

# ENGAGE DATA REQUEST & AUTHORSHIP POLICY & PROCEDURES

## INTRODUCTION

The Engage Study is a national multisite study in Vancouver, Toronto, and Montreal with clinical and laboratory data (including data obtained from biobanked specimens), questionnaire and qualitative interview components. These data provide information on the individual, social and community-level factors that affect HIV transmission among gay, bisexual, and other men who have sex with men (gbMSM).

This policy lays out the process for submitting data requests related to the Engage Study. This document also outlines the principles of authorship to properly acknowledge the work of team members. The following document has been adapted from the Momentum Health Study, Canadian Observational Cohort Collaboration (CANOC) and Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) guidelines for data requests and authorship.

Each Engage Study participating site (or province) will have the right to decide to participate or not participate in any scientific aim or sub-aim. However, by agreeing to participate, study sites have committed themselves to supplying the data elements needed to meet the research objectives listed in the study protocol.

## DATA REQUESTS

The Engage Study Data Request guidelines are sectioned into four phases, detailed below:

### PHASE 1: PROJECT REQUEST

- Researchers interested in completing a new project with Engage data should contact one of the Engage Principal Investigators (PIs) and/or the Provincial Coordinator (PC) in the province in which they reside or which is closest to where the interested researcher is located. The names and email addresses of the PIs and Provincial Coordinators are found on the Engage website. Researchers are encouraged to contact the PIs and PCs as early as possible in the process to express interest, review current and ongoing projects, and request a copy of the Engage data dictionary, once it becomes available.
- The interested researcher, referred to as the Project Lead, should complete an *initial concept sheet*, found on the Engage website: <https://drive.google.com/file/d/186a0-oodakBg14S0rF0ZXnXLIqz5GtxG/view?usp=sharing>
- Completed Engage Study concept sheets must be emailed to the relevant PC. Completing this short concept sheet will allow the PC to keep track of all current analyses which arise from their province or region.
- Once the concept sheet is written and reviewed by the PC and at least one of the Provincial PIs, the PC will circulate it to all Study PIs.
- PI teleconferences will have a standing item to review concept sheets for proposed analyses. PIs may request additional information on the concept sheet prior to the

- next PI teleconference where concept sheets will be reviewed and approved.
- Proposed concepts will be discussed and may be approved or referred back to the Project Lead with a request for modification.
  - Where two or more researchers develop similar analysis requests, the PIs will determine which researcher will be given priority for the analysis or facilitate combining the projects.
  - Graduate students or community researchers who wish to lead a project must identify a supervisor or academic collaborator for their proposed project and have the supervisor/collaborator review/approve the project before submitting to the study PIs.

## **PHASE 2: DEVELOPMENT OF DATA ANALYSIS REQUEST AND DATA ANALYSIS COMMITTEE REVIEW.**

- Following approval of the concept sheet by the Engage PIs, an *Engage Data Request Form* will be completed.
- Each Engage site will have an identified Data Manager to assist with developing datasets for analysis. The actual analysis may be completed by dedicated statisticians or appropriately trained graduated students or researchers, referred to as an Analyst/Statistician.
- The Project Lead will complete the Data Request Form and circulate to other team members involved in the project, including the provincial Data Manager and Analysts/Statistician (if already identified).
- The Data Analysis Committee (DAC) will meet on a quarterly basis to review proposed analyses. However, additional, ad-hoc meetings of the DAC may be called in advance of particular conferences.
- The DAC will consist of at least one PI from each of the three cities, one of whom will be designated as the Chair (if no National Coordinator is present) and will be supported with a secretary from one of the three Provincial Coordinators or Post-Doctoral Fellows supported by Engage.
- At each meeting the DAC will decide as to whether the Data Request was approved as submitted, approved with modifications, needs further clarification, or not approved. The DAC will communicate any revisions to Project Lead who initiated the request. If modifications are requested, the Project Lead may re-submit the revised Data Request Form and approvals may be given over email. DAC members will have 5 working days to respond to revisions to Data Requests.
- At conference times, if very large number of Project Request Forms are received, the DAC may need to prioritize these Requests and may determine a maximum of requests per Project Lead to be accepted.
- Once finalized, completed Engage Data Requests will be emailed to the Provincial Coordinator, who will submit to the Data Manager and Analyst/ Statistician, who will complete these analyses.
- For proposed analyses which only include data from one province, a concept sheet should be developed (as described in Phase 1). However, once the concept is

approved, the Data Analysis Request form does not need to be reviewed or approved by the DAC.

### **PHASE 3: COMPLETION AND REFINEMENT OF THE ANALYSIS**

- The Project Lead will be the primary liaison between the Engage team and the provincial Data Managers and Analysts/ Statisticians, as relevant.
- The assigned Data Manager and/or Analyst/ Statistician (as appropriate), will work with the Project Lead and refine the protocol outlined in the Data Request Form, if necessary (e.g., clarifying study eligibility criteria, variables, and requested analytic approaches). Once finalized, the Data Manager will prepare the requested analytic dataset and will send it to the statistician.
- Once data have been analyzed by the Analyst/Statistician, the Project Lead will review the results. If the Project Lead is a student or community researcher, they should review the results with their supervisor or academic collaborator.
- If the analysis is clear and appropriately addresses the project objectives, the Project Lead will then start writing the abstract and/or manuscript.
- However, if additional refinement of the analysis is required, the Project Lead may request the Analyst/Statistician to make modifications to the analysis. These must be limited in scope and cannot alter the previously stated objectives of the analysis. If there is a question regarding the appropriateness of additional analyses or refinements to an analysis, these questions can be referred to the Chair of the DAC.
- The Project Lead will be typically given 4 months by the DAC to complete the analysis. Students may receive up to one year to complete an analysis for submission of an abstract, conference presentation, or manuscript.
- If the analysis is not completed within 4 months of a concept sheet approval, the Project Lead must report to the DAC a) why the analysis was not completed, b) solutions to facilitate completing the analysis, and c) a revised timeline.
  - In most cases, the Project Lead will be given permission for one 4-month extension.
  - In circumstances where the DAC deems the publication of a given analysis to be important to the Engage Study research objectives, the DAC reserves the right to re-assign the analysis to another member of the Engage team who is able to complete the analysis. To avoid problems with incomplete or delayed analyses, in no case will an approved analysis be considered “reserved” for certain members of the Engage team as the lead author or co-authors on a future abstract/conference presentation or manuscript without continued explicit approval by the DAC .

### **STAGE 4: WRITING UP THE ANALYSIS**

- The Project Lead will write an abstract draft which must be circulated, and approved by all those identified on the Engage Data Request form as co-authors prior to submission.

- A minimum of 5 working days must be provided for the authors to review a conference abstract prior to submission.
- A minimum of 10 working days must be provided for the authors to review a manuscript prior to submission to a peer-reviewed journal. Efforts should be made to inform co-authors when they can expect a manuscript, so that vacation and busy work schedules can be accommodated.
- If no response is received from an author in the allotted time period, after a reasonable effort of follow up, this author will be removed from the abstract or manuscript, as they no longer meet authorship criteria.
- A final version of the abstract or manuscript will be sent to co-authors by the Project Lead no later than 3 days after submission for peer-review.

### **AUTHORSHIP**

- All co-authors must meet the criteria established by the International Committee of Medical Journal Editors (<http://www.icmje.org/recommendations/>).
- The first (lead) author will usually be the Project Lead. It is understood that this person will have written the bulk of the manuscript or abstract.
- The first author/manuscript lead will be responsible for *initially* proposing the authors and author order together with the senior author.
- Authors will typically be members of the Engage research team, including PIs, co-investigators, staff, trainees of the PIs or co-investigators or community partners. Other authors may also be included pending approval by the DAC.
- The provincial Data Manager and Analyst/ Statistician will be included as authors on all abstracts/manuscripts where these individuals have contributed to the analysis, as relevant.
- One of the Engage PIs will act as the last (senior) author and corresponding author; this role will rotate among the PIs but should be based on the amount of involvement that the PI has had in the project.
- All PIs should be offered authorship on all manuscripts. However, like all co-authors, they must meet the criteria of authorship. If a PI does not believe that his or her contribution has been sufficient to warrant authorship, he or she may suggest an alternate. This alternate must also meet the criteria for authorship.
- For city specific papers, including all study PIs is optional, but at least one PI from each site should be offered authorship. As stated above, these PIs may wish to consider whether their contribution is sufficient to warrant authorship in these cases or whether a note in the acknowledgements is sufficient.
- In the cases where the publishing journal limits the number of authors on any manuscript, the number of PIs who are included as authors may need to be restricted, but at least one PI per province should be invited. Other PIs and co-authors will be listed in the Appendix or Acknowledgements (as deemed appropriate case by case).
- The order of subsequent authors will be determined by the amount of work the individual has contributed to developing the concept, the Data Request, analyses,



feedback provided on abstracts, posters/presentations, and resulting manuscript, as well as their overall contribution to the implementation of the Engage Study.

- All members of the Study Team, including collaborators and members of the community engagement committees, co-investigators, data managers, analysts, and study coordinators will be listed in the appendix of all manuscripts.
- NOTE: It is understood that the Engage Research Team membership is dynamic and may change over time.
- Individuals who meet authorship criteria but do not wish to be acknowledged as authors are permitted to withdraw from authorship at any time.
- If any current or potential author has a grievance with the authorship list or order, the principles of open communication and collegiality will be applied to allow for immediate resolution.
- If no resolution can be found through open communication, final decisions will be made by the PIs in consultation with the project lead/primary author.

#### **AUTHORSHIP CRITERIA** (from the ICMJE)

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Authorship credit will be based on:

- (1) Substantial contributions to conceptions and design, or acquisition of data, or analysis and interpretation of data.
- (2) Drafting the manuscript or revising it critically for important intellectual content.
- (3) Final approval of the version to be published (statistical analysis, administrative, technical or material support, and supervision).
- (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**All** of these conditions must be met to qualify as an Engage author.

#### **ACKNOWLEDGEMENTS**

- Acknowledgement of the Engage participants, collaborators and partners will be included in all manuscripts:
  - Engage Participants
  - Community Engagement Committee Members
  - Affiliated Community Agencies
  - Other staff not included as authors who may have provided project support
  - Other staff who may have reviewed or commented on drafts
- Acknowledgement of funders will be included in all manuscripts and presentations:



- The Canadian Institutes of Health Research (CIHR), the Canadian Foundation for AIDS Research (CANFAR) and the Ontario HIV Treatment Network (OHTN).
- Any funding specific to a specific team member should also be acknowledged (e.g., a funded Research Chair or scholarship that supports the involvement of a given team member).
- *Please contact your local site coordinator for our acknowledgements and funding statement templates.*