UNIVERSITY OF MIAMI

SOP: Non-Committee Review Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	7/9/2019	C.Gates	C.Gates	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

3 GUIDING PRINCIPLES

3.1 The Designated Reviewer may not disapprove research.

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.

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

5.2 Review all submitted materials.

5.3 Determine the required level of review:

5.3.1 Not Human Research

5.3.2 Human Research,

5.3.3 Not Engaged

5.3.4 Exempt Human Research

5.3.5 Human Research qualifying for the expedited procedure

5.3.6 Human Research requiring full Committee review

5.4 If the research requires full Committee review, notify a Committee Support Analyst.

5.5 Determine whether additional expertise is required.

5.5.1 If the research purposefully includes prisoners and is subject to NIH 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 required, follow SOP: Consultation (HRP-051).

5.7 Determine whether the criteria for approval are met using WORKSHEET: Criteria for Approval (HRP-314) and WORKSHEET: Informed Consent (HRP-314B)

5.8 Determine whether additional determinations are required.

5.9 If the research includes children as subjects and is federally funded, subject to FDA jurisdiction or involves greater than minimal risk, complete CHECKLIST: Children (HRP-416)

5.10 If the research purposefully includes prisoners and is subject to NIH or DoD funding, complete CHECKLIST: Prisoners (HRP-415)

5.11 If the research is funded by the NIH or otherwise subject to 45 CFR § 46 Subpart B, and purposefully includes pregnant women or fetuses, complete CHECKLIST: Pregnant Women (HRP-412).

5.12 If the research includes cognitively impaired adults, complete CHECKLIST: Cognitively Impaired Adults (HRP-417).

5.13 If the research includes non-viable neonates, complete CHECKLSIT: Research Involving Non-Viable Neonates (HRP-413)

5.14 If the research includes neonates of uncertain viability, complete CHECKLST: Research Involving Neonates of Uncertain Viability (HRP-414)
5.15 If the research involves a waiver of consent, complete CHECKLIST: Waiver of Consent (HRP-410)
5.16 If the research involves a waiver of documentation of consent, complete CHECKLIST: Waiver of Documentation of Consent (HRP-411)
5.17 If the research involves a waiver of the requirement for a HIPAA Authorization, complete CHECKLIST: HIPAA Waiver of Authorization (HRP 441)
5.18 If the research involves a device, complete CHECKLIST: Devices (HRP-418)
5.19 If the research involves a drug or biologic, complete WORKSHEET: Drugs (HRP-306)
5.20 When the review is complete, upload the completed checklists and execute the "Submit Designated Review" Activity.

6 MATERIALS

6.1 SOP: Consultants (HRP-051)
6.2 CHECKLIST: Non-committee Review (HRP-402)
6.3 CHECKLIST: Waiver of Consent (HRP 410)
6.4 CHECKLIST: Waiver of Documentation of Consent (HRP-411)
6.5 CHECKLIST: Pregnant Women (HRP 412)
6.6 CHECKLIST: Research Involving Non-Viable Neonates (HRP-413)
6.7 CHECKLIST: Research Involving Neonates of Uncertain Viability (HRP-414)
6.8 CHECKLIST: Prisoners (HRP-415)
6.9 CHECKLIST: Children (HRP-416)
6.10 CHECKLIST: Cognitively Impaired Adults (HRP-417)
6.11 DATABASE: (IRB Roster (HRP-601)
6.12 WORKSHEET: Review Materials (HRP-301)
6.13 WORKSHEET: Criteria for Approval (HRP-314)
6.14 WORKSHEET: Informed Consent (HRP-314B)

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 34 CFR §350.4(c)(1)