



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

Final Rule
Discussion: Changes to Review Checklists
and Portal

Most Relevant Changes for Committee Members

- *Changes to Approval Criteria*
- *Revised Consent Checklists*
- *Checklists in the Portal – How do they work now?*
- *Meetings: Notifications, Agenda, Workspace*
- *Subject Matter Review in the Portal*

Changes to Approval Criteria

- **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

- **Broad consent stuff (UGA is not currently planning to adopt broad consent)**
- **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as *children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons*, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**

Added underlined clarification and removed pregnant women)

Revised Consent Checklists

- These checklists must be completed and attached to the record for Expedited reviews.
- For full committee reviews, these can be used to guide individual review and/or discussion at the meeting; the minutes are the “record” of the consent review and documentation of the waivers, if applicable.

Checklists in the Portal

- All checklists are in the IRB Portal Library
- For Expedited Reviews (when a board member is providing Subject Matter Review):
 - The Subject Matter Review Checklist (#319) is always needed
 - The IRB Staff may ask for additional checklists depending on the study and will notify you by Internal Comment which should appear in the History section of the submission workspace

Meeting Notifications

- Email from Committee Administrator with reminder to confirm/decline attendance for next meeting
- Email from Portal with Assignment notification (Primary and Secondary reviewers, as applicable) – Link to Meeting Workspace
- Email from Portal with Agenda (pdf)
- Sometimes: Assignment or Agenda Update email

Meeting Notifications

- **Email from Committee Administrator with reminder to confirm/decline attendance for next meeting**

“This is a reminder that the next IRB meeting is xxxday, xxxx xxth, at xxx in the xxxxx. Please confirm or decline attendance in the portal by following the link below by xxxday, xxxx xxth.

[LINK](#) TO MEETING”

Meeting Notifications

- Email from Portal with Assignment notification (Primary and Secondary reviewers, as applicable) – Link to Meeting Workspace

Notification of Reviewer Assignment

To:

[Kimberly Fowler](#)

For:

[IRB 1 meeting on 2/15/2019 12:30 PM](#)

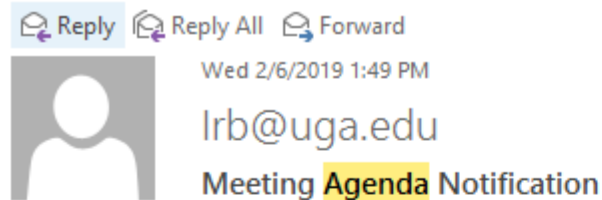
Meeting Date and Start Time:

2/15/2019 12:30 PM


You have been assigned as a reviewer for items to be reviewed at this meeting. All of your reviews should be complete prior to the start of the meeting. Click the link above to view the meeting workspace and your review assignments.

Meeting Notifications

➤ Email from Portal with Agenda (pdf)



To KIMBERLY C Fowler

 Click here to download pictures. To help protect your privacy, Outlook prevented automatic download of some pictures in this message.

Notification of Meeting Agenda

Recipient: [Kimberly Fowler](#)
context.loggedFor: [IRB 1 meeting on 2/15/2019 12:30 PM](#)
context.loggedFor.name: IRB 1 meeting on 2/15/2019 12:30 PM


The agenda for this meeting has been generated or updated and is available at the follow link:

[February 2019 IRB 1 Agenda.pdf\(0.01\)](#)

Agenda

- Email Notification has link to Meeting Workspace where Agenda is attached
- Email Notification has link to Agenda PDF
- Agenda contains links to submissions

Meeting Workspace



Institutional Review Board
UNIVERSITY OF GEORGIA

Hello, test-deptappr1 test-deptappr1 ▾

> My Inbox **Meetings** Library

Components

Create Submission

Reportable New Information

Integrated To Do List

Filter ? ID ▾ Enter text to search for Go + Add Filter ✕ Clear All

No data to display.

◀ page 1 no results ▶ 10 / page

All Projects

Filter ? ID ▾ Enter text to search for Go + Add Filter ✕ Clear All

ID	Name	Date Created	Date Modified	State	Principal Investigator	Created By	Coordinator
PROJECT00000103	Test 3/7 Exempt	2/7/2019 11:51 AM	2/14/2019 7:02 PM	Post Review	test-deptappr10	test-deptappr10	Pavich
PROJECT00000116	test 3/7 IRB member	2/7/2019 3:22 PM	2/14/2019 6:30 PM	Withdrawn	test-deptappr1	test-deptappr1	
MOD000006808	Dose effect of a plant extract on	1/14/2019 2:43 PM	2/6/2019 12:43 PM	Committee Review	Oconnor	Oconnor	Pavich

?

Meeting Workspace

➤ 45 Day Expedited Report

[Admin View](#)

IRB 1

Meeting Date & Time: 2/15/2019 12:30 PM

Agenda: [February 2019 IRB 1 Agenda.pdf\(0.01\)](#)

Minutes: Not yet created.

Meeting ID: Mee00000102

Location: 124 Tucker Hall

Agenda Items	Previous Minutes for Approval	Attendees	History	45 Day Expedited Report	
Projects: 6 instance of the Submission type and 20 instances of the IRBSubmission type.					
ID	Name	PI Last Name	Determination Date		
PROJECT00000096	Identification of motor laterality, transverse rotations, and rider asymmetry as a potential factor influencing equine forelimb kinematics	Duberstein	Mon Feb 11 00:00:00 EST 2019		
PROJECT00000062	Local Economy- Wide Impact Evaluation (LEWIE) of Coastal Economy in Guinea	Fillipski	Thu Feb 7 00:00:00 EST 2019		
PROJECT00000063	A Visual-Based Narrative Inquiry: Secondary Black Student Experiences with Racism in U.S. Public Schools and Influence on Black Student Identity Development	Bailey	Mon Feb 4 00:00:00 EST 2019		
PROJECT00000059	Understanding Students' Test Taking Strategies: Question First or Passage First	Ardoin	Thu Feb 7 00:00:00 EST 2019		
PROJECT00000130	KF - Retest - Submit/Notify PI to Submit Issue	test-deptappr10	Sat Feb 9 00:00:00 EST 2019		
PROJECT00000057	Study of Immune Responses in HIV-Mycobacterium tuberculosis (Mtb) Co-infection	Garg	Thu Jan 31 00:00:00 EST 2019		
MOD00006743	CHAMPS	Evans	Wed Jan 2 14:42:12 EST 2019		
MOD00006742	Project LIKE-Dawgs	Evans	Wed Jan 2 17:27:14 EST 2019		
MOD00006766	Rural Environments, Social Networks, and Paternal Contributions to Infant Development	Brown	Fri Jan 4 00:00:00 EST 2019		
MOD00006729	Mobile Video Directly Observed Therapy in Africa	Sekandi	Mon Jan 7 10:47:31 EST 2019		
MOD00006820	VR and Exercise	Ahn	Wed Jan 16 12:21:43 EST 2019		
MOD00006907	Online ATL ARCH Study	Hansen	Thu Jan 10 00:00:00 EST 2019		
MOD00006658	Craftmaster Dv	Cheneall	Tue Jan 8 15:20:12 EST 2019		

SMR Steps in the Portal

1. The Subject Matter Expert will be informed of an assignment by email from the portal with a link to the submission.
2. Use Read Project or Print Project and/or View Differences (for modifications) to review the submission.
3. Find the Subject Matter Review Checklist (#319) in the Library: download it, complete it, save it to your desktop or documents folder on your computer.
4. Choose Submission Checklists to upload your saved SMR Checklist (and any others).
5. Choose Submit Subject Matter Expert Review to send it back to the IRB Staff.



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Revised Common Rule:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html>
