Community Counts Data Use Request Guide

Please follow this step-by-step guide to help you complete your electronic Community Counts Data Use Request. It is recommended that you read this document in its entirety before you begin your application.

A complete list of available Community Counts variables can be found on the ATHN support site under the Community Counts tab https://support.athn.org/.

Background:

Community Counts: CDC Public Health Surveillance Project for Bleeding Disorders (Community Counts) is a national project of the Hemophilia Treatment Center Network (HTCN) as subcontractors to the American Thrombosis and Hemostasis Network (ATHN) initiated under a cooperative agreement with Centers for Disease Control and Prevention (CDC). The Community Counts project builds upon the important work started through the Universal Data Collection (UDC) project. The project goals are to provide descriptive knowledge about the populations of hemophilia, von Willebrand disease, other bleeding disorders and VTE receiving care at HTCs and to monitor health indicators among populations with bleeding disorders. CDC, ATHN and the HTCN are committed to providing investigators the opportunity to use and analyze data collected as part of Community Counts and/or UDC, consistent with the purposes for which they were collected and patients' authorization for data use. Access to Community Counts and/or UDC data for the purpose of analysis is allowed after completion and approval of the Community Counts Data Use Request submission.

The use of the Community Counts and/or UDC data will initially be limited to HTCN staff, ATHN, and CDC. Outside investigators wishing to use the data must be sponsored by and collaborate with an HTCN, ATHN, or CDC investigator, and other HTCN investigators must be given an opportunity to serve as collaborators on the project. All investigators must complete a Terms of Access to Restricted Community Counts Data document prior to the approved data request being fulfilled. This document can be found at https://athn.smapply.io/.

Once a data request has been submitted, the review process will take approximately 4 to 6 weeks depending on the topic and data requested. Reviewers will evaluate the data request for feasibility from the Community Counts and/or UDC data availability; whether the request is scientifically sound; whether the scope of analysis is reasonable; and that there are no conflicts with existing analyses being conducted with Community Counts and/or UDC data. Additional approvals will be required for data requests that call for Regional or HTC-level descriptions or comparisons in which the identities of the Regions or HTCs would be known to the investigators. The reviewer determinations may be 1) Accepted as is, 2) Requires refinement in

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response to review, 3) Requires refinement and resubmission. Once the reviews are completed, investigators will receive an email notification with the determination and next steps.

Accessing the Electronic Application:

To access the electronic application (proposal submission), go to https://athn.smapply.io/. You can see all open awards/applications currently available at ATHN. Choose the Community Counts Data Use Request and hit the green APPLY button.

Find the log in button at the top left of the screen. You will choose ATHN log in and use your ATHN sign on that you use when registering for the ATHN Data Summit. If you do not have an ATHN sign on or you've forgotten your password, you can follow the directions on the screen.

Once you are in the application, find the tasks in the middle of the screen and click on Community Counts Data Use Request. This will take you directly to the application.

Helpful Hints Before You Get Started:

- We recommend that you read this guide prior to completing your electronic application. There are several sections throughout where you will need to upload documents and it will be helpful to have those available when needed instead of having to stop and create them.
- You can assign collaborators to work on your electronic application with you. At the left of your application is a section for you to add collaborators. Once you enter a collaborator's email address, they will be sent an invitation to join your application. Collaborators will need an ATHN sign on as mentioned above. It's important to keep in mind that collaborators can edit and enter information but only the owner of the application can submit.
- If you have questions while completing your application, please reach out to support@athn.org.

Completing the Electronic Application:

Page One:

1. Title of the Project
   Type or paste the title of your project.
2. Initial Investigator (this is where you enter your information)
   First Name
   Last Name
   Title (your job title)

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Primary Institutional Affiliation (where you work)
Institutional Mailing Address
City
State
Zip Code
Investigator email (this is your email)
Office phone

3. Enter your HTC Number
   This is your 3-digit HTC number. You need to be associated with an HTC, ATHN, or CDC to access Community Counts data.
4. Enter your co-investigators and collaborators
   This is optional. You are provided 5 spots for this. If you have more than 5, you can list the additional names in the next box.

SAVE AND CONTINUE EDITING will save your information. NEXT will take you to the next screen/page. The page must be completed to be saved.

Page Two: Project Overview

1. Terms of Access to Restricted Community Counts Data
   All investigators, co-investigators and/or collaborators must complete the electronic Terms of Access to Restricted Community Counts Data document at https://athn.smapply.io/ prior to receipt of data. *This document only needs to be completed once every 5-year award cycle (2020-2025) and is the same document you need to complete to access CDC's DBD Gateway system.*
2. Proposed audience/journal
   Type or paste this information.
3. Background and Rationale
   Type or paste your background and rationale. This includes any preliminary data.
4. Specific Aims of the Study
   Type or paste your study aims.
5. Study Plan
   You need to upload your study plan document. Your document **must** include the following:
   a. Hypothesis
   b. Overall design (i.e. cohort study, case-control, cross-sectional)
   c. Study population (inclusion/exclusion criteria; number of available subjects)
   d. Study outcomes or other end points
   e. Other factors of interest to be included (e.g., descriptors, classifiers, risk factors, or predictors of the outcomes of interest)
   f. Statistical considerations and analysis plan (sample size, power calculations if applicable, special analyses, model equations, test statistics)

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g. Staged timeline for completion of project
   Inclusion Criteria Based on Forms Available

6. <u>Form type: HTC Population Profile</u>
   Check the box for which HTC PP records you would like:
   All records
   Most recent record
   First record

7. <u>Form type: Registry visit</u>
   Check the box for which Registry visit records you would like:
   Initial only
   All visits (initial and subsequent)
   Initial and first subsequent
   Initial and subsequent in a given year

8. <u>Other forms</u>
   Check the box if you would like other forms:
   Specimen
   Mortality
   Specimen and Mortality
   None

9. <u>Other criteria</u>
   Type or paste other criteria you would like to include or exclude in your project.

SAVE AND CONTINUE EDITING will save your information. NEXT will take you to the next screen/page. Each page must be completed to be saved.

Page Three: Data Requirements and Presentation

1. <u>Data Requirements</u>
   You need to upload your data requirements in the format of the form they will be collected. There is an example included for reference. You will want to use the Community Counts variable list included at the beginning of this document.
   If you include any variables that must be calculated or transformed (such as BMI, age), explain how that will be done.
   You need to include any additional data required that is not in Community Counts and explain how you propose to obtain those data.

2. <u>Data Presentation</u>
   You need to upload a document that shows how your final data will be presented. There is an example included in the electronic application of a table that compares the annual number of joint bleeds and soft tissue hematomas in babies with Hemophilia A broken down by severity. Please keep in mind that depending upon your analysis, your data presentation may be quite different.

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3. Resources

Type or paste what components can the investigator accomplish, such as data collection, analysis, etc.

Type or paste any components that would require assistance from CDC, such as analytical support. These requests will be evaluated based on if project resources are sufficient.

Indicate if there will be funding available to the investigator for work on this study, such as K12 Career Development Award, grant, etc.

SAVE AND CONTINUE EDITING will save your information. MARK AS COMPLETE will take you to the next screen. Each page must be completed to be saved.

Submitting the Electronic Application:

Now that you have completed your electronic application, the SUBMIT button on the left of your main application screen has changed to green. Click on the green SUBMIT. The system will confirm that you want to submit. The system will post an acknowledgment confirming that your application has been successfully submitted.

If you would like to download a copy of your submission, you can click on the 3 dots on the top right of the screen. You can do this from the main screen or from your open application.

Review and Approval:

Once a data request has been submitted, the review process will take approximately 4 to 6 weeks depending on the topic and data requested. Reviewers will evaluate the data request for feasibility from the Community Counts data availability; whether the request is scientifically sound; whether the scope of analysis is reasonable; and that there are no conflicts with existing analyses being conducted with Community Counts data. Additional approvals will be required for data requests that call for Regional or HTC-level descriptions or comparisons in which the identities of the Regions or HTCs would be known to the investigators.

The reviewer determinations may be: 1) Accepted as it, 2) Requires refinement in response to review, or 3) Requires refinement and resubmission.

Once the reviews are completed, investigators will receive an email notification with the determination and next steps.

Presentation and Publication Information:

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- Once you have obtained your data and completed your project, please keep in mind that *all publication or presentation of works using Community Counts data or describing its methodologies must be evaluated and approved prior to submission to an outside organization.*
- Presentations and publications must be submitted through our electronic system using the same directions for Accessing the Electronic Application included in this document near the beginning. You will choose the Community Counts Presentation and Publication Approval Request application.
- Submissions will be reviewed to determine that they are scientifically sound and that they meet the guidelines for authorship. Approval request must be submitted by the lead author. It is the responsibility of the lead author to see that all co-authors have already reviewed the document prior to submission for approval.
- Most reviews will take approximately 4 to 6 weeks to complete. Abstracts will be due for submission for review at least 2 weeks prior to the venue submission deadline. Abstract reviews will be expedited.
- Any presentation or publication using Community Counts and/or UDC data with CDC personnel as an author must have CDC clearance prior to the submission. Ten-fourteen days after the Community Counts Presentation and Publication Approval should be allowed for clearance of an abstract; six weeks should be allowed for clearance of a manuscript.
- The reviewer determinations may be 1) Approve as is, 2) Approve with minor revisions, or 3) Revise and resubmit. Once the reviews are completed, investigators will receive an email notification with the determination and next steps.

Requirement for Manuscripts Using Community Counts Data to be Submitted to NIHMS for Inclusion in PubMed Central

Requestor agrees to:

i.   Upon acceptance for publication, submit the version accepted for publication into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system.
ii. Proof the peer-reviewed, accepted manuscript to ensure no errors were made during the conversion in NIHMS.
iii. If the author's meaning was altered during the proofing phase, ensure corrections are made to the manuscript before posting it to PubMed Central (PMC). Grammatical, formatting, readability, or copy-editing changes that do not alter the meaning of the article are not mandatory.

If there is a CDC author on the manuscript, the CDC author is responsible for doing this.

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Acknowledgement and Disclaimer:

All publications must include the following language:

Community Counts is a project supported by cooperative agreement NU27DD000020 awarded to the American Thrombosis and Hemostasis Network (ATHN) in partnership with the U.S. Hemophilia Treatment Center Network (USHTCN). The cooperative agreement is an annual financial assistance award totaling $4,171,000 which is 100% funded by the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services (HHS). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the CDC, the Department of Health and Human Services, ATHN, or the USHTCN. Data reported in this publication were collected through Community Counts: CDC Public Health Surveillance Project For Bleeding Disorders.

If you have any questions, please contact support@athn.org and include "Community Counts Data Use" in the Subject line of your email.