Orientation Manual for
Clinical Research Coordinators

Maine Medical Center Research Institute
MAINE MEDICAL CENTER RESEARCH INSTITUTE
Statement of Mission, Vision, Goals and Principles

Our Mission
To enhance the health of our population through excellence in research across the spectrum of the biomedical and health sciences.

Our Vision
To achieve premier status as a research institute by working together effectively as researchers and clinicians to advance scientific knowledge and clinical care.

Our Goals and Principles
As investigators, we are driven by curiosity and a passion for improving health care to conduct world-class research, as fostered by a uniquely collaborative and collegial environment that emphasizes respect, trust and personal growth.

As educators, we are committed to mentor and help train the next generation of investigators, physicians, nurses and other health professionals.

As a community of scientists, clinicians, staff and administrators, we work together to promote an open, inclusive, diverse and supportive workplace that stresses the value of the individual while celebrating the accomplishments of the whole.
Introduction

Congratulations on your new role as a Research Coordinator. This manual will serve as a toolkit during your orientation. It is designed for the novice researcher and therefore not every part may be applicable to you based on your experience. Please read the manual carefully and complete the required readings.

All research that is conducted by an individual and involves the use of any of Maine Medical Center’s property or facilities must conform to the standard of ethics reflected in specific regulations of the United States Department of Health and Human Services (DHHS) in order to assure that the rights and welfare of human subjects are protected. The Federal Regulations governing research involving human subjects may be obtained from your IRB Office or by accessing it online at http://www.hhs.gov/ohrp/

Name: _______________________________
Start Date: ________________________________

General Hospital Requirements:

- Meet with Security to obtain ID badge with photo.
- Meet with Employee Health to assure compliance with all mandatory healthcare requirements (i.e.: TB testing, etc.).
- Meet with Human Resources to discuss and schedule general hospital orientation needs if you are a new MMC employee.
- Contact IS for computer training regarding SCM, SRM, MIS, Group wise, etc.
- Complete Safety Training
- Complete Hazardous Material Shipping training. This is required if your role will require shipping of laboratory specimens outside of MMC. Speak to your supervisor or the Research Education and Compliance Officer at MMCRI for more information and to arrange training.

For more information, you may call the Research Education and Compliance Officer at Maine Medical Center at (207) 396-8242.
### Contact Information

<table>
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<tr>
<th>Name</th>
<th>Title</th>
<th>Department</th>
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<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Avedian</td>
<td>Director, Health Information Management</td>
<td>Health Information Management</td>
<td>662-4442</td>
<td><a href="mailto:avedij@mmc.org">avedij@mmc.org</a></td>
</tr>
<tr>
<td>Tim Bilodeau</td>
<td>Clinical Trials Unit Manager</td>
<td>Office of Sponsored Research</td>
<td>396-8074</td>
<td><a href="mailto:bilodt@mmc.org">bilodt@mmc.org</a></td>
</tr>
<tr>
<td>Frank Chessa</td>
<td>Director, Clinical Ethics</td>
<td>Medical Affairs</td>
<td>662-3131</td>
<td><a href="mailto:chessf@mmc.org">chessf@mmc.org</a></td>
</tr>
<tr>
<td>Sue Copeland</td>
<td>Staff Accountant</td>
<td>Financial Services</td>
<td>662-2576</td>
<td><a href="mailto:copels@mmc.org">copels@mmc.org</a></td>
</tr>
<tr>
<td>Tom Guare</td>
<td>Director Supply Chain Management</td>
<td>Purchasing</td>
<td>662-3949</td>
<td><a href="mailto:guarete@mainehealth.org">guarete@mainehealth.org</a></td>
</tr>
<tr>
<td>Clay Hurtubise</td>
<td>Clinical Pharmacist Drug Trial Coordinator</td>
<td>Pharmacy</td>
<td>662-2151</td>
<td><a href="mailto:hurtuc@mmc.org">hurtuc@mmc.org</a></td>
</tr>
<tr>
<td>Eric Larson</td>
<td>Chair, IRB</td>
<td>MMCRI</td>
<td>885-7565</td>
<td><a href="mailto:Larsee1@mmc.org">Larsee1@mmc.org</a></td>
</tr>
<tr>
<td>Sue Libby</td>
<td>Contracts Coordinator</td>
<td>Office of Sponsored Research</td>
<td>885-8184</td>
<td><a href="mailto:libbys@mmc.org">libbys@mmc.org</a></td>
</tr>
<tr>
<td>Lou Lisotto</td>
<td>Courier Supervisor</td>
<td></td>
<td>885-7911</td>
<td><a href="mailto:lisotl@mmc.org">lisotl@mmc.org</a></td>
</tr>
<tr>
<td>Pat Robinson</td>
<td>Research Education &amp; Compliance Officer</td>
<td>Office of Sponsored Research</td>
<td>396-8242</td>
<td><a href="mailto:robinp2@mmc.org">robinp2@mmc.org</a></td>
</tr>
<tr>
<td>Linda Reinholdtsen</td>
<td>Research Compliance Manager</td>
<td>Office of Sponsored Research</td>
<td>885-8183</td>
<td><a href="mailto:reinhl@mmc.org">reinhl@mmc.org</a></td>
</tr>
<tr>
<td>Jan Trott</td>
<td>Director, Office of Sponsored Research</td>
<td>Office of Sponsored Research</td>
<td>885-8182</td>
<td><a href="mailto:trottj@mmc.org">trottj@mmc.org</a></td>
</tr>
<tr>
<td>Julie Wooden</td>
<td>Associate VP, Information Services</td>
<td>Information Systems</td>
<td>662-2150</td>
<td><a href="mailto:woodej@mmc.org">woodej@mmc.org</a></td>
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Competency #1

Learning Objective: Conducts all research activities with the highest ethical, legal and scientific standards in accordance with Federal, State, and Institutional regulatory requirements. Applies principles of respect for persons, beneficence, and justice to all aspects of research with human subjects.

- Accesses and reads the Belmont Report
- Completes CITI training course, including HIPAA module
- Protects confidentiality of research subjects and others:
  - Signs Institutional Confidentiality Agreement
  - Reads MMC’s HIPAA Policy
  - Describes how to protect confidential study material
  - Reads MMC’s Privacy Policy
  - Reads MMC’s Conflict of Interest Policy
  - Reviews MMC’s Access Policy
- Applies principles of Good Clinical Practices and MMCRI Standard Operating Procedures to all aspects of work.
- Review MMCRI Standard Operating Procedures

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ________________________________ Date: ______________

Preceptor: ________________________________ Date: ______________
Competency #2

Learning Objective: Evaluates new research protocols considering feasibility of conduct at the site

- Obtains PI signature on the Confidentiality Agreement and returns to the Sponsor.

- Reviews protocol to determine:
  - Draft or final version
  - Phase of study
  - Type of design
  - Eligibility criteria
  - Subject safety measures
  - Timelines

- Considers the following:
  - Personnel and material resources
  - Patient availability
  - Logistical feasibility
  - Compliance with IND/NDA regulations
  - Concerns/questions that need PI or Sponsor clarification
  - Financial feasibility

- Meets with PI to determine whether to participate in the proposed study.

- Meets with Financial Services.

- Schedules a pre-study site selection visit with sponsor or Contract Research Organization (CRO), if appropriate.

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: _____________________________________ Date: _________________

Preceptor: _______________________________________________ Date: _________________
Competency #3

Learning Objective: Collaborates with other departments to plan & implement the research.

- **Laboratory:**
  - Meets with research contact at NorDx to review and plan required activities.
  - Completes “Nordx Support of Clinical Research Studies” form (Green Sheet)
  - Provides Lab Manual and supplies if a Central Lab is used
  - Demonstrates requisite skills when drawing specimens
  - Completes Hazardous Materials shipping training

- **Pharmacy:**
  - Meets with Research Pharmacist to review and plan required activities.
  - Provides Pharmacist with copy of protocol.
  - Develops plan with Pharmacist for:
    - Delivery & storage of investigational drug
    - Dispensing
    - Emergency un-blinding procedures
    - Drug accountability

- **Materials Management:**
  - Notifies Director of Materials Management when an investigational device will be used in a study
  - Notifies Clinical Engineering if device is electrical

- **Radiation Safety:**
  - Notifies Radiation Safety Officer that protocol requires non-clinically indicated exposure to radiation
  - Completes Radiation Safety Review Application & sends with protocol to Radiation Safety Officer
  - Includes standard radiation safety language in Informed Consent Form with guidance from Radiation Safety Officer
  - Receives (and files in Regulatory Binder) approval for use of non-clinically indicated radiation from Radiation Safety Committee

- **Nuclear Medicine:**
  - Notifies Lead Nuclear Medicine Tech that protocol requires nuclear medicine testing and provides protocol for review
  - Meets with Lead Tech to review requirements & determine whether that service should be outsourced
• Nursing:
  Contact Nursing Director of inpatient unit where research subjects will receive care
  Provides in service to nursing staff about research and their role
  Provides reference materials for nursing staff to access on nursing unit during the course of the research
  Provides contact information for nursing staff for questions

• Medical Information System (MIS):
  Drafts MIS order set that will be required for inpatient research subjects
  Completes the Order Set Approval Process Form
  Submits the order set to the Director of Pharmacy Services, or his designee, with supporting documentation
  Presents the proposed order set to the Order Set Committee
  Collaborates with the technical development analyst to clarify issues and determine implementation dates

• Contact Health Information Management to gain access to SRM

• Attends Department/Division study meetings as appropriate to discuss protocol

• Collaborates with the P.I. to determine the roles and responsibilities of Sub-Investigators and other members of the research team, completing a Delegation of Responsibility Form

• Schedules Peer Review meeting

• Submits a request for exemption from IRB review if questionable

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ________________________________ Date: __________________

Preceptor: ________________________________ Date: __________________

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Preceptor: ________________________________ Date: __________________

Preceptor: ________________________________ Date: __________________
Competency # 4

Learning Objective: Prepares site for study initiation

- Attends and participates in Investigator Meetings
- Prepares and submits regulatory documents to Sponsor or funding sources (e.g. NIH, Medical Research Committee) as required
- Meets with the Research Compliance Manager to review IRB process and documents
- Prepares and submits IRB documents, meeting IRB deadlines
- Arranges for receipt and storage of test article and study supplies
- Arranges for adequate supplies of required shipping materials
- Trains appropriate staff regarding the protocol and their respective roles and documents
- Schedules and coordinates the study site initiation visit

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ___________________________ Date: __________________
Preceptor: ___________________________ Date: __________________
Competency # 5

Learning Objective: Maintains ongoing communication with the IRB throughout all phases of
the research; reviews and submits completed IRB documents as appropriate and in time to meet
deadlines.

Please review the following:

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- Review IRB website
- Attends IRB meeting with PI as requested
- Reports adverse events and protocol deviations as required
- Notifies the IRB of ongoing developments in study
- Provides IRB with required Annual Progress Reports and unstamped ICF for yearly approval (progress reports may be more frequent as necessary)
- Informs IRB of trial completion and submits termination report
- Submits any changes to the approved protocol to IRB for approval (all protocol revisions including editorial changes)

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ___________________________ Date: _________________

Preceptor: ___________________________ Date: _________________
Competency # 6

Learning Objective: Coordinates completion of Clinical Trial Agreement (CTA) or Grant proposal

- Confirms that MMC Grants/Contract Administrator has received completed budget
- Meets with Financial Services to review research budget including Medicare guidelines
- Collaborates with PI, MMC Grants/Contract Administrator and Sponsor or funding agency to ensure timely completion of CTA
- Ensures that study is not initiated until signed original CTA is received from sponsor

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ______________________________ Date: ______________

Preceptor: ______________________________ Date: ______________

Preceptor: ______________________________ Date: ______________
Competency Statement # 7

Learning Objective: Participates in all aspects of the informed consent process.

- In collaboration with the P.I. and in accordance with Standard Operating Procedure, develops the Informed Consent Form (ICF) to submit to the IRB for approval, taking into account sponsor, Federal, State and Institutional requirements.

- Distinguishes between obtaining subject signature on ICF and the larger ongoing process of informed consent.

- Understands the 8 essential elements that must be in the informed consent form

- Obtains subject’s signature and date signed on ICF after reviewing in detail with subject

- Ensures that person obtaining consent also signs ICF
  
  Gives subject copy of signed ICF and places copy in subject’s medical record, retaining original in Regulatory Study File and sending copy to Pharmacy.
  Documents in subject’s medical record and source document that:
  - Study was thoroughly explained to the subject and they willingly agreed to participate.
  - Adequate time was given for subject to ask questions
  - Date/time ICF was signed by patient

- Provides subject with updated information throughout the study that may influence their willingness to continue participation

- Describe vulnerable subjects and how informed consent differs when research subjects are children

- In collaboration with PI, revises ICF as necessary when protocol changes or new information emerges and submits for IRB approval

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: _____________________________________ Date: __________________

Preceptor: ______________________________________________ Date: __________________
Competency # 8

Learning Objective: Coordinates ongoing conduct of the study from screening and enrollment through to completion

Recruitment and Screening
- Informs the IRB of screening activity preparatory to research
- Initiates the screening process and identifies candidates for enrollment by utilizing strategies including:
  - Review of patient medical records and patient registries
  - Approved advertisements and letters to referral sources
  - Raising institutional awareness of the study through presentations at applicable medical and nursing staff meetings.
- Determines subject eligibility by:
  - Careful application of and adherence to the inclusion/exclusion criteria
  - Conducting of patient interview
  - Consulting with the PI and, when appropriate, the patient’s routine care providers
- Documents the screening process by maintaining screening logs

Following Consent/Enrollment
- Notifies sponsor of subject’s enrollment per sponsor requirements
- E-mails the “Study Notification Group” for inpatient research accounts
- Establishes, maintains, and documents site/subject communication plan
- Establishes, maintains, and documents ongoing communication with the subject’s routine care providers as required
- Schedules and coordinates all study visits and associated procedures/evaluations.
- Promotes and maintains ongoing correspondence with participating departments.
- Monitors compliance of the study team with protocol, ethical, and regulatory requirements, providing ongoing education and documenting non-compliance as appropriate
- Schedules and prepares for monitoring visits
  - Ensures study files are up to date and resolves open data queries prior to the visit
  - Arranges for security clearance and medical record review
  - Provides suitable work area for the monitor
  - Schedules mutually convenient time for the P.I. to meet with the monitor
  - Reviews monitor findings and implements corrective action as appropriate
• Documents ongoing communication with the sponsor

• Documents ongoing communication with the PI/Sub-Investigators to review individual subject progress and pertinent study issues

• Undertakes and documents rigorous efforts made to contact subjects lost to follow up

• Monitors and documents subject safety throughout course of study by:
  Effectively communicating with the subject with regard to the onset of adverse events or worsening of medical conditions established at baseline
  Obtaining and reviewing records related to hospital admissions, which occur during study participation
  Implementing appropriate communication with site investigators when an adverse event, untoward change from baseline, or hospital admission occurs

• Demonstrates time management skills for effective study coordination

• Initiates and attends follow-up meetings with the research team

**Study Completion**

• Notifies the research team, including all participating departments, of study completion

• Communicates with the subject’s routine care providers

• Develops a post-study plan for the subject which may include follow-up related to ongoing adverse events and follow-up with routine care providers

• Communicates appropriately with the IRB

• Adheres to sponsor directed study closure proceedings

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: _____________________________________ Date: _________________

Preceptor: _______________________________________________ Date: _________________
Competency # 9

Learning Objective: Maintains test article accountability.

- Investigational Drug or Study-Supplied, FDA-Approved Drug:
  Provides Pharmacy with a copy of the study protocol and, when applicable, a copy of the study Pharmacy Manual
  Provides Pharmacy contact information as appropriate, ensuring proper receipt of test article
  Notifies Pharmacy when a subject is enrolled, forwarding a copy of the signed consent
  Initiates test article dispensing by:
    entering the order into SCM (inpatient)
    Giving the Pharmacist a P.I. signed prescription (outpatient)
  Assures subject receives correct allocation (e.g. dose, container #, etc.) of test article
  Retrieves unused test article supply from the subject and determines compliance
  Identifies emergency unblinding procedures and communicates to appropriate personnel

- Investigational Device:
  Notifies Materials Management of plan for receipt, storage, & billing considerations
  Notifies Clinical Engineering as necessary
  Arranges secure storage area separate from non-research devices
  Maintains Accountability Log reflecting device receipt, dispensation, and disposition of unused devices
  Arranges for initial receipt and ongoing re-supply of investigational device
  Identifies emergency un-blinding procedures

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: _______________________________ Date: ________________

Preceptor: _______________________________ Date: ________________
Competency # 10

Learning Objective: Assures subject safety.

- Observes, documents and reports adverse events appropriately including immediate notification to the IRB/sponsor any event classified as both serious and unexpected
- Reviews event details and available test results with the P.I. to assist in event classification and determination of a treatment plan, when appropriate
- Communicates adverse event related information to the subject’s routine care providers as appropriate
- Ensures appropriate event follow-up
- Develops a post-study plan for the subject which may include follow-up related to ongoing adverse events and follow-up with routine care providers
- Submits IND Safety Reports to the IRB

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ____________________________ Date: ________________
Preceptor: ____________________________ Date: ________________
**Competency # 11**

**Learning Objective:** Manages financial aspects of the clinical trial

- Consults with Financial Services to evaluate, revise, and negotiate sponsor proposed study budgets
- Consults with Financial Services to develop study budgets for investigator initiated studies and grant applications
- Consults with Financial Services to develop the internal budget worksheet
- Arranges for and documents subject payments as outlined in the informed consent
- Sends CONSFMG e-mail correspondence to the Patient Accounts “Study Notification Group” for inpatient accounts
- Reviews inpatient bills, highlighting charges to be transferred to the study account
- Initiates sponsor invoicing by Financial Services in accordance with the budget and contract
- Meets with Financial Services upon study closure to assist in end of study financial reconciliation
- Maintains finance related documents separate from regulatory and patient files

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ___________________________ Date: ________________

Preceptor: ___________________________ Date: ________________
Competency # 12

Learning Objective: Maintains study records according to sponsor and/or regulatory requirements.

- Files and maintains appropriate, updated documents in the Regulatory File
- Maintains and secures accurate and complete Case Report Forms (CRFs) or data collection forms
- Resolves data queries in timely manner
- Ensures that data captured on CRFs or data collection forms are verifiable through the development and use of source documents
- Ensures the availability of pertinent medical records, questionnaires, videotapes, audiotapes, etc. for review
- Retains documentation of verbal, written, electronic, and faxed correspondence with regulatory agencies, the IRB, the study sponsor (when applicable), the research team, and the subject
- Works with IT to ensure proper computer configuration when electronic data capture will be utilized
- Ensures de-identification of all documentation containing protected health information prior to transmittal to regulatory agencies, the IRB, and the sponsor as required

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ___________________________ Date: ______________

Preceptor: ___________________________ Date: ______________
**Competency # 13**

**Learning Objective:** Coordinates all activities for study close out

- Coordinates study close out procedures in accordance with the protocol
- Contacts study subjects with final information or instructions
- Develops a post-study plan for the subject which may include follow-up related to ongoing adverse events and follow-up with routine care providers
- Arranges for final disposition of remaining study supplies
- Obtains final test article accountability and disposition records from the Pharmacy for filing in the Regulatory File
- Submits final Progress Report to the IRB
- Notifies the research team, including all participating departments, of study completion
- Arranges for record storage

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: ___________________________ Date: ____________

Preceptor: ___________________________ Date: ____________