CLINICAL RESEARCH MAP
Objective

This clinical research map is designed to serve as a guide for investigators, study coordinators, and research nurses at Boston Children’s Hospital. The research map outlines the key steps in preparing to launch a research study and provides embedded links to institutional resources, tools and documents.

An investigator need not follow the steps on the Clinical Research Map in any particular order. There is flexibility and the steps followed will in part depend on the type of research study.

For new as well as more experienced investigators the Clinical Research Map can be used as a checklist or an investigator can use the steps on the map as points for consideration as they are developing a protocol and launching a study.

This tool is not intended to substitute for the important collaboration between a junior investigator and a senior investigator/mentor. A senior investigator plays a pivotal role in coaching and advising a junior investigator regarding the many subtleties and variations that apply to designing and implementing a protocol.

This process map cannot be inclusive of every possible task or step, but is intended as a general guide for investigators and their study teams.

Resources

There are many institutional resources at Boston Children’s Hospital designed to support investigators and their clinical research teams. In addition to links to resources, tools and documents that are embedded in the steps of the clinical research map, the last page of this document contains website addresses that will take you to additional helpful institutional resources.

Acknowledgements

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Contents

Overview: Four stages .....................................3
1st Stage: Protocol development ..................4
1st Stage: Protocol development, cont’d ...5
2nd Stage: Implementation planning ...........6
3rd stage: Study launch.................................7
4th stage: Statistical analysis, reporting and dissemination ...........................................8
Discarded specimens: Additional steps .....9
Chart review: Steps if you are completing a chart review .........................................................10
Appendix A: Resources for researchers .....11
Overview: Four stages

1. Protocol development
2. Implementation planning
3. Study launch
4. Statistical analysis, reporting and dissemination
1st Stage: Protocol development

Consultation
Tasks for investigators and study teams

- Explore resources
  - CRIT
  - CRC
  - EQuIP
  - CTSU
  - Harvard Catalyst

- TransLab

- Consult Clinical Research Center
  - CRC

- Consult statistician
  - CRC

- Arrange a consultation with CRIT

- Consider applying for grants/securing funding
  - Office of Sponsored Programs

- Complete training
  - CITI training
  - EQuIP

- Bio Bank

- Draft a protocol
  - Protocol guidelines

- Consult research pharmacist
  - Research Pharmacy
  - Rocco Anzaldi

- Start IRB application

- Study personnel
  - FDA Guidance for Investigators

- If IND/IDE application to FDA
  - Does my study need an IND/IDE?
  - Regulatory resources
1st Stage: Protocol development, cont’d

- Negotiate contract/plan budget contact Clinical Trials Business Office
  - TIDO CTBO

- Submit the grant application to OSP
  - OSP

- Consult Office Intellectual Property Technology and Innovation Development Office
  - TIDO

- Departmental Scientific Review

- Respond to IRB questions/requests for clarification

- Organize DSMB/design DSMP
  - DSMP/DSMB

- Create regulatory binder
  - Regulatory Binder Template

- Templates for Research Study Documents and Tools
  - Study Templates and Tools

- Consider blood volume for research
  - Research blood volume policy

- Confidentiality plan
  - Confidentiality guidelines

- Investigators who sponsor an FDA regulated trial

- ClinicalTrials.gov
### 2nd Stage: Implementation planning

#### Tasks for investigators and study teams

<table>
<thead>
<tr>
<th>Study logistics</th>
<th>Documentation logistics</th>
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<tbody>
<tr>
<td><strong>Establish electronic shared folder or study binder for study documents</strong>&lt;br&gt; CRIT</td>
<td><strong>Develop Case Report Forms (CRFs)</strong>&lt;br&gt; CRF guidelines</td>
</tr>
<tr>
<td><strong>Consult programmer re: database</strong>&lt;br&gt; CRIT</td>
<td><strong>Create Manual of Operations MOO Guide</strong>&lt;br&gt; Confidentiality guidelines</td>
</tr>
<tr>
<td><strong>Clarify system for screening and enrolling patients</strong>&lt;br&gt; Recruitment guideline</td>
<td><strong>Consider blood volume for research</strong>&lt;br&gt; Research blood volume policy</td>
</tr>
<tr>
<td><strong>Set date for trial launch</strong></td>
<td><strong>Finalize tracking sheet</strong>&lt;br&gt; Research Administration&lt;br&gt; Fernando Valles</td>
</tr>
<tr>
<td><strong>Research study resource manual for the clinical unit</strong></td>
<td><strong>Develop study logs/tools</strong>&lt;br&gt; EQUIP</td>
</tr>
<tr>
<td><strong>Updated protocol to nurse manager</strong></td>
<td><strong>Data storage</strong></td>
</tr>
</tbody>
</table>
| **Develop fast fact sheet for bedside staff**<br> Rocco Anzaldi | **Consult MDs/NPs on unit/clinic** | **Study implementation meeting**

- **Bold** = hyperlink
3rd stage: Study launch

Steps before trial launch

- Create a checklist outlining study action items for each subject
- Schedule weekly study team meeting
- Communicate to department faculty and multidisciplinary team announcing trial launch

Patient flow

1. Seek permission to approach potential subjects
2. Screen/enroll patients
3. Document informed consent
4. Date/time study tests
5. Send Study Tracking Sheet (STS)
6. Collection of patient data and assessing for adverse events
7. Study documents and data handling
4th stage: Statistical analysis, reporting and dissemination

**Data management**
- Data Entry
- Consult Statistician When Approaching Target Enrollment
- When Enrollment Complete: Data Cleaning

**Trial management**
- Monitor Subjects to Identify Adverse Events (CCI, sponsor, DSMB)
- Update MOO Based on Experience with First Several Patients Enrolled
- Report Adverse Events
- Weekly Study Team Meeting
- Regular Review of Data to Identify Deviations and Workflow Improvements

**Reporting**
- Annual Progress Report/Staff Report
- Plan DSMB Meeting/Interim Analysis
- Maintain Interest of Staff
- Important to See Study Progress

**Dissemination**
- Write Abstract
- Dissemination of Research Results
  - Conference
  - Internal Presentation for Colleagues
  - Publication
- Report study findings to subjects and stakeholders
**Discarded specimens:** Additional steps

- Consult with Biorepository
  - Biorepository

- Send IRB Approval to lab manager
  - Maureen Samson

- Educate staff in areas/units about sample collection

- Locate the discarded samples

- Locate the accession number in PowerChart

- Retrieve specimen
  - Mark Kellogg
  - Contact Dr. Mark Kellogg to discuss specimen retrieval.

- Follow Shipping Rules and Procedures
  - IATA
  - Shipping with dry ice instructions

- Communicate with laboratory staff
Chart review: Steps if you are completing a chart review

Database/record review guidelines

1. Complete training
   CITI Training

2. Draft a protocol
   Protocol Guidelines

3. Prepare IRB Application
   Information about the CCI
   IRB Application

4. Departmental Scientific Review

5. IRB Review

6. Develop Case Report Forms (CRFs)
   CRF Guidelines

7. Consult programmer re: database
   CRC Request

8. Respond to IRB questions/requests for clarification
Appendix A: Resources for researchers

<table>
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<tr>
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<th>Phone Number</th>
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<td>Clinical Research Center (CRC)</td>
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<tr>
<td>Committee on Clinical Investigation (CCI, IRB)</td>
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<td>Research Pharmacist</td>
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<td>Clinical and Translational Science Unit (CTSU)</td>
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<tr>
<td>Technology and Innovation Development Office</td>
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<td>Research Finance</td>
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<td>Harvard Catalyst</td>
<td>617-432-7810</td>
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<td>Regulatory Affairs</td>
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