North American AIDS Cohort Collaboration on Research & Design

Collaboration Concept Sheet
Format & Guidelines

I. Format

Please review NA-ACCORD collaboration guidelines (located on page 3) before drafting your Concept Sheet (CS).

Use the following outline to present your study plan. Take whatever space is necessary to completely respond to each section. This form will not be accepted unless each lettered section listed below is included.

Email completed Concept Sheet in a Word file to Aimee Freeman (afreeman@jhu.edu).

A. GENERAL INFORMATION

1. Study Title:

2. Submission Type: ☐New Submission ☐Amendment

3. Lead Investigator(s):

4. Institution(s):

5. Email(s):

6. NA-ACCORD Liaison (If Lead Investigator is external to NA-ACCORD):

7. Category: Select all that apply

   ☐Cancer ☐CVD ☐Liver ☐Renal ☐Quality of Care

   ☐Aging & Multimorbidity ☐Mental Health & Substance Use Disorders

   ☐Comparative Effectiveness ☐Methods

8. Will this project require data from…
   …clinical cohorts (individuals are followed as they access medical care; e.g., Kaiser Permanente, Johns Hopkins HIV Clinical Cohort)?
   ☐ Yes ☐ No
   …interval cohorts (individuals are followed at specified intervals that are unrelated to the participants' ongoing health care; e.g., MACS/WIHS)? ☐ Yes ☐ No
   …US cohorts? ☐ Yes ☐ No
   …Canadian cohorts? ☐ Yes ☐ No

9. Will this project require epidemiological/biostatistical support from the NA-ACCORD to complete the proposed aims? ☐ Yes ☐ No
   If Yes, please describe:

10. Data Sharing:
    Before data is shared, you must have both IRB approval from your institution for your study, as well as a Data Use Agreement that has been signed off by both institutions involved in the data share. Aimee Freeman (afreeman@jhu.edu) will assist with this process after your CS is approved.

    Will this project require individual-level data to be sent to you for analysis?
    ☐ Yes ☐ No

    Will this project require study findings to be sent to you for pooling with findings from other analyses? ☐ Yes ☐ No

    Does this project have IRB approval? ☐ Yes ☐ No

    If "No", provide explanation and timeline for IRB submission:

    If "Yes", include a copy of the IRB approval letter with your submission.

B. SPECIFIC AIMS AND HYPOTHESES

C. BACKGROUND AND RATIONALE

D. STUDY POPULATION / ELIGIBILITY CRITERIA

E. STUDY VARIABLES AND DEFINITIONS

F. DATA ANALYSIS AND SAMPLE SIZE CALCULATIONS

G. TIMEFRAME AND EXPECTED PUBLICATIONS

H. REFERENCES

III. Guidelines

1. Prior to Concept Sheet (CS) submission:
   - If you have questions about the feasibility of NA-ACCORD data to answer your research aims, contact Jennifer Lee (jslee@jhu.edu), Co-Director of the Epidemiology/Biostatistics Core.

   - Investigators **must** review and agree to follow the NA-ACCORD Collaboration Policies posted on the "Collaborate with Us" section of the NA-ACCORD website (naaccord.org).

   - For external investigators, an NA-ACCORD liaison is required prior to formal submission. Contact Aimee Freeman (afreeman@jhu.edu) for assistance with this requirement.

2. Email completed CS in Word file format to Aimee Freeman (afreeman@jhu.edu).

3. Once submitted, the CS will be reviewed by the Executive Committee and relevant Working Groups for approval to forward to the NA-ACCORD Steering Committee (SC). The SC members will then have a 2-week opportunity to comment and vote on the CS. Following SC review, the investigator will be notified whether the CS was approved, approved with comments, tabled for further clarification and resubmission, or rejected.

4. Once approved, the Administrative and Epidemiology/Biostatistics Cores will work with the investigators to develop a protocol that provides further detail on study eligibility criteria and data elements needed for analyses outlined in the CS. If this project requires data sharing, there must be both a Data Use Agreement that has been signed off by both institutions involved in the data share, as well as IRB approval, before data can be shared. Aimee Freeman (afreeman@jhu.edu) will assist with this process after your CS is approved.

5. Each participating cohort in NA-ACCORD has the right to decide to participate or not participate in any scientific aim or sub-aim. Data transmitted by an individual cohort will be used only to address approved scientific aims in which they have agreed to participate.

6. **All abstracts and manuscripts derived from this concept sheet MUST be submitted to the SC for review and approval before they are submitted to a journal or conference** and must acknowledge data collected through NA-ACCORD and credit all collaborating cohorts and IeDEA. Authorship listings should include the following text: "…for the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) of IeDEA." Contact Aimee Freeman (afreeman@jhu.edu) for assistance with this requirement.