

**Newton-Wellesley Hospital  
Clinical Trials Program  
Study Start-up Checklist**

**Study Name:**

**Study Sponsor:**

**PI Name:**

**CDA**

NWH/Partners Contact:  
Comments:

CDA Complete:

**STUDY FEASIBILITY**

Resources are available to conduct the study?  Comments:  
Enrollment feasibility conducted  Comments:

Ancillary Department review –

Laboratory	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:
Radiology	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:
Pharmacy	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:
Nursing	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:
OR	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:
Other	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Comments:

**SITE QUALIFICATION VISIT**

Yes  No  N/A Comments:

**TRAINING**

Investigator Meeting or Other Required Training Complete?

Yes  No  N/A Comments:

Inservices Complete?

Yes  No  N/A Comments:

**IRB APPROVAL**

Gather IRB Documents:

Protocol  Consent Form/Assent Form  
 Questionnaires/Diaries  Protocol Summary  Schema  
 Recruitment Documents  Data Collection Forms  
 Investigator Brochure/Package Insert

IRB Submission submitted in Insight  Comments  
Submitted to :  NWH IRB  Partners IRB  DF IRB  
Comments:

PI Sign Off in Insight?  Comments:

Co-Investigator/Study Staff Certifications Complete?   
Comments:

Financial Disclosures Forms Submitted?   
Comments:

CITI Trainings Complete?  Comments:

Injury Language in Consent form Reviewed?   
Comments:

If Partners IRB – Commitment Statement Signed

If NCI IRB – NWH Consent Compared to NCI Consent

ICF reviewed by sponsor

**DF Studies**

CTRF Submitted

Research Team Update Form Submitted

PI From Submitted

Co-I Forms Submitted

ICF Reviewed

Cede Review Submitted

**BUDGET APPROVAL**

Sponsor Budget Received  Comments:

MCA Needed?  Yes  No Comments:

MCA Negotiated?  Yes  No Comments:

NWH Budget Review:

Laboratory  Yes  No Comments:  
 Radiology  Yes  No Comments:  
 Pharmacy  Yes  No Comments:  
 Nursing  Yes  No Comments:  
 OR  Yes  No Comments:  
 PI  Yes  No Comments:  
 Other  Yes  No Comments:

Revised Budget sent to sponsor:  Comments:  
 Sponsor Approval of Budget:  Comments:  
 Budget Approval Signatures:  Comments:  
 Budget Shared with MRC:  Comments:  
 Budget Entered in InfoEd:  Comments:

**CONTRACT APPROVAL**

NWH/Partners Contact:

Sponsor Contact:

PI Questionnaire Complete:  Comments:

Finalized Budget provided to NWH/Partners:  Comments:

Contract checked against IFC Injury Language:  Comments:

Contract fully executed:  Comments:

**REGULATORY DOCUMENTS**

1572 Statement of Investigator  Comments:  
 Conflict of Interest Disclosure Forms  Comments:  
 Delegation of Authority Log  Comments:  
 Protocol Signature Page  Comments:  
 Training Log  Comments:  
 CVs Signed and Dated  Comments:  
 Medical Licenses  Comments:  
 CITI for all Staff  Comments:  
 Research License if applicable  Comments:  
 Lab Reference ranges/certifications  Comments:

**OTHER**

Regulatory Binder Set Up  Comments:  
 Obtain or Create CRFs  Comments:  
 Obtain Study Supplies  Comments:  
 Prepare New Patient Packets  Comments:

Create Enrollment and Screening Logs  Comments:  
If Tumor Metrics is to be used send  Comments:

**SITE INITIATION VISIT**

Yes  No  N/A Comments:

**GRANT SET UP**

Grant Set up in InfoEd:  Grant Number:

**BILLING FUND SET UP**

Study Set up in Epic?   
Financial Delegate set to HMV in Insight?   
Billing Table Set up in Epic?   
Financial Delegate set to HMV in Insight?   
Billing Instructions Communicated?  Comments

**SPONSOR INVOICE FOR IRB AND STUDY START UP FEES**

Sponsor Invoiced for Study Start-Up and IRB Fees?   
Comments: