

STARTUP & ACTIVATION CHECKLIST

Item	Done	Comments
1. IND/IDE Approval or Exemption	<input type="checkbox"/>	
2. 1572 <i>Double-sided or stapled.</i>	<input type="checkbox"/>	
3. CV of the PI <i>Signed and dated.</i>	<input type="checkbox"/>	
4. Medical License of the PI <i>Current and valid.</i>	<input type="checkbox"/>	
5. CVs for Investigators on 1572 (box #6) <i>Signed and dated.</i>	<input type="checkbox"/>	
6. Medical Licenses for Investigators on 1572 (box #6) <i>Current and valid.</i>	<input type="checkbox"/>	
7. Protocol signature page <i>Signed by the Site Responsible Investigator.</i>	<input type="checkbox"/>	
8. IDB Signature Page <i>Signed by the Site Responsible Investigator.</i>	<input type="checkbox"/>	
9. Financial Disclosure Forms		
a. Statement of Investigator <i>For PI and sub-investigators</i>	<input type="checkbox"/>	
b. Outside interest disclosure <i>When applicable</i>	<input type="checkbox"/>	
10. Lab documents <i>Certifications must be valid.</i>		
a. CLIA	<input type="checkbox"/>	
b. CAP	<input type="checkbox"/>	
c. Lab normal ranges	<input type="checkbox"/>	
11. Delegation of Authority Log <i>All sections complete. Approved by Overall PI.</i>	<input type="checkbox"/>	
12. Study team Training		
a. Protocol-Specific <i>All study team members.</i>	<input type="checkbox"/>	
b. HSP and GCP <i>All study team members.</i>	<input type="checkbox"/>	
c. DF/HCC Policies <i>All study team members.</i>	<input type="checkbox"/>	
d. EDC / System Training <i>As applicable.</i>	<input type="checkbox"/>	
13. Laboratory Director CV <i>For DF/HCC and DF/PCC facilities only.</i>	<input type="checkbox"/>	
14. IRB Submissions	<input type="checkbox"/>	
15. IRB Approvals and Responses	<input type="checkbox"/>	
16. IRB Approved Consent Form <i>Stamped</i>	<input type="checkbox"/>	
17. IRB Approved Patient Items <i>Including educational & recruitment materials, advertisements, etc.</i>	<input type="checkbox"/>	
18. Eligibility Checklist <i>Finalized with ODQ. Posted to OncPro upon activation.</i>	<input type="checkbox"/>	
19. IRB Notification of Activation	<input type="checkbox"/>	
20. Contracts and Budget <i>File separately.</i>	<input type="checkbox"/>	
21. Study Tools and Templates <i>Prepared and ready to go.</i>		
a. Screening and Enrollment Log	<input type="checkbox"/>	
b. Deviation/Violation Log	<input type="checkbox"/>	
c. Lab/Pharmacy Manuals	<input type="checkbox"/>	
d. Monitoring Log	<input type="checkbox"/>	
e. Sample Collection Log	<input type="checkbox"/>	