



SOP: Non-Committee Review Conduct

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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 11/01/2023

3 POLICY

Non-Committee Reviews are completed by Designated Reviewers (Experienced IRB Members whom the IRB Chair has designated 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.
- 4.2 The Designated Reviewer references all applicable worksheets in the review of research.

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 meets an expedited category, but the expedited reviewer determines that it is more than minimal risk, then the expedited reviewer must document the reason for this determination in the review. The research will then be reviewed by the convened IRB.
 - 5.2.2 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.
 - 5.2.3 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, FORMs 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)



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- 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 WORKSHEET New Project Reviewer Form (HRP-1304)
- 6.25 WORKSHEET CR Reviewer Form (HRP-1305)
- 6.26 CHECKLIST Non-Committee Review (HRP-402)
- 6.27 CHECKLIST Waiver or Alteration-Consent Process (HRP-410)
- 6.28 CHECKLIST Waiver of Written Documentation of Consent (HRP-411)
- 6.29 CHECKLIST Pregnant Women (HRP-412)
- 6.30 CHECKLIST Non-Viable Neonates (HRP-413)
- 6.31 CHECKLIST Neonates of Uncertain Viability (HRP-414)
- 6.32 CHECKLIST Prisoners (HRP-415)
- 6.33 CHECKLIST Children (HRP-416)
- 6.34 CHECKLIST Adults with Impaired Decision-Making Capacity (HRP-417)
- 6.35 CHECKLIST Non-Significant Risk Device (HRP-418)
- 6.36 CHECKLIST Waiver of Consent Process for Emergency Research (HRP-419)
- 6.37 CHECKLIST HIPAA Waiver of Authorization (HRP-441)
- 6.38 CHECKLIST Genetic Biobanking Studies (HRP-442)

7 REFERENCES

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).
- 7.3 45 CFR 46.120(b)(1)(i)