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. Does your proposed project relate to any of the following categories? (*Please check all that apply*)

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

   ☐Aging & Multimorbidity ☐Mental Health & Substance Use Disorders

   ☐Comparative Effectiveness ☐Epidemiologic or Biostatistical Methods

8. From which of the following would you like data for your proposed project: (*Please check all that apply*)

   a. Clinical cohorts (participants are followed as they access medical care such as Johns Hopkins HIV Clinical Cohort)?
   ☐ Yes ☐ No

   b. Interval cohorts (participants complete protocol-driven study visits for data collection e.g., MACS/WIHS Combined Cohort Study)?
   ☐ Yes ☐ No

   c. US cohorts? ☐ Yes ☐ No

   d. Canadian cohorts? ☐ Yes ☐ No

9. Which of the two options are you requesting to complete your proposed analysis? (*Please select **one** of the options below*)

☐ Assistance from the NA-ACCORD Epidemiology/Biostatistics Core (EBC)

This request will be considered based on alignment with the aims of the NA-ACCORD grant and resource availability at the EBC. You will be notified at the time of concept sheet approval whether this support can be provided and the timeline for the support.

☐ The data are shared with the lead investigators so they can conduct the analyses with their local team (i.e. a **data share**)

This request includes receipt of the data necessary to complete your proposed aims. The NA-ACCORD EBC will send you the data and will available to answer questions via e-mail as you proceed with your analysis.

10. If you are requesting a **data share** (otherwise skip these questions below):

a. This project requires (*please select **one** of the options below*):

☐ Individual-level data to be sent to you for analysis
☐ Aggregate data to be sent to you for analysis
☐ Estimates be sent to you for pooling with findings from other studies or to inform a computational model

b. Does this project have IRB approval?

☐ Yes
Please include a copy of the IRB approval letter with your submission.

☐ No
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.

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.