

# CORIHs Submission Requirements **Continuing Reviews (CR): Regular (1st-4th) and Five Year Submissions**

<b>Obtain 1-8 from IRBNet's Forms and Template Section</b>	<b>REGULAR (#1-4) CR EXPEDITED OR FULL REVIEW</b>	<b>FIVE(5) YEAR CR, EXPEDITED REVIEW</b>	<b>FIVE (5) YEAR CR, FULL REVIEW</b>
1. Registration Form (from IRBNet)	X	X	X
2. Application for Exp/Full Review (from IRBNet)			
3. Supplemental Forms A, B, C, D, E (as applicable*)		X	X
4. Continuing Review Application (from IRBNet)	X		
5. Five Year CR Application (from IRBNet)		X	X
6. Fee authorization form (industry-funded studies)		X	X
7. University Hospital Approval Form**		X	X
8. HIPAA forms (as applicable)		X	X
9. Data Safety Monitoring Board Reports	X	X	X
10. Gov't or sponsor audit/monitoring reports	X	X	X
11. Last signed, redacted consent, assent etc. documents	X	X	X
12. Clean, most currently approved, consent documents (i.e., no track changes or stamps) in word format.	X	X	X
13. Recruitment materials	X	X	X
14. Data collection sheets (e.g., spreadsheets, case report forms)		X	X
15. Surveys, Questionnaires		X	X
16. Protocol	X	X	X
17. Grant (if externally funded)		X	X
18. Package inserts (as applicable)			X
19. Investigator Brochures (as applicable)			X
20. Inclusion/Exclusion checklist (to be used for each subject)	X		X
21. Completed Inclusion/Exclusion checklist for last subject enrolled	X (full review only)		X
*Depending on your responses in the CORIHs Application; <b>A:</b> Questionably-/Non-Viable Neonates, <b>B:</b> Prisoners, <b>C:</b> International Research, <b>D:</b> Sponsor-required ICH-GCP <b>E:</b> Community Based Research			
**if your research activity involves the facilities, patients, and/or services of any of University Hospital's inpatient or outpatient locations, (with the exception of the			

outpatient clinics located at Riverhead, Southold, Plainview, or Medford)