Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Subject Matter Expert (SME) Review

Maricia Dilan, IRB Professional

mdilan@uga.edu

Definitions

- **Subject Matter Reviewer** – the person who may provide scientific or scholarly review and expert assessment of risk when the submission requires expertise outside of the IRB staff

- **Consultant –** a scientist or non-scientist from within or external to UGA who has special expertise to assist in the review of a research project at the request of the IRB

Definitions (Cont.)

- **Scientific or scholarly review** – required before the IRB can approve non-Exempt human research that:

  1. the risks to subjects are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk

  2. potential risks are reasonable in relation to anticipated benefits

Note: ***SME or Consultant may not disapprove research***

Types of Studies that Commonly Require Scientific or Scholarly Review by SME

- Studies where biological samples are collected (e.g., blood, tissue, urine, saliva)
- MRI/EEG/NIRS/Ultrasound procedures
- Studies that involve genetic analyses
- Studies with physical interventions (e.g., cold stressor or pressure tasks, electrical shock, exercise or nutritional intervention)

Types of Studies that Commonly Require Scientific or Scholarly Review by SME (Cont.)

- Studies with psychological manipulation (interaction or deception) used to obtain sensitive information
- Studies with the potential for group harm
- Studies that involve vulnerable or special populations such as prisoners, individuals with cognitive impairment, children with disabilities, pregnant women, neonates or infants, and undocumented aliens

(NOTE: These are general examples and not an all-inclusive list)

SME Responsibilities

- Assess anticipated risk and will determine if the submission meets criteria for Expedited Review or needs to be reviewed via Committee at a convened meeting
- Recommend additional subject protections and measures to mitigate risks
- Recommend approval period
  - Continuing Review
  - Progress Report

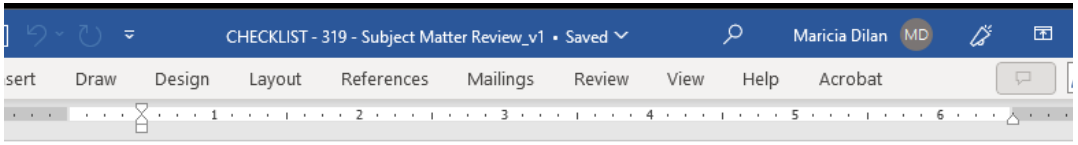
NOTE: *If the IRB does not have the necessary expertise, the IRB staff will assign a Consultant*

SME Review Process

- Receiving an email from the assigned HSO staff to confirm your availability to review a project
- Assigning you as SME Reviewer to the project
- SME Review
  - If you have comments that you wanted to resolve first prior to continuing the review, send them via email to the HSO staff and the staff will request the clarifications for you (NOTE: the portal won't allow PI to see your comments)
  - If you have comments that you think can be handled by the HSO staff, you may just put it in the SME Checklist
  - Either attach the checklist to the portal or email to the HSO Staff
- Click the **Submit SME Review** button

SME Checklist (p1)

Please don't forget to put the Expedited review category. You can select all that are applicable (e.g., Exp 2, 3, 4, 6, 7)



Human Research Protection Program
UNIVERSITY OF GEORGIA

CHECKLIST - 319 – Subject Matter Review

Section A: Conflicting Interest

1. I have a Conflicting Interest with review of this project.

☐ Yes ☐ No

Comments:

Section B: Risk Level

1. What is the level of risk for the project? Minimal Risk research may fit in one of the Expedited categories. See Section A. *More than Minimal Risk studies do not fit in any Expedited category and must be reviewed at a convened meeting.*

☐ Minimal ☐ More than Minimal ☐ Needs Discussion

Comments:

A. If the project is Minimal Risk, is it eligible for Expedited Review? Provide comments to support your selection and, if the answer is "yes", identify the applicable category in your comments.

Expedited Categories: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

☐ Yes ☐ No ☐ Needs Discussion ☐ N/A

Comments:

B. If the project is More than Minimal Risk, are there any modifications and/or circumstances in which the risk assessment would be changed no more than minimal risk of harm or discomfort? *If you select "No", add a comment to support your selection and stop here. Upload the checklist and send the submission back to the IRB staff to assign to a meeting.*

☐ Yes ☐ No ☐ Needs Discussion ☐ N/A

Comments:

2. For Expedited Review: Are the risks minimized and reasonable in relation to the anticipated benefits throughout the submission at all stages of the project?

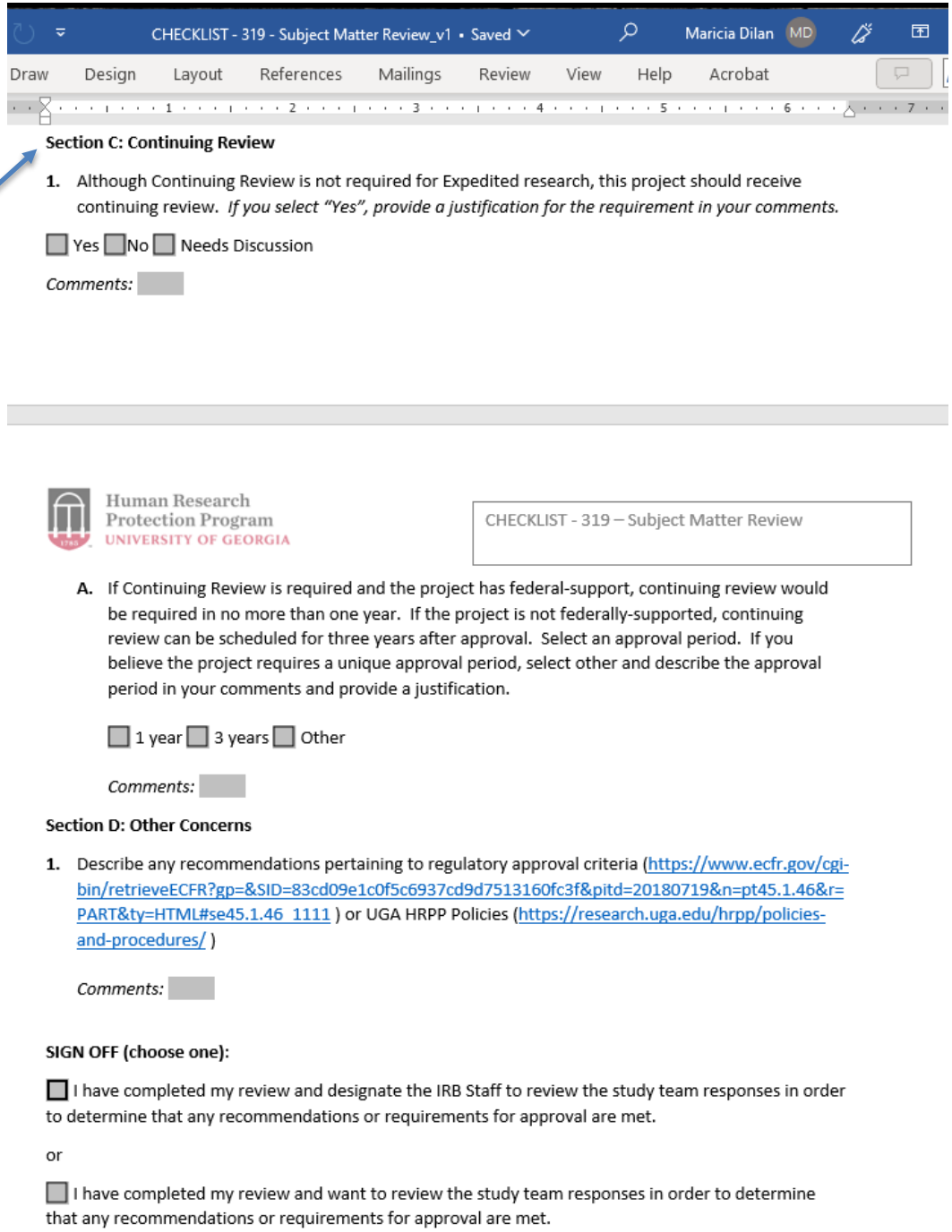
☐ Yes ☐ No ☐ Needs Discussion ☐ N/A

Comments:

SME Checklist (p2)

Continuing Review – renewal of approval prior to expiration

Progress Report – admin check-ins



CHECKLIST - 319 - Subject Matter Review_v1 • Saved — Marcia Dilan MD

Draw Design Layout References Mailings Review View Help Acrobat

Section C: Continuing Review

1. Although Continuing Review is not required for Expedited research, this project should receive continuing review. *If you select "Yes", provide a justification for the requirement in your comments.*

☐ Yes ☐ No ☐ Needs Discussion

Comments:

Human Research Protection Program
UNIVERSITY OF GEORGIA

CHECKLIST - 319 – Subject Matter Review

A. If Continuing Review is required and the project has federal-support, continuing review would be required in no more than one year. If the project is not federally-supported, continuing review can be scheduled for three years after approval. Select an approval period. If you believe the project requires a unique approval period, select other and describe the approval period in your comments and provide a justification.

☐ 1 year ☐ 3 years ☐ Other

Comments:

Section D: Other Concerns

1. Describe any recommendations pertaining to regulatory approval criteria (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1111) or UGA HRPP Policies (https://research.uga.edu/hrpp/policies-and-procedures/)

Comments:

SIGN OFF (choose one):

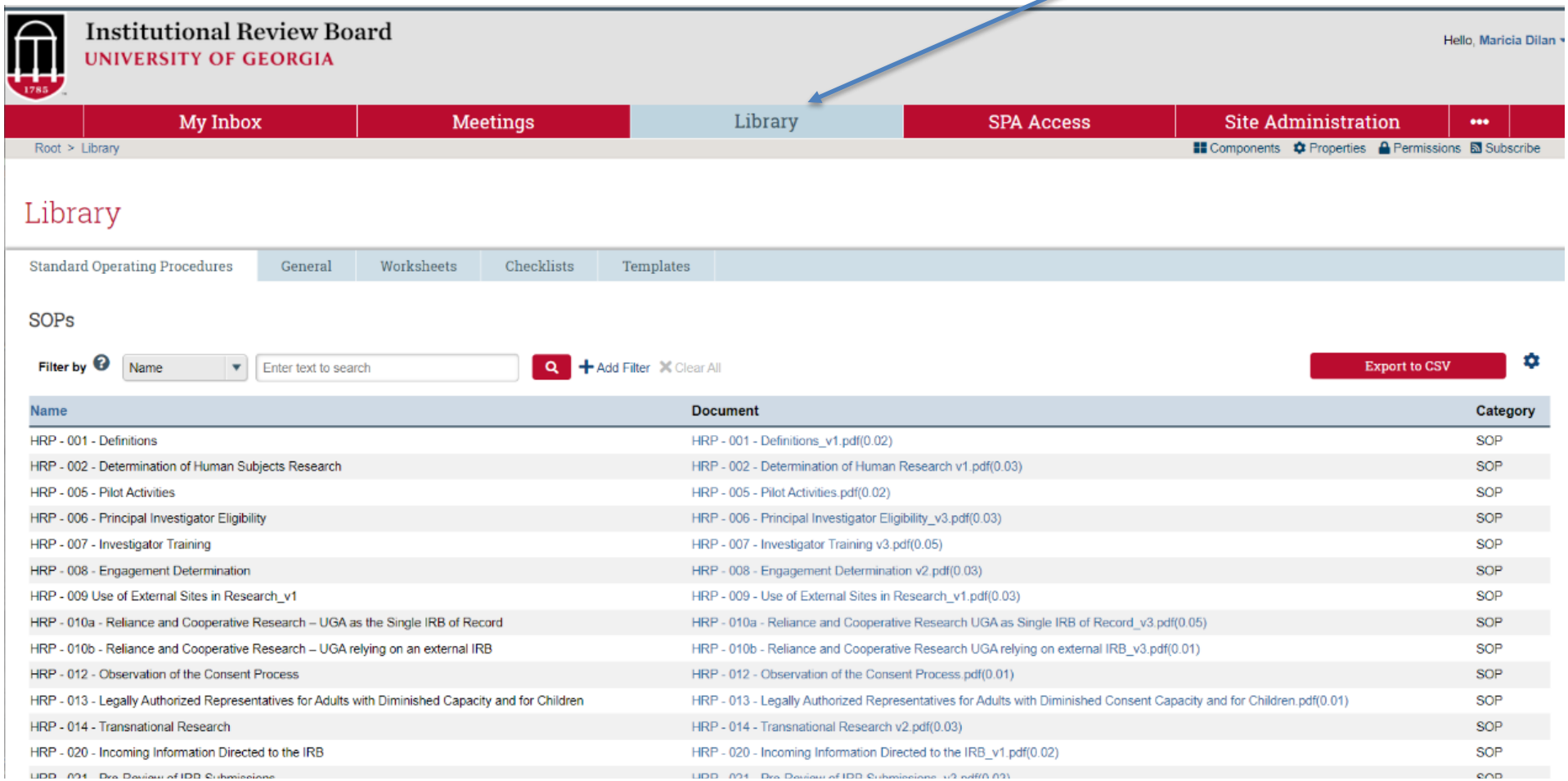
☐ I have completed my review and designate the IRB Staff to review the study team responses in order to determine that any recommendations or requirements for approval are met.

or

☐ I have completed my review and want to review the study team responses in order to determine that any recommendations or requirements for approval are met.

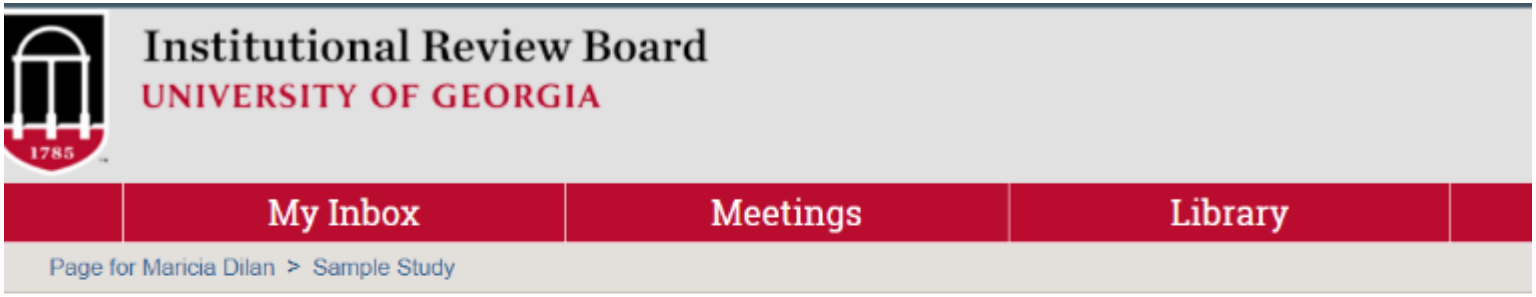
IRB Portal Library

You can always check our Policies, SOPs, Worksheets, Checklists in our **Portal Library**



Name	Document	Category
HRP - 001 - Definitions	HRP - 001 - Definitions_v1.pdf(0.02)	SOP
HRP - 002 - Determination of Human Subjects Research	HRP - 002 - Determination of Human Research v1.pdf(0.03)	SOP
HRP - 005 - Pilot Activities	HRP - 005 - Pilot Activities.pdf(0.02)	SOP
HRP - 006 - Principal Investigator Eligibility	HRP - 006 - Principal Investigator Eligibility_v3.pdf(0.03)	SOP
HRP - 007 - Investigator Training	HRP - 007 - Investigator Training v3.pdf(0.05)	SOP
HRP - 008 - Engagement Determination	HRP - 008 - Engagement Determination v2.pdf(0.03)	SOP
HRP - 009 Use of External Sites in Research_v1	HRP - 009 - Use of External Sites in Research_v1.pdf(0.03)	SOP
HRP - 010a - Reliance and Cooperative Research – UGA as the Single IRB of Record	HRP - 010a - Reliance and Cooperative Research UGA as Single IRB of Record_v3.pdf(0.05)	SOP
HRP - 010b - Reliance and Cooperative Research – UGA relying on an external IRB	HRP - 010b - Reliance and Cooperative Research UGA relying on external IRB_v3.pdf(0.01)	SOP
HRP - 012 - Observation of the Consent Process	HRP - 012 - Observation of the Consent Process.pdf(0.01)	SOP
HRP - 013 - Legally Authorized Representatives for Adults with Diminished Capacity and for Children	HRP - 013 - Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children.pdf(0.01)	SOP
HRP - 014 - Transnational Research	HRP - 014 - Transnational Research v2.pdf(0.03)	SOP
HRP - 020 - Incoming Information Directed to the IRB	HRP - 020 - Incoming Information Directed to the IRB_v1.pdf(0.02)	SOP

IRB Portal



Once you're done with the review, don't forget to hit the **Submit Subject Matter Expert Review** button

Either upload the SME checklist here or email to HSO staff

Project Editor

- Edit Project
- Print Project
- View Differences

Activities

- Discard
- Withdraw
- Submit Subject Matter Expert Review
- Submission Checklists
- Administration
- Re-assign
- Add Public Comment
- Add Additional Readers
- Submission PDF
- Edit Pre-Review
- Take Snapshot

Sample Study

ID: PROJECT00005485

Principal Investigator:	Dilan	**Contacts:**	
Reviewer:	Dilan	**Review Level:**	Expedited
Funding Source:	No results found.	**Approved Date:**	10/3/2022
Committee:	IRB 1	**Expiration Date:**	
Review Category:		**Project Status:**	Subject Matter Expert Review

Documents

Draft	Category
No Documents Found	

Final Document	Category
No Documents Found	

IRB Reminder

- We now have the Expedited Subcommittee comprising the HSO Staff as part of our Expedited Review training
- This is every Wednesday @10:00-12:00noon
- You may be invited from time to time if we need your expertise

MEMORY REVIEW

Memory Review

- For a project that loans a device to be used at home, the IRB has asked for the instructions on the use of the device (e.g., wearing, cleaning, charging, returning, issues) along with the contact info if the device is not working properly

- The IRB requires pregnancy testing when a device is use that could be risky to fetus
  - e.g., *HR-pQCT, TMS, Juvent Health - vibrating platform*). For other studies where pregnant women are excluded, screening questions about pregnancy suffice

- Lately, for issues not requiring 911, the IRB has asked for the Study Lab Safety Protocol/Emergency plan especially if the participants are coming to the lab
  - e.g., blood draw mishaps; participant is dizzy – ask family member or friend to drive him/her home; participant does not want to do a task – re-schedule or withdraw? etc.

Helpful Links/Resources:

- HRP-001 – Definitions
- HRP – 053 – Scientific or Scholarly Review
- 45 CFR 46.111 Criteria for IRB approval of Research
- **IRB Member Resources – Archived Presentations – January 20 & 25, 2016 Scientific and Scholarly Validity**
- **IRB Member Resources – Archived Presentations – August 19, 2016 – Back to Basics – Approval Criteria**

Thank you!