



Research and Publications Policy

March 2024

TABLE OF CONTENTS

TABLE OF CONTENTS	1
OVERVIEW	2
DATA HUB PROGRAMS	2
Use and Disclosure of Protected Health Information	3
RESEARCH AND ANALYTICS	3
ROLES AND RESPONSIBILITIES	5
Principal Investigator	5
Collaborating Authors	6
Data Hub Oversight Group and Subcommittees	Error! Bookmark not defined.
PROCEDURES	7
Publication Development	7
Data Access Fees	8
Exceptions and Special Circumstances	8
BIBLIOGRAPHY	9
APPENDIX A	10
A. REQUEST DATE AND TYPE	10
B. REQUESTER INFORMATION	10
C. OBJECTIVES	11
D. SCOPE	11
E. ANALYSIS	11
F. FUNDING	11
G. ATTACHMENTS	11
H. INTENT TO PUBLISH (IF APPLICABLE)	12

OVERVIEW

This document outlines the Research and Publications Policy for the ASH Research Collaborative (ASH RC) Data Hub that involve using Data Hub data for scientific publications including abstracts and manuscripts, oral and poster presentations, letters to the editor, meeting proceedings and reviews, and any form of presentation format other than use for internal purposes only.

Aggregated data derived from the Data Hub or information related to study design or Data Hub operations are the collective intellectual property of ASH RC, not those of any individual investigator, collaborating investigator, or study sponsors from industry.

The Data Hub Oversight Group (DHOG) is responsible for the development of policies and procedures regarding the ethical and secure use of Data Hub data, overseeing the review and approval of requests for use of Data Hub data, and ensuring Data Hub data are presented accurately in publications.

The underlying motivation of this Research and Publications Policy is to ensure rigorous and high-quality research to generate generalizable knowledge available to the public. Additionally, it is important that the Data Hub is informed of Data Hub research and publication activities in order to provide appropriate review and oversight. This process is not intended to prolong the publication process for investigators, nor is it intended to burden volunteer leadership and Data Hub staff with unnecessary reviews.

Review and oversight may also facilitate opportunities for involving other potential collaborators in research activities, avoiding duplication of analyses, and recognizing limitations within the Data Hub that are identified by investigators, analysts, and statisticians performing analyses.

DATA HUB PROGRAMS

The ASH RC Data Hub was created to facilitate the sharing of data on hematologic conditions to support scientific inquiry and discovery. As a major initiative within ASH RC, the Data Hub aims to create the largest shared information resource within the global hematology community.

The Data Hub is currently collecting data on:

- sickle cell disease, and
- multiple myeloma.

The long-term goal of the ASH RC is to address the entire spectrum of malignant and non-malignant hematologic diseases and plans for expansion of scope are underway.

Use and Disclosure of Protected Health Information

The Data Hub collects protected health information (PHI) as defined by the regulations issued under the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), through its outside database vendor. The Data Hub only shares de-identified and/or aggregate data with approved parties that enter into a contractual agreement with the ASH RC.

RESEARCH AND ANALYTICS

As part of its mission, the Data Hub encourages the submission of research and analytic requests. Proposals are expected to come from individual researchers and organizations interested in improving the care of patients with hematologic disease by analyzing Data Hub data and publishing the results in peer-reviewed journals. All requests for data access for research and/or analytic purposes must be submitted through the ASH RC Data Hub Research and Analytics Request process.

1. Individuals requesting data access are required to disclose their [Conflict of Interest](#).
2. Reviewers will consider the following evaluative criteria for all formal requests for data access:
 - a. Goal of the study or data analysis and its alignment with the ASH RC’s mission, vision and values,
 - b. Avoidance of potential conflicts of interest;
 - c. The scientific merit of the study or analysis and its proposed methods;
 - d. Feasibility of study based on available data elements required and the timeline;
 - e. Accurate representation of Data Hub data, including methodology used to conduct the analysis in the context of the hypothesis and analytic request;
 - f. The resources required to fulfill the request;
 - g. Any legal, regulatory, or ethical issues raised by the request.

Use of Data Hub Data is limited to the purpose specified within Research and Analytics Request Form. Recipients are prohibited from using or disclosing Data Hub data for a purpose not specified in the approved request for data access. Data Hub data may not be re-used for a similar future purpose (e.g., a follow-up study or analysis) without approval of the ASH RC. Data Hub data may also not be shared with any other parties without the prior written consent of the DH unless it is in aggregate form (i.e., does not identify specific patients, providers, or facilities). Data recipients specifically shall not use Data Hub data for any commercial purpose.

Recipients of Data Hub data must acknowledge that the Data are private and confidential, and that unauthorized use is a violation of the terms of this Research and Publications Policy and may subject the recipient and its employees to legal sanctions and termination of use of the Data Hub data.

When requesting ad-hoc analytics or data for cohort development, these outputs are to be used for **internal purposes only** and cannot be made public (e.g., no abstracts, manuscripts, marketing materials, etc.).

The [Research and Analytics Request Form](#) is included as Appendix C and should be completed by each requestor.

ASH RC leadership or a designated reviewer may provide initial review of the study proposal before a recommendation is made to proceed for formal review. **This is not anticipated to be an onerous or detailed process, though it is essential to ensure study concepts non-duplicative of existing or recent projects and meet a basic feasibility assessment in order to proceed.**

Proposals will be evaluated for the following:

- **Significance** (original/important contribution to the field)
- **Feasibility** (can be done with the current data, with manuscript submission within three months of proposal approval or abstract submission, whichever comes last).
- **Methodology** (are appropriate for observational research, describe association, and do not imply causation)
- **Study Design**
- **Analysis Plan** (should be well developed)

Rule Out Overlap

A listing of publications using Data Hub data and active research projects will be maintained by the Data Hub and made available to investigators to assess if topics have been previously researched.

In cases of potential overlap, the submitter may be contacted for further discussion and resolution; resolution may involve collaboration/co-authorship on an existing study concept. If a study concept is not approved or is conditionally approved, the submitter has the option to submit a revised study concept one additional time.

One Project Per Request Form

A Request Form is intended for a single manuscript or other form of public dissemination. Development of a manuscript may include an initial abstract. If additional manuscripts are envisioned, an additional Request Form is required and subject to the same review process.

The Rule of Two

The Data Hub encourages broad use of its data for research and has a philosophy of inclusion and equitable access to all researchers. The “Rule of Two” supports this philosophy and allows a principal investigator to have up to two active Data Hub research projects at the same time. An active project is one that has been approved by the Data Hub and has not yet resulted in submission to a peer-reviewed journal.

Direct Comparisons of Medical Products

Proposals that include direct comparisons require special review and warrant further discussions.

ROLES AND RESPONSIBILITIES

Principal Investigator

Once a proposal has been approved by the delegated ASH RC Data Hub group, the **principal investigator** (also referred to as the first author) is generally the person who takes a central role in the analysis and interpretation of results and writes the first draft of the manuscript.

The principal investigator is responsible for:

1. Ensuring the integrity of the work from conception to published abstract, manuscript or other public dissemination of the findings.
2. Establishing and communicating with co-authors and statisticians the timeline expectations for completion of the manuscript.
3. Determining appropriate listing of co-authors. In determining who to list as co-authors, the primary author should consider individuals involved in:
 - a. Proposal concept and design
 - b. Content writing
 - c. Data analysis and/or interpretation
 - d. Literature search
 - e. Critical review

The authors and contributors:

The role of authors and contributors is defined based on the contributions made and in accordance with the standards outlined within the International Committee of Medical Journal Editors ([ICJME](#)) and therefore must satisfy all of the following ICJME authorship criteria:

- Substantial contributions to conception or design of the work; or acquisition, analysis, or interpretation of the data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND

- 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.
- 4. Ensure all co-authors receive and review the most current version of this document.
- 5. Obtain from all co-authors review and approval of manuscript, presentation and/or abstract or other document drafts prior to submitting to Data Hub for final review, which is before submission for publication or presentation.
- 6. Create an “Acknowledgements” section in the manuscript, if needed. Since Data Hub does not permit inclusion of ‘honorary’ authors as co-authors, the principal investigator may consider including an acknowledgements section to cite contributors who do not meet the criteria for authorship, but whose assistance the authors would like to acknowledge. Examples of those who might be cited in a listing of acknowledgements include:
 - a. A person who provided purely technical help or writing assistance.
 - b. A mentor who provided only general support.
 - c. Colleagues, reviewers, and staff who do not qualify as authors.
 - d. Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship.
- 7. If a project team does not complete its work on an analysis, the Data Hub may reassign the roles of first author and collaborating investigator(s) to other individuals.
- 8. It is the responsibility of first authors to submit any accepted papers to the digital archives PubMed Central upon acceptance for publication, or in accordance with specific journal requirements.

Collaborating Authors

- The **senior author** is generally the person who provides overall supervision for the project.
- The **biostatistician**’s role and prominence in the author list is determined by the amount of data analysis performed.
- Other authors must be able to take full responsibility for the results and publication, and are involved in analysis design, interpretation, and writing, as defined by [ICJME](#).

Committee Members

It is allowable to include member(s) from the disease-specific ASH RC committees if they fulfill criteria for authorship. This may include, but is not limited to, contributions to the study design, analysis, interpretation and critical input into abstracts or manuscripts.

The reviewing ASH RC committee may suggest additional authors to the study team who could participate as collaborating investigators, depending on the study and type of expertise that may benefit the analysis or interpretation of the data.

PROCEDURES

Publication Development

The publication process begins with the Research and Analytics Request Form that describes the proposed analysis. The first author is notified when the proposal is submitted to the Data Hub and approved by the relevant review committee as a Data Hub-sponsored project. Other potential collaborating investigators may be suggested by the review committee. Subsequent steps including protocol development (when applicable), analysis, interpretation, and abstract or manuscript preparation are spearheaded by the first author and collaborating investigators. If a project team does not complete its work on an analysis, the DHOG or disease-specific subcommittee may reassign the roles of first author and collaborating investigator(s) to other individuals.

A listing of submitted Research and Analytics Request Forms will be maintained by the Data Hub and can be checked in advance to help investigators determine available topics. A list of published manuscripts and abstracts will also be maintained and available on www.ashrc.org.

- **Authorship order:** The person who submits the proposal generally assumes first authorship of the proposed manuscript or presentation, assuming s/he fulfills all the requirements for first authorship. Middle authors will be listed in the order of their contributions, considering involvement in protocol development and study oversight, contributions to data analysis and interpretation, and importance of comments on the abstract or paper. It will be up to the first and senior authors, in consultation with the review committee, to decide the author list and order after all contributions are considered. The composition and author positions on an abstract and the resulting paper may differ.
- **Confidentiality:** All people reviewing materials prior to submission and publication agree to treat the contents as confidential.
- **Conflicts:** Conflict of interest disclosures for all authors must be checked and disclosed for any publication. Investigators who perceive inequities in authorship or other problems relating to authorship should discuss these concerns with the Data Hub; if the difficulty cannot be settled in an informal manner, the concerned investigator should submit a letter to the Data Hub designee outlining the problem. A formal written reply will be made to the investigator.
- **Manuscript and abstract approval:** Manuscript or abstract content and format must meet accepted scientific standards. The first authors will choose the appropriate journal or meeting for submission of manuscripts or abstracts, in collaboration with co-authors and the review committee.

The ASH RC must be appropriately acknowledged within all submitted publications including manuscripts or abstracts and any other form of publication, as follows:

“The ASH Research Collaborative provided data (and if applicable, biostatistical support) for this analysis. The views expressed in this publication are solely of the authors and do not represent the opinion of the ASH Research Collaborative or the American Society of Hematology.”

ASH RC Review

The ASH RC will be given a minimum of two (2) weeks to review abstracts and presentations and four (4) weeks to review manuscripts, white pages, reports, or other content heavy documents. This period may vary depending on specific circumstances. Upon acceptance, the lead author will be notified.

- **Poster and presentation approval:** The Data Hub will be given up two (2) weeks to review and comment on poster and PowerPoint presentations. All posters and presentations should follow the ASH RC Brand and Style Guide, which will be provided upon proposal approval.
- **Other Published Materials:** Publications for other audiences such as news media, press releases, the web, and other public information sources must be reviewed and approved by the DHOG and the disease-specific subcommittee.

Data Access Fees

The Data Hub reserves the right to charge a fee to access to Data Hub data to cover the reasonable costs of preparing and transmitting the data to a requesting individual or entity, if approved.

Exceptions and Special Circumstances

This policy is intended to serve as a guide to all interested parties on the access and use of Data Hub data. Any requests for consideration of special circumstances or exceptions to the stated policies must be presented to the ASH RC, which will have final determination on data access and use in each case.

BIBLIOGRAPHY

These policies and procedures have been guided by statements from the International Committee of Medical Journal Editors (www.icmje.org) as well as other research consortia.

This Research and Publications Policy will be reviewed by the ASH RC annually and revised as deemed necessary.

Appendix A

ASH RC Data Hub

Research and Analytics Request Form

Please complete all fields below and submit to info@ashrc.org

ASH Research Collaborative Data Hub data may be requested for:

- **RESEARCH STUDY**
 - All research studies must lead to a submission for publication.
 - All sections of this form are **required**.
- **CUSTOM ANALYTICS**
 - Ad-hoc analytics and cohort development are for internal purposes only (e.g., no public-facing materials).
 - Sections A – F are required.

+++++

A. Request Date and Type

Request Date: Click or tap to enter a date.

Request Type: Choose an item.

B. Requester Information

Requester Name: Click or tap here to enter text.

ASH Member: Choose an item.

Organization: Click or tap here to enter text.

Department: Click or tap here to enter text.

Address: Click or tap here to enter text.

City: Click or tap here to enter text.

State: Click or tap here to enter text.

Zip Code: Click or tap here to enter text.

Country: Click or tap here to enter text.

Telephone Number: Click or tap here to enter text.

E-mail Address: Click or tap here to enter text.

If you are currently a student or early career researcher and/or analyst, please include the name of your mentor: Click or tap here to enter text.

C. Objectives

Title: Click or tap here to enter text.

Background/Significance: Click or tap here to enter text.

Question to be Addressed: Click or tap here to enter text.

Hypothesis (research studies only): Click or tap here to enter text.

My application focuses on reporting health disparities by race and/or ethnicity?

Click or tap here to enter text.

D. Scope

Data Hub Program: Choose an item.

Specific Disease or Condition of Interest: Click or tap here to enter text.

Inclusion Criteria: Click or tap here to enter text.

Exclusion Criteria: Click or tap here to enter text.

Primary Clinical Endpoint(s) (if applicable): Click or tap here to enter text.

Secondary Clinical Endpoint(s) (if applicable): Click or tap here to enter text.

Key Covariates: Click or tap here to enter text.

Time-Period (data available from 2015 and after): Click or tap to enter a date.

E. Analysis

Intended Tables, Figures, and/or Summary Statistics: Click or tap here to enter text.

A text description of the tables or table shells are acceptable. When sending table shells, please attach as a separate Excel spreadsheet.

Statistical Analysis Plan, Including the Estimated Study Sample Size (please note that all analyses will be performed through the ASH RC): Click or tap here to enter text.

F. Funding

Indicate the funding source for this request: Choose an item.

Click or tap here to enter text.

+++++++The following section is required for hypothesis driven research requests. +++++++

G. Attachments

Include the following with your request:

- A complete Conflict of Interest Disclosure is **required**.
Is your [Conflict of Interest Disclosure](#) complete and current? Choose an item.

- [CV or biosketch, including list of publications](#)

H. Intent to Publish (if applicable)

Potential Author List:

- First Author Name and Credentials: Click or tap here to enter text.
- Institution: Click or tap here to enter text.
- Anticipated Collaborating Author Name(s) and Credentials: Click or tap here to enter text.
- Institution(s): Click or tap here to enter text.

Publications resulting from research conducted using Data Hub data must include the following acknowledgement and disclaimer language:

“The ASH Research Collaborative provided data (and if applicable, biostatistical support) for this analysis. The views expressed in this publication are solely of the authors and do not represent the opinion of the ASH Research Collaborative or the American Society of Hematology.” ASH RC reserves the right to modify this language.

FOR ASH RC STAFF ONLY

Request received on: Click or tap to enter a date.

Number assignment: Choose an item. - Click or tap here to enter text.

(Example format SCD-001)

Reviewer assignment: - Click or tap here to enter text.

Reviewer recommendations: - Click or tap here to enter text.



I attest that I have reviewed and agree to comply with the ASH Research Collaborative Research and Publication Policy.

Signature

Date