**The NA-ACCORD FAST TRACK Concept Sheet (FT-CS) and approvals process for aggregated data and mathematical functions requests**

**Purpose**

The NA-ACCORD is a recognized resource as the largest source of longitudinal data among those who have successfully linked into HIV care in the United States and Canada. As such, the NA-ACCORD has established collaborations with modeling groups and produces a website of HIV indicators to fulfill its mission of improving the lives of people with HIV through information that can inform policy and program decision-making. In accordance with the *NIH Statement on Sharing Research Data* (NOT-OD-03-032), we propose to further define the approval process for aggregated data requests and mathematical functions. Access to aggregated data that are known HIV indicators allow timely access to inform local, state, federal, and international policies and programs. Aggregated data are also used to inform computer models as input parameters or mathematical functions; these data can be used to update older data or to expand the capabilities of the model.

The framework through which we review and approve requests for NA-ACCORD data and collaborative studies is below. Our full concept sheet approvals process (gray row) is the most frequently used. We add the process for sharing aggregated data and mathematical functions in the table below.

| | | **Approvals process** | | | | | |
|---|---|---|---|---|---|---|---|
| **Data description** | **Use of data** | **CS** | **Abstract** | **Manuscript** | **Public posting** | **Authorship opportunities for NA-ACCORD investigators?** | **NA-ACCORD Acknowledgement required?** |
| Individual-level data | Any use | Full | Full | Full | Full | Yes | Yes |
| Counts, rates, percentages, etc. | Indicators of public health or clinical significance | Fast-track (no WrG established) | EC | EC | EC | Limited* | Yes |
| | Input parameters requested and a scientific product focused on the impact of the NA-ACCORD aggregated data on model output (e.g. aggregated data needed for model development or expansion) | Fast-track (no WrG established) | SC | SC | SC | Yes | Yes |
| | Input parameters requested to update model parameters with ***no*** focused scientific product describing the | Fast-track (no WrG established) | None | None | None | No | Yes |

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| | impact of the requested aggregated data on model output | | | | | | |
| Mathematical functions | Input functions requested and a scientific product focused on the impact of the NA-ACCORD functions on model output (e.g. functions needed for model development or expansion) | Fast-track (no WrG established) | SC | SC | SC | Yes | Yes |
| | Input functions requested to update model parameters with ***no*** focused scientific product describing the impact of the requested functions on model output | Fast-track (no WrG established) | None | None | None | No | Yes |

*Authorship is limited, unless the scientific product is solely focused on the indicators from NA-ACCORD data. If this occurs, the NA-ACCORD Executive Committee (EC) will send the scientific product for full SC review.

**Approvals process descriptions noted in the table**

- CS Full: Investigators will submit a concept sheet which will undergo the routine NA-ACCORD review and approvals process
- Abstract Full: Investigators will submit an abstract to the routine NA-ACCORD review and approvals process prior to submission.
- Manuscript Full: Investigators will submit the manuscript to the routine NA-ACCORD review and approvals process prior to submission.
- Public Posting Full: Investigators will submit the aggregated data they plan to post publicly (e.g. to a website or via a scientific report) to the routine NA-ACCORD manuscript review and approvals process prior to posting publicly.
- Fast-track CS: A fast track concept sheet will be used to review the request (see *Appendix A*, adapted from the IeDEA global network). Aimee Freeman will first review the FT-CS for potential overlap with approved CS or FT-CS; she will then send to Dr. Catherine Lesko (NA-ACCORD EBC) who will review the request for feasibility. The approximate timeline for both reviews is 1 week. If Dr. Lesko deems the request feasible, the FT-CS will be sent to the EC for a one-week review. After EC approval, the FT-CS will be circulated to the Steering Committee for a one-week review during which we will solicit 1) any objections to a cohort's data being included in the requested aggregated data and 2) any concerns about the use of NA-ACCORD data for the purpose described in the FT-CS. A writing group will not be solicited for fast-track concept sheets.

- EC Abstract: The Executive Committee will review the abstract. If the abstract is heavily focused on the presentation of the NA-ACCORD-derived indicators, the EC will send the abstract to the Steering Committee for review.
- EC Manuscript: The Executive Committee will review the manuscript. If the manuscript is heavily focused on the presentation of the NA-ACCORD-derived indicators, the EC will send the manuscript to the Steering Committee for review.
- EC Public posting: The Executive Committee will review the content that will be publicly posted. If the content is heavily focused on the presentation of the NA-ACCORD-derived indicators, the EC will send the content to the Steering Committee for review.
- Limited co-authorship: Authorship to NA-ACCORD investigators is limited unless the scientific product is solely focused on the indicators from NA-ACCORD data. If this occurs, the EC will send the scientific product for full SC review; those who meet ICMJE criteria for co-authorship will be included.
- SC Abstract: The Steering Committee will review the abstract and investigators can join as a co-author or suggest other investigators to review and join as co-authors.
- SC Manuscript: The Steering Committee will review the manuscript and investigators can join as a co-author or suggest other investigators to review and join as co-authors.
- SC Public posting: The Steering Committee will review the content that will be publicly posted.
- Acknowledgement required: The abbreviated NA-ACCORD acknowledgement (posted under "Collaborate with Us" at www.naaccord.org) but be included in the final scientific product.

**Examples specific to the NA-ACCORD from which these aggregated data approvals policies were developed**

HIV indicators requested with a scientific product focused on the indicators: Maps of HIV indicators were developed using NA-ACCORD and CCASAnet data and posted on the NA-ACCORD website from 2016-2021 This project had an approved concept sheet (which produced the publication *Althoff KN, Rebeiro PF, Hanna DB, et al. JIAS 2016*).

Model inputs requested to build a model: An investigator from Yale requested anal cancer incidence rates by year and demographics for a computer model to simulate the anal carcinogenesis with the most current understanding of up-to-date data from people with HIV. She contacted us after reading *Silverberg MJ, et al, Ann Intern Med 2015*. In agreement with Michael Silverberg, the NA-ACCORD Executive Committee approved sharing estimated rates to inform her model as an extension to Michael Silverberg's approved cancer incidence concept sheet. Estimates were generated by the NA-ACCORD EBC and shared. Michale Silverberg collaborated with the Yale investigator to ensure the NA-ACCORD anal cancer incidence rates were being used appropriately in her model. A scientific paper was published focused on the development and calibration of the mathematical model of anal carcinogenesis in men with HIV (https://journals.lww.com/jaids/Fulltext/2018/09010/Development_and_Calibration_of_a_Mathematical.2.aspx). Michael Silverberg was a co-author on this work.

The following projects are potentially coming soon:

HIV indicators requested: Multi-Use Dataset (MUD) from the IeDEA Global Network: As part of this 5-year funding cycle, all IeDEA regions have committed to establishing a multi-use dataset in accordance with the *NIH Statement on Sharing Research Data* (NOT-OD-03-032). The MUD will consist of HIV indicators estimated from IeDEA data; some indicators have been previously published in peer-reviewed journals and others have not. An automated process will be established to update the indicators annually. The indicators will be available on the IeDEA website. A full concept sheet is likely going to be the most appropriate approvals pathway for this work.

Model inputs requested to expand a model: An investigator from the University of British Columbia is requesting the probabilities of changes in CD4 counts over the course of HIV disease progression after ART initiation, by demographic characteristics and accounting for gaps in ART prescriptions. The investigator will use these estimates to expand his computer model, which was recently published here: https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30033-3/fulltext. The investigator wishes to have NA-ACCORD input on the scientific product that describes the expansion of his model using NA-ACCORD data.

Aggregated data requested to update model parameters and produce a scientific publication focused on updating the inputs: An investigator from the CEPAC modeling group at MGH is requesting estimates of the incidence of opportunistic infections to update the CEPAC model inputs. She would like NA-ACCORD input and co-authors on a paper that will compare the NA-ACCORD OI estimates to pre-ART estimates of OIs. After the publication of that paper, the NA-ACCORD OI estimates will become an essential function of the model.

Aggregated data requested to update model parameters: IHME has contacted us to provide mortality rates in specific subgroups and over time to update mortality rate estimates currently used in the Global Burden of Disease Model. The NA-ACCORD would be one of numerous contributors of aggregated data estimates to inform the model.

**Please review NA-ACCORD collaboration guidelines (located on page 3) before drafting your *FAST TRACK* Concept Sheet (FTCS).**

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 *FAST TRACK* Concept Sheet in a Word file to Aimee Freeman (afreeman@jhu.edu).

## A. GENERAL INFORMATION

1. Study Title:

2. Submission Type: ☐ New Submission

   ☐ Linked to approved Concept Sheet
   Concept Sheet id and title to which the request is linked:

3. Primary Contact (s):

4. Institution(s):

5. Email(s):

6. NA-ACCORD Liaison (If the Primary Contact is external to NA-ACCORD):

7. What are you requesting? (*Please select **one** of the options below*)

   ☐ Aggregated dataset (counts, percentages, rates, etc.) created by the NA-ACCORD Epidemiology/Biostatistics Core (EBC) which will be used as stand-alone HIV indicators or as inputs into a computer model

   ☐ Mathematical functions to estimate risk factors / predictors / exposures / outcomes which will be used to inform a computer model

   *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 FAST TRACK Concept Sheet approval whether this support can be provided and the timeline for the support.*

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. 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 a letter of IRB approval or exemption from your institution for your study.

10. Will your institution require a signed data user agreement prior to the receipt of these aggregated datal?

Johns Hopkins University (JHU) does not require a Data Use Agreement to share aggregated data; however, please review your institution's requirements for data user agreements prior to receipt of aggregated data. Aimee Freeman (afreeman@jhu.edu) will assist with JHU institutional signatures on data user agreements after your FTCS is approved.

☐ Yes

Please include a copy of the data user agreement requested by your institution with your submission.

☐ No

**B. BRIEF DESCRITION OF THE AIMS AND PURPOSE OF THE PROJECT (one paragraph with references at the end of this paragraph)**

**C. DESCRIPTION OF THE AGGREGATED DATA OR FUNCTIONS REQUESTED**

**D. DESCRIPTION OF HOW THESE AGGREGATED DATA WILL BE USED IN YOUR PROJECT**

**E. EXPECTED FUTURE SCIENTIFIC OUTPUTS (e.g. journal publication, policy document, model building, and/or any public posting of the aggregated data)**

After describing the scientific outputs, please select from the following (select all that apply):

- ☐ A scientific product describing the HIV indicators requested will predominantly focus on these estimates from the NA-ACCORD
- ☐ The aggregated data or functions requested will be used to *develop or expand* a computer model *and a scientific product* will describe impact of the NA-ACCORD estimates
- ☐ The aggregated data or functions requested will be used to *update* existing input parameters in a computer model *and there will *not** be a scientific product describing the use and impact of the NA-ACCORD estimates

**F. CONFIRMATION THAT THE FAST TRACK CRITERIA HAVE BEEN MET (please check all of these boxes to confirm)**

- ☐ The request is for aggregated information, not individual-level data.
- ☐ The NA-ACCORD aggregated data (i.e. HIV indicators or other aggregated estimates) or mathematical functions are not the primary focus of the model, report, or study.
- ☐ The following NA-ACCORD acknowledged will be included in all public postings and scientific products that result from the use of the aggregated NA-ACCORD data:

  The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The NA-ACCORD is supported by National Institutes of Health grant U01AI069918

## Guidelines

1. Prior to *FAST TRACK* Concept Sheet (FTCS) submission:
   - If you have questions about the feasibility of NA-ACCORD aggregated data to meet your needs, contact Catherine Lesko (clesko2@jhu.edu), 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 FTCS in Word file format to Aimee Freeman (afreeman@jhu.edu).

3. Once submitted, the FTCS will be reviewed by the Executive Committee (EC) for approval. You will be notified whether the FTCS was approved, approved with comments, not yet approved with a request for clarification and resubmission, or rejected. The EC may reject the fit of your proposal to the FTCS mechanism and may ask you to complete a full Concept Sheet.

   The EC may also agree to the use of the FTCS for your project but wish to seek input and approval from the NA-ACCORD Steering Committee (SC) on your FTCS. If this occurs, the SC members will 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. The NA-ACCORD may request our investigators be offered the opportunity or co-authorship on scientific products.

5. Once approved, the Administrative and Epidemiology/Biostatistics Cores will work with the primary contacts to develop a protocol that provides further detail on study eligibility criteria and the operationalized definitions of the aggregated data.

6. IRB approval or exemption of your project is required before aggregated data can be shared with you.

7. If your institution requires a data user agreement for you to receive aggregated data, Aimee Freeman (afreeman@jhu.edu) will assist with this process after your FTCS is approved.

8. Each participating cohort in NA-ACCORD has the right to decide to participate or not participate in your aggregated data request.

9. **All public postings of the aggregated data or functions and all scientific products derived from them must include acknowledgement of the NA-ACCORD (see section F above).** Contact Aimee Freeman (afreeman@jhu.edu) for assistance with this requirement.