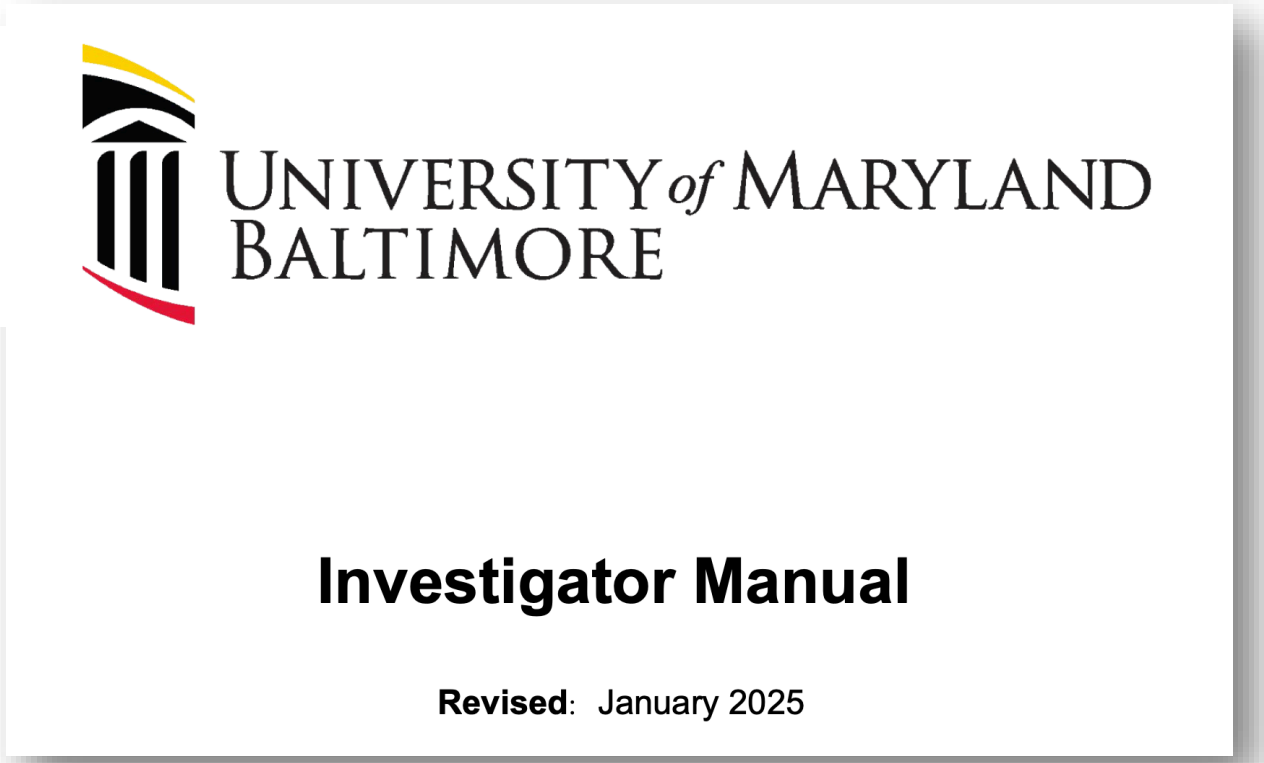
UMB Investigator Manual: Key Points and Considerations

** All individuals involved in research are expected to be knowledgeable of and follow the guidance outlined in the Investigator Manual.*



Casey Jackson, MS, CCRP

Director, Research Quality Improvement and Compliance

Office of Research and Scholarship

University of Maryland School of Nursing

Disclaimer

No conflicts of interest

I am not speaking on behalf of the UMB HRPO

Poll

For how long have you been a PI at UMB?

- 0-1 yrs
- 2-5 yrs
- 5+ yrs
- I am not a PI at UMB

Poll

How often do you consult the UMB Investigators Manual (IM)?

a) Weekly or more
b) Monthly
c) Couple of times a year
d) I forgot there was a manual/never heard of it

What is the UMB IM?

Basic guide to human subjects research policies, procedures, and resources specific to UMB

Summarizes:

-structure

-requirements

-process

What is it not?

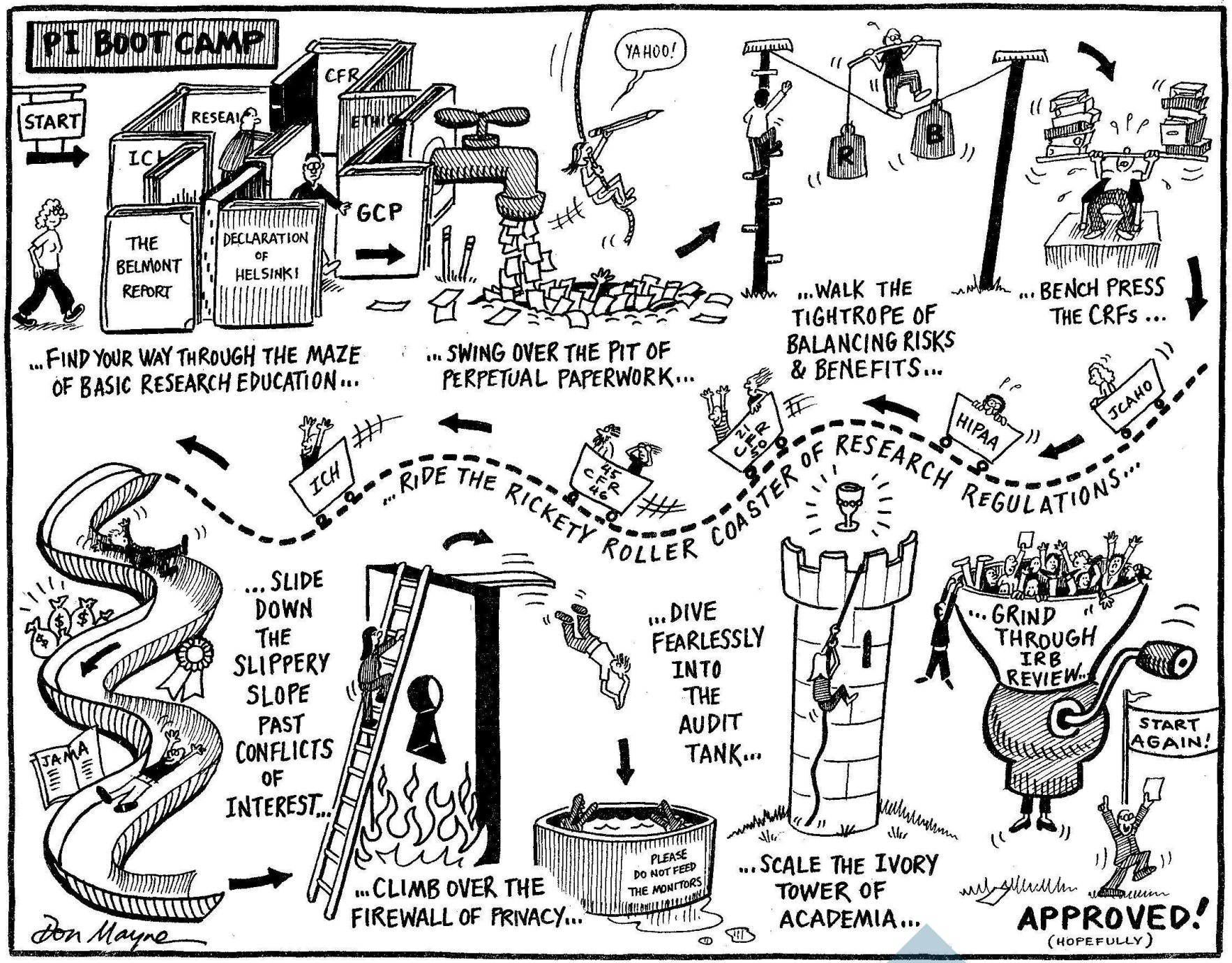
-Comprehensive overview of all PI requirements in research at UMB

-IACUC related

-The only tool in your toolbox

-To be ignored

**** All individuals involved in research are expected to be knowledgeable of and follow the guidance outlined in the Investigator Manual.***



UMB IM v. Jan 2025: Format & Overview

70 pages

- First ~29 pages= Q&A
- Pages 30-70 = appendices as applicable

Q&A format

Webpage or downloadable PDF

- Requirements (compliance)
- How-to's (as applicable)

UMB IM: Key Points*

*in my opinion. Skipping HRPP structure, Federal regs, IRB decision-making info, HUD/EU related topics

Engagement Criteria (study team)

PI Qualifications

Research Team Training Requirements (basic)

PI Obligations (study detail dependent)

Research development

Post IRB approval (i.e. reporting, documentation, record retention, etc.)

UMB IM: Key Points*, continued

- ✓ Wayfinding (how do I?)
  - Complete IRB application (CICERO); submit updates (MODs, CRs, RNIs, closure)
  - Write a protocol
  - Make a consent document; document the consent process
  - Enroll non english speakers
  - Recruit over the phone
  - Rely on an external IRB
  - Conduct a multi-site study
  - Respond to study expiration
  - Transfer my study (leaving UMB)

Engagement Criteria (UMB IM p.6)

When am I engaged in research?

You are considered "engaged" in human participants' research when you:

1) intervene or interact with living individuals for research purposes, or

2) obtain individually identifiable private information for research purposes.

Further, a site is considered to be "engaged" in human participants' research when it receives a direct Federal award to support the research. See "WORKSHEET: Engagement Determination"

Also consider: consult the HHS engagement /non-engagement criteria and the UMB HRPP v.5/2025

PI Qualifications (UMB IM p.6)

Can I be a principal investigator for a study?

To qualify as a principal investigator, you must be a full-time (>51% effort) faculty member holding one of the following titles at UMB:

- Professor
- Associate Professor
- Assistant Professor

The IM describes the process for requesting PI status.

NOTE: Students and fellows are not permitted to be Principal Investigators

Also consider: titles don't always equal experience and experience in one area doesn't always translate to another area!

Basic Training (UMB IM p.7)

Situation dependent!

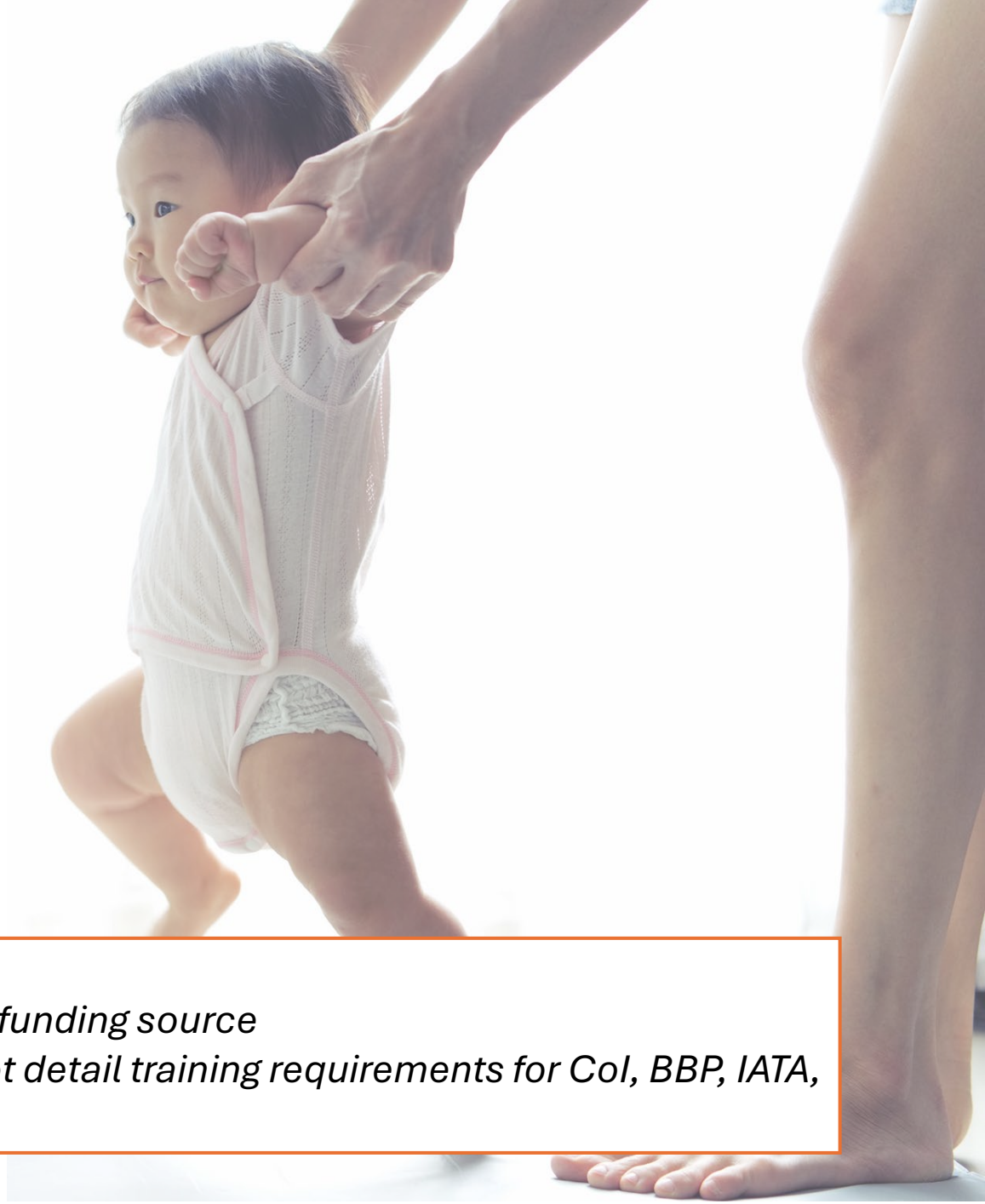
-employee vs. non-employee

-involves VA?

-NIH funded?

No current training for ALL staff =

No IRB approval (initial or continuing)



Also consider:

- *UMSON policy requires GCP training for all regardless of funding source*
- *Although required where applicable, the UMB IM does not detail training requirements for CoI, BBP, IATA, study protocol, etc.*

PI Obligations: Research Development (UMB IM p.8)

Ensure adequate resources!!

- to **protect** the rights, welfare and safety of human participants involved in the research
- **time** to conduct, oversee and complete research
- adequate number of **qualified staff**
- **facilities** in which to perform study procedures
- access to **study population**
- availability of **medical/psychological resources** for participants as a consequence of the research
- **process** to ensure that **all persons involved** in the design, conduct and/or reporting of research **are adequately informed** about the protocol and their research-related duties and functions, including following all HRPP and UMB policies and procedures

Also consider:

- *Manual of Operations for the protocol and SoPs greatly enhance your understanding the resources needed*
- *Records retention and data storage needs*

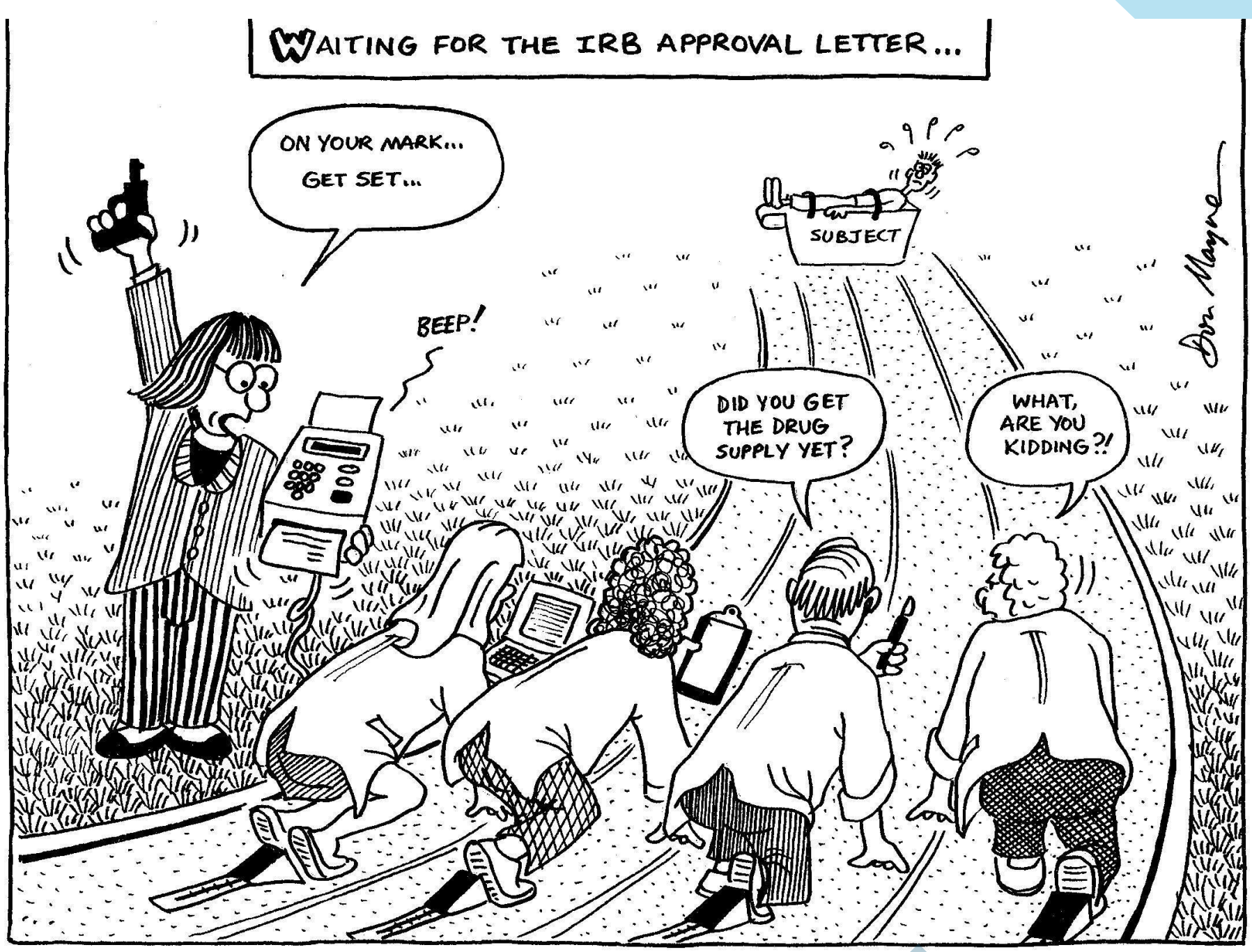
PI Obligations: Research Development (UMB IM p.8)

Situation dependent:

- grant/funding proposal alignment with protocol/IRB app
- vulnerable population protections
- billing/finances
- test article control
- liaison between sponsor and IRB
- training & oversight of involved external entities
- CCT/SPA processes
- translation services
- document storage needs

Also consider:

- *Departmental policies*
- *Tech, environment, and sample controls, etc.*
- *Ancillary reviews (i.e. GCCC, IBC, RSC, departmental, VA, etc.)*
- *Clinicaltrials.gov*



PI Obligations: Post IRB Approval (UMB IM p.20-21)

- **Personally conduct or supervise the Human Research**
- Only start once all reviews/approvals are completed
- Follow protocol; consent process
- Delegate responsibly
- Monitor the study and perform quality reviews for both:
  - Participant safety
  - Data integrity
    -Must timely address deficiencies found

Also consider:
- *Quality monitoring/Audit preparedness; Regulatory Binder/Study Documentation*
- *Protocol deviations & DSM reviews*
- *UMSON/Departmental policies*

PI Obligations: Post IRB Approval, continued…

CoI:

- PI is responsible for ensuring all staff disclose CoI initially, at annual review, and within 10 days of a change in CoI status. (p.13)
- No finders fees or bonus payments allowed (p.21)

RNI: Submission within 5 business days of awareness (p.25)

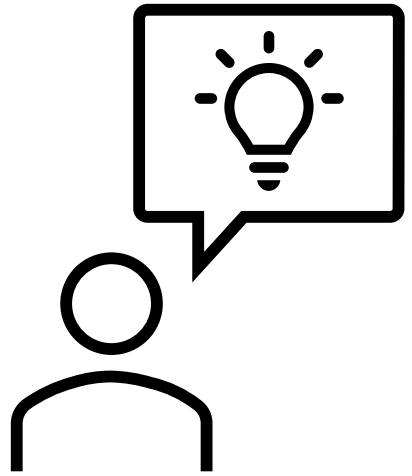
Continuing Review: must submit at least 6 WEEKS PRIOR TO THE EXPIRATION (p.27)

Records Retention: 3yrs post closure (6yrs if HIPAA) (p.28)

Also consider:

- *RNI- expected information*
- *Sponsor/Regulator record retention requirements*

Wayfinding (How do I?)



- Complete IRB (CICERO) application (UMB IM p.12-13)
- Write an investigator protocol (UMB IM p.13- 14)

Note! These sections are very basic.

- *Prescriptive step by step details on how to complete any application/submission in CICERO (i.e. Initial review, CRs, RNIs, MODs, etc.) are not given. For those, see CICERO instructional videos:* https://www.umaryland.edu/hrp/for-researchers/instructional-videos/cicero-instructional-videos/
- *Protocol templates and prescriptive instructions on how to write a protocol (i.e. required info, format, etc.) are not given. For ideas, the internet is your friend. Remember, the grant is not the protocol!*

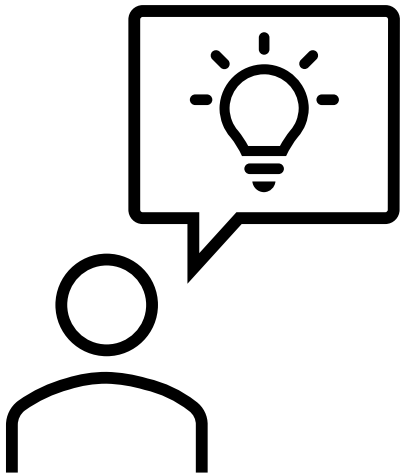
Also consider:

-CHOP Protocol Templates: https://www.research.chop.edu/services/protocol-templates

-UMSON Researchers Toolkit: https://www.nursing.umaryland.edu/research/resources/regulatory-affairs/researcher-toolkit/#m-accordian-0-1

-NIH Protocol Templates: https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/protocol-template

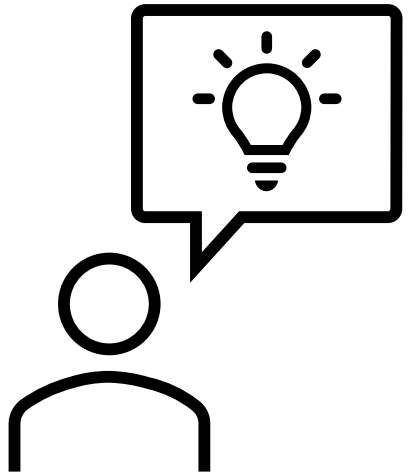
Wayfinding (How do I?)



- Make a consent document (long form & short form)
  - Note, waiver potentials outlined
- Enroll non-english speakers
  - *Native language consent document; IRB approval of non-English population*
- Recruit over the phone
  - Collection of SSN# over phone prohibited
  - Cold-calling prohibited
  - Later contact upon participant consent limited to topic in consent

Also consider:
- *consent information sheet; consent process documentation*
- *Non-English/native language study materials; translation services; additional protections*
- *Recruiting over video calling, internet, email, snail mail; protect against fraud/bad actors*

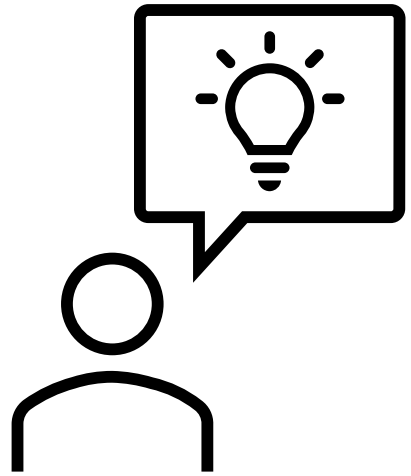
Wayfinding (How do I?)



- Rely on an external IRB
  - Reach out to HRPO for prescriptive instructions between the departmental review and external IRB reliance steps
- Conduct a multi-site sIRB study
  - Consult with UMB HRPO regarding IRB capacity to serve as single IRB
  - Work closely with all sites to understand their requirements and processes
  - Adequate resources to serve as the coordinating center/sIRB

Also consider:
- *SMART IRB site resources* https://smartirb.org/resources/

Wayfinding (How do I?)



- Respond to study expiration (p.27)
  - Cease ALL study activities until approval
- Transfer my study (leaving UMB)
  - Options (close, transfer to new institution, transfer to another PI)

Also consider:
- *External IRB CR timing; UMB required Bb training; RNI submission along with CR*
- *Ownership of study data; processes for materials transfer; quality oversight*

Takeaways

- UMB IM is not to be ignored
- Required understanding
- Useful baseline training material; not prescriptive
- Strengthened by supplemental tools
- Situation/protocol dependent content
- Supported by federal regulations and local policies
- Reach out to the HRPO for questions

Resources

UMB:

https://www.umaryland.edu/hrp/

https://www.umaryland.edu/media/umb/oaa/hrp/documents/HRP-101---HRPP-Plan.pdf

https://www.umaryland.edu/hrp/for-researchers/

https://www.umaryland.edu/hrp/for-researchers/investigator-manual/

https://www.umaryland.edu/ord/

UMSON:

https://www.nursing.umaryland.edu/research/resources/regulatory-affairs/researcher-toolkit/