Green Light checklist for studies conducted in the Clinical Research (Support) Unit

Study name:

Principal Investigator:

CRSU # _____

Study is Regulated ☐ Unregulated ☐

Item	**Yes/No/NA** Add comment for No or NA	**Add version (if applicable)**	**Comment**
Protocol			
Patient Information Leaflet			
Informed Consent Form			
Executed Contracts/Agreements			
Ethics Committee application			
Ethics Committee Approval			
*HPRA Approval**			
*Completed Site Specific Assessment Form**			
UL Insurance checklist			
*Confirmation of CIS cover**			
*Clinical Trial Insurance certificate**			
CVs of study staff			
GCP Certificates of study staff			
*Investigational Brochure**			
Completed Delegation Log			
Completed Training Log			
Approved DPIA			
Composition of Ethics Committee members			
Site file complete – confirm if paper or electronic Index			
Agreed monitoring plan (if applicable)			
Safety reporting requirements – sufficient to refer to section of protocol			

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Item	**Yes/No/NA** Add comment for No or NA	**Add version (if applicable**)	**Comment**
Access to electronic data capture system for relevant members of the research team			
Other study specific documents (please list)			

* ***Regulated trials only***

Additional comments:

Prepared by:

_____ _____

Signature (electronic signature permitted) ***Date***

Print name:

Position:

Approved by Clinical Operations Manager.

_____ _____

Signature (electronic signature permitted) ***Date***

Print Name:

Communication & record of this authorization:

Email sent to	
Date	
Added to CR(S)U Quality Files	