ATTACHED IS THE AGENDA FOR YOUR REVIEW BEFORE THE NEXT IRB MEETING

PLEASE NOTE: This is the only copy of the Agenda distributed to a committee member.

You may be asked questions at the meeting referring to these materials. Please review them to ensure that all activities they contain are included in the research description and, as appropriate, in the consent form.

If the protocol involves an NIH sponsored clinical trial, please compare the "risks" and "alternatives" sections of the sample NIH approved consent and the PI prepared consent to ensure that they are identical in substance.

Please see page 2 for the IRB Member Primary Reviewer Guide which has been included for your convenience.

IRB Member Primary Reviewer Guide

ORI staff assign a primary reviewer based on the IRB member's educational background and expertise.

The member assigned as the primary reviewer of the study receives an Agenda which includes protocols with the following additional materials, if applicable:

- ☐ Sponsor's grant application;
- ☐ Device proposal or labeling indications(if the protocol involves testing safety/effectiveness of a medical device);
- ☐ Sponsor's detailed protocol and investigator's brochure (if the protocol involves the administration of drugs);
- ☐ Financial disclosure questions,
- ☐ Signature Assurance sheet;
- ☐ Other committee review/approval materials when applicable, e.g., Institutional Biosafety Committee review;
- ☐ Other federal agency checklist, e.g., Dept. of Defense, Dept. of Justice, etc.; and
- ☐ All other application materials.

The primary reviewer is responsible for:

- ☐ Comparing the detailed grant application or industry protocol with the IRB application;
- ☐ Informing the full IRB of any discrepancies between the detailed protocol and the summary application materials;
- ☐ Determining whether the project involves a NIH multi-center clinical trial (e.g., cooperative group trial) and, if so, comparing the "Risks" and "Alternatives" section of the NIH-approved sample informed consent document with the UK proposed form to ensure consistency;
- ☐ Ensuring that a Data and Safety Monitoring Plan (DSMP) exists IF research is greater than minimal risk or an NIH funded or FDA regulated clinical investigation;
- ☐ Reviewing the financial disclosure questions and alerting the IRB if a "yes" disclosure is made;
- ☐ Reviewing the other committee review/approval for consistency in human subjects protection measures;
- ☐ Checking the Signature Assurance sheet for appropriate signatures; and
- ☐ Conducting an in-depth review.

PLEASE NOTE: This information was derived from the ORI and IRB Initial Review SOP available at **https://www.research.uky.edu/office-research-integrity/policies-guidance** under Standard Operating Procedures.

Primary Reviewer Responsibilities

- Comparing the detailed industry protocol with the IRB application;

- Informing the full IRB of any discrepancies between the detailed protocol and the summary application materials;

- Determining whether the project involves a NIH multi-center clinical trial (e.g., cooperative group trial) and, if so, comparing the “Risks” and “Alternatives” section of the NIH-approved sample informed consent document with the UK proposed form to ensure that the NIH and UK sections of the consent are consistent;

- Ensuring that a Data and Safety Monitoring Plan (DSMP) exists IF research is greater than minimal risk or an NIH funded or FDA regulated clinical investigation;

- Reviewing the financial disclosure questions and alerting the IRB if a “yes” disclosure is made;

- Reviewing the other committee review/final approvals for consistency in human subjects protection measures;

- Checking the Signature Assurance sheet for appropriate signatures; and

- Conducting an in-depth review.

Medical IRB Sample Agenda Email

From: Kearns, Jennifer L.
Sent: Friday, August 21, 2020 11:32 AM
To: IRB Members (#2)
Cc: Martin, Paul <paul.martin@uky.edu>;
Subject: IRB #2 Tuesday, September 1, 2020 Agenda Information

Dear IRB #2 Members,

The agenda for the September 1, 2020 IRB meeting is available for review.

PLEASE NOTE: some agenda items are attached to this e-mail, and some are available in E-IRB.

See below for more information about the location of each item:

1. The following items are attached in this mailing:

-Agenda & Agenda Cover Page

2. The following items are in E-IRB:

https://ris.uky.edu/irb/Dashboard/login.aspx

-IR [redacted] **(Primary Reviewer:** [redacted]**)**
-IR [redacted] **(Primary Reviewer:** [redacted]**)**

-CR [redacted]
-CR [redacted]
-CR [redacted]

-MR [redacted]

-AE [redacted]

3. The following will be sent in a separate mailing:

-MM 7/21/20

E-IRB INSTRUCTIONS:

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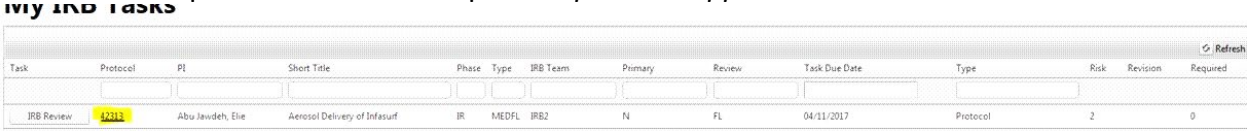
Follow this link to log in with your LinkBlue credentials: ris.uky.edu/irb/Dashboard/login.aspx

IRB member reviewer instructions

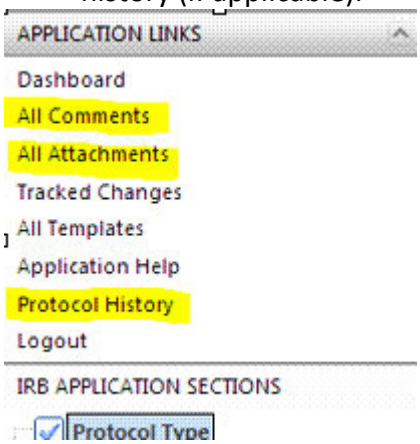
To complete the review assigned to you, at a minimum please do the following starting from your IRB Dashboard:

1. Click on the protocol number to open the *protocol application:*

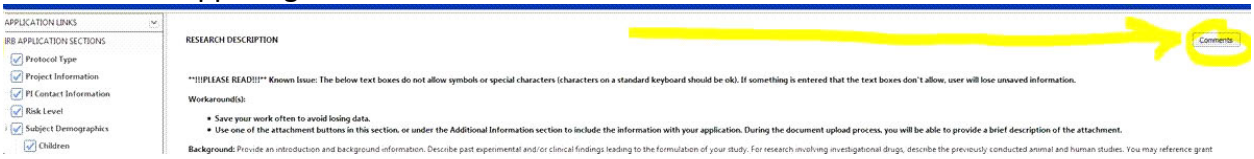


a) In the menu on the left under the heading titled APPLICATION LINKS:

i. click "All Comments" to review comments inserted into the application by the PI, ORI, and/or IRB;
ii. click on "All Attachments" to access all attachments submitted with the application:
iii. click on "Protocol History" for access to previous versions of the application and review history (if applicable).

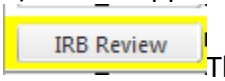


2. Review the content of each IRB APPLICATION SECTION (see menu on left hand side for sections) and corresponding attachments. To add a comment on a section, use the Comment button in the upper right corner of the section.



3. Return to your Dashboard (button in top left corner):

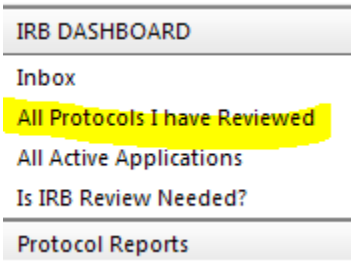
a) For the application you just reviewed, click on the "IRB Review" task button.



This button will open the IRB REVIEW TASK WINDOW which will prompt you to enter determinations applicable to the type of review you've been assigned.

b) If you have been assigned reviewer forms to complete, in order to fill a form out download the form to your computer first, save your work when completed, then upload using the Upload feature in your IRB Review task window (note the applicable "document type" for each attachment will need to be selected for each form).

c) Completing your "IRB Review" task will remove the application listing from your Inbox. To revisit applications you reviewed, in the Dashboard menu on the left, select "All Protocols I have Reviewed".



If you have any questions, please contact ORI at (859) 257-9428.

Thank you,
Jennifer

Jennifer Kearns
Office of Research Integrity
University of Kentucky
309 Kinkead Hall
Lexington, KY 40506-0057
(859) 257-0581

Please note: individuals conducting human subjects research must review and comply with the requirements of the **VPR's Resumption of Research Phased Plan** before initiating or resuming any in-person research.

IMPORTANT NEWS!!
The University of Kentucky currently operates under a linkblue-secure, web-based IRB application system called "E-IRB." To log-in and keep apprised on news and updates about E-IRB, please visit the E-IRB Info web page and online resources. To learn how to navigate in the new system, review the various E-IRB Video Tutorials.

Have questions? Need help? Come to ORI Office Hours or Request a Consult! Click here for more information. Stay informed and sign up to receive ORI news and announcements.

University of Kentucky | Office of Research Integrity
IRB, RDRC

MEMO: Medical Institutional Review Board

FROM: Paul Martin, Professional Associate II
Office of Research Integrity

SUBJECT: Time, Location and Agenda for the Next IRB Meeting

DATE: August 20, 2020

A Committee meeting is scheduled for **1:15 p.m. Tuesday, September 1, 2020,** via teleconference. The attached protocols will be discussed and voted upon in the following order:

INITIAL FULL REVIEWS

1:20 p.m. [redacted]
[redacted]
Primary Review: [redacted]

1:40 p.m. [redacted]
[redacted]
Primary Review: [redacted]

CONTINUATION FULL REVIEWS—see E-IRB agenda for full listing

COMMITTEE BUSINESS

No time [redacted]
[redacted]
Modification Request

INTERNAL ADVERSE EVENTS

No time [redacted]
[redacted]

MINUTES OF PREVIOUS MEETINGS—to be sent separately

July 21, 2020

Members wishing to see details about an item listed as expedited (or exempt) review should contact ORI for additional materials (859-257-9428 or jlkear0@uky.edu).

Meeting Date/Time: 1:20 PM Tuesday, September 01, 2020
Meeting Location: 410 Bosomworth HSRB.

The following items will be discussed and voted upon in order:

Meeting Agenda

Time	Event
1:20 - 1:40 PM	[redacted] - IR - FL - [redacted]
1:40 - 2:00 PM	[redacted] - IR - FL - [redacted]

Full reviews without a timeslot

Protocol	IRB #	Title	PI	Process Type	Review Phase	Other Review #	Other Type
[redacted]	IRB2	[redacted]	[redacted]	FL	CR		
[redacted]	[redacted]	[redacted]	[redacted]	FL	CR		
[redacted]	IRB2	[redacted]	[redacted]	FL	MR	[redacted]	
[redacted]	IRB2	[redacted]	[redacted]	FL	MR		
[redacted]	IRB2	[redacted]	[redacted]		CR		

Other Meeting Discussion

Meeting Minutes 7.21.20

Expedited Approvals (IR)

[redacted] eventive Therapies Affect Periodontal and Dental Caries Disease
IRB2 - IR - XP - *XP*
8/20/2020

[redacted]
IRB2 - IR - XP - *XP*
8/18/2020

[redacted]
IRB2 - IR - XP - *XP*
8/17/2020

Expedited Approvals (CR)

[redacted]
IRB2 - CR - XP - *XP*
8/19/2020

[redacted]
IRB2 - CR - XP - *XP*
8/17/2020

[redacted]
IRB2 - CR - XP - *XP*
8/17/2020

[redacted]
IRB2 - CR - XP - *XP*
8/15/2020

[redacted]
IRB2 - CR - FL - *XP*
8/14/2020

Expedited Approvals (MR)

[redacted] IRB2 - MR - FL - *XP*
8/20/2020

[redacted] IRB2 - MR - XP - *XP*
8/19/2020

[redacted] IRB2 - MR - XP - *XP*
8/19/2020

[redacted] IRB2 - MR - XP - *XP*
8/19/2020

[redacted] IRB2 - MR - XP - *XP*
8/17/2020

[redacted] IRB2 - MR - XP - *XP*
8/15/2020

[redacted] IRB2 - MR - FL - *XP*
8/15/2020

[redacted] IRB2 - MR - FL - *XP*
8/15/2020

[redacted] IRB2 - MR - FL - *XP*
8/13/2020

[redacted] IRB2 - MR - XP - *XP*
8/13/2020

[redacted] IRB2 - MR - FL - *XP*
8/13/2020

Internal Unanticipated Problems

No records to display

External Unanticipated Problems

No records to display

Non-Prompt Unanticipated Problems

[redacted] IRB2 - CR - FL - *XP*
8/19/2020

[redacted] IRB2 - MR - FL - *XP*

8/19/2020

[redacted] IRB2 - MR - FL - *XP*

[redacted]

8/18/2020

Protocol Violations

[redacted] IRB2 - MR - FL - *XP*

[redacted]

8/14/2020

Approval Termination Due to Non-Response

Withdrawals

IRB Conflicts of Interest

The following RB members are listed as study personnel on protocols listed as full review on this agenda:

[redacted] *[DP], [IRB Alternates]*
[DP], [IRB1]
[SP], [IRB3]
[SP], [IRB3]
[PI], [IRB Alternates]
[SP], [IRB Alternates]

If you would like to review a list of applications that met the exemption criteria for the time frame covered by this agenda, please contact ORI at 859-257-9428.