 CAMPBELL UNIVERSITY	IRB SOP: Assigning a Reviewer		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-131	IRB Chair, IRB Office Campbell University	10/08/2019

1 PURPOSE

- 1.1 This procedure establishes the process to assign an IRB member(s) or designated reviewer to conduct a review.
- 1.2 The process begins when an IRB Office staff member identifies an application as being eligible for Full Committee review or possibly eligible for a FLEX Review, Exempt/Exempt-Limited Review or Expedited Review or NHR/NHSR determination.
- 1.3 The process ends when the IRB member has been noted in the *IRB Submission Log 20XX-20XX* to conduct the review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 IRB member rosters are maintained using *IRB Membership Roster*.
- 3.2 IRB Members are provided all submitted materials, members are expected to review the materials listed in the *Review Materials Worksheet* according to their role: *Documents Provided to All IRB Members and Alternate IRB Members, Additional Items Provided to Primary and Secondary Reviewer, Documents provided to Exempt/Exempt-Limited Reviewer, Documents Provided to Expedited Reviewer, Documents provided to IRB staff for HSR/NHSR determination and/or FLEX Review for Registration Projects.*

4 RESPONSIBILITIES


- 4.1 IRB Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Refer to *IRB Membership Roster 20XX-20XX* and select a Primary and Secondary Reviewer for full committee review or a Designated Reviewer for all other submissions.
- 5.2 Enter the name of the assigned reviewer(s) into *IRB Submission Log 20XX-2011* and save.
- 5.3 Email the assigned reviewer(s) access to the protocol record located in the Egnyte shared drive. The appropriate and completed IRB Coordinator Checklist, and other required review documents should be included in the protocol record for review, as required using the *Review Materials Worksheet*.
- 5.4 Update *IRB Submission log 20XX-20XX* with the date; place a copy of the email sent to the designated review in the protocol record located on the IRB Egnyte shared drive.

6 MATERIALS

- 6.1 IRB SOP: Designated Reviewer
- 6.2 Review Materials Worksheet
- 6.3 IRB Member Roster 20XX-20XX
- 6.4 IRB Submission Log 20XX-20XX

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- 6.5 IRB Coordinator Amendment Checklist
- 6.6 IRB Coordinator Continuing Review or Closure Checklist
- 6.7 IRB Coordinator Exempt/Expedited Checklist
- 6.8 IRB Coordinator Initial Submission Checklist
- 6.9 IRB Coordinator Registration Project Checklist

7 REFERENCES

- 7.1 45 CFR 46.110(b)
- 7.2 21 CFR 56.110(b)