



Multi-site Closeout Guide

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The CCSN Mission

Our mission is to foster a sustainable, shared research infrastructure to enhance collaborative multi-site clinical research in order to improve health care for our plan members, our communities, and our nation. The CCSN is committed to the principles of transparency, flexibility, innovation, and discovery.

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If you have comments or suggestions please contact Ella Thompson, Group Health Research Institute, 1730 Minor Avenue, Suite 1600, Seattle, WA 98101 thompson.e@ghc.org or 206.442.5211

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INTRODUCTION AND PURPOSE OF THIS GUIDE

Project closeout is the administrative and scientific completion of a research project with attention to final participant contact (if applicable), finalizing of datasets, data archiving and destruction plans, and administrative considerations.

This guide was developed by members of the HMO Research Network to assist with multi-site study closeout. It is not intended to duplicate or replace funding agency or institutional requirements and procedures. Rather, we provide here a detailed discussion of those topics most relevant to multi-site studies and address the needs of different types of data collection. That is, those using primary data collection from volunteers and studies based solely on automated medical records.

Careful thought needs to occur long before the end of the study as to how to best set up systems and documentation for study closeout. This guide provides checklists and spreadsheets that staff can use as templates for their closeout process. The materials are meant to be used as a starting point or reference with the understanding that each study will have its own challenges and nuances. Please feel free to adapt the materials to your individual needs.

SPECIAL CONSIDERATIONS FOR MULTI-SITE STUDIES

A Steering Committee or Advisory Group which includes members from all study sites should have the responsibility for managing and overseeing all phases of the study. In this way all sites are invested, can give input, and a clear path of communication to each site is established and maintained. Project closeout should be one of the tasks of the Steering Committee. The group needs to delegate an individual, from the outset, who will create and monitor the timeline and process for addressing closeout-related issues. As with all studies, but especially for multi-site studies, including closeout considerations in initial project planning will make the project run smoother.

Importance of developing procedures

Multi-site data studies pose a number of unique project closeout problems that need to be addressed. The participating sites' requirements and desires should be considered in the process of defining closeout procedures. Multi-site studies typically have some data residing within local environments at the individual sites (e.g., source files and documentation) and additional data stored at the primary site for analyses. The prime site has primary responsibility for implementing project closeout procedures, including archiving, establishing clear guidelines for data access and storage, authorship, and additional analyses.

The checklist that follows can be used to help guide discussion about assigning responsibility.

Table 1. Closeout Responsibility Checklist Template*

TASK	RESPONSIBLE PARTY		NOTES
	PRIME	SUBS	
<input type="checkbox"/> Closeout considerations discussed at study outset			
<input type="checkbox"/> Closeout meeting held			Typically led by prime site or administrative core
<input type="checkbox"/> Financial and institution-specific requirements complete			
<input type="checkbox"/> Study documents file complete			Typically responsibility of prime site or coordinating center/core
<input type="checkbox"/> Data documentation and files in order			Note owner(s), location(s), retention and access information
<input type="checkbox"/> Planned manuscripts and other dissemination in progress and tracked			
<input type="checkbox"/> Final report sent to IRB and sponsor			Prime site and subs will have different requirements
For primary data collection from human subjects...			
<input type="checkbox"/> Consent/authorization forms are filed			
<input type="checkbox"/> If drugs are used, dispensing forms are complete and remaining drugs have been returned/destroyed			

* Based on Woodin and Schneider 2003

PLANNING FOR CLOSEOUT

A study is ready for closeout when

- the scope of work is complete,
- the study is terminated due to problems, or
- a clearly and previously defined phase is completed in studies with multiple assessments; for example, after an initial assessment in a long-term follow-up study.

Certain closeout topics warrant attention at the very beginning of the study. These are much easier to incorporate into initial procedures than to add on later. Additionally, partnerships with operational leaders from the beginning will help improve the opportunity to have the results obtained from the research implemented in clinical practice. Below are advantages to addressing closeout issues at an early stage in planning.

- Ensures responsibility for tasks is clear and nothing falls through the cracks, thereby increasing efficiency and compliance.
- Minimizes length of closeout period; this is essential for maximizing limited funding available per site for multi-site studies.
- Improves data quality.
- Allows efficient access to data and documents if needed for any reason (e.g., audit, manuscript revisions, additional analyses, or development of new grant submissions).

Topics to discuss early in the lifecycle of a project might include:

- Intellectual property.
- Authorship and presentation policies.
- Likelihood of auxiliary studies.
- Likelihood of producing public use datasets.
- Potential for integrating findings into clinical practice.

FINANCIAL AND INSTITUTIONAL REQUIREMENTS

Each institution should ensure the study is closed out according to their requirements. These include financial, IRB, staffing and other considerations. For multi-site studies it is especially important that the prime site understands the specific requirements of each participating site.

In addition, the prime site or administrative core has the responsibility to communicate information regarding any information it needs to closeout the project with the sponsor as well as notifying sub-recipients of no-cost extensions.

STUDY DOCUMENT AND RECORD RETENTION

Study documentation will be different depending on the type of study, who funded it, and the policies of individual institutions. The following are general guidelines.

Study Materials

All investigators should have a copy of, or web-based access to, the following study materials:

- The final study protocol (including the analytic plan).
- Study instruments.
- Data tables.

Study files, including such things as study consents, IRB submissions and approvals, protocols, reports, and financial information should be retained for a minimum of three years, per OMB circular A-110, which states that,

"Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency.."

Study files related to FDA regulated clinical trials must be retained for at least two years after notification from the sponsor that the drug/device has been approved for the indication that was investigated or it is determined that development has been discontinued. These files should be kept for a longer period if indicated by contract. (ICH Guidelines 4.9.5).

Studies must retain HIPAA-related documentation, as required by 45CFR164.316, for 6 years from the date of its creation or the date when it last was in effect, whichever is later. This would include such things as IRB-issued HIPAA waivers, signed authorization forms, business associate agreements, and so on.

Table 2. Grid of document closeout responsibilities and retention periods

TYPE OF DATA	WHO HAS A COPY	WHERE ORIGINAL RESIDES	RETENTION PERIOD
Report of Project Status: A record of project summaries or evaluations prepared during the course of a study or at the end of a funding period.	PI-individual sites	Prime	3 years after study termination if research is not grant/contract funded; transfer to Archives for review
Research Data -- Exempt from Human Subjects Review:	PI-individual sites	HS office-individual sites	Check requirements for individual sites.
HIPAA Related Documentation	PI-individual sites	Individual site	6 years from the date of its creation or the date when it last was in effect, whichever is later.
Human Subjects Review Committee Applications -- Approved	PI-individual sites	HS office-individual sites	Check requirements for individual sites.
Financial Records	Typically, Project Coordinator at each site	Typically, Grants and Contracts office at each site	Minimum of 3 years, per OMB Circular A-110.
Data Analysis Files	Depends	Depends	Determined according to analysis and writing plans and data protection protocols. See Data Retention Section for more details.

The CCSN website is an option for storing shared documents. Access to each document is granted to a specific set of users.

ORGANIZING DATA DOCUMENTATION AND FILES

The guiding principle of good programming documentation is that project investigators should be able to recreate final analyses without difficulty. This is regardless of whether the source data were stored centrally or locally at the participating sites. Understanding the data process from beginning to end should be simple and everything needed to understand the process should be in one place.

The first step towards organizing data for closeout is establishing and following a protocol to ensure that analyses are complete and that any study files are complete before closeout. Especially when data collection is decentralized, auditing procedures should be established and the appropriate de-identification procedures should be implemented.

Any dataset used to generate the final analytic files (intermediate datasets) should be retained until scheduled destruction. Final datasets should be clearly designated by name and described in a separate document; for example, with a printed PROC CONTENTS if using SAS.

Data documentation should specify every step of the data creation and analytic process, including the location of all project datasets, who has access to the data, relevant local contacts for data access, storage procedures, and the location of relevant programs and related output. This documentation should be stored centrally and available to all investigators.

Often in multi-site studies, instructions or code will be sent from one site to others to guide programming and analyses (often referred to as workplans). The prime site and all participating sites should:

- Retain all workplans and programs.
- Keep all final versions and all related output returned by sites.
- Include a header with information such as the programmer, dates, datasets used, and output generated on all final programs.

The final programs should be fully annotated to allow a different programmer to understand the steps taken in the programming. If the output from a program is used to create specific tables in a report or publication, it should be noted in the program (e.g., this program generates the data for Table 4 of the XXX manuscript). Some of the descriptive detail in the programs can't be done until the end of the project.

The analyst(s) should create a final program documentation and flowchart document that lays out the process used to create the final results. Often analyses involve multiple steps, programs and datasets - all of which should be clearly described to show how the project proceeded from raw data to the final results tables in a publication/report.

If public use datasets are created, both internal and external documentation may be required.

Documented data destruction procedures must describe who will oversee the process and who will destroy files. The procedures set up for each study must be carefully followed.

Table 3. Data Retention Workplan: Template

	WHO IS RESPONSIBLE	SENT TO SHARED FILE YES/NO & WHERE	WHERE STORED? COMPUTER & HARDCOPIES	FILE NAME	DATE TO DESTROY	COMPLETED YES/NO
Regulatory Files (IRB), HIPAA						
IRB applications						
Continuation Reports						
Subject Research Files*						
Study Protocol and Related Docs						
Questionnaires						
Data Dictionary						
Analysis Plan						
Final Data Set Files and documentation						

*If the study involves an Investigational New Drug, or if the trial may be used in support of a licensing application to the FDA, all records pertaining to the trial must be maintained for the longer of:

- 1) two years after the FDA approves the marketing application in the last country seeking approval, or
- 2) two years after FDA notification that a trial has been discontinued at all sites.

Studies for which a signed HIPAA authorization to use or disclose protected health information is obtained must be retained for minimum of six years.

MANUSCRIPTS AND OTHER DISSEMINATION

Typically, a project's steering committee or executive committee oversees the manuscript writing process or assigns a subcommittee. The committee brainstorms or solicits ideas for manuscripts and oversees and tracks the designation of lead and co-authors. Publication committees should make an effort to ensure that all key contributors join writing groups, especially if they are junior investigators.

The publication committee or central staff should maintain a log of manuscripts in progress or published, including status and authors.

The CCSN website is an option for storing shared documents.

NIH Public Access Policy

The National Institutes of Health (NIH) Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research (Public Access Policy), which took effect on May 2, 2005, requests and strongly encourages all investigators to make their NIH-funded peer-reviewed, author's final manuscript available to other researchers and the public through the NIH National Library of Medicine's (NLM) [PubMed Central](#) (PMC) immediately after the final date of journal publication. The NIH has developed a password-protected, Web-based, [NIH Manuscript Submission](#) (NIHMS) system to implement the NIH Public Access Policy. Submitting a publication through this system fulfills the grant requirement that all NIH-funded manuscripts be submitted to NIH.

Integrating Research and Practice

Hopefully, operational leaders of health care delivery systems and/or health plans have been involved as partners from the beginning of the research and are ready to implement lessons learned. If not, developing such partnerships should be a priority. This could be accomplished, for example, via presentations to operational leaders and clinicians (if applicable) within your organization and community.

IRB AND RESEARCH REVIEW

Final human subjects, Data Safety Monitoring Board (DSMB) and sponsor reports should be submitted by the prime site. Sub-recipients should furnish any requested information to the prime site and comply with institutional requirements.

SPECIAL CONSIDERATIONS FOR STUDIES INVOLVING PRIMARY DATA

Participant Communication

Plan a final communication for studies where participants have repeated contact with study staff (e.g., a thank you letter). Discuss up-front if volunteers will be notified of study findings. If so, how will they be notified and by whom? Options include:

- personalized letter,
- generic letter with preliminary results in lay language, and
- copy of eventual published articles.

Also, make sure to discuss early on whether participants or providers will be notified of the original randomization assignment or continuing treatment options. If so, determine when and by whom they will be notified.

UNUSUAL BUT IMPORTANT SITUATIONS

There are situations which either cause early closeout or require a closed-out study to be reopened. Should one of these situations occur, careful consultation with IRB and other compliance expert sites and affected sites is recommended. However, with successful planning and archiving, a study team will be reasonably well prepared for unusual scenarios, regardless of whether final data and documentation are retained entirely by the lead site or not.

Early Closeout

Early closeout can happen if a study is terminated early due to a safety or efficacy problem.

After studies are closed, they may be reopened for various reasons. Study information can be required to be shared subject to a Freedom of Information Act request. Also, new research questions or findings may arise that warrant secondary data analysis or even recontacting a study cohort. The possibility of reopening a study depends on its consent and confidentiality procedures. If investigators think that secondary or other future analyses are likely for a research study, they should give careful thought to procedures that enable this at the outset. Maintaining careful records of data destruction dates and study procedures will allow the study team to determine feasibility of secondary data analysis and recontacting the cohort. Take note of relevant state privacy laws (see the CCSN website for more information).

Commercial Products

If the research study has the potential to yield a commercial product, it is essential that the research team agree, ideally at the contracting stage of the project, on terms for intellectual property and technology transfer.

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ADDITIONAL RESOURCES

De-identifying Protected Health Information Under the Privacy Rule

Covered entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. Covered entities seeking to release this health information must determine that the information has been de-identified using either statistical verification of de-identification or by removing certain pieces of information from each record as specified in the Rule.

The Privacy Rule allows a covered entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members; these elements are enumerated in the Privacy Rule. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
 - a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
 - b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.

11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Covered entities may also use statistical methods to establish de-identification instead of removing all 18 identifiers. The covered entity may obtain certification by "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable" that there is a "very small" risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information. The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination. A covered entity is required to keep such certification, in written or electronic format, for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

References:

U.S. Department of Health and Human Services, National Institute of Health, HIPAA Privacy Rule Information for Researchers. <http://privacyruleandresearch.nih.gov>

Data documentation: Documentation and archiving for research projects conducted by the Pharmacoepidemiology Group, DACP, Harvard

Data Documentation

DACP : Guidelines for Documentation and Archiving of Research Projects

Developed by the DACP Pharmacoepidemiology Group and the HMORN CERT Data Coordinating Center, Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, Boston, MA

Prepared by K. Arnold Chan

Updated by Michelle Platt, Jim Livingston, and Jeff Brown

Last Updated: October 2006

I. General information

The purpose of this document is to describe the required documentation procedure within the DACP Pharmacoepidemiology Group. Proper documentation is an essential component of good research practice. Consolidation of the related documents in a single project folder or binder and under one project directory facilitates communication between investigators, programmers/ analysts, and research assistants.

Although the level of documentation detail is not specified, a general guideline is that someone without any knowledge of the study, who is reasonably knowledgeable in epidemiology, HMO claims, and SAS, can reconstruct the major findings of the study with the archived information.

Documentation is an ongoing process that is most efficiently done along with the progress of the study. The process starts before data are queried or collected. At the end of each project, the project notebook should contain all major paper documents for project archival, and all relevant electronic information should be stored under the project directory. Should a project be audited by a funding agency, the project notebook and the computer archive will serve as the focal points of the audit.

The following sections describe the general structure and content of the project notebook and the project directory. This is a guideline and it is anticipated that the investigator will work with the programmer/ analysts and research assistants of each project to prepare the documentation. The research team should feel free to modify the structure of the notebook and/or the directory for specific projects.

An ancillary study based on an existing study should have its own project notebook and its own subdirectory under the project directory of the existing project.

For each project, a member of the study team should be designated to be in charge of documentation. That person could be an investigator, a programmer/ analyst, or a research assistant, who will coordinate documentation activities within the study team.

The investigator has the ultimate responsibility to ensure that documentation is done in a timely manner.

II. Project Notebook

The project notebook is a binder or a folder for paper documents. Each paper document in the notebook should have a corresponding electronic version. Key paper documents without an electronic version (e.g. IRB approval letter and signature pages) should be scanned, and the scanned image should be stored under the appropriate project directory. The title and project number should appear on the outside of the binder or folder and on the first page of the notebook.

The notebook should contain the following:

1. Printed version of the approved protocol and the subsequent revisions.

Drafts of the protocol should not be included in the binder, but the electronic versions, along with the communication with co-investigators, should be stored under the subdirectory /PROTOCOL.

2. Contract or subcontract, IRB approvals, and amendments.

The electronic version should be stored under the subdirectory /DOCUMENT.

3. Project team contact list.

A list of e-mail addresses, telephone numbers, and fax numbers of study personnel, including contacts at each participating site of multi-site studies should be included. Change in study personnel should be updated. The electronic version should be stored under the subdirectory /DOCUMENT.

4. Workplan and analysis plan.

The final analytic plan and all distributed or utilized data development workplans and data requests should be included in this section. A file describing details of the programming steps also should be included. Subsequent discussions and clarifications of do not need to be printed, but should be stored under the subdirectory /WORKPLAN. The final documentation should be clearly specified in the file names.

5. Timeline and milestones.

A projected timeline should be prepared at the onset of the study, and revised accordingly.

Timing of key events should be recorded. Key events include the contracting date, the date of the data request, the delivery date of datasets, date of interim report(s), the date that the analytic file is locked, date of log SAS output, date medical records were retrieved (if there were records used in the study), and the date that the manuscript is submitted for publication. These dates should be stored under the subdirectory /DOCUMENT with the file name KEY_EVENTS.

6. Blank data forms / abstract forms, surveys, tools used for research purposes, and manual of operations.

All relevant forms should be included in the binder and the electronic versions should be stored under the subdirectory /FORMS.

7. Contents of project subdirectories.

A list of all files in each subdirectory should be put under this section. Include a printout of the readme.txt file under each directory, which briefly describes each file under that directory. There is no need to print each SAS program, but there should be adequate comments in each program to describe the programming steps.

8. Dataset documents.

PROC CONTENTS output of all production SAS datasets along with a sample printout of the data (no PHI) should be included. Data dictionaries, documentation of file structures (e.g., an ASCII file), format libraries and lookup tables also should be included.

9. Analysis results (in *.saslog or .tab format).

All analytic results should be either printed for inclusion in this section or described with a reference to the location of the electronic version. All program logs should be included.

10. Study report.

Interim and final reports to the sponsor, and manuscripts submitted for publication are stored under this section. The electronic version should be stored under the subdirectory /REPORT.

11. Other documents.

Important e-mails, faxes, notes, or any other documents pertaining to the project that were not stored under the previous sections. The electronic version should be stored under the subdirectory /DOCUMENTS.

12. Manuscripts and reprints.

Any submitted/ published manuscripts should be archived. Tables and reported data in the manuscripts should be annotated to a specific page of SAS output or a spreadsheet. A publisher's reprint can supplement the final manuscript document.

The project number, protocol, contract with the funding agency, IRB approval letter(s), protocol amendment, interim report(s), and the final report are minimal requirements for the project notebook.

For a small-scale single-institution study, a folder that holds all these documents will serve the purpose. Documentation for other studies will best be implemented with a binder.

III. Project directory

In general, there are three types of files: data files (SAS, ASCII, spreadsheet or dbf format), SAS programs, and documents (in word processor or scanned image format). All electronic files should be stored under the project directory of the Pharmacoepidemiology Group folder for project archival. In general, a project directory would have the following subdirectory.

/PROTOCOL	protocol and amendments
/DOCUMENT	contract, IRB approval, signature page, personnel contact information, and record for key events
/WORKPLAN	workplan and analysis plan
/FORMS	data forms and manual of operation
/DATA	data files (for multi-site studies, create subdirectory for each site) *Spreadsheet linking figures/reported data to final reports/manuscripts.
/PROGRAM	SAS programs to create analytic files
/ANALYSIS	SAS programs for data analysis For projects with more than one manuscript, a separate subdirectory may be created for each manuscript.
/REPORT	reports and manuscripts; interim reports are stored under separate subdirectories /INTERIM1, /INTERIM2, etc.

Include a README.TXT file under each directory and subdirectory that briefly describes the files under that directory. The README file should be updated periodically, and whenever the actual project location or layout is modified.

IV. Project archive

At the conclusion of the study, the project directory should be purged of preliminary versions of analysis programs and datasets. The final, production versions (often in .zip format) may be left in place, so that the project directory itself serves as the project archive.

Alternatively, if data storage policy should require offline archiving of completed projects, the entire project directory may be written to external electronic media (which for present technology includes tape cassettes, tape cartridges, CD-ROMs, or DVDs).

Ideally, the project notebook will contain a copy of the external medium, so that the entire project can be restored on-line when necessary. Project notebooks will be kept indefinitely, either locally, or at a remote storage location with assured retrieval service.

V. CERT-CRN Website

For applicable projects, namely the CERT studies, project documentation should be posted to the CRN web site. The goal of this site is to facilitate collaborative project management.

Concurrently, the CERT-CRN web site will function as a location to collect necessary documentation from each HMO for the archival process. No PHI or any sensitive information may be posted on this site. Transmission of this type of materials must be coordinated between study teams and the individual who is preparing the overall project documentation.

Access to this site must be approved and granted by Gary Ansell (gary.ansell@kpchr.org).

The link to the web site is: <https://www.kpchr.org/CRN2/system/login.aspx>

The individual who is placed in charge of managing the CERT projects on the website will have to undergo specific training for that purpose. The CERT-CRN web site is meant only to be a supplement to the in-house archiving at the DACP. Complete CERT archives will remain a DACP responsibility. . This multicenter site is in no way intended to serve as the sole site to store electronic documents.

SAMPLE PROJECT NOTEBOOK TABLE OF CONTENTS

PROTOCOL:

- Approved protocol
- Any subsequent protocol revisions

DOCUMENTS:

- Contracts
- IRB approvals
- Study team contact list
- Important e-mails, faxes, or notes
- Documentation of medical record storage

WORKPLAN:

- Data requests
- Descriptions of programming tasks
- Preparations of analytic files
- Anticipated format of summary tables
- Formulas

KEY EVENTS:

- Original timeline
- Any subsequent revised timelines
- Record of the following dates:
 - Contract signed
 - Data requests sent out
 - Requested datasets returned
 - Interim report
 - Log of SAS outputs
 - Analytical file was locked
 - Date that medical records were sent to storage
 - Manuscript submitted for publication

FORMS:

- Blank data forms
- Abstract forms
- Manual of operations

REPORTS:

- Interim report to sponsor
- Final report to sponsor
- Manuscripts submitted for publication – have a version of manuscript with links between figures/results and programs that produced those results
- Spreadsheet with SAS output linking to tables and/or reports

Record Retention

HealthPartners: Administrative Closeout Meeting Checklist

Project:					
PI:			Date:		
Present:					
		Outstanding Issue?			Action Plan
	Topics	Yes	No	NA	
Contract	Contract end date identified				
	Continuation needed?				
Budget	On target versus contract?				
	Activity for over-runs				
	Activity for excesses				
	Final effort certifications				
Charging	Invoicing-final				
	Reimbursing departments				
	Copier codes deletion				
	Phone code deletion				
	Est. date of Activity # close				
Archiving	Electronic				
	Paper				
Reporting	IRB				
	ACUC				
	Sponsor				
	Research Committee				
Other					

HealthPartners: Policy on Closeout Meetings

HEALTHPARTNERS RESEARCH FOUNDATION		
Policy: Project Close Out Meetings		No. 003.09
Subject: Project Closure		Origination Date: 3/1/05
		Supersedes:
Source: Research Admin	Effective Date: 07/06/05	Review Date: 07/06/06

Purpose

In order to facilitate the closure of research projects, it is highly recommended that the PI holds a project closure meeting(s) to address closure and file archival issues.

Other Related Procedures

003.03; 003.10

Procedure

Who?

- The Principal Investigator calls the meetings. While this meeting may be most necessary for those implementing federal or foundation grants at the 8100 site, any PI ending a project may request a meeting with any or all of the recommended attendees. Recipients of HPRF internal grants and new investigators are especially encouraged to hold these meetings.
- Recommended attendees include the PI, the Manager of Research Operations, the accountant who has been handling the project, and all project staff involved in any phase of the project (i.e. Data Collection Center manager, programming staff, coordinator).

When?

- The meetings should be scheduled to take place about three months prior to the end of the funding period.

How?

The meeting will address the following issues:

- The status of the budget
- A plan for effort certification that is consistent with remaining funds
- Final reporting requirements, both contractual and regulatory
- Plan for close out of funding excesses or deficits
- De-identification of data (removal of all elements per HIPAA, includes removal of dates)
- Consolidation of data into a minimum number of locations and files
- * Applicable file retention periods
- Final Invoicing procedures

The Mgr of Research Operations will bring the project file and accountant will bring the latest financial information to the meeting.

HealthPartners: Policy of Archiving and Record Retention

HEALTHPARTNERS RESEARCH FOUNDATION	
Policy: Record Archiving & Record Retention	No. 3.10
Subject: Foundation and Research Project Records Source: Research Privacy & Security Liaisons	Origination Date: 6/1/2000
	Supersedes: Research Study Information Retention Policy
Effective Date: 3/1/05	Review Date: 3/1/06

Purpose

To protect confidentiality and security of project data and assure compliance with applicable law, regulation, and other standards.

Scope

All records, as defined below, created and/or maintained for the purpose of research or organizational business at HealthPartners Research Foundation.

Definitions

Record:

A Record is recorded information that is created or received in connection with the operation of the organization's business. Records contain relevant information relating to the research project, operations of HealthPartners Research Foundation and general business activities. A Record has business relevance or memorializes official decisions or other services. "Relevance" is to be determined based on whether the document is listed on Appendix A, industry practice and the underlying purpose of the document.

A Record can be created or maintained in any medium, including paper documents and correspondence, letters, x-rays and other diagnostic images, cards, books, maps, photographs, blueprints, sound or video recordings, microfilm, magnetic tape, digital media or electronic media.

Examples of Records include correspondence with outside parties, memoranda, corporate governance documents, legal opinions, policies and procedures, official meeting minutes, personnel records, purchasing requisitions and invoices, accounts payable and receivable documents, tax documents, reimbursement and expense documents, completed and signed forms, completed and signed contracts, insurance documents, general ledgers, audit reports, financial reports, health records, designated record sets, appointment logs, provider schedules, test orders, research forms and reports, regulatory reports and filings, accreditation and compliance materials, credentialing and enrollment records, quality reports and peer review materials. The foregoing may be, but are not necessarily, "Records," depending upon whether they have business relevance or memorialize official decisions of the organization or project team.

Records do *not* include duplicate copies of original Records (such as multiple distributions of the same document, email or file), blank forms, publications or other distributed materials, magazines, publications from professional organizations, newspapers, public telephone

directories. Records do not include transitory messages with little or no long-term administrative/business value that are used primarily for the informal communication of information, such as voice mail, meeting schedules, unofficial meeting notes, drafts of documents, informal or multiple-broadcast emails (and attachments) and telephone messages.

A research project record is recorded information of essential documents that is created or received in connection with the design and implementation of a research study. It is maintained in any medium, including paper, images, recordings, or electronic data files.

Essential documents that are a part of a research project record may include, but are not limited to, a protocol, protocol amendments, case histories, IRB and sponsor communication, financial data, signed consent/authorization forms, monitoring visit reports, programmer and research staff documentation describing research plan implementation, final analytic data sets, and reports of results. For more information related to clinical research records, see ICH (International Conference of Harmonization) Guideline for Good Clinical Practices at www.ifpma.org/ich.

Research records do *not* include duplicate copies of original records, blank forms, or publications from professional organizations. Records do not include transitory messages, interim data sets, meeting schedules, unofficial meeting notes, or drafts of documents.

Other Related HealthPartners Procedures and Guidelines

- Corporate Integrity Records Retention Policy; HPRF CI-10
- ICH Guideline for Good Clinical Practice
- 21 CFR 312.62 (FDA-regulated studies)
- "Recordkeeping in Clinical Investigations" FDA Information Sheet
- 45 CFR 46.115
- 45 CFR 74.53

Procedure Summary:

All Records, except those specified in Appendix A (attached), will be retained for a period of no less than seven years from the date of last active use.

Records identified in Appendix A will be retained for no less than the period identified in Appendix A, beginning with the Period Start Time identified in Appendix A.

Records affected by retention requirements or disposition moratoria created by court orders or regulatory actions, or other Records identified by the HealthPartners Law Department, will be retained as directed in writing by the Law Department.

Records having a retention period specified in a contract with a business partner will be retained for a period no less than the longer of the period identified in this policy or the period identified in the contract.

Records which may fall under more than one Record Type or Record definition in Appendix A will be retained for the longer of the applicable retention periods.

Who?

All project team members, including programmers, coordinators, Data Collection Center, and support staff have a role in preparing their project documentation for archiving. Investigators are responsible to assure that all project records are archived according to this procedure.

Managers at HPRF are responsible to assure that records generated in their areas are archived according to this procedure.

Record Custodian

The HealthPartners Research Foundation Executive Director will designate the Office Coordinator as Record Custodian to perform the duties described below under the direction of the Manager of Operations.

The Record Custodian is responsible for performing general administrative duties to support the departmental record management process, including but not limited to:

- Establishing and documenting methods for retaining active records and nonrecords in Department files to ensure they are organized, indexed, accessible and retrievable for destruction at the end of the retention period
- Establishing procedures for when non-active records can be shipped off-site
- Establishing an annual review to ensure proper maintenance of the department's records management practices
- Maintaining inventory of records stored on and off-site
- Preparing/shipping boxes to off-site storage vendor
- Reviewing monthly/quarterly lists provided by off-site storage vendor to ensure recent additions to inventory have been recorded properly
- Requesting Destruction Reports on a regular basis
- Ensuring Destruction Report is reviewed, signed by appropriate manager, returned to off-site storage vendor for timely processing
- Processing requests for documents stored off-site

When?

- Identifiers are destroyed as soon as they are no longer needed.
- Team members prepare documents for archiving and instruct remaining team members and PI where they are located before ending their involvement with a project.

How?

Research Project Archiving

Once the investigator determines that the research project is ready to be archived, the following preparations for archival are accomplished:

All essential documents associated with the project should be consolidated and stored in boxes in a secure location.

- The investigator or coordinator of industry-sponsored research contacts the sponsor to review contractual obligations and processes for record archiving.
- Investigators of all other sponsored studies must use judgment to determine essential documents. All electronic data files (including CDs, discs, DVD's) that are determined to contain essential documents are copied on disc for storage with paper documents.
- Destroy interim data sets, duplicative documents and files, blank forms, and worksheets. Shred non-essential documents containing protected health information or other private information (if this has not already been accomplished).
- Submit any copies of CDs, discs, or DVDs or non-essential documentation containing protected health information to the Information Services department for destruction.
- Destroy identifiers and links to identifiers unless retaining them is required by law, ie. FDA regulated studies (if this has not already been accomplished).
- Contact the departmental Authorized Requester to de-activate any access permissions to systems that are no longer needed, i.e., EPIC access.

- Contact the departmental Authorized Requester to destroy any project folders ([\\researchdm\projects](#)) that are no longer needed.

The Record Custodian will ask the PI to complete a form so that the boxes can be properly labeled. Note, the HPRF Record custodian will not destroy project records without making a reasonable effort to confirm destruction approval with the investigator after target destruction dates have passed.

Once the final Continuing Review has been approved by the IRB (Institutional Review Board) the project is ready to be archived at a secured location. This secured location may be in a HealthPartners facility, the HPRF locked storage room, or other institutionally-approved off-site storage facility (i.e. Iron Mountain).

Other HPRF Record Archiving (Not Project Related)

The Record Custodian will ask the responsible party to complete a form so that the boxes can be properly labeled. Note, the HPRF Record custodian will not destroy records without making a reasonable effort to confirm destruction approval with the responsible party after target destruction dates have passed.

The investigator or designee may contact HealthPartners Research Foundation Record Custodian at 952-967-5001 for questions regarding this procedure or locating secure space for record storage.

HealthPartners: Record Archiving and Retention Procedure

Since records may fall under more than one Record Type or Record category, review all categories in the appendix to determine the record retention period for specific records. Note, not all of these documents will be located in HPRF Files. Some will be in HealthPartners Human Resource Department, Legal Department, etc.

RECORD TYPE	RECORD	RETENTION PERIOD	PERIOD START TIME
Corporate Assets Real Estate	Construction documents	6 years	Disposition of property and assets
Corporate Assets Real Estate	Capital equipment and fixtures	6 years	Disposition of assets
Corporate Assets Real Estate	Leases	6 years	Termination of lease
Corporate Integrity	Investigation Files	10 years	Closure of file
Corporation	Nonprofit corporation records - articles, by-laws, board/director/mbr/ committee meeting minutes	6 years	Dissolution of corporation
Corporation	Business corporation records: articles, by-laws, share register, shareholder mtg minutes, BOD meeting minutes, reports to shareholders	3 years	Dissolution of corporation
Financial	Financial Statements and Audit Reports	6 years	Dissolution of Corporation
Financial	Gross earnings tax records	6 years	Date return rendered to state
Financial	Tax records (except gross earnings tax and employment tax records)	6 years	Dissolution of Corporation
Financial	Accounting records	6 years	Later of end of Accounting period or creation or records
Financial	Physician compensation cost allocation reports	5 years	End of cost reporting period
Financial	Effort Certification Forms	6 years	End of reporting period

RECORD TYPE	RECORD	RETENTION PERIOD	PERIOD START TIME
Financial	Financial records: HHS awards	3 years	Submission of final expenditure report; for renewing awards, from submission of quarterly or annual financial report
HIPAA	HIPAA Privacy, Security and EDI implementation records, policies, procedures	7 years	Date of creation or date last in effect, whichever is later; date of signature for subject research authorizations
Human Resources	Employee medical records	30 years	End of employment
Human Resources	Employee exposure records	30 years	Date of Exposure
Human Resources	Personnel records	7 years	End of employment
Human Resources	Payroll records	5 years	End of calendar year records created
Human Resources	OSHA records (OSHA 300 Log, privacy case list, annual summary, and the OSHA 301 Incident Report forms)	5 years	End of calendar year that records cover
Human Resources	Employee Right To Know Act (ERTKA) training records and OSHA human pathogen training records	3 years	End of training
Human Resources	Form I-9	3 years	Date of hiring, or one year after termination of employment, whichever is later
Human Resources	Supervisor's File	3 years	End of employment
Human Resources	FMLA records	3 years	End of FMLA activity
Human Resources	Job applications and resumes when applicant is not hired	1 year	Date of receipt
Intellectual Property	Trademark, Patent and Copyright Assignments	Permanent	N/A
Intellectual Property	Original Letters Patent, Trademark Certificates & Copyright Certificates	Permanent	N/A
Intellectual Property	Copyright application files	95 years	Date of first publication
Intellectual Property	Patent, trademark and copyright litigation files	15 years	Termination of litigation
Intellectual Property	Trademark infringement/policing files	7 years	Matter has terminated or become inactive

RECORD TYPE	RECORD	RETENTION PERIOD	PERIOD START TIME
Intellectual Property	Trademark opposition/cancellation files	7 years	Matter has terminated or become inactive
Intellectual Property	Agreements (e.g., confidential disclosure, license)	7 years	Termination or expiration of agreement
Intellectual Property	Trademark, patent and copyright validity and infringement opinions	7 years	Date of opinion
Intellectual Property	Patent search files	7 years	Date of search
Intellectual Property	Invention disclosures	7 years	Date of disclosure
Intellectual Property	Patentability opinions	7 years	Date of opinion
Intellectual Property	Trademark acquisition files, such as licensed trademarks	6 years	Abandonment of the trademark or after termination of license agreement, whichever is later
Intellectual Property	Patent files	6 years	End of patent protection
Intellectual Property	Trademark search files	3 years	Later of date of search or last use
Intellectual Property	Trademark application files	2 years	Date trademark has been abandoned, expired, or cancelled
Legal	Subrogation Files	7 years	Close of file
Legal	Inter-company Agreements	7 years	Expiration of Agreement
Legal	General claim files (pleadings and correspondence)	7 years	Close of file
Legal	Litigation logs	7 years	End of litigation
Legal	Taxable Status Determination Letters	6 years	Dissolution of Corporation
Research	HIPAA Authorization Forms	7 years	Date of authorization signature
Research	IRB records	3 years	Completion of research
Research	Project Records: HHS research grants	3 years	Submission of final expenditure report; for renewing awards, from submission of quarterly or annual financial report
Research	Research conflicts of interest and financial disclosures	3 years	Submission of final expenditures report

RECORD TYPE	RECORD	RETENTION PERIOD	PERIOD START TIME
Research	Scientific misconduct inquiries	3 years	Termination of inquiry
Research	Project Records under FDA Rules	2 years	Date of approval of new drug application or withdrawal of application
Research	Project Files under contractual agreements	per contract	per contract

Kaiser Permanente-Center for Health Research: No –Cost Extensions for NIH Grants

Responsible person: Project Manager

Nuts and bolts

- Unless specifically restricted in the NGA, a project can exercise the option of extending the grant for one year without needing prior approval from the project officer/grants management officer – you are telling them you are extending the project for an additional year – you technically aren't "requesting", (although it never hurts to be polite). See attached NIH guidelines.
- KFRI needs to notify the NIH grants management officer by email 10 days in advance of project's scheduled end date (or through the eRA Commons) that a no-cost extension is planned. A sample email is attached. I would interpret the 10 days as being business days and would therefore make sure my request was ready to go at the beginning of the month the grant is scheduled to end. You should contact John Moore in Finance to let him know that an extension is planned.
- KFRI sends the actual email (or eRA Commons request) in John Doolittle's name as he is the business official for the grantee (KFRI), but you need to prepare the text and Finance (John or Paul) will forward it to Pat Ryan at KFRI. This allows Finance to put the request in the grant folder and we can also extend the SPLAN accordingly.
- Upon receipt of the request, NIH will adjust the grant expiration date and send a confirming email and/or eRA Commons reply to KFRI, which Pat will forward to the John and the PI. Ask that Pat & John CC you if your PI tends to lose things. A sample email showing the extension confirmation is also attached

Words of advice

- The PI and project manager need to originate this process – neither KFRI or Finance will come to you with a reminder that you need to start this process & follow through.
- While you get one extension without prior "approval", a second extension is generally a red flag and needs to be discussed with and approved by the project officer in well advance of the end of the first extension.
- Extensions of your IRB approvals are NOT synonymous with this process and you need to follow your normal IRB continuing review procedures for this.

In the future, CHR may be able to extend projects through the eRA Commons but we aren't able to do this yet – stay tuned.

Kaiser Permanente-Center for Health Research: Final Reports for NIH Grants

Nuts & Bolts...

- Are due no later than 90 days after the close of your project, or no-cost extension period.
- Typically have cover letter, signed by the PI and KFRI, the mainbody of the report (10-20 pages), and an Inventions and Patents statement (HHS-568 form) which must be signed by the PI and KFRI.
- Receipt location and detailed instructions for the final report are shown in your final year NGA –read carefully as they vary from grant to grant.
- AHRQ has a more defined report format. If you have an AHRQ grant, follow these instructions.
- A copy of the final Financial Status Report (FSR) is prepared by KFRI and is sent to a separate NIH close-out office.

Words of advice...

- Again, the PI and project manager need to be on top of this process –neither KFRI or Finance will come to you with a reminder that you need to start this process & follow through.
- As in all correspondence with NIH, clearly identify the grant title, number, and PI name on all documents.
- When in doubt, call your project officer and grants specialist to get their guidance and find out what exactly they want you to submit and in what format. Requirements can vary across institute and NIH project staff. Check your final NGA for specific instructions
- NIH received an audit deficiency on its handling of grant closeouts and is being more rigorous in following up on late reports & begins sending ominous emails to both KFRI and the PI within days of the report being overdue.

Publication policies

Cancer Research Network: Publication and PresentatPolicies and Procedures

Cancer Research Network CRN PUBLICATIONS COMMITTEE: POLICIES AND PROCEDURES

Revised January 2005

SUMMARY OF REPORTING DUTIES

WHO	DUTY	SCHEDULE	SECTION
Project director	Maintain the Quarterly Publications Tracking Report	Quarterly to coincide with Publications Committee meetings	III
Site PI	Recruit lead authors for core and methods papers, ensure productivity of all lead authors at their sites	Quarterly following Publications Committee reports	II
Project PI	Report all plans for manuscript development to the CRN Program Director's office as	During the early months of the project.	IVB
	Report the progress of all Project writing groups	Quarterly beginning at the completion of data collection	IVB
Lead authors	1. Informing the Project PI about the progress of the writing group. 2. For writing groups that are not affiliated with a project, the lead author shall report the group's progress to the CRN Program Director's office.	Quarterly	IVB
Publications Committee	Advocacy and progress report to the Steering Committee	Quarterly	II, III

I. MEMBERSHIP AND SPECIFIC DUTIES

A. Membership

The Publications Committee consists of several investigators from the CRN projects, nominated by the CRN Steering Committee to serve two-year terms. At least one junior-level CRN

investigator will be a member of this committee. In addition, the CRN Project Director serves as an ex-officio member.

B. Specific duties

The specific duties of the Publications Committee are as follows:

- Foster a high volume of quality scientific papers and presentations (Section II).
- Track the progress of all CRN writing groups (Section III).
- Promulgate guidelines for the formation and activities of writing groups (Section IV).
- Develop and update authorship guidelines (Section V).
- Review manuscripts (Section VI).

C. Schedule

The Publications Committee shall meet no less than quarterly with the following agenda:

- Identify core and methods papers that could be developed
- Track the progress of all CRN writing groups
- Elect new Publications Committee members as needed
- Prepare a report for the Steering Committee.

The report to the Steering Committee shall include the following:

- The number of written articles (1) published, (2) in press, (3) submitted, (3) reviewed by the Publications Committee, and (4) scheduled to be written.
- The number of written articles scheduled to be written that (1) have cross their preliminary due date by 1 day, 3 months, 6 months, 9 months, 12 months, and more than 12 months.
- The number of presentations given at national meetings, and the number given but not yet drafted into a manuscript.
- A list of core and methods papers that are in need of lead authors.
- A request for time on the agenda to publicize the need for presentations and papers.

II. PROCEDURES TO FOSTER A HIGH VOLUME OF QUALITY SCIENTIFIC PAPERS AND PRESENTATIONS

Core and methods papers. On a quarterly basis, the Publications Committee shall discuss the specific content of manuscripts needed to describe the CRN core and CRN methods, including validation studies. A list of preliminary titles shall be maintained by the CRN Project Director. This list shall be brought before the Steering Committee to add ideas, identify authors, and set submission deadlines.

Advocacy. On a quarterly basis, the Publications Committee shall request time on the Steering Committee agenda to publicize the need for presentations and papers. The duties of Site and Project Investigators to recruit lead authors can be stressed at this time.

III. PROCEDURES FOR TRACKING THE PROGRESS OF ALL CRN PAPERS AND PRESENTATIONS

The CRN Program Director's office shall maintain a Quarterly Publications Tracking Report containing the following:

- Citations for manuscripts published, in press, and submitted and the specific project, core, or spinoff study from which they are derived
- Presentations given at a national level.
- Manuscripts reviewed by the Publications Committee
- Manuscripts scheduled to be written (provided and updated by Project PIs or lead authors)
-

On a quarterly basis, the Program Director's office will prepare a Quarterly Publications Tracking Report that contains the following information:

- The number of written articles scheduled to be written that (1) have crossed their preliminary due date by 1 day, 3 months, 6 months, 9 months, 12 months, and more than 12 months.
- The number of presentations given at national meetings, and the number given that have have/have not drafted into a manuscript six months or longer after presentation.
- A list of core and methods papers that are in need of lead authors.

All writing groups should be prepared to report on their progress when contacted by the CRN Program Director, the Project PI, or the Publications Committee.

It is expected that Presentations given at the national level shall be developed into manuscripts within 3 months assuming the completion of data collection. This does not apply to preliminary presentations not yet ready for publication.

The Publications Committee shall review the Tracking report and (1) identify high-priority manuscripts that merit the attention and support of the CRN PI and Steering Committee, (2) devise actions to stimulate renewed activity when writing groups stop making progress, (3) devise assistance to authors whose manuscripts that have been repeatedly rejected. In this instance, they may recommend the formation of an ad hoc group of senior investigators to offer feedback and advice. In the cases of a non-responsive writing group, the Publications Committee may recommend changing the writing group leader. Final decisions regarding a change in lead authorship on a multi-project paper will be made by the Steering Committee.

IV. GUIDELINES FOR THE FORMATION AND ACTIVITIES OF WRITING GROUPS

A. Types of documents

Presentations. Presentations of CRN work at professional meetings should be undertaken with the long-term goal of publishing the content presented. Presentations should be developed by writing groups using the guidelines described below in Sections IIIB and IIIC.

Papers involving data from only one participating health plan. Although the Publications Committee will not be involved in formation of these writing groups, the Committee will track their progress. The lead author of these papers is responsible for notifying the Publications Committee when the writing group is formed.

Papers involving only data from only one CRN project. Writing groups for papers and presentations that involve only one project will be appointed by the Project PI and do not need to be approved in advance by the Publications Committee. However, the Project PI is responsible to promptly notify the Publications Committee when new writing group is formed.

Papers involving data from multiple CRN projects or non-project data from multiple health plans. CRN investigators wishing to write a paper or presentation based on multiple CRN projects and data should prepare a written description of the rationale and proposed analysis, including a description of the data to be used. This should be circulated to other interested CRN investigators. These writing groups need advance approval from both the Publications Committee and the Steering Committee. The Publications Committee is responsible for reviewing these proposals for possible overlap with other writing groups or conflicts with CRN project goals or activities. When approved by the Publications Committee, the lead investigator will assemble the writing group with the assistance of site PIs. Authorship should be offered to representatives of each institution involved in the paper assuming that they are willing to meet the requirements for authorship discussed below. Investigators are encouraged to confer with the PIs of all involved projects early in the process to ensure that the proposed manuscript does not overlap with papers within the project.

B. Responsibilities of CRN writing group members

With multiple authors located in as many as ten or more institutions, manuscript development is challenging. The purpose of this guideline is to outline the roles and expectations for Project PIs, as well as lead authors and co-authors once a writing group has been formed.

Responsibilities of Project PIs. The responsibilities of Project PIs with respect to forming writing groups are as follows:

- Select the lead author early during project development in a manner agreed upon by the project investigators.
- To the extent possible, identify opportunities for interested investigators to take the lead on writing projects.
- Equitably assign project investigators to the writing groups.
- Encourage the appropriate representation of investigators from CRN sites on scientific papers.
- Encourage junior-level investigators to participate on writing groups.
- Find experienced mentors for junior-level investigators leading writing groups.
- Regularly monitor the progress of writing groups.
- Report all plans for manuscript development to the CRN Program Director's office as during the months of the project.
- Report the progress of all project writing groups to the CRN Program Director's office on a quarterly basis beginning at the completion of data collection.

Responsibilities of the Lead Author. The lead author has overall responsibility for organizing the writing group and completing the manuscript in a reasonable amount of time. Specific duties include:

- Lead authors of writing groups that are not affiliated with a project shall report the group's progress to the CRN Program Director's office on a quarterly basis.
- Upon request, informing the Project PI about the progress of the writing group.
- Managing communications for the writing group.
- Identifying an appropriate mechanism for sharing drafts and using it consistently (i.e. fax, express mail, email, FTP site).
- Writing a detailed outline of the paper or presentation.
- Coordinating the development of a written data request (if necessary).
- Coordinating the writing of each section of the manuscript.
- Combining all sections of the manuscript into a completed paper.

- Monitoring all controversies in the writing group, documenting subsequent decisions, and discussing these decisions with the other authors.
- Coordinating the final editing and approval of the paper by all authors.
- Determining the order of authorship based on the relative contributions of each co-author.
- Shepherding the final draft of the paper or presentation through the Publications Committee review.
- Submitting the approved manuscript for review by a journal or professional group.
- Coordinating the response to reviewers.
- Providing reasonable deadlines for each review/revision and promoting an understanding among collaborators that these will be adhered to unless scheduling issues are discussed with lead author prior to a review deadline.

Responsibilities of co-authors. Co-authors are expected to actively participate in all aspects of the writing process. Specific responsibilities include:

- Participating actively in all writing group meetings.
- Reasonably considering of appropriate writing assignments.
- Promptly completing of all writing assignments.
- Promptly responding to requests for review and editing of manuscript drafts.
- Working cooperatively with the other authors in resolving disagreements.
- Take responsibility for the accuracy and content of the final manuscript in its entirety.
- Prompt responding to recommended revisions from peer review.

C. The writing process

The Publications Committee encourages early deliberation about papers that are likely to result from a research project, with designation of a leader or first author for each paper. We further encourage open discussion among co-authors of each paper about the order of authorship early in the research process, **with final decisions made by the first author**. We recognize that final authorship order may change during the writing and editing of the paper – it is the responsibility of the lead author to communicate such changes to the writing group. In the event of disagreements regarding authorship on a given manuscript, the Project PI or Publications Committee will arbitrate the dispute.

The lead author should schedule regular meetings of the writing group, either in person or via telephone conference call. Lead authors will be responsible for finding the resources for scheduling and conducting these meetings. In some cases project funds may be available for conference calls, in other cases the lead author will need to find other resources for conference calls. Each member of the writing group is expected to participate in the conference calls and to promptly complete their writing and editing assignments.

Most of the work of the writing groups will be done off-line, with individuals and small working groups taking responsibility for various tasks such as preparing a data request, literature reviews, writing sections of the manuscript, etc. Writing, editing, and discussion of the paper will continue until the lead author feels that the paper is ready for submission. At times there may be methodologies or analytic disagreements that are difficult to resolve through the editing process. The Project PI, or, in the case of papers that include data from more than one CRN project, or the Publications Committee will serve as mediator for any issues where necessary. If an author cannot agree with the final consensus then they may withdraw authorship, recognizing that the paper will still go forward as a CRN paper.

- D. Responsibilities of PIs of CRN spinoff studies (i.e., separately funded studies that include a CRN component, core, or other element).

The long-term viability of the CRN is dependent on its ability to demonstrate its impact, including those studies not funded under the core award. PIs of separately funded grants that include a CRN component accept and acknowledge their responsibility to inform the CRN Central Office of their publications and presentations from studies in which the CRN is involved and using the same timelines and tracking requirements applied to CRN projects.

V. AUTHORSHIP GUIDELINES

The CRN Publications Committee will adjudicate disputes regarding authorship for multi-project or within-project manuscripts. The latter will occur when project investigators and the PI cannot come to agreement regarding authorship of a particular manuscript. In such cases, Publications Committee members with an apparent conflict of interest will not participate in the deliberations. Investigators who are not satisfied with the decision of the Publications Committee have the option of bringing their dispute to the CRN Steering Committee.

The following statement of the International Committee of Medical Journal Editors should be used as the guiding standard in dealing with authorship issues in the CRN. A complete version of that document may be found at <http://www.icmje.org>.

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.

Authorship credit should be based only on substantial contributions to (1) conception and design, or analysis and interpretation of data; and to (2) drafting the article or revising it critically for important intellectual content; and on (3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author. Editors may ask authors to describe what each contributed; this information may be published.

Increasingly, multicenter trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the acknowledgments or in an appendix.

The order of authorship should be a joint decision of the co-authors. Because the order is assigned in different ways, its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to explain the order of authorship in a footnote. In deciding on the order, authors should be aware that many journals limit the number of authors listed in the table of contents and that the US National Library of Medicine (NLM) lists in MEDLINE the first 24 plus the last author, when there are more than 25 authors.”

All persons designated as authors on CRN publications should fulfill the three criteria of authorship listed above. These criteria provide an inclusive rather than exclusive approach to authorship, but rightfully exclude “guest” authors. Furthermore, CRN publications should not

have “ghost” authors, persons who made substantial contributions to a research project or wrote substantial portions of a manuscript without attribution.

VI. PROCEDURES FOR MANUSCRIPT REVIEW BY THE CRN PUBLICATIONS COMMITTEE

A. Overview

At the request of the CRN Steering Committee, current CRN guidelines require that all papers from the CRN research program be reviewed by the Publications Committee. This review must occur before submission for review by a scientific journal or other source of publication. The CRN publication policy may be found on the program web site (<https://www.kpchr.org/crn2>). Anyone planning to write a CRN paper should read the policy before starting. The procedures presented here will be used by the Publications Committee in performing its review.

B. Submission of manuscripts to the Publications Committee

Manuscripts to be reviewed by the Publications Committee should be sent to CRN Project Director at the Group Health Research Institute (GHRI) in Seattle. If the Project Director is unavailable, manuscripts can be sent to the [CRN Research/Administrative](#) Specialist at the Group Health Research Institute. Sending manuscripts by electronic mail will speed up transmission (and therefore review time), but hard copy submissions are also acceptable. Hard copy submissions should include eight copies.

C. Review criteria

The Publications Committee reviews manuscripts to ensure that the following binding criteria are met:

- The Project PI has approved the paper.
- Each health plan name and research center name appear according to the site PIs preference.
- Clear affiliation with the CRN is acknowledged and adequately described (refer to the Appendix). CRN affiliated projects are expected to include the following sentence in the methods section: “This study was conducted with-in the Cancer Research Network, a consortium of research organizations affiliated with non-profit integrated healthcare delivery systems and the National Cancer Institute.”
- No conflicts with other CRN papers or writing groups.
- No **serious or major** scientific flaws in study design or data interpretation.

With respect to the last point, the Publications Committee may provide content feedback and suggestions for the authors, but these comments generally will not influence the Committee's decision to approve or disapprove the manuscript. However, if the Committee believes that the manuscript contains flaws in methodology or interpretation of data that are sufficiently serious that they reflect negatively on the scientific integrity of the CRN, then the manuscript will be disapproved. If the author disagrees with this disapproval, the issue and decision may be discussed with members of the Publications Committee or brought before the Steering Committee for resolution.

D. Time for review

The Publications Committee will make every effort to review papers within ten business days of receipt at CHS, except in August and December, when vacations may extend review times by a few business days. Longer transit times for hard copy submissions will extend the review time somewhat.

E. Review Structure

The entire Committee will review all submitted papers. Each committee member will send their review comments (using the form provided in the email) to all other committee members by electronic mail. Committee members are asked to review papers within seven business days of receipt, and the Committee Chair will make the approval decision based on the available comments. In the event that the Chair is unavailable, the CRN Project Director has the authority to approve a paper for publication if it meets the criteria described above in the opinion of all other Committee members. However, if there is any doubt about the suitability of a paper for publication, the decision should be delayed until the chair is available.

The Committee decisions will be sent to the CRN Project Director, and she will notify the corresponding author.

F. Appeals

As stated above in the CRN Publications Policies, decisions of the Publications Committee can be discussed directly with Publications Committee members and appealed to the Steering Committee.

VI. CONTACTING THE PUBLICATIONS COMMITTEE

Routine communications should be sent to the CRN Project Director at the Group Health Research Institute, Seattle. An additional contact is the Chair of the Publications Committee.

APPENDIX: Description of the CRN

To ensure correct and consistent description of the CRN aims, the member health plans and research organizations, please use the following text.

“This study was conducted with-in the Cancer Research Network, a consortium of research organizations affiliated with non-profit integrated healthcare delivery systems and the National Cancer Institute.”

The following paragraphs can be used in the acknowledgements or methods sections of papers.

"The Cancer Research Network (CRN) consists of the research programs, enrollee populations and databases of 11 integrated healthcare organizations that are members of the HMO Research Network. The health care delivery systems participating in the CRN are: Group Health Cooperative, Harvard Pilgrim Health Care, Henry Ford Health System/Health Alliance Plan, HealthPartners Research Foundation, the Meyers Primary Care Institute of the Fallon Healthcare System/University of Massachusetts, and Kaiser Permanente in six regions: Colorado, Georgia, Hawaii, Northwest (Oregon and Washington), Northern California and

Southern California. The 11 health plans, with nearly ten million enrollees, are distinguished by their long-standing commitment to prevention and research, and collaboration among themselves and with affiliated academic institutions.

The *overall goal* of the CRN is to increase the effectiveness of preventive, curative and supportive interventions that span the natural history of major cancers among diverse populations and health systems, through a program of collaborative research. This overarching aim of the CRN, coupled with the expertise of the investigative team, and geographically-dispersed population base, fosters efficient and effective research on variations in cancer prevention and treatment policies and practices.

HealthPartners: Publication and Presentation Policy

For Research Teams

A research project is only as good as its ability to disseminate its lessons, particularly in publications. The biggest problem with most projects is that they do not produce enough publications, usually because there are too few serious writers, but also because of too much effort to control the process or too little effort to stimulate papers.

Goals:

1. To encourage presentations & publication of as many good papers in indexed journals as possible
2. To assure fairness and appropriate recognition and acknowledgements
3. To control project analytic resource use for addressing priority project aims
4. To prevent inappropriate, duplicate, or conflicting statements or use of data

Process:

1. The PI will:
 - a. establish policies and procedures
 - b. suggest key needed articles and presentations
 - c. review and approve individual articles and presentations
2. Anyone wishing to make a presentation or write an article should submit a brief abstract (see below)
3. After PI review, proposed abstracts will be circulated to all interested parties, so anyone who might want to be included or to suggest changes can do so
4. Both the original abstract and the final draft must be approved by the PI before submission
5. The first author is the one who prepares the initial draft, coordinates the input and contributions of co-authors, and has the last word in any differences of opinion. Subsequent authors are in approximate order relative to contribution as decided by the first author.
6. Requirements for being listed as an author are (from the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," Can Med Assoc J 1995; 152:1459-65):
 - a. Each author should have participated sufficiently in the work to take public responsibility for the content. (i.e., should be able to explain and defend the article's content and conclusions).
 - b. All 3 of the following conditions must be met:
 - (1) Substantial contributions to either conception and design or else analysis and interpretation of data.
 - (2) Substantial contributions to drafting the article or revising it critically for important intellectual content.
 - (3) Final approval of the version to be published.
 - c. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship.

Therefore, any potential co-author who does not respond to requests for reactions to drafts or the final version of the paper in a timely way will be assumed to no longer wish to participate in authorship

7. All papers must acknowledge grant support and use the following notation:
"This project was supported by grant number ___ from the _____"
8. Most papers should acknowledge the clinics, departments, and people who contributed to the project

Abstract for Proposed Publications and Presentations

1. Descriptive title
2. Main question or hypothesis to be addressed in the paper
3. Brief description of analyses or data needed
4. Authors in approximate order
5. Audience and journal targeted
6. Target date for submission

HEIRS Study: Publications, Presentations, and Ancillary Studies Policy

Note: In addition to the below policies, current Steering Committee-approved decisions include that:

- 1) Manuscripts on completed phases of the study, which have “cleaned” data sets available are permitted. Currently, the initial screen, acceptability sub study, Post Result Forms and the de-identified CCE dataset meet these requirements.
- 2) While ancillary study abstracts and manuscripts will be reviewed and approved by the P&P and the NHLBI, there will be no verification of the results by HEIRS. (This should be handled amongst the ancillary study investigators).

HEIRS Study Policies

Overview

The HEIRS Study is a study on the prevalence, genetic and environmental determinants, and potential clinical, personal, and societal impact of iron overload and hereditary hemochromatosis in a primary care based setting of 100,000 adult participants from five clinical centers. The study involves genetic testing and will study attitudes towards genetic testing. The sample will include a large component of minorities. As a multicenter study, it involves Investigators from each of the clinical centers, the HEIRS Coordinating Center (CoC), the HEIRS Central Laboratory, the National Heart, Lung, and Blood Institute (NHLBI), which is the lead funding agency, the National Human Genome Research Institute (NHGRI), and several consultants to the study. The official HEIRS data set is maintained at the Coordinating Center.

The success of the HEIRS Study will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of the HEIRS data, timely completion of manuscripts, and adherence to the principles of authorship. The HEIRS Publications and Presentations (P&P) Committee oversees these activities on behalf of the HEIRS Steering Committee. While outside collaborators with meritorious proposals are welcome, HEIRS requests that individuals working on projects involving HEIRS data work closely with at least one of the HEIRS Investigators and follow the policies of the study.

Role of the Publications and Presentations (P&P) Subcommittee

The Publications and Presentations (P&P) Committee is under the direction of the Publications Chair (currently Dave Reboussin) and reports to the Steering Committee. The P&P Committee has the responsibility to set priorities, monitor and approve the proposal of mainstream publications and abstracts, approve all publications and presentations before they are submitted for publication or presented in a public forum, and approve all nominated writing groups. "Mainstream" publications refer to all publications and abstracts not originating from ancillary studies. "Key results" publications refer to the design paper and similar study-wide key mainstream publications. "Local presentations" refer to the discussion of the results of the HEIRS study, done locally at the Field Centers, which may be exclusively on HEIRS or part of a general presentation on hemochromatosis or iron overload. The Steering Committee may decide who assumes lead responsibility for a paper if there is more than one interested candidate. The Steering Committee also may re-assign lead responsibility if reasonable progress on completing an abstract or manuscript has not occurred.

A. Publications and Presentations Policy

A.1 Objectives

- To have scientifically accurate presentations and papers from HEIRS Study investigators and to assure that press releases, interviews, presentations, and publications of HEIRS Study materials are accurate and objective, and do not compromise the scientific integrity of this collaborative study;
- To assure and expedite orderly and timely presentations to the scientific community of all pertinent data resulting from the HEIRS Study;
- To assure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide presentations of HEIRS papers;
- To establish procedures that allow the HEIRS Steering Committee and the NHLBI to exercise review responsibility in a timely fashion for HEIRS publications and presentations;
- To maintain a complete up-to-date list of HEIRS presentations, approved manuscript proposals and publications, and to distribute such lists to all HEIRS investigators on a regular basis; and
- To assure that membership in writing committees for HEIRS papers will serve as an opportunity to participate in formulating plans for analysis and the writing of manuscripts by active participation in the preparation of the respective paper.

A.2. Selection of Writing Group and Lead Authorship

To initiate the process that leads to a presentation at a scientific meeting or writing paper for publication, all HEIRS investigators are invited to submit ideas for abstracts or papers to the Publications and Presentations (P&P) Committee. Lead authorship is assigned by the Steering Committee, and is generally the individual who submitted the topic. If more than one person submits the same or similar topic, the Steering Committee may decide who will assume the lead.

Proposals are submitted using the Manuscript Proposal Form (see section A.4) or the Abstract Proposal Form. Before submitting a proposal, the investigator reviews the database of approved proposals to determine if any overlap exists (See Section B). For manuscript proposals, the form is submitted to the P&P Committee chairman (currently Dave Reboussin) and Coordinating Center Project Manager (currently Brenda Craven) via e-mail. The proposal is then distributed to the rest of the P&P Committee for approval. A manuscript number is assigned only to the P&P approved proposals for tracking purposes by the CoC via the HEIRS web site.

Once the manuscript proposal is approved, the P&P representative from each study agency should discuss the proposal with their staff, and then nominate up to two people per study agency to be part of the writing group within 30 days of approval. The lead author can petition the P&P committee at any time for an exception to this two per study agency writing group rule. The P&P committee approves the nominated writing group. The lead author contacts the CoC for assistance in setting up a conference call with the members of the approved writing group. It is likely that the expertise of a Coordinating Center staff person will be needed on most, if not all, papers. The lead author is encouraged to contact the Coordinating Center for analytic plans.

The P&P Committee is responsible for promptly submitting suggested outlines of all P&P approved presentations and publications to the Coordinating Center for review. Final drafts of proposed outlines are circulated to the Steering Committee, and other investigators involved in the writing group, for expression of any concern that they might have regarding the accuracy or appropriateness of the presentation or

publication. The Steering Committee then votes their approval or disapproval. Additions of other interested and qualified HEIRS researchers to the writing group can be made at this time.

Each Principal Investigator has the right to publish data from his/her own clinic population after approval by the P&P/Steering Committee. Usually, local data presentations and publications will be limited to those data already presented from study-wide results.

A.3. Co-authorship

The P&P approves all nominated writing groups. Each co-author must be actively involved in the preparation of the manuscript or abstract in accordance with proposed Guidelines on Authorship of Medical Papers (1,2). Participation must include each of the following, so that persons named as authors can take public responsibility for the content of the paper:

- Conception or design of the work, or analysis and interpretation of the data, or both.
- Drafting the manuscript or abstract or revising it for critically important content.
- Final approval of the version to be published.

If during the completion of the manuscript or presentation it becomes apparent that the contributions of one or more co-authors do not merit authorship, the lead author should discuss the possibility of removing the names of the individuals from the list of authors. In addition, each co-author should critically examine his/her role in the process and volunteer to remove his/her name if warranted. The lead author should attempt to reconcile divergent views of the co-authors with his/her own. However, sometimes a co-author may elect to remove his/her name because of disagreements in the interpretation of the data or in the style of writing, even though substantial contributions were made.

Contribution Codes are listed for categories, which may be considered for co-authorship. Attendance at a Steering Committee meeting without significant independent contribution to a manuscript would not be an acceptable criterion for co-authorship.

- a Conception and design
- b Analysis and interpretation of the data
- c Drafting of the article
- d Critical revision of the article for important intellectual content
- e Final approval of the article
- f Provision of study materials or patients
- g Statistical expertise
- h Obtaining of funding
- i Administrative, technical, or logistic support
- j Collection and assembly of data

A.4 Manuscript and Abstract Proposal Form

The HEIRS Proposal Forms (one to two pages each) are submitted by the lead author to the P&P Committee and includes this information. Submissions are not encouraged until the data has been collected.

Title: Short version for list (maximum of 26 letters)

List of writing committee members

Time line (estimated dates for tabulations and first draft)

Scientific background and rationale (Reason and need for the report)

Main Hypotheses

Data/Analysis Methods (variables, time window, sources, inclusions/exclusions)

List of HEIRS manuscript/abstract numbers of approved proposals that involve similar variables or hypotheses, and brief discussion of overlap issues.

Lead author full name, academic affiliation and title, address, telephone number, fax number and e-mail address, enabling easy access to contact information.

Administrative data recorded on the proposal form includes:

Manuscript/Abstract number

Date received

Date approved

Priority

A copy of these forms is provided in Appendix 1 and Appendix 2.

A.5 Preparation and Submission of Papers

The following steps are followed in the preparation of the HEIRS manuscripts. The lead author of a writing group:

- Contacts each writing group member and reviews the specific charge to his/her respective group;
- Works with the Coordinating Center staff and other writing committee members to determine appropriate analysis and data display for the paper. This involves determining the subjects and variables to be included in an analysis data file;
- Ensures that the current official version of the HEIRS data set as distributed by the Coordinating Center is being used;
- Is encouraged to include the co-authors throughout the analysis and manuscript writing process;

- Contacts the P&P Chair and CoC if a change in lead author is necessary (for instance due to workload), and informs them of the request to transfer the lead to another individual;
- Keeps the P&P Chair and the CoC informed of the manuscript's progress;
- Within the cover letter of a draft manuscript, provides a time line to co-authors for returning comments. The lead author may clearly state that the co-author will be removed from the manuscript if a response is not received on any iterations by the specified date. A turnaround time of two weeks is recommended for a co-author after receiving a request from the lead author. The lead author should ensure that the co-author has received notification. Statistical analysis based on centrally collected data should be sent to the Coordinating Center for verification.
- Submits the final version of a manuscript for review/approval by the P&P and the NHLBI Project Office (send to: ebpdocs@nhlbi.nih.gov) before the paper is submitted to a journal for publication,
- Keeps the Publications Chair informed of journal submission(s) (dates and journal name), results of reviews (acceptance, rejection or request for revision) and final acceptance by journal on a semi-annual basis and prior to any Steering Committee meetings.
- Send a copy of each (should there be multiple submissions or revisions) submitted version as well as a copy of the cover letter to the Coordinating Center. This will allow the Coordinating Center to have on file the final copy of all submissions whether accepted, rejected, or under revision and also to compile data on journal responses to HEIRS manuscripts; and
- Discusses any substantial changes to an approved manuscript prior to publication, whether required by the journal or not, with the co-authors. Co-authors should receive proposed re-submissions at least one week prior to journal re-submission.

If an individual wants to join a writing group already in progress, he/she contacts the lead author, who in turn informs the Publications Chair and CoC. The P&P subcommittee must approve the addition to the writing group.

The Coordinating Center's role is to:

- Identify areas of conflict with respect to proposed analysis tables, or data requests, between two or more writing groups, as well as assist the respective writing committees with relevant analyses as needed and appropriate. If any conflict should arise that cannot be resolved by the chairpersons of the respective writing groups, the Steering Committee serves as the final arbitrator.
- Maintain a web site publications tracking report.

A.6 Authorship/Acknowledgment of Study Support

The author list of all HEIRS papers should contain the writing group, followed by "for the Hemochromatosis and Iron Overload Screening Study Research Investigators" or "for the HEIRS Study Research Group." It is the intent of the Policy for all professional staff of each HEIRS study agency, who have worked collaboratively in the design and conduct of the Study, to claim credit for these papers. This includes the staff of the Coordinating Center, Central Laboratory and Project Office.

For other mainstream papers and presentations, the lead author of each writing group, with the concurrence of other members of the group, determines the order of authorship. A major criterion for this determination is the effort and contribution made by the members of the writing group in preparation of the manuscript. Disagreement about the order of authors, which cannot be resolved by the chairman of the writing group, is resolved by the P&P Committee, with the Steering Committee as the final arbitrator.

For other HEIRS papers, the authorship is determined by the principal investigators of those centers which have collaborated in the conduct of the ancillary study work leading to the publication.

To enable easy identification of HEIRS Study papers and presentations, "HEIRS Study" or "Hemochromatosis and Iron Overload Screening (HEIRS) Study" should be included in the title of each manuscript, abstract or other publication. Each paper includes a statement citing the NHLBI/NHGRI contract support for the work, listing the appropriate number. (Appendix 3) If the paper results from an ancillary study funded by NIH, this support also is cited. In addition, a credit roster of major HEIRS centers, with their members is listed at the end of each mainstream paper in the acknowledgment section (Appendix 4). Other HEIRS units, when appropriate, also appear at the end of the paper.

All requests for reprints of final and mainstream papers are directed to the HEIRS Center associated with the lead author of the paper.

A.7. Review of Manuscripts and Abstracts

The purpose of manuscript and abstract review is to evaluate the scientific merit, the clarity of the writing and the consistency with other HEIRS findings.

The P&P Committee has the authority on behalf of the Steering Committee to review and approve all HEIRS papers for the HEIRS investigators, including papers on ancillary studies, substudies, or local center data for publication.

Three copies of the manuscript, or abstract, are submitted: one to the P&P chair; one to the Coordinating Center; and one to the Project Office. The P&P circulates the manuscript or abstract to the P&P Committee for review. This review is completed within two weeks of receipt. The completed review is returned to the P&P chair and the Coordinating Center via e-mail. The P&P Committee discusses the review and manuscript during conference call or by e-mail within two weeks. If no comments are received within this time period, the manuscript is considered approved. Data in the abstract or manuscript must be verified by the Coordinating Center prior to submission.

NHLBI requires review of contract-supported manuscripts, abstracts and all ancillary studies manuscripts and abstracts.. Review by NHLBI Staff does not lead to approval or rejection of a manuscript per se; rather it provides scientific peer review and guards against the inadvertent dissemination of inconsistent findings from NHLBI-supported studies that share common data elements. The lead author will submit P&P Committee approved manuscripts for NHLBI review, which is completed within four weeks. Abstracts should be submitted at least one week prior to submission deadline. This review can be concurrent with the P&P Committee review, but it may be delayed if the HEIRS P&P Committee feels it is premature to submit a given manuscript for NHLBI review. The lead author will be notified directly of the review results.

It is understood that the procedures outlined above are not intended in any way to stifle initiation of ideas by investigators to produce meaningful and relevant manuscripts, but rather to enhance it.

Since not all circumstances that might cause disagreement among investigators on the merit of a given paper can be foreseen, these disagreements are resolved by the Publications and Presentations Committee and, ultimately, by the HEIRS Steering Committee.

A.8 Manuscript Progress

The HEIRS Investigators are committed to publishing findings from the HEIRS study and recognize that publication productivity may serve as a measure of progress of a study. Specific papers of high priority may be followed up with more frequent contact with the lead author if deemed necessary by the P&P or Steering Committee.

If the writing group does not produce the draft manuscript within three months (the time determined by the P&P Committee and approved by the HEIRS Steering Committee) it may be disbanded. Similarly, if some writing group members do not perform their assigned tasks within a reasonable time, they will be excused from further work in the group and from authorship of the report in preparation.

A.9 Preparation and Submission of Abstracts for Meetings

The HEIRS P&P Committee maintains a current list of all relevant meetings and their deadlines for submission of abstracts.

Abstracts submitted to the P&P Committee for review are accompanied, if appropriate, by copies of tables and graphs that include data on which the text of the abstract is based, so that the data may be reviewed along with the abstract. It is understood that some descriptive abstracts may not require data submission. Detailed analysis dealing with special topics are reserved for the preparation of the text for presentations or the manuscript for publication. Data in the abstract must be verified by the Coordinating Center prior to submission.

Abstracts are approved by the HEIRS P&P Committee and by the NHLBI before submission to any national or international organization for consideration. The time limit for review and approval of an abstract is one week after the chairman has received the abstract. Abstracts are sent by the lead author via e-mail to the P&P Chair, the NHLBI Project Officer, the NHLBI (**ebpdocs@nhlbi.nih.gov**) and the Coordinating Center Project Manager, who forward the abstracts via e-mail to the other members of the P&P Committee.

Once the abstract is approved by both the P&P and the NHLBI, the slides for oral presentations and/or panels for posters should be reviewed by the co-authors and must be verified by the CoC before the meeting presentation, since the material presented becomes part of the “public domain.” The slides or poster presentations do not need P&P approval, however, if the CoC has any concerns with the data presentations, then the P&P committee may be consulted. All correspondences regarding the final co-author reviews should also copy the NHLBI Project Officer. All presentations should be sent to the CoC Project Manager so that they may be posted to the HEIRS web site.

All abstract citations should be sent to the CoC Project Manager so that the HEIRS bibliography can be updated accordingly.

No prior clearance is needed for requests received by Principal Investigators, or their staff, to present or discuss at local meetings any previously published HEIRS data, as detailed in section A.13.

A.10 Selection of Presenters

The selection of the person presenting the material in the abstract at the respective national or international meeting is decided by the respective writing group (if any). If a writing group has not been constituted, the P&P Committee will make the selection of the presenter, and forward it to the HEIRS Steering Committee for approval. Preparation of slides is the responsibility of the writing group.

Once a mainstream or other paper has been presented at a scientific meeting, the tables are available for use by HEIRS professional staff at other scientific meetings. However, such subsequent presentations

are not to appear in published form unless the data in the original paper are already published and appropriately referenced.

In the case of papers scheduled for presentation before organizations issuing press releases, approval by the P&P Committee, HEIRS Steering Committee, and NHLBI and NHGRI press officers is needed before the text is released to the press.

A.11 Invited Papers and Presentations

It is anticipated and welcomed that Investigators associated with HEIRS will be invited as individuals to prepare papers or give oral presentations concerning findings or other aspects of HEIRS. When such invitations are received, the invitee should inform the inviter that acceptance will need to be approved by the P&P Committee. The P&P Committee will decide whether such a paper or presentation is appropriate and who should give the presentation or take the lead in writing the paper. (Papers and the list of authors will need final approval as described above.) Among other factors, these decisions take into consideration possible conflicts with other planned data analyses or competition for use of other HEIRS resources within the time allowed for completion of the invited paper or talk.

If an inviter has special reasons for choosing the particular invitee (e.g., special qualifications, previous or other involvements with the organization), these should be submitted by the inviter or invitee to the P&P Committee to assist it with the decision. Any disagreements should be resolved by the P&P Committee, with referral to the Steering Committee if necessary.

Unless approved beforehand by the P&P Committee, all presentations in response to such invitations are to be based on published HEIRS reports. Presentation of unpublished HEIRS data must be approved by the P&P Committee and reviewed by the NHLBI prior to the date of presentation.

A.12 Publication Costs

The costs of slides for specific presentations, publication of specific manuscripts and reprints are the responsibility of the main author. Hard copies of slides requested by other centers are paid for by those requesting them. Copies of PowerPoint slides, or other electronic versions of slides, should be sent to the Coordinating Center for posting on the HEIRS web site. The PowerPoint software allows for "notes" to be appended to the slides. Addition of these "notes" is recommended for the slides submitted for posting to aid any subsequent presenters. These submitted slides are considered "previously published" and may be used by HEIRS investigators in local presentations without additional approval.

A.13 Local HEIRS Presentations

Local presentations are talks done on the results of the HEIRS study at the Field Centers level (i.e., Grand Rounds) that may be exclusively on HEIRS or part of a general presentation on hemochromatosis or iron overload. Only data already published in abstracts or manuscripts can be presented locally, as well as previously approved slide presentations. The approved slide presentations will be posted on the HEIRS website for accessibility, and can be used for local presentations without authorization. No web-based data can be presented locally unless it is also published. Local presentations should not be published in journals or appear on the Internet.

The unauthorized submission of local HEIRS data as abstracts to specialty meetings or as medical/scientific manuscripts without the approval from the HEIRS Publications and Presentations Committee, the HEIRS Steering Committee or the NIH is strictly prohibited.

B. Publications Database

The Coordinating Center will provide access to a publications database. The list of papers in progress is available on the HEIRS web site, located under the "P&P" menu and is called "Publications". This report lists the lead author, working title and journal submission title, date of P&P receipt and date of P&P approval, the status of the proposal and the list of the P&P approved writing group. The intent is to enter a paper from the moment it is proposed and to trace it through to publication, so that bottlenecks can be identified and eliminated. In particular, the dates of stage entry and expected change to next stage can be used to ensure that a publication does not spend undue time in an incomplete state. By clicking on the title of the proposal, the actual manuscript proposal can be reviewed to check for any overlapping issues. This publications web site report also allows for current manuscript drafts to be loaded to the web site and contains an option to email the writing group to alert them that a new draft has been posted. The lead author is responsible for corresponding requests and timelines to the writing group.

The following reports will be distributed at each Steering Committee meeting:

- Manuscript Status List - number, title, Lead, date received, status, priority, date submitted, and date approved.
- Manuscript Publication List - full citation and HEIRS manuscript number.
- Abstract Presentation List - full citation and HEIRS manuscript number, date, and meeting.

C. Ancillary Studies

Investigators are encouraged to propose and conduct ancillary studies. Such studies enhance the value of the HEIRS and ensure the continued interest of the diverse group of investigators who are critical to the success of the study as a whole. To protect the integrity of HEIRS, ancillary studies are reviewed and approved by the Steering Committee before their inception. An ancillary study is one based on information from HEIRS participants in an investigation which does not coincide with a scientific aim or study question addressed by the HEIRS, and requires data which are not collected as part of the established HEIRS data set. In general, ancillary studies require external (non-HEIRS) funding.

Funding for an ancillary study must cover the costs incurred by the HEIRS Central Laboratory (e.g., to process and/or ship samples), and to the Coordinating Center (for tasks such as to process and ship analysis files, provide documentation, participate in statistical analysis, and integrate the new ancillary data back into the combined HEIRS database). No funds for this purpose are available within the main contract study.

It is an expectation that an HEIRS principal investigator or co-investigator be included as a co-investigator in every ancillary study proposal. A co-investigator from the HEIRS Coordinating Center is included as a co-investigator in every ancillary study proposal, unless the Coordinating Center deems this not to be necessary.

The HEIRS Steering Committee is responsible for initial review of the ancillary study. Investigators provide a two to three page summary of the proposed study to describe the study to HEIRS investigators and discuss the scientific rationale for the question(s) being addressed.

This summary includes:

- A. Identifiers:
Title

Initiating investigators, collaborators, and sites involved
Planned-starting date
Funding plans and estimated cost

B. Design and Methods:

Brief background and rationale
Study questions or hypotheses
Sample size, justification
Methods, data to be collected, analytic plan
Burden on HEIRS study participants
Impact on the main study

C. Data Requirements:

Data needed from HEIRS analysis files
Specimens needed from the HEIRS repositories, specifying type and amount
Expected impact on Coordinating Center or local sites

D. Handling of HEIRS Data and Specimens:

Disposition of stored samples from main study and those processed by the ancillary study
Disposition of ancillary study data at the conclusion of the ancillary study

E. Lead Investigator Contact Information:

Affiliation, address, telephone number, fax number, e-mail address

The Steering Committee considers this information to assess the priority of the proposed study and determine its potential impact on the main study (HEIRS). Highest priority is given to studies which: 1) do not interfere with main HEIRS objectives or overburden HEIRS participants, 2) have the highest scientific merit, 3) have objectives closest to those of HEIRS, and 4) can draw on the unique characteristics of the HEIRS cohort.

The Steering Committee reviews the proposal to determine that it does not compromise, hinder, or jeopardize the conduct of the HEIRS. Review of proposed ancillary studies for scientific merit is not the primary responsibility of this review process, but optional suggestions of a scientific nature may result from the review. Ancillary study proposals approved by the Steering Committee must be submitted to the Monitoring Board, who recommends approval or disapproval to NHLBI. NHLBI approval is required before grant applications or requests for funding are submitted. A letter detailing the review outcome will be sent by the OSMB Executive Secretary (currently Richard Fabsitz) to the ancillary study PI.

The HEIRS investigator collaborating with the ancillary study PI is expected to facilitate the preparation of the ancillary study proposal, its submission to the HEIRS Steering Committee, and the communication between the collaborating studies throughout this process. The HEIRS investigator provides a copy of the HEIRS ancillary study policy to the outside investigator(s), and assists in the preparation of the proposal. After favorable review by the HEIRS Steering Committee, the HEIRS study makes available a copy of its publications policy to the ancillary study investigators. When applications for (non-HEIRS) funding for an ancillary study to HEIRS are submitted, it is requested that a courtesy copy be sent at that time to the HEIRS Project Officer.

Prior to the time of distributing HEIRS specimens and/or information, the HEIRS PI responsible for that portion of the HEIRS data base (Coordinating Center, Central Laboratory) makes explicit arrangements with the ancillary study PI for the security of these study materials, and for their final disposition at the conclusion of the ancillary study. These arrangements are to be detailed in the HEIRS Data Distribution Agreement as appropriate depending on whether or not the ancillary study investigator is an HEIRS investigator. The safety and confidentiality of the HEIRS data at the collaborating institution is the responsibility of the ancillary study PI, as is the appropriate disposition of these materials after the study has been completed. Left-over DNA and laboratory specimens is destroyed or returned, as appropriate; files of HEIRS data are returned or deleted, as established at the outset of the collaboration. An archival

copy of the newly collected data and/or laboratory results is sent to the HEIRS Coordinating Center at the conclusion of the data analysis and publication of the main (ancillary) study hypothesis. This transfer is the responsibility of the ancillary study PI and his/her HEIRS collaborator(s).

The Steering Committee monitors the development of the ancillary studies, receipt of funding, initiation dates, and progress. A written progress report on ancillary studies is made periodically to the Steering Committee and the Monitoring Board. Publications resulting from ancillary studies follow the same policies as described in the document on HEIRS Publication and Presentation policy, except analyses does not need verification from the CoC, and the P&P does not have to approve writing group nominations . The timing of publications resulting from the ancillary study with respect to the results from the main study should be addressed during consideration of the study proposal by the SC.

References

1. Huth EJ. Guidelines on authorship of medical papers. Ann Intern Med 1986; 104:269-274
2. Instructions for authors. JAMA August 7, 1996; 276(5):348

APPENDIX 1-----

HEIRS MANUSCRIPT PROPOSAL

FOR ADMINISTRATIVE USE

Manuscript #: _____ Priority: _____

Date Sent/Rec'd: _____ Date Approved: _____

1. Title:

2. Writing Group (list lead responsibility first):

- | | | |
|-----|----|----|
| *1. | 4. | 7. |
| 2. | 5. | 8. |
| 3. | 6. | 9. |

3. Timeline (approximate dates for): Starting Analyses:

First Draft:

Submission for Publication:

4. Scientific Background and Rationale:

5. Main Hypothesis:

6.Data/Methods of Analysis (variables, time window, source, inclusions/exclusions):

Template tables of the analyses being considered should be included to help the review process.

7. List of HEIRS manuscript and abstract numbers of approved proposals that involve similar variables or hypotheses, and brief discussion of overlap issues.

8. Analysis by Data Coordinating Center or by Local Investigator?

9. Target Journal?

10. Lead author contact information (affiliation, address, telephone number, e-mail address):

APPENDIX 2

HEIRS ABSTRACT PROPOSAL

The time limit for review and approval of an abstract is one week after the chairman has received the abstract.

FOR ADMINISTRATIVE USE

Abstract #: Priority:

Date Sent/Rec'd: _____ Date Approved:

1. Title:

2. Writing Group (list lead responsibility first):

- | | | |
|-----|----|----|
| *1. | 4. | 7. |
| 2. | 5. | 8. |
| 3. | 6. | 9. |

3. Timeline (approximate dates for):

First Draft:
Submission for Meeting

4. Scientific Background and Rationale:

5. Main Hypothesis:

6. Data/Methods of Analysis:

Template tables of the analyses being considered should be included to help the review process.

7. List of HEIRS manuscript and abstract numbers of approved proposals that involve similar variables or hypotheses, and brief discussion of overlap issues.

8. Analysis by Data Coordinating Center or by Local Investigator?

9. Target Meeting?

10. Lead author contact information (affiliation, address, telephone number, e-mail address):

APPENDIX 3

HEIRS Contract Numbers

The HEIRS Study was initiated and funded by NHLBI, in conjunction with NHGRI. The following HEIRS contract numbers should be used to acknowledge support in manuscripts.

N01-HC-05185 (University of Minnesota)

N01-HC-05186 (Howard University)

N01-HC-05188 (University of Alabama at Birmingham)

N01-HC-05189 (Center for Health Research, Kaiser Permanente)

N01-HC-05190 (University of California, Irvine)

N01-HC-05191 (London Health Sciences Centre)

N01-HC-05192 (Wake Forest University)

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APPENDIX 4

Acknowledgment List

FIELD CENTERS

Birmingham, AL--University of Alabama at Birmingham:

Dr. Ronald T. Acton (Principal Investigator), Dr. James C. Barton (Co-Principal Investigator), Ms. Deborah Dixon, Dr. Susan Ferguson, Dr. Richard Jones, Dr. Jerry McKnight, Dr. Charles A. Rivers, Dr. Diane Tucker and Ms. Janice C. Ware.

Irvine, CA--University of California, Irvine:

Dr. Christine E. McLaren (Principal Investigator), Dr. Gordon D. McLaren (Co-Principal Investigator), Dr. Hoda Anton-Culver, Ms. Jo Ann A. Baca, Dr. Thomas C. Bent, Dr. Lance C. Brunner, Dr. Michael M. Dao, Dr. Korey S. Jorgensen, Dr. Julie Kuniyoshi, Dr. Huan D. Le, Dr. Miles K. Masatsugu, Dr. Frank L. Meyskens, Dr. David Morohashi, Dr. Huan P. Nguyen, Dr. Sophocles N. Panagon, Dr. Chi Phung, Dr. Virgil Raymundo, Dr. Thomas Ton, Professor Ann P. Walker, Dr. Lari B. Wenzel and Dr. Argyrios Ziogas.

London, Ontario, Canada--London Health Sciences Center:

Dr. Paul C. Adams (Principal Investigator), Ms. Erin Bloch, Dr. Subrata Chakrabarti, Ms. Arlene Fleischhauer, Ms. Helen Harrison, Ms. Kelly Jia, Ms. Sheila Larson, Dr. Edward Lin, Ms. Melissa Lopez, Ms. Lien Nguyen, Ms. Corry Pepper, Dr. Tara Power, Dr. Mark Speechley, Dr. Donald Sun and Ms. Diane Woelfle.

Portland, OR and Honolulu, HI--Kaiser Permanente Center for Health Research, Northwest and Hawaii, and Oregon Health and Science University:

Dr. Emily L. Harris (Principal Investigator), Dr. Mikel Aickin, Dr. Elaine Baker, Ms. Marjorie Erwin, Ms. Joan Holup, Ms. Carol Lloyd, Dr. Nancy Press, Dr. Richard D. Press, Dr. Jacob Reiss, Dr. Cheryl Ritenbaugh, Ms. Aileen Uchida, Dr. Thomas Vogt and Dr. Dwight Yim.

Washington, D.C.--Howard University:

Dr. Victor R. Gordeuk (Principal Investigator), Dr. Fitzroy W. Dawkins (Co-Principal Investigator), Ms. Margaret Fadojutimi-Akinsiku, Dr. Oswaldo Castro, Dr. Debra White-Coleman, Dr. Melvin Gerald, Ms. Barbara W. Harrison, Dr. Ometha Lewis-Jack, Dr. Robert F. Murray, Dr. Shelley McDonald-Pinkett, Ms. Angela Rock, Dr. Juan Romagoza and Dr. Robert Williams.

CENTRAL LABORATORY

Minneapolis, MN --University of Minnesota and University of Minnesota Medical Center, Fairview:

Dr. John H. Eckfeldt (Principal Investigator and Steering Committee Chair), Ms. Susie DelRio-LaFreniere, Ms. Catherine Leiendecker-Foster, Dr. Ronald C. McGlennen, Mr. Greg Rynders, Dr. Michael Y. Tsai and Dr. Xinjing Wang.

Coordinating Center

Winston-Salem, NC--Wake Forest University:

Dr. David M. Reboussin (Principal Investigator), Dr. Beverly M. Snively (Co-Principal Investigator), Dr. Roger Anderson, Ms. Aarthi Balasubramanyam, Ms. Eleese Bostic, Ms. Brenda L. Craven, Ms. Shellie Ellis, Dr. Curt Furberg, Mr. Jason Griffin, Dr. Mark Hall, Mr. Darrin Harris, Ms. Leora Henkin, Dr. Sharon Jackson, Dr. Tamison Jewett, Mr. Mark D. King, Mr. Kurt Lohman, Ms. Laura Lovato, Dr. Joe Michaleckyj, Ms. Shana Palla, Ms. Tina Parks, Ms. Leah Passmore, Dr. Pradyumna D. Phatak, Dr. Stephen Rich, Ms. Andrea Ruggiero, Dr. Mara Vitolins, Mr. Gary Wolgast and Mr. Daniel Zaccaro.

NHLBI PROJECT OFFICE

Bethesda, MD--Ms. Phyliss Sholinsky (Project Officer), Dr. Ebony Bookman, Dr. Henry Chang, Ms. Kristianne Cooper, Dr. Richard Fabsitz, Dr. Cashell Jaquish, Dr. Teri Manolio and Ms. Lisa O'Neill.

NHGRI PROJECT OFFICE

Bethesda, MD--Dr. Elizabeth Thomson.

Dr. Jean MacCluer, Southwest Foundation for Biomedical Research, also contributed to the design of this study.

