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 xx\textsuperscript{th}, at xxx in the xxxxx. Please confirm or decline attendance in the portal by following the link below by xxxday, xxxx xx\textsuperscript{th}.

\textbf{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)

---

**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 following link:

[February 2019 IRB 1 Agenda pdf](http://example.com/irb1agenda201902.pdf)
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
# Meeting Workspace

## 45 Day Expedited Report

**IRB 1**

**Meeting Date & Time:** 2/15/2019 12:30 PM  
**Location:** 124 Tucker Hall

**Agenda:** February 2019 IRB 1 Agenda.pdf (0.01 MB)  
**Minutes:** Not yet created

---

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>PI Last Name</th>
<th>Determination Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROJECT06000096</td>
<td>Identification of motor laterrality, transverse rotations, and rider asymmetry as a potential factor influencing equine forelimb kinematics</td>
<td>Dubenstein</td>
<td>Mon Feb 11 00:00:00 EST 2019</td>
</tr>
<tr>
<td>PROJECT06000062</td>
<td>Local Economy- Wide Impact Evaluation (LEWIE) of Coastal Economy in Guinea</td>
<td>Filipski</td>
<td>Thu Feb 7 00:00:00 EST 2019</td>
</tr>
<tr>
<td>PROJECT06000063</td>
<td>A Visual-Based Narrative Inquiry: Secondary Black Student Experiences with Racism in U.S. Public Schools and Influence on Black Student Identity Development</td>
<td>Bailey</td>
<td>Mon Feb 4 00:00:00 EST 2019</td>
</tr>
<tr>
<td>PROJECT06000059</td>
<td>Understanding Students' Test Taking Strategies: Question First or Passage First</td>
<td>Arden</td>
<td>Thu Feb 7 00:00:00 EST 2019</td>
</tr>
<tr>
<td>PROJECT06006130</td>
<td>KF - Retest - Submit/Notify PI to Submit Issue</td>
<td>test-deptppr19</td>
<td>Sat Feb 9 00:00:00 EST 2019</td>
</tr>
<tr>
<td>PROJECT06000057</td>
<td>Study of Immune Responses in HIV-Mycobacterium tuberculosis (Mtb) Co-Infection</td>
<td>Garg</td>
<td>Thu Jan 31 00:00:00 EST 2019</td>
</tr>
<tr>
<td>MOD00006743</td>
<td>CHAMPS</td>
<td>Evans</td>
<td>Wed Jan 2 14:42:12 EST 2019</td>
</tr>
<tr>
<td>MOD00006742</td>
<td>Project LIKE-Dawgs</td>
<td>Evans</td>
<td>Wed Jan 2 17:27:14 EST 2019</td>
</tr>
<tr>
<td>MOD00006766</td>
<td>Rural Environments, Social Networks, and Paternal Contributions to Infant Development</td>
<td>Brown</td>
<td>Fri Jan 4 00:00:00 EST 2019</td>
</tr>
<tr>
<td>MOD00006729</td>
<td>Mobile Video Directly Observed Therapy in Africa</td>
<td>Sakandi</td>
<td>Mon Jan 7 10:47:31 EST 2019</td>
</tr>
<tr>
<td>MOD00006329</td>
<td>VR and Exercise</td>
<td>Ahn</td>
<td>Wed Jan 16 12:21:43 EST 2019</td>
</tr>
<tr>
<td>MOD00006907</td>
<td>Online ATL ARCH Study</td>
<td>Hansen</td>
<td>Thu Jan 10 00:00:00 EST 2019</td>
</tr>
<tr>
<td>MOD00006859</td>
<td>Cybersecurity Day</td>
<td>Chappell</td>
<td>Tue Jan 8 14:42:12 EST 2019</td>
</tr>
</tbody>
</table>
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.
Revised Common Rule: