



Instructions for Documenting Qualification Activities

Investigators and Delegates: Use this template to document completed activities that qualify you to conduct clinical trials in your professional role. Qualification activities are any relevant learning activities that develop your experience, knowledge, skills, or expertise. You should adjust this template, adding or deleting sections, to meet your needs and showcase your qualifications in clinical trials conduct. Update this document as you engage in new activities, and share it with sponsors and CROs as testament to your qualification.

Sponsors and CROs: Please accept this documentation of the named clinical research professional's 1) completion of previous relevant training and 2) continued application of knowledge and skills during the conduct of clinical trials. This documentation has been provided to you as evidence of qualification for conducting clinical trials.

To complete: Complete the relevant fields based on the embedded instructions, and delete those fields that do not apply. To review CTTI's recommendations related to Investigator Qualification, click [here](#).

Qualification Activities for Sample Principal Investigator

Qualifications Summary *(title, years of experience, high level list of qualification activities)*

Principal investigator (PI) with over 12 years of clinical research experience and participation in over 75 studies. Served as a PI in both an academic setting as well as private practice clinic.

FEASIBILITY

Encompasses site team activities to evaluate the possibility of conducting a clinical trial (timelines, targets, cost, resources, skills, qualifications, and abilities).

Protocol Experience

Therapeutic Area	Number of Years	Protocol Phases	Study Design	Number of Studies	Number of Subjects Enrolled	Clinical Trial Number (where available)
Ophthalmology (wet macular degeneration, cataracts, glaucoma)	8	III-IV	Double blind	25	300	
Cardiovascular (hypertension, CV endpoint, coronary artery disease, atrial fibrillation)	4	II-III	Double blind	15	500	
Neurology (multiple sclerosis, Parkinson's disease, epilepsy)	12	II-IV	Double and single blind	40	1,000	

Additional Notes:

Over 2,500 subjects screened, 70% randomization rate



Protocol Feasibility Assessment

Feasibility is a careful process at our site, it involves an in-depth protocol review by the PI, Sub-Investigator (Sub-I), site director, and a preliminary chart review of possible subjects by a study coordinator (SC) to estimate our recruitment numbers.

Protocol Management Experience

I am involved in 10-12 studies at any given time. Serving as PI on 4-5 and as a Sub-I on 5-7

Protocol Design Specifics

The majority of my experience is in late phase; multi center; randomized double blind trials.

Recruitment, Retention Measures, and Previous Successes

Over 1,800 subjects randomized

Low number of lost to follow up and early withdrawal subjects (~5%)

Subjects are sent monthly postcards and health related newsletters as well as quarterly thank you notes from site staff to promote engagement.

Partnered with six area hospitals for advertisement

Site Organization Chart

On staff: Site director (1), Senior SC (3-5), SCs (7-10), research assistant (1-3), Sub-I's (10)

Site organization chart available upon request

Support Structure within the Organization

Staff Meetings:

All research staff department meetings held every week

Protocol / sponsor specific staff meetings on a monthly basis

PI / Sub-I department meetings monthly

Job Shadowing:

SCs new to a protocol or therapeutic area routinely shadow a more experienced SC prior to conducting a study visit on their own

Knowledge Sharing:

Research teams share best practices across different studies during the weekly research team meeting

Research Staff Details:

Site staff allocation is dependent on complexity of protocol and number of subjects enrolled.

Sub-I: 2-4 per study

SC: 1 senior SC per study as well as 2-5 back up SCs

Research assistant: 1 per study

Site staff are training on an ongoing basis with internal training, study training, and during job shadowing.

Senior SCs have >5 years' experience, SCs have an average of 3 years' experience

Sub-Is range in experience from 1 to 10+ years

Education, Previous Training(s), and Certification(s)

Course/Certification Name	Awarded By	Date
Understanding Study Participant Recruitment and Retention Measures: Find the Barriers and Address Them	XYZ	2015
Business Administration for Clinical Research Practices	ABC	2007

Additional Notes:

STUDY CONDUCT

Encompasses site team activities required for all operations of a clinical trial.

Internal Site Communications and Teamwork Structure

All research staff encouraged to ask time sensitive questions via email or phone. SOP for response time is > 24 hours.

All other questions are addressed during the weekly research staff meeting.

Professional Memberships, Conferences Attended, Committees/Boards

ACRP 2005-present (attended ~5 conferences)

SOCRA 2005-present

Chair of the University of Blank Clinical Research department

Process for Ongoing Training

Research staff complete our internal onboarding training as well as supplementary training as needed (based on studies, knowledge gaps, identified protocol deviations) or requested.

Our site uses the online trainings available from ACRP.

I stay up-to-date on the industry by attending applicable industry conferences and webinars.

Mentor or Mentee Partnerships

Previously mentored by a former colleague with 25 years of research experience who is a key opinion leader in wet macular degeneration.

Currently mentoring three sub-I's on the responsibilities of a PI.

Data Entry Metrics

Follow study specific guidelines or internal metric of entry within 3 days of visit completion; whichever comes first.

Query Resolution Metrics

SOP to resolve all queries within 10 business days of a monitoring visit
 EDC queries are resolved in 2-5 business days of site awareness depending on level of importance
 Urgent safety queries are resolved in > 24 hours of site awareness
 Site process: A SC or research assistant reviews EDC queries once a week for all studies

Data Handling and Storage Throughout Study Lifecycle

Archived Data stored on-site for easy access at a secure storage locker in the basement of the clinical research department. Current study charts are stored in the research department office, which is locked and secured.

Education, Previous Training(s), and Certification(s)

Course/Certification Name	Awarded By	Date
Certified Clinical Research Investigator	ABC	July 2010
Expert GCP Exam	XYZ	January 2016
Understanding Recruitment and Retention measures	123	April 2012

Additional Notes:

Additional study specific trainings and industry webinar attendance available upon request.

STUDY PARTICIPANT SAFETY

Encompasses site team activities affecting the rights, safety, and well-being of the trial subjects including informed consent, withdrawal criteria, retention, and safety reporting.

Mechanism for Proper Oversight/Delegation

Protocol specific study team members meet every week
 PI/Sub-Is review reported safety events throughout the week (designated time on M, W, F)
 Subjects meet with an investigator at every study visit
 I participate in study visits as often as possible. If I am unable to participate the Sub-I and/or SC present will provide me with a summary of the subject visit afterwards.

Resources for Safety Event Reporting During and After the Trial:

Investigators are available 24 hours a day for safety event reporting. Internal SAE hotline for after-hours emergencies.
 Post study closure one SC is assigned to a trial as a point of contact for all post-study event reporting.

Standard Operating Procedure (SOP) for Study Participant Safety *(informed consent process, adverse event/serious adverse event reporting, care of human subjects, etc.)*



Informed Consent is given following our internal ICF SOP (available upon request). An investigator is always present and available for subject questions during the process.

AE/ SAE reporting and review performed weekly following Hospital of Blank's SOPs

Study Participant Satisfaction Surveys

Not implemented at our site

Process for Communication with the Study Participant's Treating Physicians

A 'dear doctor' letter is sent to subject's PCP after randomization. Subjects are given copies of relevant tests and labs throughout the study to share with their PCP and / or faxed to the PCP upon subject's request.

Quality Control Measures to Limit Errors and Deviations

Internal QA department performs a spot check of a percentage of subject charts on an ongoing basis; findings are shared with SC and PI

Investigational Product Processes for Handling, Receipt, and Administration

Full time pharmacist on staff

Internal SOP on IP available upon request

Education, Previous Training(s), and Certification(s)

Course/Certification Name	Awarded By	Date
Safety reporting and SAE reporting	XYZ	2014

Additional Notes:

THIRD PARTY ENGAGEMENT

Encompasses site team activities related to third-party engagement and communications.

Industry (Sponsor/Contact Research Organization) Partnerships

Organization	Duration	Number of Studies
ABC Pharmaceuticals	2012-present	12
XYZ CRO	Preferred site from 2015-present due to high site performance	14
EFG Pharmaceuticals	2012-2014	7

Additional Notes:



Systems Experience *(electronic data capture, interactive voice response system, electronic study participant reported outcomes, electronic diaries, and electronic questionnaires)*

System/Device Name	Number of Studies & Number of Years	Date of Last Training
XYZ EDC	25 studies over 8 years	June 2017
ABC EDC	40 studies over 10 years	April 2015
123 IVRS	6 studies over 3 years	June 2011
XYZ company (diaries and questionnaires)	3 studies over 2 years	May 2009
XYZ company (diaries and ePRO)	1 study over 1 year	January 2018

Vendor Experience *(central labs, central institutional review board, central advertising, and recruitment)*

Experience working with central labs as well as local labs for 15 plus years
No central advertising or recruitment experience.

Previous Study Achievements

Received the 'Gold Star' award from XYZ sponsor for high rates of retention in 2010, 2012, and 2017
Top enroller in 15 phase II studies

Prior Findings and Observations *(including outcomes and implementation of corrective and preventive actions)*

Participated in 17 audits (both internal and external); no serious findings related to study participant safety noted.

One finding in 2012 on a Phase III neurology study was failure to document email correspondence with subjects in the subject chart. Study Coordinators are now kept in cc on all emails and SCs print emails and file in subject charts on a weekly basis.

FDA audit in 2016 on a Phase III cardiovascular study: No major observations or 483 issued

Education, Previous Training(s), and Certification(s)

Course/Certification Name	Awarded By	Date
Certified Preferred Site Status	ABC Pharma	2016

Additional Notes:

Certified Preferred Site status is awarded by ABC pharma to sites who meet their criteria of excellence. Some of this criteria is to meet or exceed projected enrollment, have a low number of protocol deviations, routinely meet or exceed query resolution timelines, and routinely meet or exceed data entry timelines.