SOP: Non-Committee Review Conduct			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-032	Executive Director, IRB Office Northwestern University	05/20/2020	Page 1 of 2

1 PURPOSE

1.1 This procedure establishes the process 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 submits the review to an IRB staff member.

2 PREVIOUS VERSION

2.1 Revised from previous version dated 01/21/2019.

3 POLICY

Non-Committee Reviews are completed by Designated Reviewers (Experienced IRB Members who have been designated by the IRB Chair to conduct Non-Committee Reviews).

3.1 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.2 Determine the required level of review. (Not Human Research, Human Research not Engaged, exempt Human Research, Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB).

5.2.1 If it is Human Research that requires review by a convened IRB, notify the IRB Staff. IRB Staff will prepare and assign for a convened IRB meeting.

5.2.2 If Non-Committee Review is appropriate, proceed to step 5.3.

5.3 Confirm the adequacy of expertise and representative capacity (where applicable for reviews involving special populations) to conduct the review.

5.3.1 If expertise and representative capacity is not adequate or appropriate to conduct the review, notify the IRB Staff. IRB Staff will re-assign to another Designated Reviewer.

5.4 Determine if consultation is needed. If so, follow SOP: Consultation (HRP-051).]

5.5 Consult IRB SOPs, WORKSHEETs, CHECKLISTs, and guidance documents that are applicable to the review.

5.5.1 Where CHECKLISTS are applicable, they must be completed with the review, as indicated in the CHECKLIST. (e.g. CHECKLISTS for waivers and subpart determinations).

5.6 If additional information, clarifications or changes are needed from the PI, execute the "Request Clarification by Designated Reviewer" activity to return the submission to the PI with a list of the items to be addressed or notify the IRB Staff.

5.7 When ready to make a determination and log the review, execute the "Submit Designated Review" activity.

6 MATERIALS

6.1 SOP: Consultation (HRP-051)

6.2 SOP: IRB Review of Conflict of Interest (HRP-056)

6.3 WORKSHEET Human Research Determination (HRP-310)

6.4 WORKSHEET Engagement Determination (HRP-311)

6.5 WORKSHEET Exemption Determination (HRP-312)

6.6 WORKSHEET Expedited Review (HRP-313)

6.7 WORKSHEET Criteria for Approval (HRP-314)
6.8 WORKSHEET Advertisements (Recruitment Materials) (HRP-315)
6.9 WORKSHEET Payments (HRP-316)
6.10 WORKSHEET Short Form of Consent Documentation (HRP-317)
6.11 WORKSHEET Additional Federal Agency Criteria (HRP-318)
6.12 WORKSHEET: Limited IRB Review (HRP-319)
6.13 WORKSHEET Scientific or Scholarly Review (HRP-320)
6.14 WORKSHEET Reportable New Information Items (HRP-321)
6.15 WORKSHEET Emergency Use (HRP-322)
6.16 WORKSHEET Contracts (HRP-324)
6.17 WORKSHEET HIPAA Authorization (HRP-330)
6.18 WORKSHEET FERPA Compliance (HRP-331)
6.19 WORKSHEET NIH GDS (Genomic Data Sharing) Certification (HRP-332)
6.20 WORKSHEET Certificate of Confidentiality (HRP-333)
6.21 WORKSHEET Media Relations (HRP-334)
6.22 WORKSHEET GDPR Data Protection (HRP-335)
6.23 WORKSHEET Mobile Apps and Mobile Medical Apps (HRP-336)
6.24 CHECKLIST Non-Committee Review (HRP-402)
6.25 CHECKLIST Waiver or Alteration-Consent Process (HRP-410)
6.26 CHECKLIST Waiver of Written Documentation of Consent (HRP-411)
6.27 CHECKLIST Pregnant Women (HRP-412)
6.28 CHECKLIST Non-Viable Neonates (HRP-413)
6.29 CHECKLIST Neonates of Uncertain Viability (HRP-414)
6.30 CHECKLIST Prisoners (HRP-415)
6.31 CHECKLIST Children (HRP-416)
6.32 CHECKLIST Cognitively Impaired Adults (HRP-417)
6.33 CHECKLIST Non-Significant Risk Device (HRP-418)
6.34 CHECKLIST Waiver of Consent Process for Emergency Research (HRP-419)
6.35 CHECKLIST HIPAA Waiver of Authorization (HRP-441)
6.36 CHECKLIST Genetic Biobanking Studies (HRP-442)

7 REFERENCES

7.1 21 CFR §56.110(b).
7.2 45 CFR §46.110(b).