


Advocate
Health –
Wake Forest
University
School of
Medicine IRB

- Institutional goal is to have a single IRB serving all regions of Advocate Health by the end of 2023.
 - Currently ~5000 active studies in the Southeast
 - Currently ~1000 active studies in the Midwest
 - Midwest has 2 convened meetings per month
 - Southeast has 16-20 convened meetings per month
- 



Updates

- Updates to accommodate differences in both regions to have a single unified process.
- Updates include:
 - Policy and Procedure Manual
 - Consent form templates
 - Electronic submission system

FAQ

- Will existing participants need to be re-consented because of this change? **No.**
- Can we still partner with WCG and other external IRBs? **Yes.**
- Will we have to re-apply to the new integrated IRB? **No.**
- Will the pre-IRB submission process change? **No.**
- Are tutorials and users guides available to help with the new submission website? **Yes.**
- Will I log-in using my Advocate Health credentials? **Yes.**



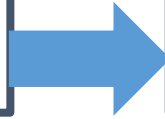
Workflow-Sequence of events

- Boxes outlined in blue are steps in the process that will remain unchanged for Advocate researchers.

- Boxes outlined in yellow are steps that will be modified to incorporate the enterprise-level processes.

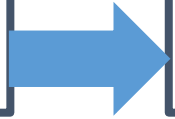
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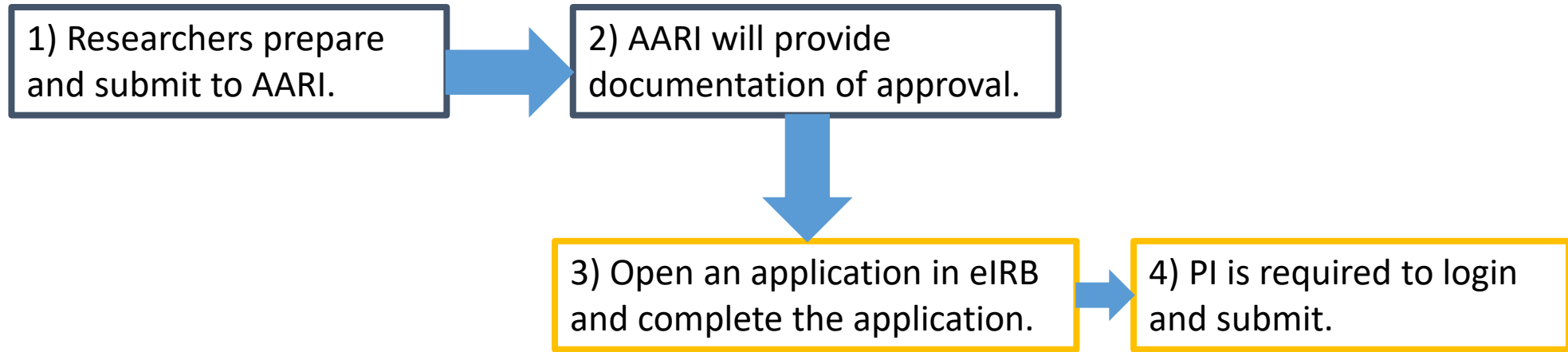
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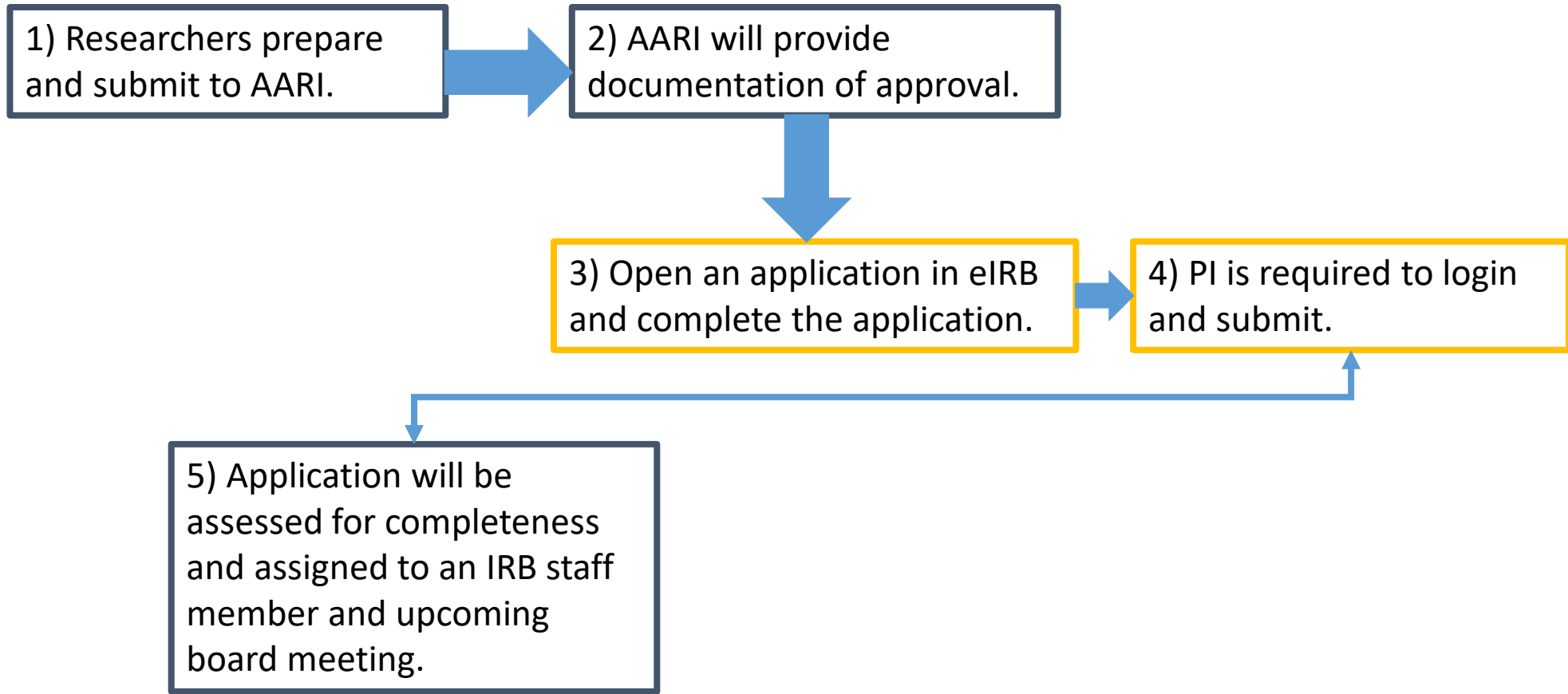


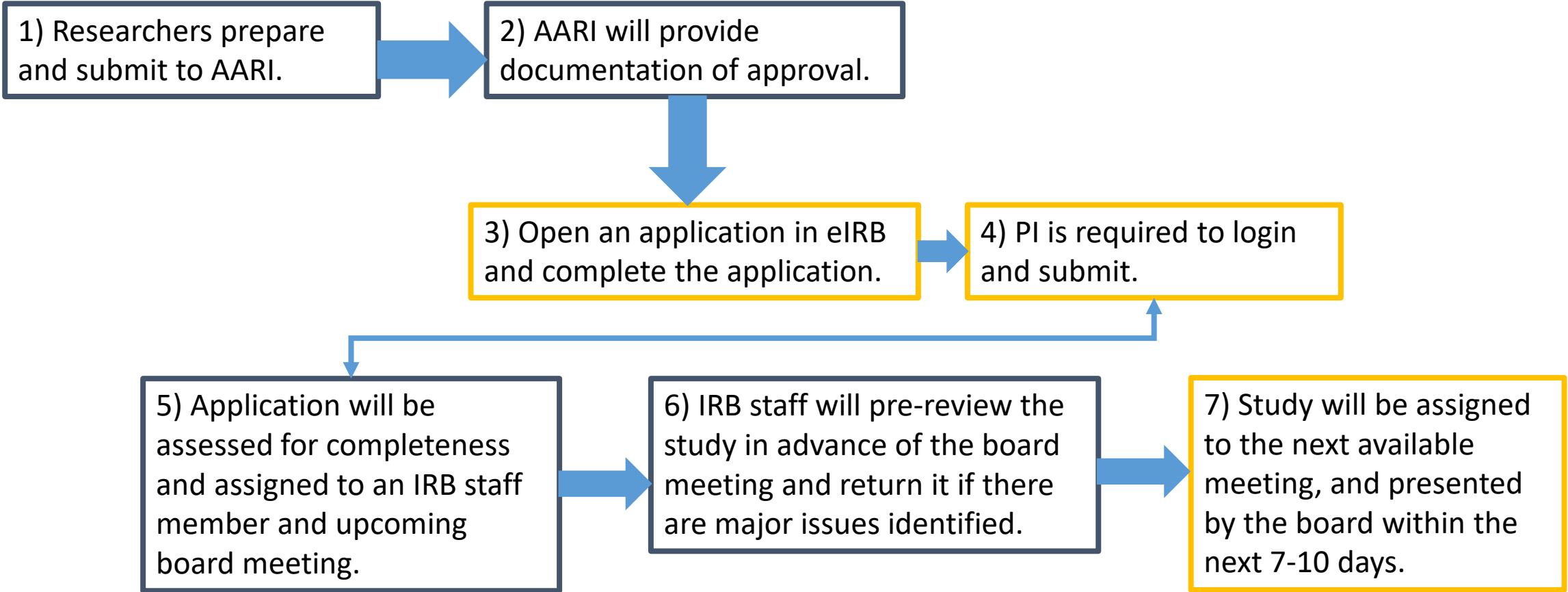
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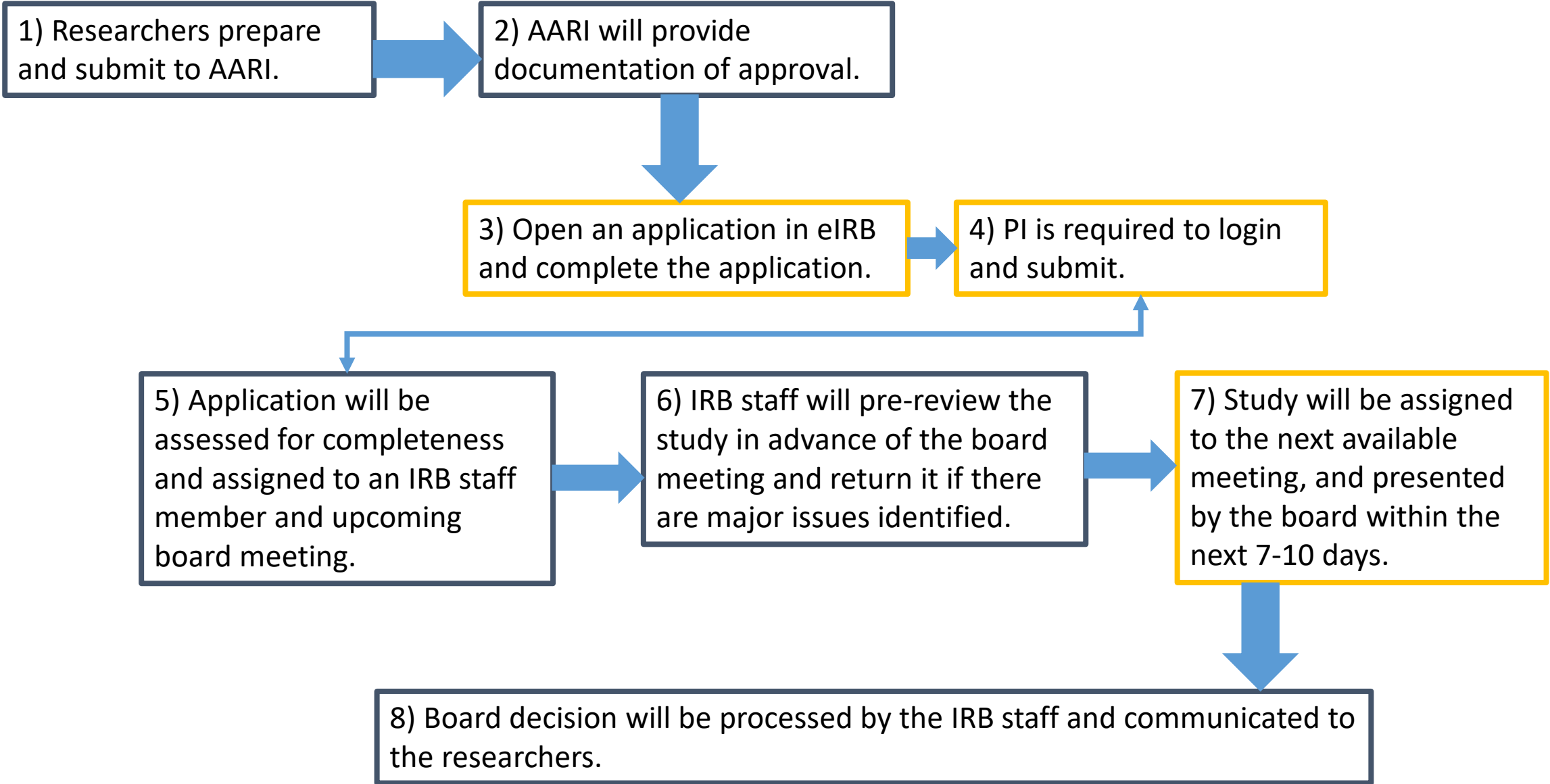


3) Open an application in eIRB and complete the application.









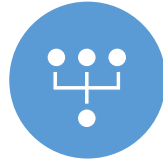
IRBNet vs eIRB



Data migration will be completed for as much information as possible.



Updates to existing studies will be **progressive** over time.



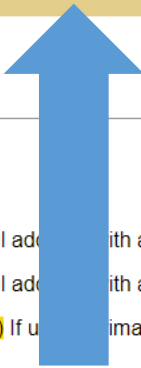
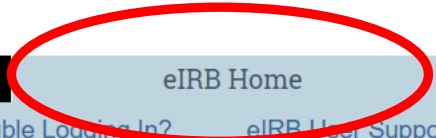
Branching logic will be used to customize the application.



All information is **self-contained** so that other forms are not needed.



Protocol, consent, and other **documents can still be uploaded.**



- IRB General Information
- Trouble Logging In?
- eIRB User Support
- Forms, Templates, and Tips
- Contact Us
- Certification Date Listing
- Site Manager Resources

Request an account... [Registration](#)

IRB Login Process Updated:
Effective: September 20, 2023

- Users with a primary email address with an @wakehealth.edu extension will continue to login using these credentials.
- Users with a primary email address with an @atriumhealth.org will now use their atriumhealth credentials.
- (UPDATE)** If user's primary account was initially an @carolinashealthcare.org account as their primary (issued 2018 and before) they will use their carolinashealthcare.org credentials.
- Use of incognito windows and separate browsers should no longer be necessary.

Issues or questions can be sent to eirbhelp@wakehealth.edu.

Important Information

eIRB has been updated successfully. Some of the new changes can be found in the link below.

[eIRB Update Information](#)

Welcome to eIRB
This is the online protocol submission and review system for the Institutional Review Board (IRB) at Wake Forest University. eIRB provides a collaboration workspace for the IRB and the Human Subjects Research community and is the location for IRB review activities. Principal Investigators and their study teams can initiate new study applications, make amendments to existing studies, submit continuing review applications and report safety events through this site.

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Folder for Brian Moore

Study Staff

My Roles

- Administrative Workspace
- Ancillary Committees
- Board Chair (not used)
- Board Member
- Copy of Site Manager
- IRB Administrator/Director
- IRB Director (not used)
- Monitoring & Oversight
- SB IRB Administrator/Director
- Site Manager
- Study Staff

Create

New Application

Convert to eIRB

Convert Paper Study

My Web Page Links

Consent Forms ...

Help

eIRB User Support ...

Questions? Check the FAQ Section ...

Folder for Brian Moore

Welcome to your Personal Folder, the central resource for managing your Research Study Applications. Use the following guidelines to process your Applications:

- Process all items in your Inbox. Items appearing here require immediate action by the Study Team to speed your submission through the review process.
- The system will automatically notify you when action is required by you or another member of the Study Team.
- Monitor the progress of your submissions using the Applications, Continuing Reviews, Amendments, Safety Events and Reports tabs.

My Inbox

Applications Continuing Reviews Amendments Safety Events

This tab displays all Applications, Amendments, Continuing Reviews and Safety Events which currently require you to perform an action. Click on the items for more information.

New Application

ID	Name	Date Modified	Type	State
IRB00101221	ATRIUM RESUBMISSION- 9156 (SPORT144) HTT ACL	10/19/2023 2:03 PM	Application	Concerns Pending (administrator)
Ame37_IRB00068852	Amendment 6 for IRB Study #IRB00091676	10/19/2023 1:58 PM	Amendment	Minor Board Concerns
IRB00101477	Amendment 37 for IRB Study #IRB00068852	10/19/2023 1:50 PM	Amendment	Concerns Pending (administrator)
IRB00101477	Latino Community Assets & Needs Assessment	10/19/2023 1:44 PM	Application	Concerns Pending (administrator)
IRB00096908	Change Afib	10/19/2023 1:19 PM	Application	Local Context Review Complete
IRB00101020	NANO	10/19/2023 1:15 PM	Application	Local Context Review Complete
Ame12_IRB00084073	Amendment 12 for IRB Study #IRB00084073	10/19/2023 12:43 PM	Amendment	Pre Submission
IRB00102808	Molecular Characterization of GI symptoms in Children with ASD	10/19/2023 2:02 PM	Application	Pre Submission
Ame49_IRB00043872	Amendment 49 for IRB Study #IRB00043872 (Personnel Change Request)	10/19/2023 11:51 AM	Amendment	Pre Submission
SE5_IRB00027118	Safety Event 5 for IRB Study #IRB00027118 (Other Safety Event)	10/19/2023 11:31 AM	Safety Event	Concerns Pending (Monitoring & Oversight)

Editing: IRB00099517

- Human Subjects Research**
- Study Identification
- Research Facilities
- Sponsorship
- Clinical Trials
- Protocol
- Risk/Benefit
- Study Participants
- Safety, Confidentiality, and Privacy
- Consent Process
- Ancillary Reviews - Advocate/Aurora
- Waiver of Authorization - Part 1
- Waiver of Authorization - Part 2
- Waiver of Authorization - Part 3
- Waiver of Authorization - Part 4

Human Subjects Research

1.0 * **Principal Investigator** - click the select button and choose a PI:

Brian Moore [select] [x]

Email: jbmoore@wakehealth.edu

Biosketch: [document icon] Moore Biosketch(0.03) [select] [share icon]

CITI Date: 1/1/2020
ICH-GCP: 9/2/2019
Training: 12/18/2018

2.0 * **Study Coordinator** - click the select button and choose the individual coordinating overall regulatory and administrative activities for the study:

Deborah Wesley [select] [x]

Email: dwesley@wakehealth.edu

Biosketch: [document icon] Placeholder.docx(0.01) [select]

CITI Date: 11/2/2022
ICH-GCP: 12/21/2020
Training: 12/24/2018

3.0 * **Study Short Title** - enter a short descriptive title for this study (65 characters maximum):

Advocate test

4.0 * **Study Full Title** - enter the full study title:

test

5.0 * **Abstract** - enter a summary, purpose, and rationale for this study. Please include the objectives, interventions, methods, and outcome measures:

test

Active

Edit Application Form

Print-Friendly Application

Admin View

View WISER/Oncore Determination Page

Amendment History

Description:	Dissemination and Implementation of Brenner FIT in the Atrium Health Enterprise		
PI:	Justin Moore	Coordinator:	Rahma Ajja
IRB Number:	IRB00095648	Review Type:	Expedited
Date Created:	4/4/2023 11:20 AM	Date Submitted:	4/24/2023
Date Approved:	5/11/2023	Continuing Review Due:	5/10/2024
IRB Office:	WFU Health Sciences	IRB Memo:	Approval Memo(0.01) ...
WISER Protocol #:		Link to Meeting:	Go To Meeting
Primary PI Region:	Winston-Salem		
Research Location:	Winston-Salem Charlotte		

My Activities

- SS Agree to Participate
- Watermark Documents
- Generate Expedited Approval Memo
- IRBD Suspend the Study
- SS Initiate Study Closure (study team)
- IRBA Notify Team to Stop Activity
- IRBA IRB Close
- IRBA Edit Memos and Forms
- Send Email to Study Team
- IRBD Re-assign Owner
- OR Edit GTS Number
- Copy
- Log Private Comment

History	Attachments	Amendments	CRs	Safety Events	DSMB Reports	Audit/Monitoring Report	Concerns	Pre IRB Reviews
Activity		Author		Activity Date				
	Amendment 5 for IRB Study #IRB00095648 Opened		Ajja, Rahma J. Y.					7/13/2023 5:23 PM

- Application (jforrest)
- Edit Sponsor Contact Information
- Stop ICF Draft Email
- Administrative Updates
- Run WISER-OnCore updateProtocol Webservice Request
- Run WISER-OnCore createIrbReview Webservice Request
- Run WISER-OnCore saveProtocolAttachments Webservice Request
- Enter WISER-OnCore Protocol Number
- Run WISER-OnCore createIrbReview Webservice Request For Closure
- Update IRB Workspace Link
- IRBA IRB Support Activity
- AUTO CR Reminders CLT
- Generate PDF

Amendment 3 for IRB Study #IRB00051794 (Personnel Change Request) Opened	Spernoga, Penny Vestal	10/11/2020 8:41 PM
View Amendment workspace		
Continuing Review 2 for IRB Study #IRB00051794 Approved	Wesley, Deborah	2/4/2020 8:26 AM
Amendment 2 for IRB Study #IRB00051794 (Personnel Change Request) Completed	Wesley, Deborah	1/17/2020 9:03 AM
Amendment 2 for IRB Study #IRB00051794 (Personnel Change Request) Opened	Spernoga, Penny Vestal	1/16/2020 12:01 PM
View Amendment workspace		
Continuing Review 2 for IRB Study #IRB00051794 Opened	Spernoga, Penny Vestal	1/16/2020 11:59 AM
View Continuing Review workspace		
Continuing Review Due within 60 days - warning message sent to Study Team	Alert, Auto	12/25/2019 2:19 AM
Amendment 1 for IRB Study #IRB00051794 Completed	Moore, Brian	3/8/2019 1:43 PM
Amendment 1 for IRB Study #IRB00051794 Opened	Spernoga, Penny Vestal	2/27/2019 2:43 PM
View Amendment workspace		
Continuing Review 1 for IRB Study #IRB00051794 Approved	Moore, Brian	2/27/2019 9:45 AM

Create...

- New Safety Event
- New Application Amendment
- New Personnel Amendment
- New Continuing Review

(Approved Template)

Important Dates

- **11/30/2023:** All activities in IRBNet must be completed. Any outstanding unapproved actions will not transfer.
- **12/1/2023:** IRBNet data will be pulled and sent to Wake Forest developers.
- **12/4/2023:** Most data will be imported to eIRB.
- **12/5/2023:** Open for submissions.



Resources

- <https://eirb.wakehealth.edu/irb>
- **Training**
 - <https://rise.articulate.com/share/-7JquVWjsdlztNlXggsx2FfonA-baftL#/lessons/Hg1qNb2MWNStKc3dJneCegaPLGIzavP1>
- eirbhelp@wakehealth.edu

