

Curriculum on Research Danbury Hospital Residency Programs

Office of Clinical Outcomes and Health Services Research
Department of Medical Education and Research

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Educational Purpose and Goals

The research program is designed to support each resident in developing an independent research project that is an integral part of their residency experience. Residents will be introduced to the methods of evidence-based, hypothesis-driven research. This curriculum will supplement clinical experience by teaching approaches for conducting an IRB approved clinical research study, as well as interpreting the published literature with the aid of resources and didactic sessions. At culmination, residents will present their completed projects in a forum that will acknowledge their accomplishments in addition to advancing patient care.

This document provides the following information to guide you through this challenging, yet rewarding process:

- 1) Structure of the Residency Research Program
- 2) Timeline and Milestones
- 3) Research Proposal Guidelines
- 4) Types of Studies
 - a. Case Report
 - b. Retrospective (generally, medical record reviews)
 - c. Prospective ~ Clinical, Biomedical, Epidemiologic
- 5) Maintaining Patient Confidentiality
 - a. Institutional Review Board (IRB)
 - b. Guidelines
 - c. Process of Obtaining Informed Consent
- 6) Preparation and Submission of Scientific Work to Conferences and Peer-Reviewed Journals
 - a. Selecting a Journal
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- 7) Summary of Expectations
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1) Structure of the Residency Research Program

The research curriculum is structured around the time constraints of residency. A variety of resources are available to support research efforts, so that residents may successfully complete their projects and experience presenting research methods and findings.

Residents will work on their respective projects throughout their residency tenure. Specific and general milestones are described below. By the culmination of residency, residents will be expected to produce a finalized manuscript for publication. Residents will also be required to submit research projects in abstract format to state and/or national professional research conference(s). Projects should also be submitted as a poster or oral presentation to Danbury Hospital's Annual Belsky Research Day, which is held each May.

2) Timeline and Milestones

***PGY-1**

Meet with the research faculty early to begin the process of developing a research question and study plan. It is recommended that you work in teams with fellow residents. In the second half of your first year, you will begin your ambulatory medicine elective. Internal Medicine and Primary Care resident schedules include a full week per year to focus solely on your research project. While your time during your research rotation should be spent wisely, expect to spend more than three weeks to move your research to publication or presentation. Research should be an active part of your residency program.

Before October:

- Meet with Joann Petrini in the Research Department for an overview of your requirements. Internal Medicine residents are scheduled to have a research rotation during which they are provided time to work on their projects. **Please meet with Dr. Petrini before your research rotation begins.**
- Meet with Amanda Pomeroy in the library for brief trainings on RefWorks and PubMed to ensure a thorough, efficient, and effective literature search.
- Sign and return form indicating your understanding and agreement to information found within this manual/curriculum.

October – December: Attend the Research Methods and Research in Progress seminars.

By January:

- Identify a research area of interest, a mentor, and a research question.
- Complete the NIH “Protecting Human Subjects Research Participants” training and provide certificates of completion to the Research Department (OB/GYN residents provide certificates to Jennifer Ballard, Coordinator);
<http://phrp.nihtraining.com/users/login.php>.

Before May:

- Meet with Dr. Petrini to finalize the research question and to begin to develop a research proposal for submission to the Internal Review Board (see below for Research Proposal Guidelines).

May: Attend Belsky Research Day.

Any resident/intern who has not completed the NIH training and signed the attached form indicating their understanding and agreement with the information found in this manual may not begin working on their research project.

***PGY-2**

Continue your research efforts during your PGY-2 year. **You must have IRB approval for all research project(s).** Work with Dr. Petrini and Julie Burgess, IRB Administrator, to submit paperwork as soon as possible to obtain approval and allow adequate time to work on your project.

October – December: Attend the Research Methods and Research in Progress seminars.

In addition:

- Finalize and submit your research proposal to Dr. Petrini and submit paperwork to IRB.
- Following IRB acceptance, and only upon acceptance, begin work on study.
- Check in with Dr. Petrini and identify medical students who may be interested in assisting you.
- Begin meeting on a monthly basis with your study team to discuss your projects. Remember, the Research Department is available to provide technical assistance.

Remember:

- March: Abstracts due for Research Day
- April: Mandatory preparation session for Research Day presentations
- May: Attend Belsky Research Day

***PGY-3/4**

Your project should be complete and ready for submission, for presentation and/or publication. The Research Department and your faculty mentor can provide helpful resources to move you toward this goal. Presentation at a national meeting, approved by the program director(s), is strongly encouraged and supported. Dr. Petrini and your faculty mentor should review any external submission of your work (i.e., to a conference or for publication). Submit your final manuscript as a requirement for graduation. Utilize research elective time to finalize writing and submit your manuscript.

- Identify your target journal/meeting.
- Obtain the journal/meeting submission requirements.
- Particularly for meetings, consult Dr. Petrini and your faculty mentor for strategies to increase your chances of acceptance.
- Begin to outline your manuscript considering the requirements for your target journal (see *Notes for Authors* on the journal web site).
- Analyze data (note: allow Dr. Petrini is available to assist with this).
- Finalize writing and submit manuscript.

Remember:

- March: Abstracts due for Research Day
- April: Mandatory preparation session for Research Day presentations
- May: Attend Belsky Research Day

3) Research Proposal Guidelines

1. The research proposal should be developed under the guidance of your faculty mentor.
2. All research conducted by staff of Western Connecticut Health Network must be approved by the IRB.
3. Proposals should include the following information:
 - a. Background information: Briefly describe the information that supports pursuit of this research project and why it is important; you can include preliminary data if available.
 - b. Research Question and Hypothesis: List explicitly what your specific aims are for the research project. State your research question in one sentence. Also, state what your hypothesis is regarding the anticipated result of the research project.
 - c. Research Methods: Describe the research methods you will use for pursuing your specific aims of the project. Use explicit subheadings including study design, data collection, and data analysis.
 - d. References / Literature Cited

4. The Research Department will help you fully develop your proposal and to prepare it for IRB submission~(203) 739-6882 or email joann.petrini@wchn.org.

4) **Types of Studies**

Case Report

A case report is a report of a single case of a disease, usually with an unexpected or interesting presentation, which typically describes the findings, clinical course, and prognosis of the case. It is often accompanied by a review of other cases previously reported in the literature to put the reported case into context.

Single case reports do not require a separate IRB application. Use the IRB contact form to send the completed abstract and prepared article, if applicable, to the IRB administrator:

<http://www.danburyhospital.org/en/Research-and-Academics/IRB/Contact-IRB.aspx>

This step must be done and approved prior to submitting your article to a journal.

Retrospective (generally, medical record review)

A retrospective study is a study in which a search is made for a relationship between one phenomenon or condition and another which has occurred in the past. Retrospective studies have various advantages and disadvantages as compared to prospective studies. Among the disadvantages are that some key statistics cannot be measured, and large biases may be introduced in the selection of controls and in the recall of past exposure to risk factors. Some advantages include generally short duration for completion and ease of subject recruitment.

For the appropriate IRB form for a retrospective study or record review, use the following application. Please note this application must be completed and approved prior to beginning any work on the study:

http://www.danburyhospital.org/Research-and-Academics/IRB/~media/Files/IRB/IRB_MedRecReview.ashx

Prospective ~ Clinical, Biomedical, Epidemiologic

A prospective study is an analytic study designed to determine the relationship between a condition and a characteristic shared by some members of a specified population. This implies that the group selected in the present is followed into the future. A significant advantage of a prospective study is that, due to the longitudinal nature of the study, recall error is minimized. For the same reason, these studies often take longer to conduct and subject recruitment is more difficult.

For the appropriate IRB form for a prospective/longitudinal study, use the following application. Please note this application must be completed and approved prior to beginning any work on the study:

http://www.danburyhospital.org/Research-and-Academics/IRB/~media/Files/IRB/IRB_Application.ashx

5) Maintaining Patient Confidentiality

Institutional Review Board (IRB)

Under FDA regulations, an Institutional Review Board (IRB) is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Guidelines for Maintaining Patient and Participant Confidentiality

These guidelines outline the methods taken to protect the confidentiality of each patient and research study participant in accordance with both Western Connecticut Health Network standards and HIPAA protocol. To best establish confidentiality, specific items will be implemented. These items are:

1. Unique Study Identifiers: combinations of numbers or a unique combination of letters, numbers, and/or symbols used to identify a research participant.
2. Key Files: documents that link the unique study identifier with the identifying information of the research participant.

Responsibility

It is your responsibility to maintain patient and participant confidentiality to the fullest extent as agreed upon by the completion of the *Danbury Hospital Confidentiality and Information Access/Usage Agreement Form* upon commencement of employment at Danbury Hospital. During the research process, it is the added responsibility of the residents, Research Department directors, qualified investigators, and/or Principal Investigators to ensure data and privacy protection; this

includes, but is not limited to both physical (premise and equipment) as well as logical (access control) security of research data. While the data safeguarding measures may be delegated to an appropriately trained research team member, it is still ultimately the responsibility of the residents, Research Department directors, qualified investigators, and/or Principal Investigators to protect the integrity of any personal health information of the patient or research study participant.

Unique Study Identifiers

Unique study identifiers must not include personal health information of research participants, such as name, date of birth, and medical record number.

- A unique study identifier (e.g. unique study number/code) must be used to collect and store data (electronic or hard copy) pertaining to research participants.
- Any information leaving Western Connecticut Health Network (case report forms, data collection forms, other study documents), including electronically captured data, must only be identified with a unique study identifier.
- Video recording, photographs, and other identifying images of research participants must be securely stored in locked cabinets or on a secure server separate from the research participants' study data.
- Electronic data files with unique study identifiers or personal health information must be stored on a secure server. If this is not possible, data is to be encrypted (e.g. laptop, USB key) and, where applicable, hard copy data files with unique study identifiers or personal health information securely stored in locked cabinets.
- Unique study numbers should not appear on consent forms. Generally, unique study numbers and health information should appear together only in the key file and on screening/tracking forms as applicable (e.g. in prospective studies).

Key File

A key file, including the research participant's name, date of birth, medical record number, and unique study identifier must be created.

- Only designated person(s) identified on the study task delegation log are allowed to access the key file and assign unique study identifiers to research participants.
- Regardless of the data medium used, key files must be securely stored separately from the research participants' study data, most likely on an encrypted flash drive. Only one file should link the study identifier with identifying information of the research participant.
- Except for long-term secure record retention, the key file, and the information contained therein, must not leave Western Connecticut Health Network or be shared with anyone not identified on the study task delegation log without the written approval of the Research Department directors.

Transmitting Identifiable Information

- Sending personal health information off-site (e.g. to a sponsor) is not permitted unless it is either:
 - a. De-identified; or
 - b. The Research Department director has approved and participants have consented to disclosure
- To send de-identified data: black out identifiers (such as patient name, date of birth, medical record number, and signature) on consent forms, case reports, and other study documents.

Definitions

De-identification: to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual

Designated person: the Research Department directors, qualified investigator, Principal Investigator, or an appropriately trained member of the research team who has been designated by the sponsor/investigator, qualified investigator, or Principal Investigator to handle data and privacy protection for a specific research study

Identifiable information: information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual

Task delegation log: a document that lists the delegation of trial specific duties by the Principal Investigator to other research personnel in the trial

Data Storage and Sharing

All data collected as part of an IRB-approved study must maintain patient confidentiality. As such, the Department of Medical Education and Research has password-protected flash drives which may be loaned to study personnel for work on these studies. Once assigned a flash drive, all study-related protected health information must be saved to the flash drive and not directly to a hard drive or other unsecure device. The flash drive's password should not be shared with anyone who is not directly involved in the study and should not be changed at any time without approval from the Research Department. If the flash drive is lost or stolen, the password is forgotten, or there are any other questions or concerns, Amber Butler should be contacted at (203) 739-6398 or amber.butler@wchn.org.

Process of Obtaining Informed Consent

Personnel permitted to obtain informed consent from patients or study participants include house staff, Research Department staff, fellows, and residents. Medical students and volunteers are not permitted to obtain informed consent.

When obtaining informed consent, study personnel must take care to thoroughly and completely explain to the participant the purpose of the study, the participant's expected involvement, the potential benefits of participation, and the potential risks of participation. The participant must have ample time to review all consent documents and to ask questions of the study personnel before signing. After the participant has signed a consent document, the study personnel must also sign, indicating the above protocol has been adhered to. Once signed by the participant and the study personnel, a copy of all consent forms should be given to the participant.

Consenting Non-English Speaking Patients

If for any reason it is anticipated that many participants in a given study will be non-English speaking, any consent forms, HIPAA forms, questionnaires, etc. must be translated. All translated documents must be approved by an official translator and must be submitted to the IRB.

In the event that a large non-English speaking population is not anticipated and translated documents have not been prepared and approved, a non-English speaking participant may still be enrolled in the study, as long as the study personnel on hand are fluent in the participant's native language. The study personnel should explain, in the participant's native language, what information is contained in the English consent and HIPAA forms. The participant must be given the opportunity to ask questions in his/her native language and those questioned must be answered in his/her native language. Only when the participant clearly understands the information presented, should he/she sign the consent and HIPAA forms. Once a non-English speaking participant is enrolled in the study, study personnel who speak the participant's native language must be available for the duration of the participant's involvement in the study.

6) Preparation and Submission of Scientific Work to Conferences and Peer-Reviewed Journals

Selecting a Journal

The selection of the journal to which you will submit a manuscript is a vital step in preparing the document. Whenever possible, it is important to identify the journal to which you would like to submit before beginning work on your manuscript. Be sure that you choose a journal whose focus is relevant to the content of your manuscript. In the event that you wish to submit an article other than a standard original research report (e.g. a case report, brief report, or review), confirm that the journal

you choose accepts such submissions for publication. Another noteworthy selection criterion should be the journal's impact factor. The Thomson Reuters Impact Factor is a measure of the frequency with which the "average article" in a journal has been cited in a particular year or period and is related to the journal's prestige. As you continue to publish, you should strive to submit to journals with increased impact factor.

Specific formatting and content conditions differ between journals. Therefore, once you have chosen the journal to which you will submit, visit the "Instructions for Authors" page on the journal's website. Here you may find details on the journal's requirements such as headings and subheadings, word count limits, and other general formatting requisites. It is important to be mindful of these conditions during all stages of the writing process. Doing so may significantly reduce the extent of editing needed upon completing a draft of the manuscript. In the same manner, if applicable, be attentive to requirements for tables and figures, including the number of each allowed to be included, software which must be used, and whether the journal charges for color printing.

It is strongly encouraged to begin writing a draft of the "Methods" section before the study commences and to update this draft as the study is underway. Doing so will help to ensure accuracy and will reduce the work load upon completion of the study.

Carefully review the journal's requirements for manuscript submission and be sure to submit any and all necessary documents which often may include: a submission agreement, cover letter, title page, the abstract, manuscript, references, figure titles, figures, tables, a statement of author responsibilities, and/or a disclosure of conflict of interest. Before submitting, it is the responsibility of whoever is doing so to be sure that all authors have reviewed and approved the final version of the manuscript.

Authorship

The compilation of research findings through publication of articles in peer-reviewed journals is highly valued in our institution. Authorship of such articles is the exclusive claim of those who have made a substantial contribution to the research conducted and is therefore limited to those who have done the following:

- Conceived the idea or experiment design
- Participated actively in the execution of the study
- Analyzed and interpreted the data
- Written the manuscript

Multiple Authors

From the start of a study, there are a number of processes that should be performed to ensure ease for future formal writing regarding the conducted research. For each study, a document should be kept detailing the names of the active staff members participating and what each member has contributed during their time with the study. Also, from the inception of the study, it is important that there is

communication regarding authorship expectations among the staff in collaborative research. When any publishable material is produced, it is imperative that there is mutual respect, open communication, and fairness between all those involved.

Order of Authorship

First author: For all scientific writing done as a result of original studies involving the Research Department, the first author, often the principal investigator, will be fully accountable for the entire paper or product as an accurate and verifiable report on the research conducted. The first author is also defined as the person by which all or most of the following was completed:

- Research design
- Performance of research
- Contribution of new reagents or analytic tools
- Data analysis
- Writing of the actual paper

Additionally, it is also the responsibility of the first author to comply with the policies and procedures of Western Connecticut Healthcare.

Co-Authors: Any research team member with intentions of being co-author on a document must contribute significantly to a successfully published product as outlined by the respective journal. The co-author should accept responsibility for the quality and satisfactory completion of a significant part of the project by accomplishing a variety of tasks including but not limited to:

- Creating high quality data sets
- Reviewing data sets that appear on the final product
- Writing a portion of the final product
- Making a substantial contribution to the interpretation of the results/data

While recommended, it has also been found that the number of co-authors on a project can reach a point in which it is more difficult to efficiently complete the project. With each additional author there is a correlated increase in both the amount of time and effort put into communication and coordination. With the number of co-authors exceeding approximately four people, the individual contributions of each member becomes less meaningful. For this reason, it is advised that, whenever possible, the fewer authors per project, the better. The specific requirements of the target journal should also be considered as many journals limit the number of authors.

Last Author/Senior Author: Senior authors serve as the supervisor of the team of researchers as well as the scientific guarantor.

Acknowledgements

People who contribute access to property, funding, or assisted with field work but are not accountable for the paper as an accurate, verifiable report of the research should be listed in the “acknowledgements” section of published works. The funding body and assistance of the organization should be put in the acknowledgements as well, but a disclaimer similar to the following should be used: “however, this study does not necessarily reflect the opinion of the funding body or all members of the Western Connecticut Health Network, nor does it anticipate its future policy in this area.”

Special Approval

The following listed situations regarding publications and authorships require approval; verbal or written depend on the situation, from a representative of the Research Department:

- Any idea for a paper
- Papers to be publicly presented
- Co-authorship with an outside investigator
- Press release or media coverage
- Materials for Congress

7) Summary of Expectations

1. Successfully complete NIH training; <http://phrp.nihtraining.com/users/login.php>
2. Learn to conduct literature searches using PubMed
3. Attend Research Methods and Research In Progress seminars
4. Regularly meet with research faculty, mentors, and colleagues regarding your project
5. Maintain strict adherence to rules and guidelines (HIPAA, IRB, etc)
6. Safeguard protected health information and data by utilizing encrypted and password-protected flash drives provided by the Research Department
7. Attend the annual Belsky Day Research Forum
8. Keep national and local meetings of interest in mind
9. Ultimately develop a finalized manuscript for publication

8) Available Resources

- Danbury Hospital Horblit Health Sciences Library and librarians (Amanda Pomeroy and Mary Shah)
- Medical Education and Research Department (Joann Petrini, PhD, MPH, Director, Clinical Outcomes and Health Services Research)
- Internal Review Board (Julie Burgess, IRB Administrator)
- Clinical References link on the Danbury Hospital intranet
- Access to and training on PubMed
- Access to scientific journals in print and online
- Access to and training on RefWorks
- Clinical Outcomes and Health Services Research division of the Department of Medical Education and Research
- Research Seminars
- Danbury Hospital Annual Belsky Research Day (held each May)
- National/local meetings of interest

Research Curriculum Agreement Form

My signature below indicates that I have read, understand, and agree to the information presented in the Curriculum on Research for Danbury Hospital Residency Programs.

Resident Name (please print)

Resident Signature

Date