Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Sponsor Green Light**		
SOP Reference Number:	QUB-RGEI-023	Version Number:	FINAL v1.0
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	Name and Position	Signature	Date
Author:	Research Governance, Ethics and Integrity Team	----------	----------
Reviewed and Approved by:	Chair, Research Governance, Ethics and Integrity Committee	----------	----------

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

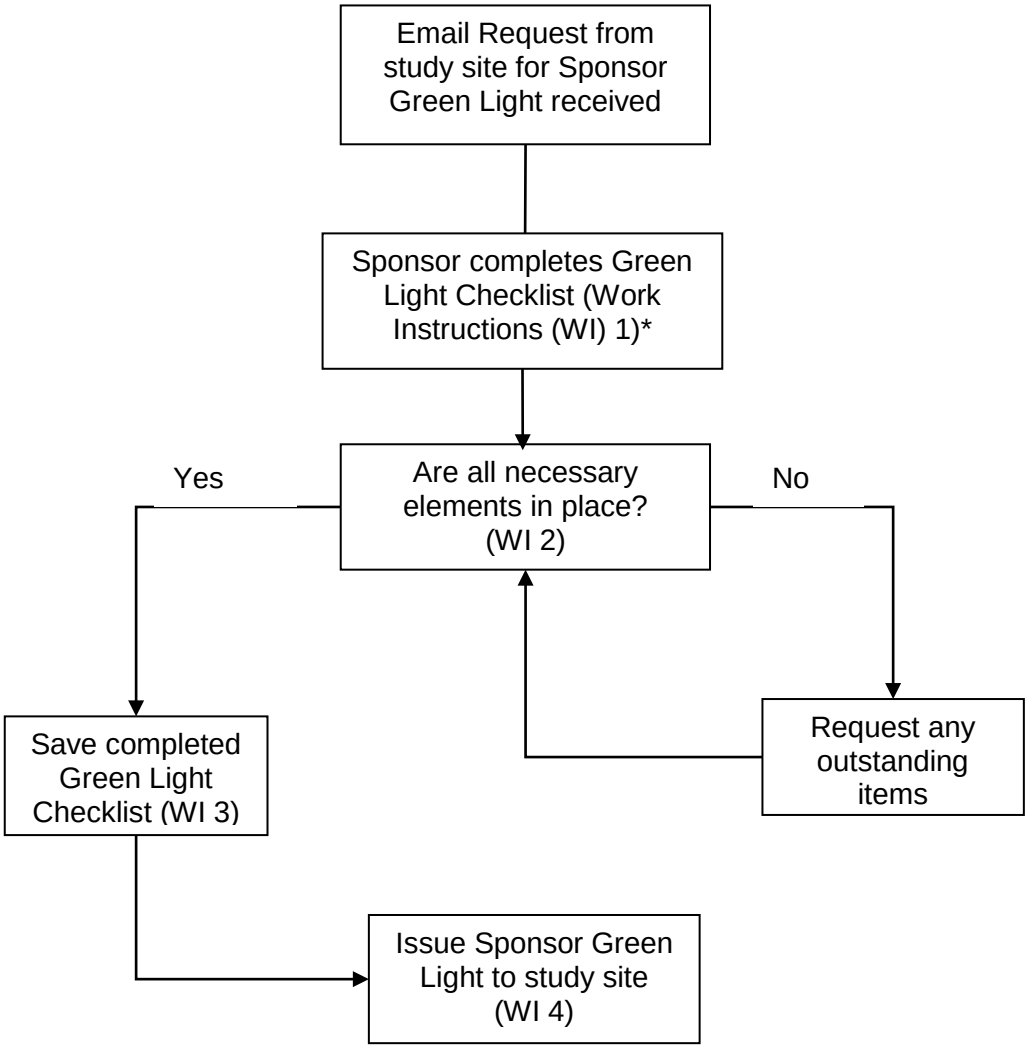
1. Purpose

This Standard Operating Procedure describes the process used by the Research Governance, Ethics and Integrity Manager to determine whether Sponsor Green Light can be confirmed and recruitment may begin at a study site.

2. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

3. Procedure



***Where the green light process has been delegated to a Clinical Trials Unit or Clinical Research Organisation their SOPs shall be followed*

4. Appendices

Work Instructions 1 – Green Light Checklist
Work Instructions 2 – Completeness Check
Work Instructions 3 – Saving Green Light Checklist
Work Instructions 4 – Issue Sponsor Green Light

Appendix 1: Sponsor Green Light Checklist

Work Instructions 1 – Green Light Checklist

1. The Sponsor Green Light Checklist Template (Appendix 1) should be populated with the following information:
    a. Study Title
    b. Chief Investigator Name
    c. IRAS id, REC reference, QUB reference
    d. Site Name

Work Instructions 2 – Completeness Check

1. The study file should be checked to ensure that the following are in place:
    a. NHS/HSC REC Favourable Opinion Letter
    b. NHS/HSC Trust R&D Permission / Confirmation of Capacity and Capability
    c. HRA Approval (where there are study sites in England, Wales or Scotland)
    d. Other Regulatory Authority Approvals (as applicable)
    e. Fully Executed Agreements (as applicable)
2. If any required items are not available, these should be requested from the CI
3. Once all relevant documents are received, checked and appropriately filed, then the Sponsor Green Light Checklist should be signed and dated.
4. The 'Action' field should be completed to state 'Sponsor Green Light issued' and the date on which this is done entered.

Work Instruction 3 – Saving Green Light Checklist

1. The completed, signed Sponsor Green Light Checklist should be converted to pdf and saved to the relevant site folder in the electronic study file.

Work Instruction 4 – Issue Sponsor Green Light

1. An email should be sent to the R&D Office at the study site, copied to the Chief Investigator, Principal Investigator (if applicable). This should name the site, state sponsor reference, REC reference and IRAS project id, as well as the study title. The email should state that this should be accepted as sponsor green light, and give the effective date.

GREEN LIGHT CHECKLIST

REVIEW AND APPROVAL

Study Title:		
Chief Investigator:		
IRAS ID:	**REC Ref:**	**QUB Ref:**
Site:		

Required Documents	**Approved/ Received** *(Yes or N/A)*	*Comments*
NHS/HSC REC Favourable Opinion Letter		
NHS/HSC Trust R&D Permission/Confirmation of Capacity and Capability		
HRA Approval Letter (if applicable)		
Regulatory authority approvals eg CAG (list all required)		
Fully Executed Agreements		
• Co-sponsorship Framework		
• mNCA		
• Material Transfer Agreement		
• Funding Agreement		
• Other (please list)		
Other eg Site initiation Visit		

GREEN LIGHT AUTHORISATION

Name (print)	**Signature**	**Date (dd/mm/yy)**

Action	**Date (dd/mm/yy)**

Filed in Sponsor File
