

Appendix A. Ancillary Study Development and Review Process

Ancillary Investigator: Development

1. Study Concept Development

- Discuss your study concept with ARC Chairs and/or an ARC Member
- Contact the NEPTUNE DACC for:
 - Bio-sample availability
 - Limited bio-sample requests (also see the NEPTUNE ancillary study policy)
 - Public-private partnerships (also see the NEPTUNE ancillary study policy)
 - Data exploration in tranSMART and nephVS
 - Working with NEPTUNE infrastructure
 - NEPTUNE RDCRN Registry contacts
 - Budgeting for NEPTUNE resource use

Start Early: Allow 3 months prior to funding source deadline to explore study concepts.

2. Ancillary Study Application

- The application is short form to describe NEPTUNE resource needs and study design. Download from NEPTUNE website.
- Using information collected from NEPTUNE DACC, tranSMART, nephVS, and other NEPTUNE resources, complete the ancillary application
- Review and sign the NEPTUNE data sharing policy statement
- Send to NEPTUNE-STUDY@umich.edu

Allow 2+ months before funding deadline for Review.

NEPTUNE Consortium: Review

3. NEPTUNE DACC Review

The DACC is responsible for assessing feasibility:

- Biospecimen availability and appropriateness
- Strength of analytic resources
- Plan for new data and/or new sample generation
- Participant burden

DACC meets every Monday. Submit by previous Thursday to get onto agenda.

4. Ancillary study Review Committee (ARC) Assessment

ARC responsible for assessing:

- Suitability for integration into NEPTUNE
- Burden to the consortium
- Scientific merit, if the study will not have external funding review
- Recommendation to SC for approval

Two cmte members review

Committee votes for recommendation to SC to approve

Cmte members have 2 weeks to review proposals. ARC meets the 1st Friday of the month. Plan to get proposal to DACC a month before.

5. Steering Committee (SC) Approval

SC reviews ARC's recommendation and votes to approve.

SC meets the third Friday of the month.