UNIVERSITY OF MIAMI

SOP: Non-Committee Review Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	12/10/2021	F. Conte	K. Viamonte	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to prepare for a Designated Reviewer to conduct a Non- Committee Review.

1.2 The process begins when the Designated Reviewer has the provided materials.

1.3 The process ends when the Designated Reviewer completes the review and submits the review in the electronic system or notifies a Committee Support Analyst that the submission requires full Committee review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 02/26/2018

2.2 06/13/2019 – Minor clarifications; updated further for consistency with electronic workflow

2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 POLICY

3.1 The Designated Reviewer may not disapprove research.

3.2 The Designated Reviewer utilizes all applicable worksheets in the review of research.

3.3 All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.

3.4 All applicable criteria for approval in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent when appropriate).

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Determine if a conflict of interest exists between the reviewer and the research.

5.2 If a conflict of interest exists notify HSRO staff or reassign the review

5.3 Review all materials.

5.4 Determine the required level of review:

- 5.4.1 Not Human Research,
- 5.4.2 Human Research not Engaged,
- 5.4.3 Exempt Human Research (including exempt Human Research that requires Limited IRB Review),
- 5.4.4 Human Research approved using the expedited procedure, or
- 5.4.5 Human Research that requires review by a convened IRB.
  - 5.4.5.1 If the research requires full Committee review, notify a Committee Support Analyst, when applicable.

5.5 Review HRP-601 - DATABASE - IRB Roster to determine whether additional expertise is required.

- 5.5.1 If the research purposefully includes prisoners and is subject to HHS or DoD funding, involve a prisoner representative in the review.
- 5.5.2 If the research purposefully involves disabled individuals and is funded by the Department of Education or the National Institute on Disability and Rehabilitation, involves a reviewer who has expertise with individuals with disabilities.

5.6 If consultation is needed follow HRP-051 - SOP - Consultation.

5.7 For non-exempt human research:

- 5.7.1 Determine whether the criteria for approval are met using HRP-314 - WORKSHEET - Criteria for Approval.
- 5.7.2 Consult the reviews tab to assess whether special determinations are required.

5.7.3 Refer to HRP-301 - WORKSHEET - Review Materials to assess any required checklists/worksheets.

5.8 For exempt human research requiring Limited IRB review:

5.8.1 Make the appropriate determination.

5.9 When the review is complete, upload the completed checklists and execute the "Submit Designated Review" Activity.

5.10 Return all materials and completed checklists to the HSRO staff in a timely manner.

6 MATERIALS

6.1 HRP-051 - SOP - Consultation
6.2 HRP-301 - WORKSHEET - Review Materials
6.3 HRP-312 - WORKSHEET - Exemption Determination
6.4 HRP-314 - WORKSHEET - Criteria for Approval
6.5 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
6.6 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 21 CFR §56.110(b)
7.2 21 CFR § 50 Subpart D
7.3 21 CFR § 312
7.4 21 CFR § 812
7.5 45 CFR §46.110(b)
7.6 45 CFR § 46 Subpart A
7.7 45 CFR §46 Subpart C
7.8 45 CFR § 46 Subpart D 7.9
7.9 34 CFR §350.4(c)(1)
7.10 AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3, II.5.A