North American AIDS Cohort Collaboration on Research & Design

New Data Element Request Format & Guidelines

Please review NA-ACCORD guidelines for requesting new data elements (located on page 2) *before* drafting your new data element request.

Use the following outline to draft your request to add a new data element(s) to the NA-ACCORD's annual data request. There are no space limitations when responding to each section.

Email your completed request as a Microsoft Word file (.docx) to Aimee Freeman (afreeman@jhu.edu).

1. Name(s): *List the name(s), email address(es), and affiliation(s) of individuals involved in drafting this request.*

2. Description of new data element(s): *List the new data element(s) being requested and the source of the elements (e.g., laboratory measurement, ICD-10 diagnosis code, prescribed medication). Please note if any data elements will need review (medical record or otherwise) to determine the reliability or validity of the new data element(s).*

3. Does the new data element(s) relate to any of the following categories? *Please check all that apply.*

__ Aging & Multimorbidity	__CVD	__Comparative Effectiveness
__Liver	__Malignancy	__Mental Health & Substance Use
__Methods	__Quality of Care	__Renal
__STI (other than HIV)	__TB	__COVID

4. Background & Rationale: *Include details to support the importance/significance of the new data element(s). If changing clinical guidelines may impact the new data elements, please include a timeline and reference of guideline changes.*

5. Specific scientific aim(s) you wish to initially pursue that requires the new data element(s):

6. Potential ascertainment/useability issues: *Describe potential data quality/ascertainment issues that would impact how these data will be used for the aim(s) you described above. Please provide detail on needed review (medical record or otherwise) to determine the reliability or validity of the new data element(s).*

7. References

Process Timeline*

May – August

1. Ideas for new data elements may arise during the spring (May – August) Scientific Working Group (SWG) or during discussions outside of SWGs.

2. Once there is an idea for a new data element (and prior to submission of this request), please contact Jennifer Lee (jslee@jhu.edu), Co-Director of the Epidemiology/Biostatistics Core, to confirm the data elements you are proposing are not already available.

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

4. Once submitted, the request will be reviewed by the Administrative Core (AC), Data Management Core (DMC), and Epidemiology/Biostatistics Core (EBC); please allow up to 3 weeks for this review. During this review, the cores will determine if the new data elements need external funding to support collection (and will advise on how to proceed if funding is needed). Questions/concerns raised during this review step must be addressed by investigators before proceeding to the next step. A revised version of your request must be sent to Aimee Freeman (afreeman@jhu.edu) at ***least 2 weeks prior to the fall SWG call*** that is relevant to the proposed new data element.

September – January

5. The request will be shared with relevant Scientific Working Group (SWG) Chairs for dissemination to SWG members at least 2 weeks prior to the fall SWG call. The SWG(s) will discuss the request during their fall SWG calls (September-December). You will be asked to join the SWG meeting(s) to briefly present the request and engage in questions/discussions with SWG members. Questions/concerns raised during this review step must be addressed by investigators before proceeding *to the next step.* A revised version of your request must be sent to Aimee Freeman (afreeman@jhu.edu) by ***January 15***.

February – April

6. The EC will review the revised version of the request in preparation for the annual NA-ACCORD meeting. The Steering Committee (SC) will then review the requests for new data elements during the Annual NA-ACCORD meeting, which occurs in March. The SC and the EC will determine inclusion of new data elements in the annual NA-ACCORD Data Submission Request (distributed in April to contributing cohorts).

April

7. If the new data elements are approved, they will be included into the annual NA-ACCORD Data Submission Request. The new data elements will be available for analysis in 15 months.

**Exceptions to this timeline include requests for new data elements that are outside of collection via the annual NA-ACCORD Data Submission Request (e.g., medical record review to validate specific outcomes).*

Abbreviations		
AC: Administrative Core	DMC: Data Management Core	EBC: Epidemiology/Biostatistics Core
EC: Executive Committee	SC: Steering Committee	SWG: Scientific Working Group