



Collaboration Toolkit

A guide to multi-site research
in the HMO Research Network

Purpose and Description

This guide provides investigators and their research teams with tips, tools and resources to plan and carry out multi-site research within the HMO Research Network (HMORN).

The content is organized parallel to the life cycle of a project:

- Finding collaborators and developing a grant
- Working through administrative start up processes
- Standardizing recruitment and primary data collection across sites
- Utilizing the virtual data warehouse (VDW)
- Closing out a project and translating results into practice

This guide also serves as a repository of resources from which you can download templates, forms, and other information that will facilitate planning and implementing a collaborative project, including:

- Proposal development resources, such as a budgeting template and estimating tool
- Boilerplate for member sites and Network collaborations and other useful tables and figures
- Links to IRB forms and guidelines from most HMORN sites
- Data sharing guidelines and detailed information about the Virtual Data Warehouse (VDW)
- Best practices in recruitment, data collection, and project closeout

Comments or Questions

If you have questions about HMORN multi-site research not sufficiently addressed here, please refer to your local site administrator.

If you have specific questions or comments about this Toolkit, please contact Ella Thompson at Thompson.e@ghc.org.

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CHAPTER 1: COLLABORATORS AND GRANT DEVELOPMENT

[1.1 Essential Considerations for Investigators](#)

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[1.4 Multi-site Budgeting Tips and Best Practices](#)

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Working with other HMORN sites can greatly facilitate multi-center clinical, epidemiological, and health services research. Whether two sites or twelve, multi-center research offers many advantages to HMORN investigators and their partners—including, to name a few:

- a diversity of disciplines, participants and practice arrangements
- cross-site mentors
- the breadth and depth of biostatistical and methodological expertise
- availability of mature, comprehensive data systems
- infrastructure resources that support collaboration

HMORN partnerships are highly valued for intellectual enrichment, community and collegiality. The Network stands apart for its capacity to disseminate and translate research results into health care settings.

1.1 Essential Considerations for Investigators

Multi-site projects require more attention and nurturing than single-site projects. As such, investigators should approach multi-site projects knowing the challenges they are likely to encounter. There are key considerations in four domains as multi-site networks are developed and sustained: (1) [scientific](#), (2) [technical](#), (3) [interpersonal](#), and (4) [financial](#).

Scientific

- **Leadership** – The principal investigator(s) will set the tone for the overall project and must do so at the inception of the collaboration. Critically important are the need to build authentic relationships and the need to establish an environment that appropriately balances various governance strategies (democracy, consensus building, and rare moments of autocracy). Leaders must be able to justify both unilateral and group-driven decisions, and their communications must always be constructive and credible.
- **Accountability** – It's important to cultivate an environment where everyone feels responsible for the success of the project. Hold collaborators to milestones and deliverables, but be willing to renegotiate when circumstances warrant. Avoid blaming or shifting blame if something goes wrong.
- **“What’s in it for me?”** – Every stakeholder needs to have a clear understanding of what they will gain from participating. Ideally, everyone who wants a first-

authored paper will have a chance to produce one. Larger projects may benefit from each scientific collaborator taking responsible for a particular aim/sub-aim that reflects their scientific interests and contributions.

- **Gestalt** – Effective study design and team constitution yield a project in which the whole is greater than the sum of the parts. Individually and collectively, each site and the full team provide added value and capitalize on the multi-disciplinary nature of the team and/or demographic make-up of the participating sites.
- **Documentation** – Determine and abide by a documentation strategy, then revisit it as the project moves through stages. Detailed minutes or a decision log is essential in the development phase and during analysis. Once a project is in maintenance, shorter summaries or lists of action items may be adequate. Ensure that project documentation is available to everyone, either via a Web site or wiki, or by regular and timely dissemination via email.
- **IRB Review** – Several strategies can help alleviate this potentially time-consuming aspect of multi-site studies, including detailed understanding of local contextual issues, application deadlines, and requisite materials for IRB applications. Also consider what degree of site-to-site protocol variation is tolerable, and build an overall project timeline that anticipates an iterative process.
- **Data Privacy** – Respect for participants and their data is a high priority and investigators are expected to use the minimum data needed to perform analyses. HIPAA data security and privacy compliance should be well understood by investigators at every site involved. Potential roadblocks can be alleviated by de-identifying data to be transferred for the analytic data set. When this is not possible and a DUA is needed, the HMORN has developed a [DUA toolkit](#) to help navigate the process and provide general info, best practices and common pitfalls, and contacts and signatories for each site.

Technical

- **Hardware and software capabilities** – From the outset, be aware of any hardware or software constraints or requirements that each site brings to the table. For example from site to site, it is useful to know:
 - Mac vs. PC computing environment
 - Browser(s) used
 - Type of Email system and ability to view HTML email
 - Cap on size of attachments sent or received
 - Variable knowledge of hardware or software products used
- **Data availability** – The [virtual data warehouse \(VDW\)](#) is an evolving resource that relies on dynamic legacy data sources. Electronic Medical Records (EMR) also vary from site to site. Open discussions of data needs must occur early and often.

- **Analytic capacity** – If the eventual plan is for multiple sites to lead various analyses:
 - Ensure that each site will have biostatistical support at the appropriate level for the study, or determine the role the coordinating center will play in collaborators' analyses.
 - Create [data use agreements \(DUAs\)](#), [subcontracts](#), and data sets (or limited data sets), in a manner that tries to anticipate all possible analytic scenarios.
- **Level playing field or least common denominator?** – If one or more sites are not at the same technical proficiency or lack a critical data element, acknowledge this at the outset and discuss whether to develop the study such that all sites contribute equally, or if there are aspects in which some sites participate at a different level.

Interpersonal

The potential exists for stepping on interpersonal landmines, especially in the early stages of a new collaboration. Positive interpersonal dynamics are more likely when both leaders and participants in multi-site collaboration are able to commit to the following:

- **In-person meetings** – Meet face-to-face at least once per year, more if possible, especially as a new collaboration is launched. During in-person meetings, carve out time for social interaction and emphasize getting to know collaborators as people.
- **Communications** – Ensure that communication is as open as possible and that decision-making is transparent. Leaders should be prepared to explain the “who, what, when, why, where and how” of decisions.
- **Decision-making** – Larger multi-site projects (e.g., 7 or more sites) might benefit from an executive leadership committee, particularly if a project is comprised of two or more major sub-projects. Making every decision via a large committee may become cumbersome or even tedious.
- **Sub-grouping** – Inevitably, small sub-groups of collaborators may form, which could result in alliances and sidebars. These can be potentially detrimental to overall project functioning. Such alliances may be driven by diverging opinions on how to handle particular project issues, or may be an artifact of pre-existing relationships. Forging strong overall team cohesion is one mitigation strategy.
- **Damage control** – Behavior patterns to monitor and curb if necessary include regular second-guessing of the leader's or group's decisions, infighting, non-adherence to tasks and deliverables, and non-response.

Financial

- **Equity** – There are too many variables to ensure that every collaborator will receive an equal share of the pie. But to the extent possible, if sites are

performing equivalent tasks, the allocations should be as similar as possible with respect to staffing/FTE levels.

- **Administrative simplicity** – Some multi-site projects have developed budget checklists and related instruction documents. These, plus clear timelines, can ease some of the administrative complexities and ensure consistent dissemination of information.
- **Anticipation** – Prevent surprises by collecting information early about F&A (indirect) rates, benefit rates, and salaries. Determine whether a project is likely to exceed the NIH \$500,000 cap and plan accordingly.
- **Research administration staff** – Projects should involve grant and contract personnel as full team members from project development through the early post-award phase, as contracts and schedules are developed. Conference calls between all sites' grant administrators may be warranted at key junctures of a project. Whenever possible, pivotal cross-site discussions should also include study personnel from other departments, e.g. survey research and information technology (IT).

1.2 Building a Multi-Site Team

The culture of collaboration in the HMORN is one of intellectual partnership and shared opportunities. Previous research has shown that “mutual interdependence” is a key characteristic of successful collaborations, wherein all parties gain something that would not otherwise be gained in a non-collaborative environment. In addition, the HMORN has found that thoughtful communication is essential for successful ongoing collaborations. It is crucial to identify strategies that enable us to collaborate efficiently, and maximize both scientific opportunities and financial gains. A second imperative is the promulgation of effective approaches to data sharing and assurance of data protection. All of these goals can be simultaneously achieved through open communication and thoughtful understanding of site-specific concerns.

1.3 Finding Collaborators

A collaborating investigator must be enlisted for each center that will participate in a multi-site project. Since HMORN centers vary widely in terms of number and interests of faculty, this can be difficult—especially for relatively uncommon research topics. Yet finding colleagues you

Ten tips for successful collaborations

- 1) **Be proactive.** Construct data use agreements and policies that anticipate collaborative analysis and publication.
- 2) **Avoid second guessing.** Leaders solicit input appropriately and decision making is transparent.
- 3) **Build trust.** Leaders are attentive and respectful.
- 4) **Capitalize on efficiencies** and products of other HMORN studies.
- 5) **Clarify roles and expectations** among leaders and team members at the onset. But be realistic—investment and engagement will vary from person to person, site to site.
- 6) **Discuss papers** early and often.
- 7) **Don't strain resources** or relationships. Be wary of “scope creep”.
- 8) **Empower success.** Delegate authority, but design a safety net when assigning responsibility to individuals or subgroups.
- 9) **Maximize face time.** One in-person meeting is worth more than 10 conference calls.
- 10) **Share opportunities** and mentor junior scientists.

respect and work well with is important regardless of whether they are across the hall or across the country.

Collaboration on multi-site projects can take different forms. In some studies, depending on budget, study needs, and data availability, a site may participate in scientific collaboration or other aspects of the study without being a data collection site.

Local investigators already involved in HMORN projects

Investigators already involved in multi-site studies can be called upon to assist. They may be willing to put you in touch with their colleagues at other sites to help find investigators with related interests at other research centers.

Search tool on the [HMORN website](#)

You can comb through the content of HMORN centers' public sites to search for a research topic then narrow your search results by Investigator. This is limited to what the sites keep on their public sites.

HMORN investigators and research interests

Updated in August 2008, the [PI Directory](#) offers a complete list of Investigators per site as well as contact information and individual interests for each investigator. There are also links to bios and personal pages for most investigators.

The annual HMO Research Network conference

The conference offers many opportunities to meet and interact with researchers from across the HMORN—many of whom are experienced with multi-center projects. A variety of scientific interest groups and new investigator sessions are held each year at the annual conference. Visit the [HMORN website](#) for upcoming dates and locations.

Investigator exchanges

Such arrangements can allow newer investigators a chance to spend time at another center to network and build relationships, as well as for mentoring. Contact your research center director to explore whether or not this may be an option for you.

Local research administrators

These staff are typically willing to work with you to let local investigators know you are looking for potential collaborators. Contact information for research administrators can be found in the [Key Contacts Directory](#).

1.4 Multi-site Budgeting Tips and Best Practices

At a minimum, budgets typically include FTE for a local investigator, project manager, and programmer at each site. Whenever feasible, budget for travel for face-to-face meetings at key points in the project (e.g., kick-off, onset of analysis).

Naturally, all of this can add up to a good deal of cost. If the budget is over \$500,000 per year, you have to get permission from the project officer at NIH prior to submission. The number of sites may be scaled back to meet budget constraints. It is important for the lead investigator(s) to employ good communication and transparency if scaling back is needed. This will help you avoid misunderstandings and bad feelings between sites. Other key considerations include:

- Remember that general office supplies are often calculated as a percentage of FTE by site.
- Be aware that various organizational and billing structures may result in additional costs at some sites (for example, costs to pull hard-copy charts for validation studies).
- Indirect (F&A) costs vary across research centers. Most percentages range from the low-40s to the upper-60s. This is usually not an issue since federal funding mechanisms typically only consider direct costs.

1.5 Proposal Development Resources

[Key contacts directory for proposal development](#)

This document gives important points-of-contact from each HMORN site for various components of proposal development, such as:

- Organizational descriptions and resources
- Biosketches and other support
- Investigator IRB training certifications
- Indirect cost rates

[Statement of intent to establish a consortium agreement](#)

This document provides a suggested standardized format for collecting required information for multi-site grant applications. The document is divided into 3 sections; Site Information, Project Information, and Statement of Intent. The lead site can determine the timeline for submission of specific information.

[Checklist of application elements needed from each site](#)

The lead site can set forth specifics about what materials are needed and when they are due back from each site. The form also includes formatting reminders and contact information for routing and questions.

[Template budget sheet](#)

The budget sheet provides a suggested format to standardize the collection of budget information from non-prime institutions involved in the grant.

[Administrative best practices](#)

This is a compilation of shared research administration 'best practices' documents submitted by various HMORN sites. Sections are: grant tracking tools, policies and procedures, HIPAA tools, and training and communication.

Boilerplate*

- [HMO Research Network](#)
- [15 HMORN research centers](#)
- [HMORN collaborations](#)
- [HMORN and CTSAs](#)
- [Virtual Data Warehouse \(VDW\)](#)

Tables and figures

- U.S. Maps with HMORN member locations ([Style 1-Teal](#)) ([Style 2-Blue](#))
- [Table: HMORN Scientific resources by site](#)
- [Table: Large consortium projects](#)
- [Table: Demographics for member health plans](#)
- [Table: VDW data systems rollouts across HMORN sites](#)
- [Table: Type of VDW data and year available by site](#)

References and Presentations

A [collection of HMORN and/or VDW references](#) is available. This should not be considered a complete listing.

[HMO Research Network: The research partner of choice for those seeking to shape public health and health care delivery](#). Presented to CTSA Community Engagement Steering Committee workgroup on Community and Academic Practice Partnerships, July 24, 2008 by Dr. Mark Hornbrook of the Center for Health Research, KP Northwest.

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*If boilerplate is out of date, contact sites directly for the information you need.

CHAPTER 2: RESEARCH REVIEW, SUBCONTRACTS, AND DATA USE AGREEMENTS

[2.1 Multi-center IRB Review](#)

[2.2. Multi-site Subcontracts](#)

[2.3 Data Use Agreements](#)

2.1. Multi-center IRB Review

The investigator at each research center is responsible for obtaining approval from their local IRB. All approval memos from collaborating sites should be submitted to the prime site for their records.

Investigators are wise to allow extra time for multi-site IRB review. Divergent modifications, site-specific protocol differences resulting from variations in local laws, and difference between review committee interpretations can all add time. More sites and higher risk can result in longer time to approval. It is recommended that you plan for an extra one to six months, depending on the complexity of your project.

Resources for multi-site IRB review

Using the [Key Contacts Directory](#) to find local IRB administrators, reviewing committee meetings dates across the sites involved in your project, and previewing site IRB forms may all contribute to a smoother process. The table below has been developed to aid in understanding such issues by site. Along with this, a list of links to [external IRB resources](#) has been compiled.

Understanding the review cycles and deadlines at the sites involved in your multi-site project can help you proactively plan for timely review and avoid delays. We have compiled [review dates and timelines](#) from most sites to aid with this process, as well as

HMO Research Network Site	Site IRB Info & Materials	IRB Staff Contacts
Geisinger Health System – Center for Health Research	IRB Documents	Geisinger
Group Health Cooperative – Group Health Research Institute	IRB Documents	Group Health
Harvard Pilgrim Health Care – Dept of Ambulatory Care & Prevention	IRB Documents	Harvard Pilgrim
Health Partners – Health Partners Research Foundation	IRB Documents	HealthPartners
Henry Ford Health System – Center for Health Services Research	IRB Documents	Henry Ford
KP Colorado – Institute for Health Research	IRB Documents	KPCO
KP Georgia – Center for Health Research Southeast	IRB Documents	KPGA
KP Hawaii – Center for Health Research Hawaii	IRB Documents	KPHI
KP Northern California – Division of Research	IRB Documents	KPNC
KP Northwest – Center for Health Research Northwest	IRB Documents	KPNW
KP Southern California – Department of Research & Evaluation	IRB Documents	KPSC
Lovelace Health Plan – Lovelace Clinic Foundation	IRB Documents	Lovelace
Marshfield Clinic/Security Health Plan – Marshfield Clinic Research Foundation	IRB Documents	Marshfield
Fallon Community Health Plan – Meyers Primary Care Institute	IRB Documents	Meyers/Fallon
Scott & White	IRB Documents	Scott & White

Streamlined IRB review process for low-risk, data only HMORN studies

The [Standard Operating Procedure](#) for facilitated review documents policies and procedures for IRB review of low risk research conducted between HMORN sites. The facilitated review process is currently approved only for data-only studies in epidemiology, health services, health economics, & related research areas.

2.2. Multi-site Subcontracts & Data Use Agreements

The Network has developed complementary [HMORN SubAward](#) and [HMORN Data Use Agreement](#) (DUA) templates. The corresponding [Instructions for Use](#) should be reviewed prior to using the templates. In the past, administrative delays have negatively impacted the science and timelines of HMORN projects. The purpose of these templates is to minimize the amount of time needed to execute such agreements.

The HMORN Board of Governors has strongly endorsed the use of this template suite for all new HMO Research Network projects. ARRA awards could particularly benefit from using the SubAward and DUA templates due to tight timelines.

Please note the following:

- The HMORN DUA template should NOT be used with any other SubAward Agreement.
- The DUA has been reduced to 3-pages of essential required content; any contractual elements appearing in the past are now in the SubAward template.
- The DUA template refers to IRB approved protocol so as to minimize or eliminate the need for DUA modifications should data needs change
- When the SubAward template is used, contract staff should inform the PI and PM so that they are aware that the streamlined DUA template can be used.
- As templates, these documents are intended to be a starting place for negotiations. It is critical to bear in mind as changes are negotiated that the language in both documents was developed specifically for joint use. It is strongly advised that modifications be as minimal as possible.

The HMO Research Network has asked all sites to use these documents as a starting point. A [Memorandum of Understanding](#) has been sent to all sites to sign, indicating willingness to do so.

2.3 Data Use Agreement (DUAs)

A [DUA Toolkit](#) has been developed for PIs and PMs. The toolkit covers when data use agreements (DUAs) are needed, the steps involved in putting a DUA in place, best practices and common pitfalls. Several appendices provide links to outside resources, answers to frequently asked questions, and a glossary of terms. DUA recipients and signatories for each site can be found in the [Key Contacts Directory](#).

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CHAPTER 3: RECRUITMENT AND DATA COLLECTION

[3.1 Guide to Cluster Randomized Trials](#)

[3.2 Improving Provider Participation](#)

[3.3 Tools to Support Recruitment and Primary Data Collection](#)

3.1 Guide to Cluster Randomized Trials

The HMORN offers a unique environment for conducting comparative effectiveness research, including cluster randomized trials, a study design used to randomize at the health plan, clinic or regional level – to name a few.

A [guide to understanding cluster randomized trials](#) within the context of the HMORN specifically, including forms, tables, templates, and special consideration, is available.

3.2 Improving Provider Participation

Recommendations to improve provider participation in clinical trials

A study involving 10 HMORN sites examined cardiologists' and organizational leaders' interest in clinical trial participation and perceived barriers and facilitators to participation. A [set of recommendations for the HMORN](#) based on study findings is provided here as a planning tool.

Manuscript:

Carol P. Somkin, Andrea Altschuler, Lynn Ackerson, Dennis Tolsma, Sharon J. Rolnick, Robert Yood, W. Douglas Weaver, Ann Von Worley, Mark Hornbrook, David J. Magid, Alan S. Go. Cardiology clinical trial participation in community-based healthcare systems: Obstacles and opportunities. Contemporary Clinical Trials - 09 April 2008 (10.1016/j.cct.2008.02.003)

3.3 Tools to Support Recruitment and Primary Data Collection

[Table of site-specific recruitment requirements and resources](#)

This table indicates the presence or absence of resources, expertise, requirements, and facilities for 9 of the 15 HMORN sites. These include:

- On-site survey department, chart abstractions, research clinic
- Requirement for provider notification, provider consent, subject invitation letter
- Permissibility of cash incentives
- Past experience with web recruitment, focus groups, in-depth interviewing
- Availability of opt out protocols, bilingual interviewers
- Status as a clinical trials coordinating center
- Additional notes

[Guide to optimizing recruitment and data collection in multi-site studies](#)

This resource identifies various strategies to optimize recruitment and data collection in a multi-site environment. Content areas include:

- Overview and optimization of recruitment approaches (mail, telephone, in-person, web, community outreach, and mixed model)
- Procedures for enhancing response rates and retention
- Considerations for special populations
- Success stories
- Appendices (references, “must reads,” examples of study materials)

[PRISM Readability Toolkit](#)

This resource was created by the Group Health Research Institute (formerly known as Group Health Center for Health Studies) as part of the Program for Readability In Science & Medicine (PRISM), a readability initiative that aims to address health literacy concerns in the research context. The PRISM Toolkit helps research teams develop study materials that are readable and participant-centered.

The Toolkit includes the following modules:

- Background information on health literacy, plain language, and why both are important in the research context
- A detailed explanation of the principles of plain language
- An at-a-glance summary of strategies that support plain language
- Information and advice about using readability formulas
- Editing checklist for participant materials
- Resources for consent forms and HIPAA authorizations, including easy-to-read template language and links to helpful templates and guidelines
- Alternative wording suggestions for hundreds of complex terms commonly used in medical and research settings
- Examples of improved readability and improved formatting
- A list of web-based resources and publications focused on health literacy, readability, and plain language

[Interviewer training manual](#)

This manual was developed primarily for telephone interviewing in multi-site studies; however, a special section for in-person interviewers is included. It is intended as an introduction to interviewing for people who have never been formally trained in conducting a research interview.

The information and techniques in the guide help train staff to conduct interviews with the goals of obtaining complete and accurate information in a systematic way and maximizing interviewer response. It is meant to be used in conjunction with interviewer training conducted by study staff. Therefore, matters pertaining to a specific study would be incorporated into each study's training manual.

Topics covered include:

- Professional ethics
- Introduction to interviewing
- General interviewing practices
- Active listening
- Refusal avoidance
- Additional considerations for in-person interviewing.

[Abstraction recommendations for common chart variables](#)

Recommendations were developed by looking at abstraction forms from fifteen studies. The aim was to determine if study variables collected via chart review could be standardized. Some measure of uniformity helps increase efficiency in developing abstraction forms and collecting data.

Recommendations are included for the following items:

- Age and date of birth
- Gender
- Race
- Height and weight
- Marital status
- Smoking status
- Age at menarche
- Menopausal status

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CHAPTER 4: VIRTUAL DATA WAREHOUSE (VDW)

[4.1 Overview](#)

[Figure 1. The HMORN VDW and how it works](#)

[4.2 Data Areas](#)

[Figure 2: HMORN VDW data structures](#)

[4.3 Steps for Using the VDW](#)

[4.4 General VDW Resources](#)

[4.5 VDW Programming Resources](#)

Multi-center research can be greatly facilitated by the HMO Research Network Virtual Data Warehouse (VDW). This section provides context and tools to help investigators discover the potential of the VDW and navigate obstacles to using it in research projects.

4.1 Overview

One of the hallmarks of the HMORN is the variety and amount of electronic administrative data about the health and health care utilization of the sites' enrollees. To make these data more easily accessible for multi-site research projects, we have constructed a virtual data warehouse—the VDW. The VDW is not a centralized data warehouse—it is “virtual”, consisting of parallel databases set up identically at each of the HMORN sites (see Figure 1) that can be easily merged across sites. These databases have been constructed by extracting data from the local electronic data systems and reconfiguring them to use standard variable names and coded values.

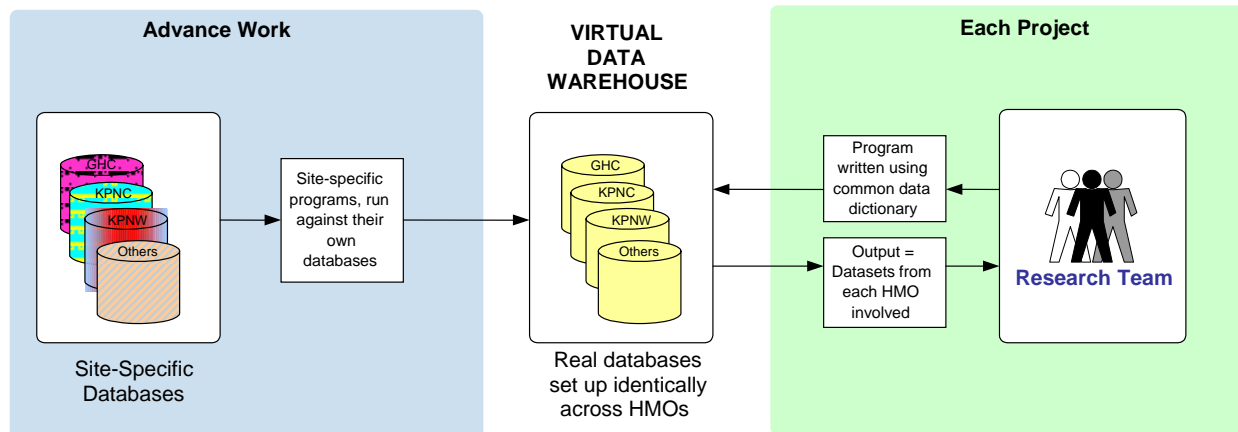
With the VDW, much of the preparatory work for pooling existing data across multiple sites has been done in advance. A project's analyst writes a program based on the VDW data dictionary. The program is then sent to the other participating sites to be run locally with the output files securely transferred to the project. Final results or datasets are assembled from these files.

The VDW is constantly being expanded and improved as each project uses it. Currently, it contains data that support a wide variety of research studies, including studies using surveys and/or chart abstraction, as well as those directly aimed at analysis of electronic administrative data. For example, the VDW has been used to identify subjects for extensive chart abstraction in a study of treatment and outcomes for older women with early stage breast cancer. A current project to develop a test of oral health literacy will use the VDW to select potential subjects residing in neighborhoods with a variety of average educational levels; each site will then extract additional contact information from their local data sources.

Example VDW projects

A great deal of research can be conducted using only VDW data. Commonly VDW data supplements other data gathered from subjects, as well. A [table of some recent VDW studies](#) illustrates the breadth of possibilities.

Figure 1. The HMORN VDW and how it works

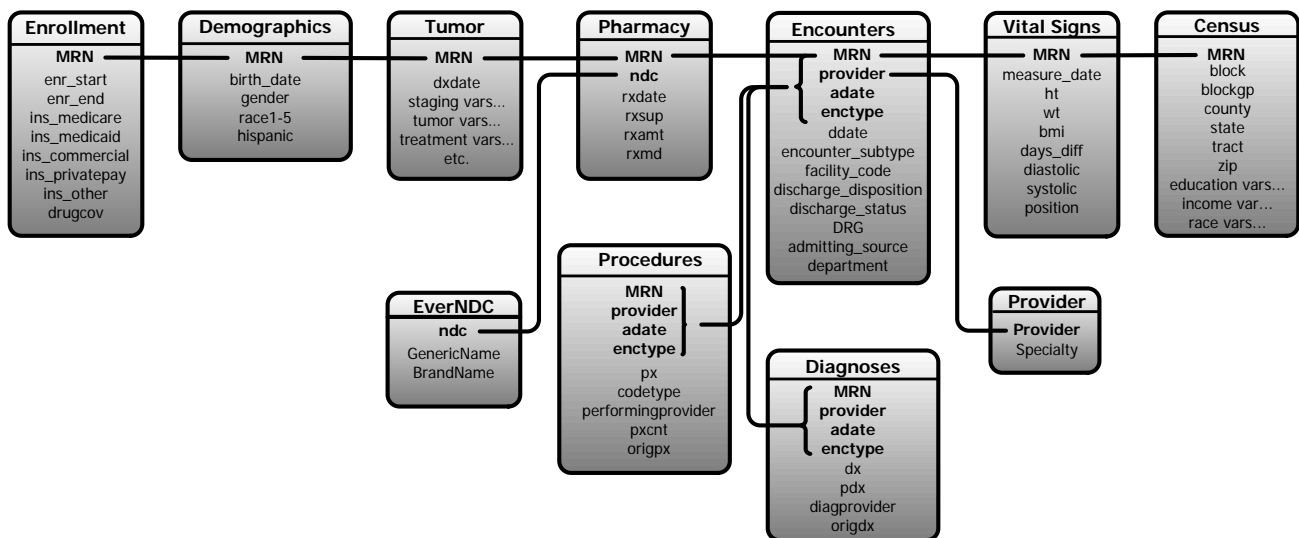


Standardized VDW data sets are already well established at most HMORN sites. Site programmers and data managers are actively involved in on-going discussions and quality control efforts and are familiar with the process of using the VDW for research projects.

4.2 Data Areas

As of March 2007, VDW data areas include enrollment, demographics, tumor registry, outpatient pharmacy, encounters (procedures and diagnoses), vital signs and census data – as shown in the figure below.

Figure 2: HMORN VDW data structures



Catalog of VDW macros

Site programmers have developed a catalog of SAS macros, or reusable code. VDW users can employ the macros to define standard methods for sampling and data abstraction within the VDW.

Commonly used VDW SAS macros include:

- Flexible definitions of “continuous enrollment”
- First disenrollment after an index date
- Comorbidity scores including Charlson and RxRisk
- Age calculation
- Cases with invasive breast cancer between specific dates
- Outpatient pharmacy fills for a given sample
- Outpatient pharmacy fills for a given list of national drug codes (NDCs)
- Counts of fills for a given list of NDCs
- BMI calculation
- Vital sign measures for a given sample
- Census data for a given sample

These and additional SAS macros developed for on-going projects are made available to all HMORN programmers through the Cancer Research Network (CRN) website:

[Log in here](#) or contact your site data manager to register. You may also contact Roy Pardee at pardee.r@ghc.org for assistance.

4.3 Steps for Using the VDW

The VDW is ideally suited for supporting the development of grant proposals, carrying out preliminary studies, identifying subjects, and assembling study data.

Using the VDW for grant proposal development

- Discuss the potential study with an investigator at your site experienced with HMORN multi-site projects (e.g., CRN, CERT, CVRN, DEcIDE, etc.).
- Review descriptive information on the VDW data structures to identify available data for preliminary counts, as well as data elements that will be used for the research study itself. ([see VDW resources below](#))
- Review information about the HMORN sites to consider potential relevant participants. ([see VDW resources below](#))
- Find collaborating investigators at these sites. ([see Chapter 1](#))

- Obtain prep-to-research IRB approval. ([see Chapter 2](#))
- Work with your local site programmer and/or Gene Hart at Group Health to develop programs for extracting preliminary counts of critical data elements from the VDW at the participating sites. See the [list of VDW data managers](#).
- Get boilerplate text and figures for the proposal. ([see Chapter 1](#))

Using the VDW within a funded research project

- Complete the preliminary steps of IRB, subcontracting, and data use agreements (DUAs). ([see Chapter 2](#))
- Establish the data elements needed for the study via conference calls with site investigators and programmers.
- Many HMORN programmers and data managers are very knowledgeable about data elements in the VDW and common issues that arise. Take full advantage of their expertise!
- Select the central project programmer, typically a programmer at the lead site who is familiar with the VDW.
- Sometimes this is a programmer from a participating site with more experience using the VDW.
- Work with the central project programmer to develop the data extraction programs.
- As you design the process for extracting and merging data, consider what is minimally necessary to complete the study.
- The data extraction program sent to the sites can directly extract and transfer data to the central project site for analysis or the program can be constructed to calculate site-level results and transfer them to the central project site to be merged. The latter is safer since you do not transmit any individual level data, but it is less flexible and not always sufficient for the analytic demands of the project.
- Test the program at one of the participating sites and revise as necessary.
- Distribute the program across the sites.
- Transfer the extracted data to the central project programmer for testing and merging results or analytic datasets.

4.4 General VDW Resources

- [Figure: HMORN VDW data structures](#)
- [Table: Detailed VDW data set structures](#)
- [Site Data Managers](#)
- [Searchable Table: VDW data available at each HMO by year](#)
- [Table: Demographics for member health plans](#)
- [Table: VDW data systems rollouts across HMORN sites](#)
- [Table: Type of VDW data and year available by site](#)
- [Presentation: Getting Your Questions Answered with the VDW](#)
- [Presentation: How the VDW Will Change Your Life](#)

4.5 VDW Programming Resources

- [Laboratory Test Reference for VDW Laboratory File](#)
- [The HMO CRN website](#) – Contact your site data manager to register for access.
- [The VDW Programmer's guide](#) – Available via the HMO CRN website
- [Presentation: VDW Tutorial for Programmers](#)
- [VDW Users listserv](#) – Log in or subscribe

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CHAPTER 5: CLOSEOUT AND DISSEMINATION

[5.1. Closeout and Multi-site Documentation](#)

[5.2. Optimizing the Translation of Research into Practice \(TRIP\)](#)

5.1. Closeout and Multi-site Documentation

Careful thought needs to occur long before the end of a multi-site study as to how to best set up systems and documentation for study closeout.

[Multi-site Closeout Guide](#) ([Additional resources](#))

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.

5.2. Optimizing the Translation of Research into Practice (TRIP)

The HMORN is an excellent laboratory for translational research as it is comprised of a diverse group of health care delivery systems, all with associated research staff. A study focused on modifiers, facilitators, and barriers with regards to translating research results from HMORN Center's into practice at the parent health plan was conducted.

A [summary of methods, findings and recommendations](#) for increasing translation and dissemination of new research to our "parent" health plans is available.

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INDEX OF LINKED RESOURCES

Chapter 1: Collaborators and Grant Development

[HMORN investigator directory](#)

[Key contacts directory: collaborations; proposal development](#)

[Statement of intent to establish a consortium agreement](#)

[Checklist of application elements needed from each site](#)

[Template budget sheet](#)

[Administrative best practices](#)

Boilerplate

[HMO Research Network](#)

[15 HMORN research centers](#)

[HMORN collaborations](#)

[HMORN and CTSA's](#)

[Virtual Data Warehouse \(VDW\)](#)

Tables and Figures

U.S. Maps with HMORN member locations ([Style 1-Teal](#)) ([Style 2-Blue](#))

[Table: HMORN Scientific resources by site](#)

[Table: Large consortium projects](#)

[Table: Demographics for member health plans](#)

[Table: VDW data systems rollouts across HMORN sites](#)

[Table: Type of VDW data and year available by site](#)

References and Presentations

[Collection of HMORN and/or VDW references](#)

Hornbrook, M. [*HMO Research Network: The research partner of choice for those seeking to shape public health and health care delivery.*](#) Presented to CTSA CE CAPP workgroup, July 24, 2008.

Chapter 2: Research Review, Subcontracts, and Data Use Agreements (DUAs)

[External Links to IRB Resources](#)

[IRB review dates and timelines](#)

[SOP: facilitated IRB review for low risk, data only HMORN studies](#)

[HMORN SubAward template](#)

[HMORN Data Use Agreement \(DUA\) templates](#)

[HMORN SubAward and DUA template instructions for use](#)

[Memorandum of Understanding for HMORN SubAward and DUA templates](#)

[Data use agreement toolkit](#) (helpful when sharing a limited data set)

[Key contacts directory: IRB administrators; DUA recipients and signatories](#)

Chapter 3: Recruitment and Data Collection

[Cluster Randomized Trial \(CRT\) Toolkit](#) (guide for multisite CRTs)

Recommendations to improve provider participation in clinical trials:

[Proposal from the CCSN Systems Liaison Working Group](#)

[Table of site specific recruitment requirements and resources](#)

[Guide to optimizing recruitment and data collection in multi-site studies](#)

[PRISM Readability Toolkit](#) (tips and tools for easy-to-read study materials)

[Standardized interviewer training manual](#)

[Standardized abstraction recommendations for common chart variables](#)

Chapter 4: Virtual Data Warehouse (VDW)

[Example VDW projects](#)

[Figure: HMORN VDW data structures](#)

[Table: Detailed VDW data set structures](#)

[Key contacts directory: Site data managers](#)

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[Presentation: Getting Your Questions Answered with the VDW](#)

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[Presentation: VDW Tutorial for Programmers](#)

Chapter 5: Closeout and Dissemination

[Multi-site closeout guide](#) (tips for multi-site project completion)

[Additional closeout resources](#)

[Recommendations for translating research into practice \(TRIP\)](#)

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