



Principal Investigator	Dept./Division
Contact Info: ext./pager	Additional Contact
Protocol #	Funding Type
Protocol Title	
Risk Determination	Review Type
<input type="checkbox"/> Minimal with potential <input type="checkbox"/> Minimal without potential <input type="checkbox"/> Greater than minimal with potential <input type="checkbox"/> Greater than minimal w/o potential	<input type="checkbox"/> Full Study Review <input type="checkbox"/> Partial Study Review <input type="checkbox"/> Informed Consent
Type of Protocol ↳ Check all that apply	<input type="checkbox"/> Medical Intervention <input type="checkbox"/> Study Drug <input type="checkbox"/> Study Device <input type="checkbox"/> Behavioral Intervention <input type="checkbox"/> Observational <input type="checkbox"/> Quality Improvement
QI Specialist	

→ **Eligibility for EQuiP Review**

<input type="checkbox"/> Selection Type	<input type="checkbox"/> Random Date Selected: _____ Group#: _____
	<input type="checkbox"/> PI/Staff-Requested Date Requested: _____ Reason: _____
	<input type="checkbox"/> IRB-Requested Date Requested: _____ Reason: _____
<input type="checkbox"/> Required Reviews	<input type="checkbox"/> Principal Investigator/Staff <input type="checkbox"/> Research Pharmacy <input type="checkbox"/> Institutional Review Board/CCI <input type="checkbox"/> General Clinical Research Center <input type="checkbox"/> Other Department/Institution → Specify: _____
	<input type="checkbox"/> Obtain CCI/IRB Protocol File Date retrieved: _____ <input type="checkbox"/> Update EQuiP Board <input type="checkbox"/> Verify protocol info and status Document changes/notes: _____
<input type="checkbox"/> PI Notification of Review	<input type="checkbox"/> Email Date: _____ <input type="checkbox"/> Hard-Copy Date: _____
<input type="checkbox"/> PI Contact: Verification of Status	Date of Contact: _____
	Evaluate: <input type="checkbox"/> Study Activity <input type="checkbox"/> Enrollment Confirm: <input type="checkbox"/> Study Risk <input type="checkbox"/> Funding Type <input type="checkbox"/> Study Type
<input type="checkbox"/> INELIGIBLE	Reason: _____
<input type="checkbox"/> DEFERRED (contact later)	Reason: _____
<input type="checkbox"/> ELIGIBLE	Schedule Review – complete checklist.

→ **NOTES:**

→ **Study Review Checklist: Principal Investigator/Research Staff**

Schedule: Initial Meeting and Review

Planned Date and Time: _____
 Location/Room: _____
 Planned Attendees: _____

Subject Selection

Number Selected: _____ Total Enrolled: _____
 Subjects Selected: _____
 Date PI Notified: _____

Review Preparation

Review CCI/IRB
 Prepare Study Monitoring Forms and Initial Meeting Notes
 Prepare Subject Monitoring Forms

Initial Meeting

Date and Time (Length): _____
 Attendees: _____

Study and Subject Review

Date and Time (Length): _____

Draft Report Prepared and Approved

Date: _____

Final Meeting

Date and Time (Length): _____
 Attendees: _____

Final Report and PI Response

Date Prepared: _____
 Date Sent via Email: _____ Date via Mail: _____

PI Response Returned

Date: _____

PI Responses Reviewed and Approved

Date: _____

Thank You Email

Date sent: _____

Update CCI Database for QI Review

Date entered: _____

Update CCI Training Database

Date entered: _____

EQuIP Memo for CCI Study File

Date sent: _____

➤ **NOTES:**

