

IRB Reviewer Form for Protocol Renewal

Protocol # **Previous Protocol #** **PI:** **IRB Committee#: SELECT**

(Items marked with an asterisk(*) = Return Criteria if submitted within specified timeframe – see Summary section)

Modifications:

Modifications submitted/approved since last renewal	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Protocol Amendment(s) included with this renewal	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Change in Study Personnel	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Other New Material submitted with this renewal	<input type="checkbox"/> No		<input type="checkbox"/> Yes	

Subjects Section:

* Subjects section is incomplete or inaccurate:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Enrollment data discrepancies or questions:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Demographic data discrepancies or questions:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	

Vulnerable Subjects:

Pregnant Women; Past Subpart B Determination	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Source: _____				
Prisoners; Past Subpart C Determination	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Source: _____				
Children; Past Subpart D Determination	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Source: _____				
Wards / Foster Children enrolled	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Subpart D 406 without a second signature line on the consent	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Child Involvement section is required but missing:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Child Involvement section is incomplete:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Investigator's Risk Assessment differs from Board's	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
PI's Risk Assessment: _____				
"New" Vulnerable Subjects (not previously reported)	<input type="checkbox"/> No		<input type="checkbox"/> Yes	

Oversight Monitoring:

Serious Adverse Events reported since the last renewal	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
Deaths at this site	<input type="checkbox"/> No		<input type="checkbox"/> Yes	
*Annual Summary of Adverse Events is missing	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Data Safety Monitoring report is missing w/o explanation	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Current Progress Report missing w/o explanation:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	

Training:

Study personnel need to complete CITI training:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Study personnel need to complete HIPAA training:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Study personnel need to complete Human Subjects training:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	

Miscellaneous:

*Cancer Center review is required, but is not listed under Research Facilities:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Complete copy of the Grant is not attached	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*IBC Appendix C is not attached (study involves human specimens)	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Investigational products section is blank (Drug & Device studies)	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
*Other necessary documents or data are missing:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Cancer Center renewal form is required, but missing:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Certificate of Confidentiality has lapsed	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Current approvals from collaborating institutions missing:	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Protocol Tracking number is missing (CUMC only):	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
QA revealed unresolved issues from prior IRB review	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Translations do not have appropriate certification	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Other Issues	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	

Consent Form:

	<input type="checkbox"/> N/A	<input type="checkbox"/> Closed to enrollment		
Non-English speaking subjects enrolled using short form:	<input type="checkbox"/> No	<input type="checkbox"/> Not Stated	<input type="checkbox"/> Yes	# _____ consented by this method out of _____ (total enrolled)
Consent Form translation may be required	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	Enrolled _____ % subjects
Clean (unstamped) CU consent form is missing	<input type="checkbox"/> No	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Other Issues?	<input type="checkbox"/> No		<input type="checkbox"/> Yes	

SUMMARY FOR RASCAL NOTES:

Renewal Pre-review Comments & Recommendations:

Review completed by: **Date:**

Protocol #: **Previous Protocol #:**
Date of Expiration: **Renewal Submitted:**

Recommended level of review:

Original level of review:

Last Renewal:

Past Primary Reviewer(s):

Current Status:

(NOTE: Pre-reviewer should delete all fields that are not applicable to this renewal)

Change in Literature:

Modifications:

Subjects:

Vulnerable Subjects:

Past Subpart Determination:

Oversight Monitoring:

Training:

Miscellaneous:

Consent Form:

Renewal will be: Logged in

Renewal will be Returned

Reason For Return (delete all that do not apply):

- Subjects section is incomplete or inaccurate
- Child Involvement section is required but missing
- Cancer Center review is required, but is not listed under Research Facilities
- Annual Summary of Adverse Events is required, but missing
- Latest Data Safety Monitoring or Progress Report is not attached & no explanation is provided
- IBC Appendix C is required, but not attached
- Investigational product section is blank
- Other necessary documents (grant, protocol, unstamped consent) are missing

Correspondence for return:

1)

Return criteria listed above applies only when the protocol expiration date is ≥ 4 weeks for Full Board studies and ≥ 2 weeks for Expedited studies. For expiration dates in the near future (< 4 weeks for Full Board studies; < 2 weeks for Expedited studies), the renewal should not be returned but exceptions noted for IRB review only

When applicable, returns of renewals should occur after prior contact with study personnel, to ensure their ability to resubmit in time for completion of IRB review, prior to the expiration date. If returned, any other possible exceptions, i.e. lack of required training, cancer center renewal form, enrollment and/or demographic data discrepancies, other required approvals (Cancer Center, JRSC, IBC, etc.), and proposal tracking number, if applicable, should be included in the return correspondence.