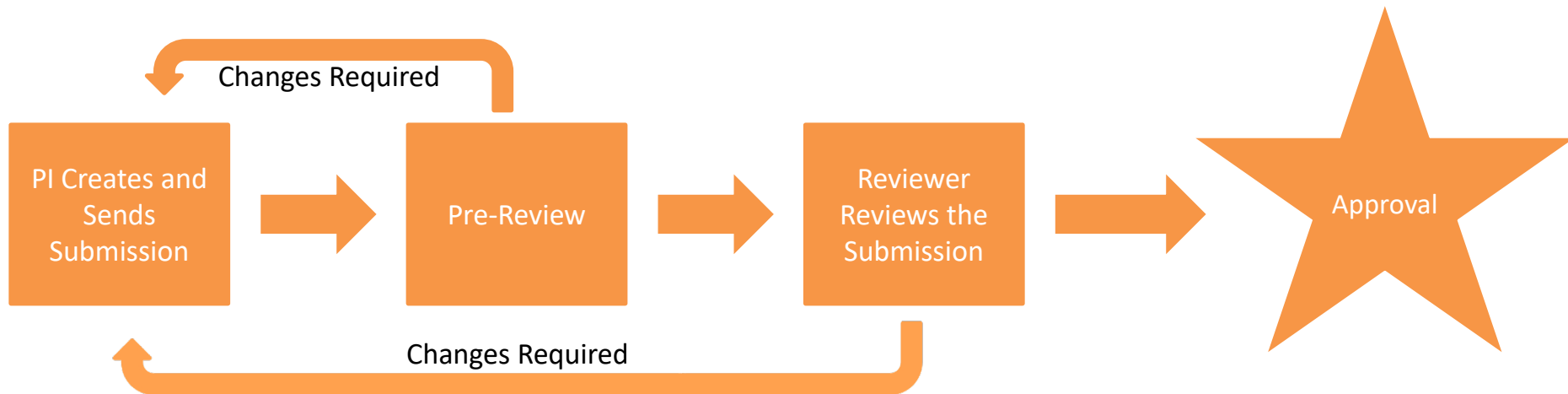
Seek Additional Guidance

If you still have questions after completing the worksheet, reach out to the HRPP staff via your college liaison or email utkirb@utk.edu for further assistance.

Request an Official Determination Letter

For formal documentation, email your worksheet results and a brief summary of your project to utkirb@utk.edu. Please include "HSR Determination Letter Request" in the subject line.

IRB Review Process



Turnaround Time (2024 Data)



Types of Risk in Human Research

Greater than
Minimal Risk

- Greater than the risk encountered in every day life

Not Greater
than Minimal
Risk

- Not greater than the risk encountered in every day life

DASH Research IRB

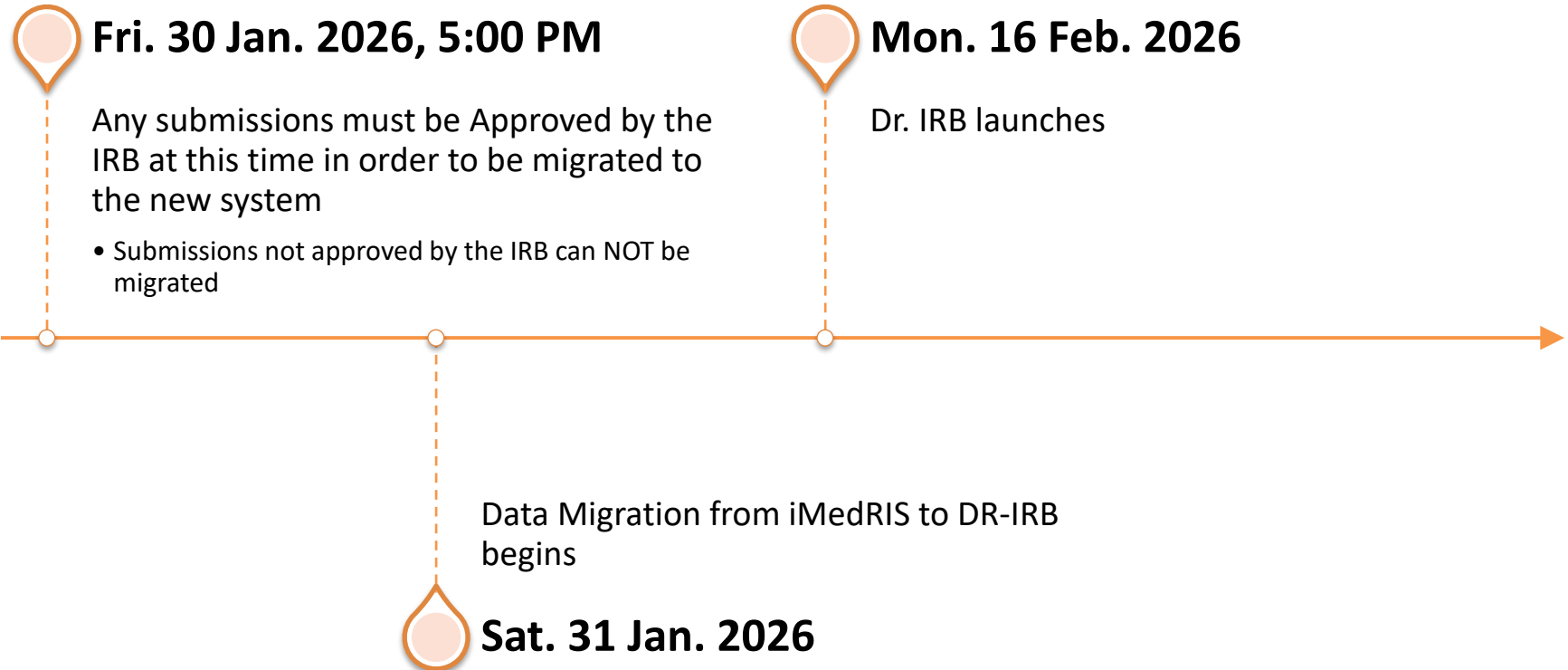


DR-IRB

Who is Adopting This System?



Key Dates



IRB Services During Blackout Period

- Researchers will have access to their protocols
- Requests for reviews will occur on a case-by-case basis, with the knowledge that all documentation must be placed into the new electronic system at launch
 - Information that may affect the health, safety, or welfare of participants
 - Mandated reporting requirements (federal, state, or institutional)
 - Critical timeline needs
 - 118 Determinations
 - NHSR Determinations
 - Pre-Review of Submissions
- Educational services

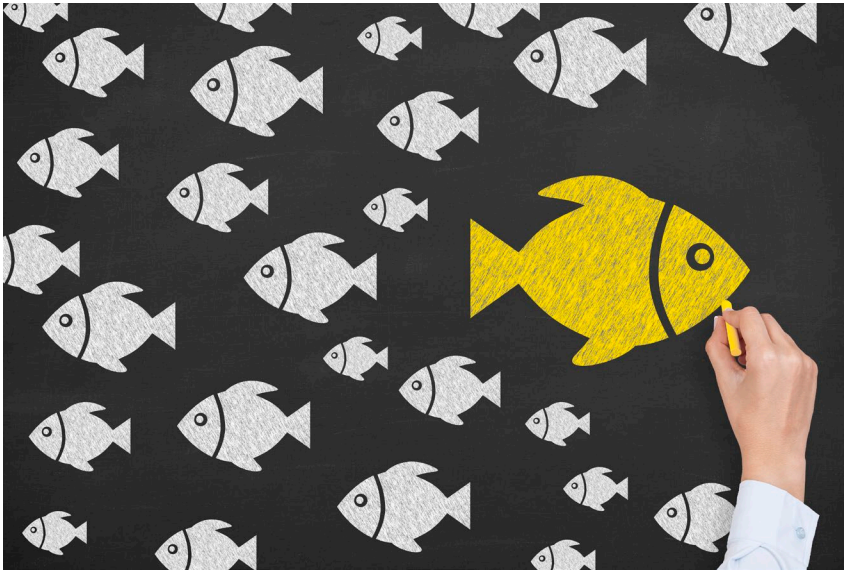
Data Migration

- All studies listed in iMedris as “Approved” or “Closed to Enrollment: Analysis Only” will be migrated
 - All documents listed as Approved
- Expired studies, Closed studies, Draft studies, or Studies in progress (Pending, Deferred, or Incomplete) will NOT be migrated

13 result(s) found...

Click to open Project Dashboard	Project Status	Review Board	RB Number
	Approved		Will be Transitioned
	Closed to Enrollment: Analysis Only		Will be Transitioned
	Draft		Will NOT be Transitioned
	Expired		Will NOT be Transitioned
	Pending - Corrections		Will NOT be Transitioned
	Pending - Submitted for Initial Review		Will NOT be Transitioned

What is Different About Dr. IRB?



New look and feel

Streamlined submission processes

Submission access

- Protocol creation and submission is initially limited to 2 individuals: a PI and a PI Proxy

Departmental Review

- “Ancillary Review” in the system
- Initially managed by IRB Staff

Limited SmartForm Requirements

- Protocols (formerly applications) are now managed in Microsoft Word
 - No more clunky routing in iMedris Applications
 - No more guessing at question numbers
 - No more guessing at what the IRB will ask

DR-IRB Protocol Templates & Appendices

Protocols = Study Review Type

Expedited/Full

Exempt

Survey

Interview

Secondary Data Analysis

External Reliance

Appendices = Special Populations or Circumstances

Children & Wards of
the State

Incarcerated
Persons

Pregnant persons &
Neonates

Devices

HIPAA

Cognitively Impaired

International
Research

Waiver or Alteration
of Consent

Drugs

Blood Draws

Depending on the study, researchers will always have one protocol document but may have zero or multiple appendices

Roadblocks at Launch

- Individuals not in the HR feed must obtain a sponsored account from OIT before they can access DR-IRB (or any DASH modules)
 - The plan is for students that are currently in iMedRIS to be loaded into the system at launch – this *should* only affect students attempting to access the system for the first time.
- PI Proxies
 - PI Proxies must be assigned in the system to:
 - Send submissions to the IRB
 - Receive system communications (review outcomes, etc.)
 - For migrating studies, this will need to be done at launch.
 - For new studies, this can be done by the person who creates the study.

Upcoming Education

- Welcome Back Educational Series:
 - January 26th - Follow on submissions
 - January 29th - Follow on submissions
 - February 3rd - New Study Submission
 - February 5th - Practice Lab
 - February 9th - Practice Lab
 - February 13th - Practice Lab
- Post Launch Educational Series:
 - February 17th – New Study Submission
- Additional education available on demand!

More to come!

Ways to Help

- Encourage PIs to be ready to add students as PI Proxies at launch
- Spread the word on education
- Consider formalizing processes for students to obtain “sponsored” accounts
- Preach patience!
 - Any new launch will have unanticipated “bumps” along the way our team will be prepared and ready to assist all researchers in navigating the process

Resources

General Inbox

- utkirb@utk.edu

Office staff and office hours (times in EST):

- Linda Zerby (lzerby@utk.edu) - Mondays 2 – 4 pm
- Becca Massey (relias@utk.edu) – Tuesdays 11 am – 1 pm
- Kadie Rome (krome1@utk.edu) – Wednesdays 1 – 3 pm
- Rob Withrow (rwithrow@utk.edu) – Thursdays 9-11 am

HRPP Website (<https://tiny.utk.edu/hrpp>)

- For Researchers Page (<https://research.utk.edu/research-integrity/human-research-protection-program/for-researchers/>)