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 reconsented 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.
1) Researchers prepare and submit to AARI.
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2) AARI will provide documentation of approval.
1) Researchers prepare and submit to AARI.

2) AARI will provide documentation of approval.

3) Open an application in eIRB and complete the application.
1) Researchers prepare and submit to AARI.

2) AARI will provide documentation of approval.

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

4) PI is required to login and submit.
1) Researchers prepare and submit to AARI.

2) AARI will provide documentation of approval.

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

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5) Application will be assessed for completeness and assigned to an IRB staff member and upcoming board meeting.
1) Researchers prepare and submit to AARI.

2) AARI will provide documentation of approval.

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

4) PI is required to login and submit.

5) Application will be assessed for completeness and assigned to an IRB staff member and upcoming board meeting.

6) IRB staff will pre-review the study in advance of the board meeting and return it if there are major issues identified.

7) Study will be assigned to the next available meeting, and presented by the board within the next 7-10 days.
1) Researchers prepare and submit to AARI.

2) AARI will provide documentation of approval.

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

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6) IRB staff will pre-review the study in advance of the board meeting and return it if there are major issues identified.

7) Study will be assigned to the next available meeting, and presented by the board within the next 7-10 days.

8) Board decision will be processed by the IRB staff and communicated to the researchers.
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.
eIRB 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.
- 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.
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 @carolinashighcare.org account as their primary (issued 2018 and before) they will use their carolinashighcare.org credentials.
- Use of incognito windows and separate browsers should no longer be necessary.

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

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**Important Information**

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

[eIRB Update Information](#)
New Application

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.

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

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Editing: IRB00099517

Human Subjects Research

1.0  **Principal Investigator** - click the select button and choose a PI.
   - Brian Moore  
   - Email: jmoore@wakehealth.edu  
   - Biosketch:

2.0  **Study Coordinator** - click the select button and choose the individual coordinating overall regulatory and administrative activities for the study.
   - Deborah Wesley
   - Email: dweisky@wakehealth.edu
   - Biosketch:  

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

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

5.0  **Abstract** - enter a summary, purpose, and rationale for this study. Please include the objectives, interventions, methods, and outcome measures.
   - [Blank]
**Description:** Dissemination and Implementation of Brenner FIT in the Atrium Health Enterprise

**PI:** Justin Moore  
**Coordinator:** Rahma Ajja

**IRB Number:** RB00095648  
**Review Type:** Expedited

**Date Created:** 4/4/2023 11:20 AM  
**Data Submitted:** 6/2/2023

**Date Approved:** 6/11/2023  
**Continuing Review Due:** 5/10/2024

**IRB Office:** WFU Health Sciences  
**IRB Memo:** Approval Memo 0.01

**WSER Protocol #:**

**Primary PI Region:** Winston-Salem

**Research Location:** Winston-Salem

Charlotte

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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](https://eirb.wakehealth.edu/irb)

- **Training**
  - [https://rise.articulate.com/share/-7JquVWjsdlztN1Xggx2FfonAbaftL#/lessons/Hg1qNbe2MWNStKc3dJneCegaPLG1ZavP1](https://rise.articulate.com/share/-7JquVWjsdlztN1Xggx2FfonAbaftL#/lessons/Hg1qNbe2MWNStKc3dJneCegaPLG1ZavP1)

- [eirbhelp@wakehealth.edu](mailto:eirbhelp@wakehealth.edu)