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.

Sample NonMedical Agenda Email

From: Miller, Lori
Sent: Wednesday, July 1, 2020 3:28 PM
To: NonMedical IRB Members
Cc: Vaughn, Robert C. <craigvaughn@uky.edu>; Stafford, Pam <pastaf3@uky.edu>
Subject: Nonmedical Agenda for July 10th meeting

Greetings All:

Hope you are all doing well and staying safe. We have a regular nonmedical IRB meeting coming up on Friday, July 10, at 1:15pm. You should receive notice soon, if you have not already, that the agenda has been assigned to you.

This will be a regular meeting held via Zoom, and we encourage all of you to continue attending via Zoom. Craig and I will still be physically present (but distanced from each other) in Kinkead to run and record the meeting.

This is what we have on the docket for Dr. Rojas's first meeting as the Chair.

1. **Full IR #[redacted]**: new initial review from [redacted] **I have left comments in the protocol to assist your reviews.**

2. **Full IR #[redacted]**: new initial review from [redacted]. **I have left comments in the protocol to assist your reviews.**

3. **Full CR #[redacted]: A full CR from [redacted]. Craig has left comments in the application to assist your reviews.**

4. May Meeting Minutes: The minutes from the regular May 2020 meeting, which you'll find attached in this email.

5. **Committee Business, [redacted], Protocol #[redacted]. Please find the committee business item attached to this e-mail. The PI will not be required to attend the review.**

6. **Committee Business, [redacted] Protocol #[redacted]. Please find the committee business item attached to this e-mail. The PI will not be required to attend the review.**

Craig or I will send out a Zoom link to the meeting sometime early next week. Please do not share the Zoom link with anyone else once we send it to you. The link will be active, but the meeting itself will not be active until the scheduled time.

Please let us know if you will not be able to attend the meeting since this could impact quorum. Additionally, please let us know if you have any questions or if we can help with anything.

Stay safe and we will “see” you all via Zoom next week.

Lori

Lori M. Miller, Ph.D., M.S.L.S.
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(859) 257-6072
lmi232@uky.edu

Have Questions? Need Help? Come to Office Hours or Request a Consult! Click here for more information. Stay informed and Sign-up to receive ORI news and announcements

Meeting Date/Time: 1:20 PM Friday, July 10, 2020
Meeting Location: Room 3, Kinkead Hall

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]
2:00 - 4:20 PM	Placeholder
4:20 - 4:40 PM	Placeholder

Full reviews without a timeslot

Protocol	IRB #	Title	PI	Process Type	Review Phase	Other Review #	Other Type
[redacted]	NMED	[redacted]	[redacted]	FL	CR		
[redacted]	NMED	[redacted]		XP	IR		

Other Meeting Discussion

Minutes Vote
Committee Business - [redacted]
Committee Business -

Expedited Approvals (IR)

[redacted] - [redacted]
NMED - IR - FL - *XP*
7/10/2020

[redacted]
NMED - IR - FL - *XP*
7/10/2020

[redacted]
NMED - IR - XP - *XP*
7/9/2020

[redacted]
NMED - IR - XP - *XP*
7/9/2020

[redacted]
NMED - IR - XP - *XP*
7/8/2020

[redacted]
NMED - IR - XP - *XP*
7/6/2020

[redacted]
NMED - IR - XP - *XP*
7/6/2020

[redacted]
NMED - IR - XP - *XP*
7/1/2020

[redacted]
NMED - IR - XP - *XP*
6/25/2020

[redacted]

NMED - IR - XP - *XP*

6/24/2020

[redacted]

NMED - IR - XP - *XP*

6/19/2020

[redacted]

NMED - IR - XP - *XP*

6/16/2020

[redacted]

NMED - IR - XP - *XP*

6/13/2020

Expedited Approvals (CR)

[redacted]

NMED - CR - XP - *XP*

7/6/2020

[redacted]

NMED - CR - XP - *XP*

7/3/2020

[redacted]

NMED - CR - XP - *XP*

7/2/2020

[redacted]

NMED - CR - XP - *XP*

7/2/2020

[redacted]

NMED - CR - XP - *XP*

6/30/2020

[redacted]

NMED - CR - XP - *XP*

6/30/2020

[redacted]

NMED - CR - XP - *XP*

6/29/2020

[redacted]

NMED - CR - XP - *XP*

6/29/2020

[redacted]

NMED - CR - XP - *XP*

6/19/2020

[redacted]

NMED - CR - XP - *XP*

6/19/2020

[redacted]

NMED - CR - XP - *XP*

6/15/2020

[redacted]

NMED - CR - XP - *XP*

6/15/2020

Expedited Approvals (MR)

[redacted] NMED - MR - XP - *XP* 7/10/2020

[redacted] NMED - MR - XP - *XP* 7/2/2020

[redacted] NMED - MR - XP - *XP* 7/2/2020

[redacted] NMED - MR - XP - *XP* 7/2/2020

[redacted] NMED - MR - XP - *XP* 7/1/2020

[redacted] NMED - MR - XP - *XP* 6/30/2020

[redacted] NMED - MR - XP - *XP* 6/30/2020

[redacted] NMED - MR - XP - *XP* 6/30/2020

[redacted] NMED - MR - XP - *XP* 6/29/2020

[redacted] NMED - MR - XP - *XP* 6/29/2020

[redacted] NMED - MR - XP - *XP* 6/24/2020

[redacted] NMED - MR - XP - *XP* 6/19/2020

[redacted] NMED - MR - XP - *XP* 6/19/2020

[redacted] NMED - MR - XP - *XP* 6/19/2020

[redacted] NMED - MR - XP - *XP* 6/18/2020

[redacted] NMED - MR - XP - *XP* 6/18/2020

[redacted]

NMED - MR - XP - *XP*

6/15/2020

[redacted]

NMED - MR - FL - *XP*

6/15/2020

[redacted]

NMED - MR - XP - *XP*

6/15/2020

[redacted]

NMED - MR - XP - *XP*

6/13/2020

Internal Unanticipated Problems

No records to display

External Unanticipated Problems

No records to display

Non-Prompt Unanticipated Problems

No records to display

Protocol Violations

No records to display

Approval Termination Due to Non-Response

Withdrawals

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.