

# CLINICAL TRIALS

The Process  
From Query to Completion

# Clinical Site Information

- Study Site Organization
  - Queen's University
  - Kingston General Hospital, Hotel Dieu Hospital and/or Providence Care
- Study Site Information
  - List contact information of research lab
- Principal Investigator
  - List contact information
- Co-Investigator(s)/Sub-Investigator(s)
  - List contact information if applicable

# Principal Investigator

- DEFINITION: A Principal Investigator is the person responsible for the conduct of the clinical trial at a trial site. If the trial is conducted by a team of individuals at a trial site the Principal Investigator is the responsible leader of the team.

# Co-Investigator/Sub-Investigator

- A Co-Investigator or Sub-Investigator is any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or make important decisions (e.g., associates, residents, research fellows). A Sub-Investigator must have appropriate current medical credentials that allow for making medical decisions regarding a Subject's medical care.

# Study Coordinator and Research Nurse

- Study Coordinator and/or Research Nurse is responsible for assisting with the conduct of clinical trials using GCP under the auspices of the Principal Investigator. Although the Principal Investigator is responsible for the conduct of the trial, it has been said that the Study Coordinator and/or Research Nurse are *"the heart and soul of the research study and that, ultimately, it is these individuals who carry forward the research goals, thereby playing a significant role in the success of the clinical trial."*
- Their responsibilities may include but not limited to obtaining HSREB approval, contract and budget negotiations, study initiation and closing at site, subject recruitment, obtaining consent from subjects, carrying out study-related procedures and administering questionnaires, source documentation and case report forms, adverse event reporting, and being a liaison between Principal Investigator, Monitors and/or Industry Sponsor.

# Clinical Trial Protocol Review

- Protocol Review
  - The Principal Investigator is responsible for the overall review of all protocols sent to them for consideration.
  - Co-Investigator/Sub-Investigator and Study Coordinator/Research Nurse may also be asked to review study protocols and to provide the Principal Investigator with an assessment of the feasibility of the site to conduct the clinical study.

# Clinical Trial Protocol Review

- In some cases, the Principal Investigator is approached by Sponsors to review clinical trial protocols prior to distribution to other sites, in order to provide input to the design so that the protocol can be conducted properly at the Investigator's site and other sites.
- The Principal Investigator will receive, from the Sponsor, a copy of the final protocol for approval for site conduct. The Principal Investigator is also responsible for obtaining HSREB approval before initiating the protocol (entering the first patient). The Co-Investigator)/Sub-Investigator or Study Coordinator/Research Nurse may also be asked to assist the Principal Investigator in obtaining HSREB approval.

# Clinical Trial Registration

- All clinical trials need to be registered on a public registry.
- The clinical trial registry that the University and Hospitals supports/endorse is the National Institutes of Health (NIH) registry: <http://clinicaltrials.gov/>.
- Clinical trials only need to be registered once, so if the Sponsor has registered the clinical trial, then the Principal Investigator does not need to register the trial. *However, the clinical trial must be registered prior to the enrollment/recruitment of any subject into the clinical trial at the site.*
- To register a trial: <https://register.clinicaltrials.gov/>
  - You will need a username and password to access the registry, so contact Veronica Harris-McAllister at (613) 549-6666, ext. 3653 or [harrismv@kgh.kari.net](mailto:harrismv@kgh.kari.net).

# The Process and the Paper

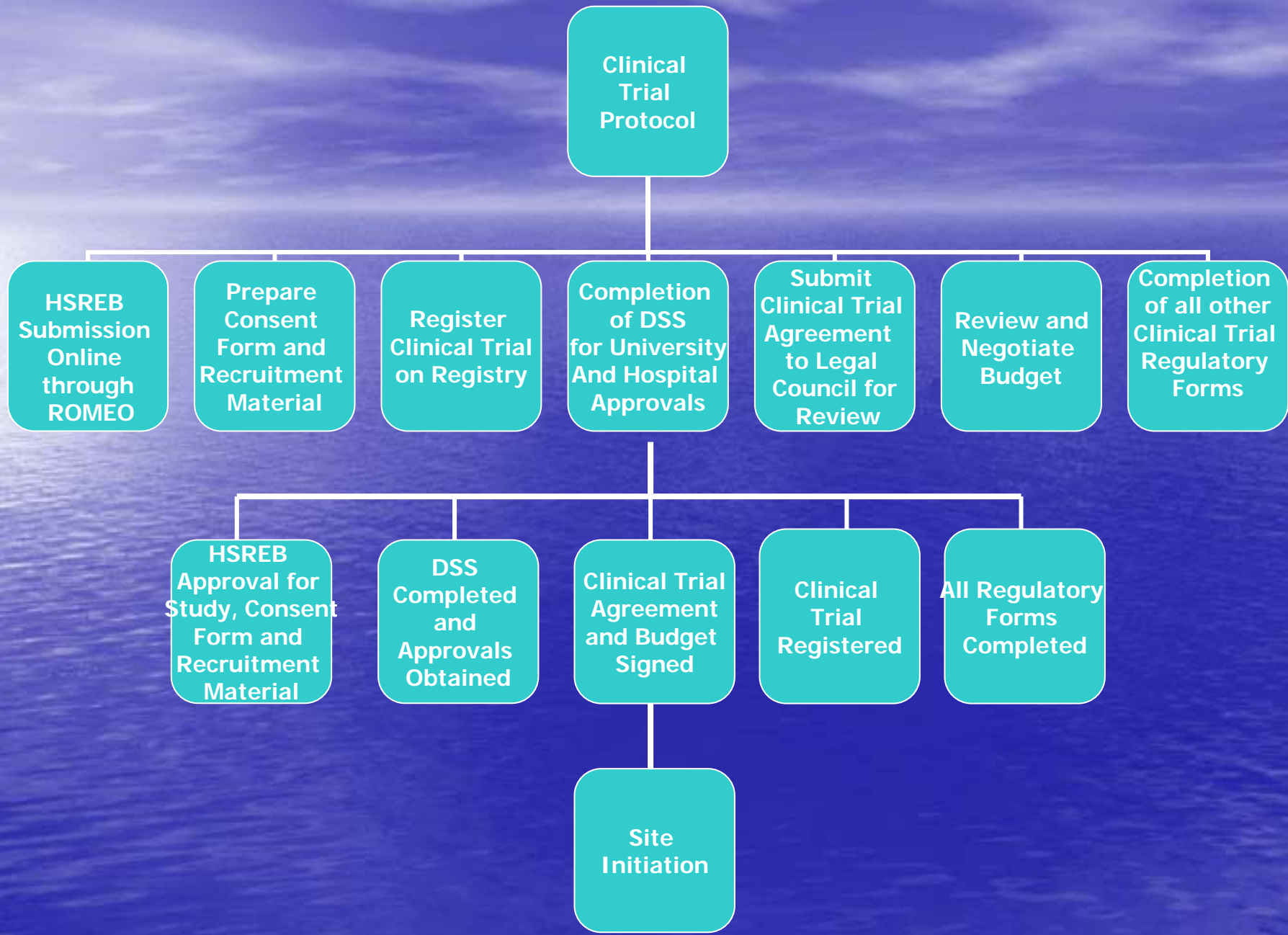
- Budget
- Financial Disclosure
- CVs (Qualified Investigator)
- FDA 1572
- Confidentiality Disclosure Agreement
- Clinical Trial Agreement
- Protocol
- Information/Consent Template

# Clinical Trial Agreement

- Budget
  - All costs for the completion of the study including staffing, tests etc – generally outlined in a cost/patient enrolled format
- Clinical Trial Agreement
  - Outlines the expectation of the sponsor of the clinical site (*i.e. number of patients to be enrolled, timelines, publication issues, indemnity issues etc.*)
- Confidentiality Disclosure Agreement
  - Patient and Company (proprietary information) confidentiality
- Financial Disclosure
  - Ensures that no one on the investigative team has financial ties or obligations to the company or the drug under study

# Investigator

- CVs (Qualified Investigator)
- FDA 1572
  - Agreement to carry out trial according to GCP
- Protocol
- Information/Consent
  - Patient Safety
- HSREB submission
  - Patient Safety, Protocol review, financial disclosure
  - Online through Queen's Ethics ROME0:  
<http://www.queensu.ca/ors/researchethics/queensethicsromeo/registrationlogin.html>



**Clinical  
Trial  
Protocol**

**HSREB  
Submission  
Online  
through  
ROME0**

**Prepare  
Consent  
Form and  
Recruitment  
Material**

**Register  
Clinical Trial  
on Registry**

**Completion  
of DSS  
for University  
And Hospital  
Approvals**

**Submit  
Clinical Trial  
Agreement  
to Legal  
Council for  
Review**

**Review and  
Negotiate  
Budget**

**Completion  
of all other  
Clinical Trial  
Regulatory  
Forms**

**HSREB  
Approval for  
Study, Consent  
Form and  
Recruitment  
Material**

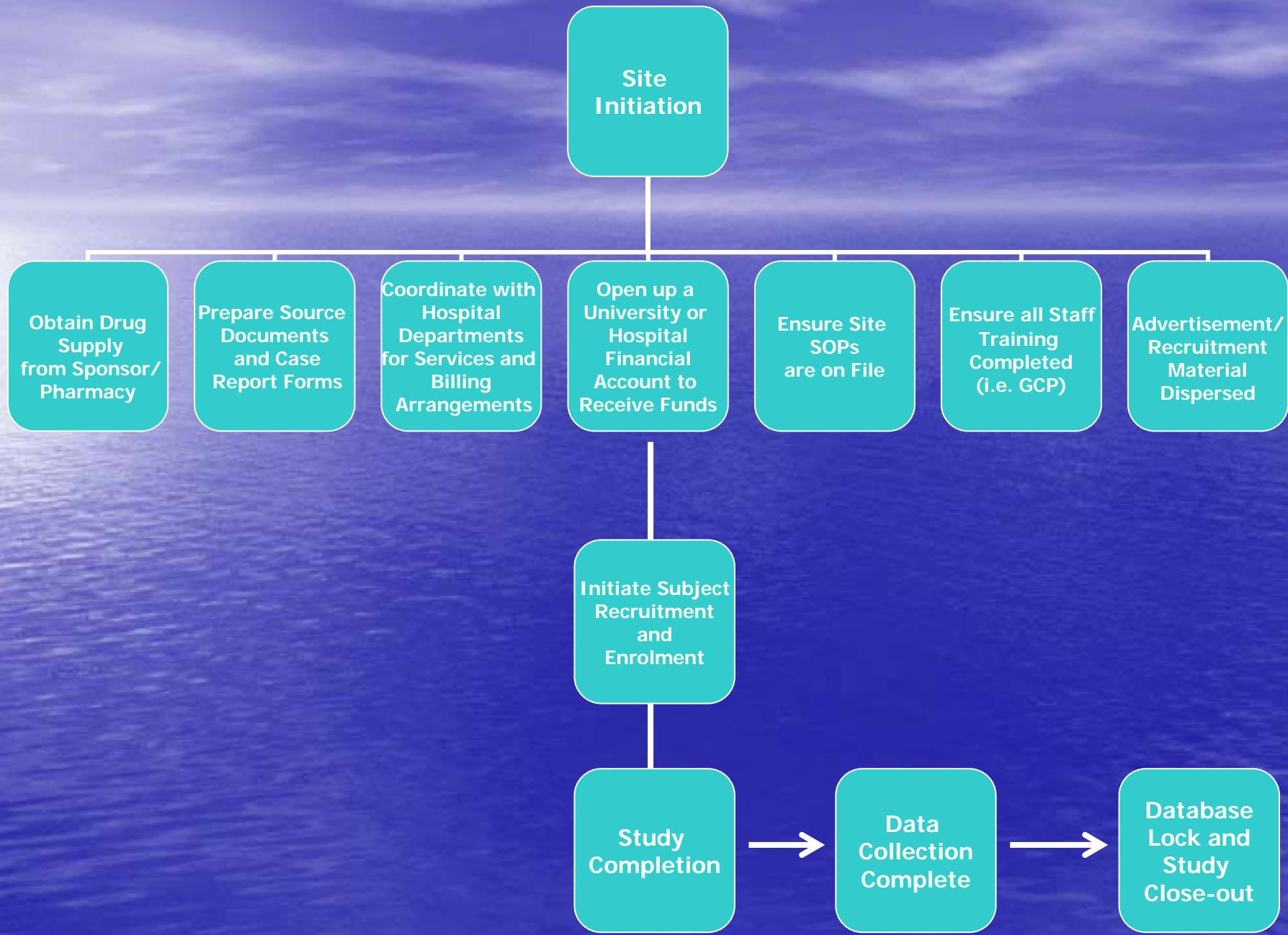
**DSS  
Completed  
and  
Approvals  
Obtained**

**Clinical Trial  
Agreement  
and Budget  
Signed**

**Clinical  
Trial  
Registered**

**All Regulatory  
Forms  
Completed**

**Site  
Initiation**



**Site Initiation**

**Obtain Drug Supply from Sponsor/ Pharmacy**

**Prepare Source Documents and Case Report Forms**

**Coordinate with Hospital Departments for Services and Billing Arrangements**

**Open up a University or Hospital Financial Account to Receive Funds**

**Ensure Site SOPs are on File**

**Ensure all Staff Training Completed (i.e. GCP)**

**Advertisement/ Recruitment Material Dispersed**

**Initiate Subject Recruitment and Enrolment**

**Study Completion**

**Data Collection Complete**

**Database Lock and Study Close-out**