IRB UPDATES 2024

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ACCREDITATION

- **THE UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE AND SCHOOL OF NURSING DESIGNATES THIS LIVE ACTIVITY FOR A MAXIMUM OF 1.0 *AMA PRA CATEGORY 1 CREDITS.*™ PHYSICIANS SHOULD CLAIM ONLY THE CREDIT COMMENSURATE WITH THE EXTENT OF THEIR PARTICIPATION IN THE ACTIVITY.**
- **THE UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE AND SCHOOL OF NURSING AWARDS 1.0 CONTACT HOUR FOR NURSES WHO PARTICIPATE IN THIS EDUCATIONAL ACTIVITY AND COMPLETE THE POST ACTIVITY EVALUATION.**
- **THE UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE AND SCHOOL OF NURSING AWARDS 1.0 HOUR OF PARTICIPATION (CONSISTENT WITH THE DESIGNATED NUMBER OF *AMA PRA CATEGORY 1 CREDIT(S)*™ OR ANCC CONTACT HOURS) TO A PARTICIPANT WHO SUCCESSFULLY COMPLETES THIS EDUCATIONAL ACTIVITY. THE UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE AND SCHOOL OF NURSING MAINTAINS A RECORD OF PARTICIPATION FOR SIX (6) YEARS."**

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DISCLOSURES

- THE SPEAKER, HEATHER FERRERI, MPH, CIP, HAS NO PERSONAL OR PROFESSIONAL FINANCIAL RELATIONSHIPS WITH A COMMERCIAL ENTITY PRODUCING HEALTHCARE GOODS OR SERVICES.
- THE PLANNING COMMITTEE MEMBERS, KATIE REA, MSCR, BSN, RN, CCRC; LORI ELDER, RN, BSN, CCRA, AMY SMITH, MSHS CERTIFICATE ; KIMBERLY UNDERWOOD, BS, CCRC; AND MARIA DAVENPORT, MPH, CCRP; HAVE NO PERSONAL OR PROFESSIONAL FINANCIAL RELATIONSHIPS WITH A COMMERCIAL ENTITY PRODUCING HEALTHCARE GOODS OR SERVICES.

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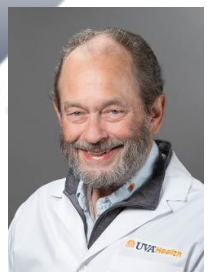
ACTIVITY CODE

- **ACTIVITY CODE: 150726**
- **INSTRUCTIONS FOR CLAIMING CREDITS/CONTACT HOURS CAN BE FOUND HERE.”**

OBJECTIVES

- DISCUSS NEW IRB-HSR STAFFING & CONTACT INFO
- LEARN TIPS FOR EFFICIENT PROTOCOL
- REVIEW UPDATES & FUTURE PLANS FOR IRB-HSR

Meet the IRB-HSR



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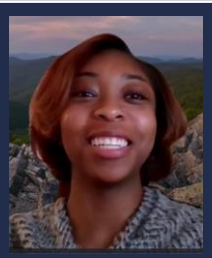
Reliance on Non-UVA IRB/sIRB

MEET THE IRB-HSR

New Submissions



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Full Board Submissions

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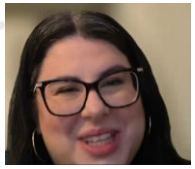
IRB-HSR RESOURCES



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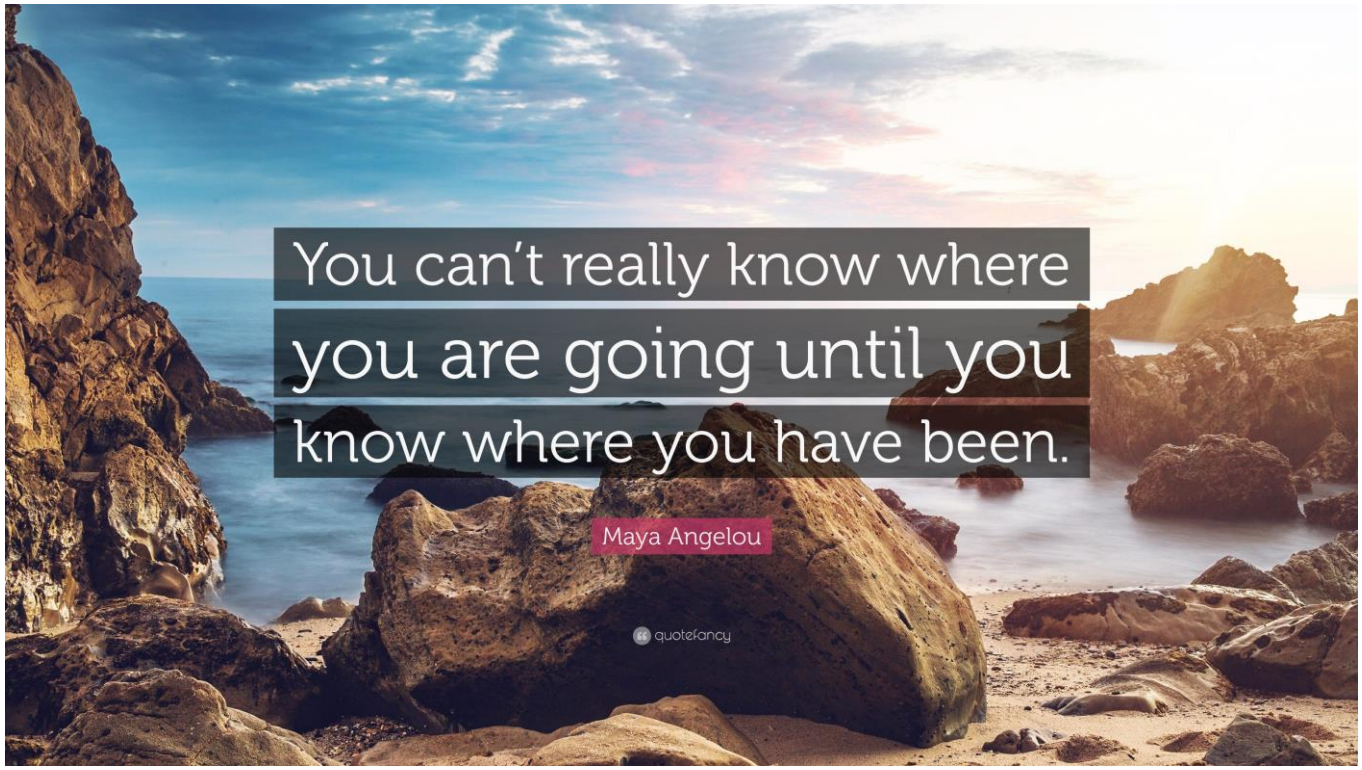
WHERE WE HAVE BEEN &
WHERE WE ARE GOING



IRB-HSR TRANSITIONS

THE GOOD & THE BAD

- Changes in staffing, leadership, membership
- Common Rule Changes (45 CFR 46)
- Proposed FDA Mandate Changes
- Launching of IRB Pro for documents
- Self-service personnel changes
- Virtual environment

STAFFING, LEADERSHIP, MEMBERSHIP

STAFFING & OFFICE LEADERSHIP

PRE-2020: 9 COORDINATORS, 2 ADMINISTRATIVE, 2 DIRECTORS

2020-MID 2023: 5 COORDINATORS/ANALYSTS, 0 ADMINISTRATIVE, 1 INTERIM DIRECTOR

2024: 8 ANALYSTS, 1 ADMINISTRATIVE TO BE HIRED, 3 DIRECTORS, 1 PROJECT MANAGER TO BE HIRED

BOARD MEMBERSHIP LEADERS

PRE-2020: 1 CHAIR & 2 VICE CHAIRS

2020-2023: 1 CHAIR

JULY 2023: 1 INTERIM CHAIR

NOV 2023: 1 CHAIR & 1 VICE CHAIR

2024: 1 VICE CHAIR & 2 VICE CHAIRS

And don't forget…

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REVISED COMMON RULE

- **Continuing Reviews: Studies approved on/after January 21, 2019, Expedited studies (not FDA regulated) receive IRB update forms. IRB update forms are shortened versions of protocol status reports and are processed as receipts and do not receive approvals.**
- **Exemptions: The revised common rule created new exempt categories and modified some existing categories.**
- **Limited IRB Review: The revised common rule regulations also incorporate an alternate pathway of review for studies qualifying for exemption, but working with identifiable information or biospecimens.**
- **Informed Consent: The revised common rule regulations include new process requirements for the content, presentation, and organization of information so that potential participants have all of the information they need to make an informed decision.**

REVISED COMMON RULE

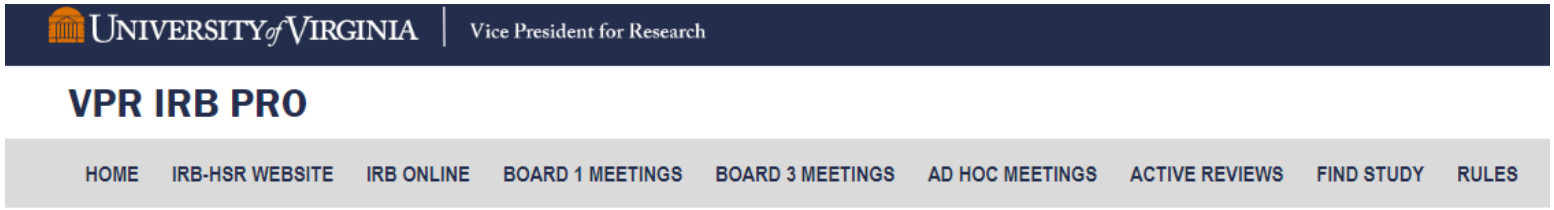
Clinical Trials: For federally-sponsored clinical trials, a requirement has been added that a copy of the consent form must be posted to a "publicly available, federal website" post-recruitment and no later than 60 days after the last study visit by any subject. ClinicalTrials.gov

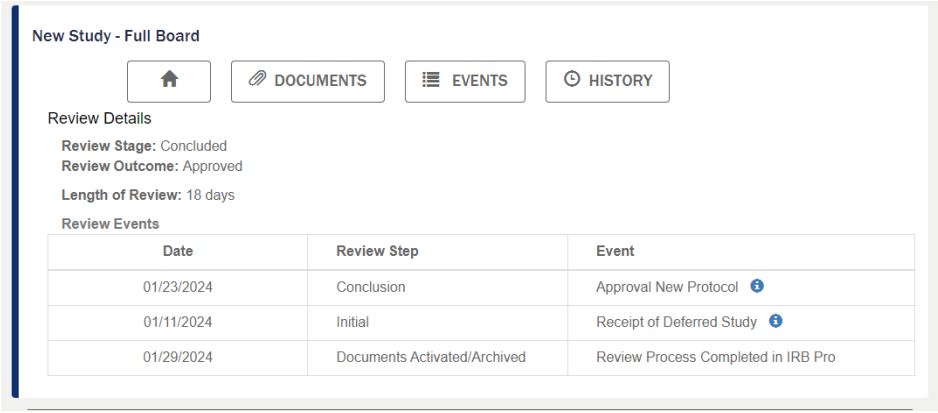
Single IRB-of-Record (sIRB): Most federally funded (NIH) collaborative research projects located in the U.S. will be required to use a single IRB starting January 20, 2020.

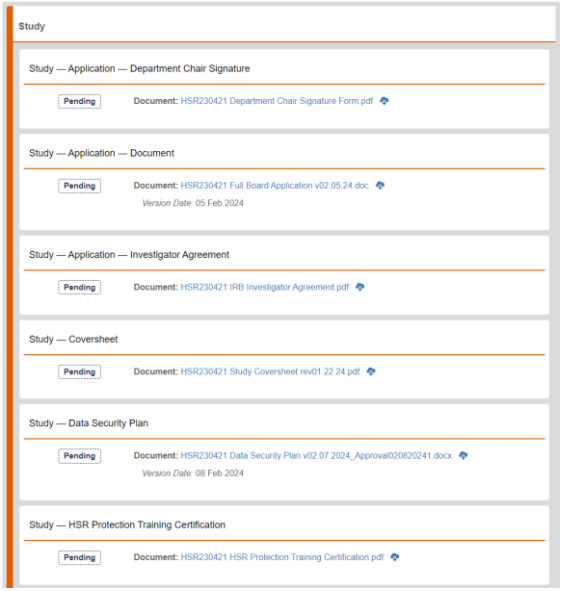
PROPOSED MANDATE

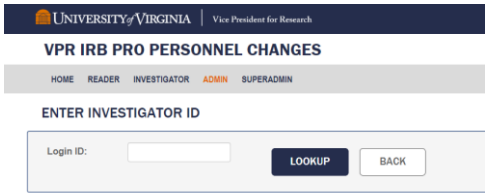
FDA has proposed a mandate that all FDA regulated multi-site research studies will require sIRB review as well.

LAUNCHING OF IRB PRO









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PRIMARILY VIRTUAL ENVIRONMENT

- All IRB-HSR Staff are mainly remote
- All IRB-HSR Full Board Meeting take place virtually
- All documents are processed electronically
- Physical Office is located at 1 Morton Drive and houses paper files, IRB-SBS hybrid workspace.

TIPS FOR EFFICIENT PROTOCOL APPROVALS

While acknowledging that the IRB-HSR had a backlog in the second half of 2023 that led to delays in approvals…

- **A lot of our studies in our queue are "pending resolution", which means that we have conducted the administrative review and have asked for clarifications or updates to the study and have yet to received the requested materials.**
  - **Email communication**
  - **Submit all necessary documents**
  - **Make sure documents are consistent (protocol, consent form, application)**
  - **Answer PB questions correctly, so that the sections that need to be completed populate and all necessary ancillary reviews are completed.**
  - **Make sure all CITI training is complete and current.**

TIPS FOR EFFICIENT PROTOCOL APPROVALS

- Use lay language as much as possible in the consent form (8th grade reading level).
- Include all supporting documents: telephone script, email template, letters of support, data collection instruments (surveys/questionnaires), user's manual, etc.
- Provide complete responses with details (who, what, when, where, how, & why).
- Always start in PB for new submissions.
- Proofread your submission thoroughly.

TIPS FOR EFFICIENT PROTOCOL APPROVALS

- **Use posted full board studies submission deadline calendar as a guide:**

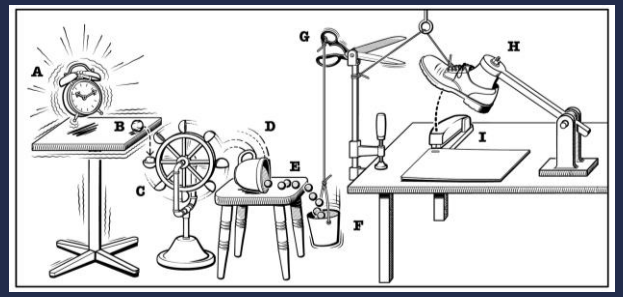
Submission Deadline Submissions must be received electronically by NOON on the dates below **for consideration** at the next Full Board meeting.	**Full Board Meeting Dates** Meetings are held on the 2nd and 4th **TUESDAY** of the Month **2024**
Friday, December 8, 2023	January 9, 2024
Friday, December 15, 2023	January 23, 2024
Friday, January 12, 2024	February 13, 2024
Friday, January 26, 2024	February 27, 2024
Friday, February 9, 2024	March 12, 2024
Friday, February 23, 2024	March 26, 2024
Friday, March 8, 2024	April 9, 2024
Friday, March 22, 2024	April 23, 2024
Friday, April 12, 2024	May 14, 2024
Friday, April 26, 2024	May 28, 2024

https://research.virginia.edu/irb-hsr

WHERE ARE WE GOING?

- IRB PRO build out for continuations and status updates (Summer 2024)
- HRPP Project Manager will facilitate the review of possible NEW electronic protocol submission systems (Huron, etc) and the option to continue building out IRB PRO.

- Elimination/Replacement of Protocol Builder
  - In the meantime, IRB-HSR will make improvements by assessing the Protocol Builder questions and attempting to eliminate redundancy in an effort to improve applications, protocols, and consent form sections generated by PB.



WHERE ARE WE GOING?

- IRB Zoom Office Hours to begin 4/1/24
- Continue to update our website to simplify the information presented (Research Navigator)
- Marina Muchnik to re-launch IRB 101 & 201
- Develop additional training opportunities with Katie Rea & Marina Muchnik
- Increased sIRB Review given the NIH Policy Change mandating sIRB Review for grants that involve multiple institutions, as well as the FDA's proposed mandate that all FDA regulated multi-site research studies will require sIRB review as well. (sIRB Analyst)
- AAHRPP Re-Accreditation
- ONE HRPP. ONE SYSTEM.

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THANK YOU!

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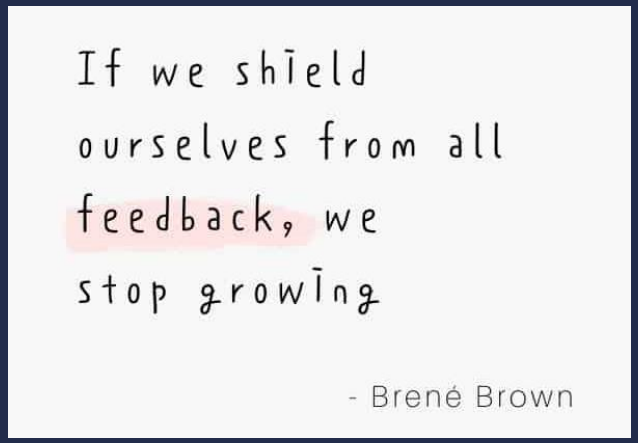
QUESTIONS? & FEEDBACK



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