North American AIDS Cohort Collaboration on Research & Design

Collaboration Concept Sheet
Format & Guidelines

I. Format

Please review NA-ACCORD collaboration guidelines (located on page 4) 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, PDF or RTF file to Aimee Freeman (afreeman@jhu.edu).

A. GENERAL INFORMATION

1. Study Title:

2. Date of submission:

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 HIV Care

   ☐Aging & Multimorbidity ☐Mental Health & Substance Use Disorders

   ☐Comparative Effectiveness ☐IeDEA ☐Other

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, the NA-ACCORD must receive IRB approval from your institution for your study. Additionally, there must be a Data Use Agreement in place that has been signed off by both institutions involved in the data share. Aimee Freeman (afreeman@jhu.edu) and Brenna Hogan (bhogan7@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", please provide explanation and timeline for IRB submission:

    Time period of IRB approval: _____ to _____

    Local IRB reference #:

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. All investigators are encouraged to review their proposed research with the NA-ACCORD Principal Investigator and relevant NA-ACCORD Working Groups prior to submission. For external investigators, an NA-ACCORD liaison is required prior to formal submission.
2. Once submitted, the proposal 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 concept sheet. Following SC review, the investigator will be notified whether the concept was approved, approved with comments, tabled for further clarification and resubmission, or rejected.
3. 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 concept sheet. If this project requires data sharing, there must be a Data Use Agreement in place that has been signed off by both institutions involved in the data share before data can be shared. Aimee Freeman (afreeman@jhu.edu) and Brenna Hogan (bhogan7@jhu.edu) will assist with this process after your CS is approved.
4. Each participating cohort in NA-ACCORD will have 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.
5. Investigators agree to follow NA-ACCORD publication policy (posted on the web at http://statepiaps.jhsph.edu/naaccord/Collaboration/index.html).
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.