

GCIG Harmonization Committee

SITE APPROVAL FORM

Participating Group:

Site Name:

Site City and Country: _____

Principal Investigator: _____

For the above named site:

- 1. Ethical and Regulatory approvals have been obtained to participate in the [STUDY NAME] trial.
- 2. Participating Group has ensured signature for Investigator agreement.
- 3. CVs have been collected for the Principal and Co-Investigators
- 4. The site selection checklist has been completed
- 5. Signature list and delegation of responsibilities log for all trial personnel, [including Pharmacy, Laboratory, Radiology, or other staff] has been signed by all Trial Personnel at the site.
- 6. Site training [slides, visit, virtual] log for all trial personnel, [including Pharmacy, Laboratory, Radiology, or other staff] has been signed by all Trial Personnel at the site
- 7. [if applicable, Sample "study drug " labels have been reviewed by the Participating group]
- 8. Trial Personnel have been adequately informed about trial procedures, including those for Safety Reporting.

Date of Ethical Approval:	
Date of Regulatory Approval (where applicable):	
Date of Site Activation:	

Name of GCIG Representative:

(Print in capitals letters)

Role of GCIG Representative:

(Print in capitals letters)

Signature: _____ Date: ____