SAMPLE APPROVAL FOR SINGLE ETHICS REVIEW OF MULTICENTRE RESEARCH

(Letter Head of The Single Ethics Committee)

(Add rows/lines as per requirement)

To, Date: DD/MM/YYYY
Name of Coordinating Principal Investigator (c-PI)
Designation & Department
Name & Address of Coordinating Institution

Subject: Single Ethics Committee Approval/Decision Letter

Title of the study: _____
Study reference no: _____
Date Initial submission: _____ Revised (if applicable): _____

Single Ethics Committee (Single EC) meeting was held at (institution name) on (Date). Meeting was attended by the following members:

_____(Chair)_____(Vice Chair)
_____(Mem. Sec.)_____(Alt Mem. Sec.)
_____(Clinician)_____(Clinician)
_____(Basic Scientist)_____(Basic Scientist)
_____(Legal Expert)_____(Legal Expert)
_____(Soc Scientist)_____(Soc Scientist)
_____(Lay Person)_____(Lay Person)
_____(Ind Consultant)_____(Community/Patient Rep)
_____(PI/Co-PI)_____(PI/Co-PI)

It is confirmed that none of the study team members were present during the decision-making process for this study. Conflict of interest (COI) were declared prior and members recused themselves_____
_____

List of Documents Reviewed by the Single EC *(Add rows as applicable)*			
S.N	Documents	Version No./ Dated	Date of Submission
1.	Covering Letter		
2.	Peer review/ Scientific Committee approval with comments		
3.	Initial Review Form (site information, roles, contact details)		
4.	Multicentre protocol stating site-specific ethical considerations, PI/Co-PI, contact details of participating sites.		
5.	Informed consent documents in English, including master ICF, PIS and recruitment material.		
6.	CVs and training certificates of all PIs and Co-PIs.		
List of Documents Reviewed by EC Secretariat *(Add rows as applicable)*			
7.	Recruitmenet Material & Inf Consent translations (*Language1)*		
8.	Recruitmenet Material & Inf Consent translations (*Language2)*		

The Protocol titled "_____" (Version No. ___, dated ___), Informed Consent Document (Version No. ___, dated ___), Recruitment material/ Translations (Version No. ___, dated ___), and the other study-related documents listed above were approved/ approved with the following suggestions/ comments:

- Study must be initiated within 6 months and the date of start be intimated to EC
- List other study-related suggestions pointwise, if any_____
  _____
  _____

APPROVED PARTICIPATING SITES *(Add rows as applicable)*

S.N	Institution/ Site Name & Address	Site PI (Name/Designation) Contact (Ph/ Email)	Suggested Safeguards/ Remarks
1.			
2.			
3.			
4			

CONTINUING REVIEW

☐ Quarterly ☐ Biannually ☐ Annual ☐ Any other (for specific site)_____

Provide details: _____

_____

CONDITIONS OF APPROVAL

This approval is granted subject to the following conditions:

- Approval is valid for 1 year from the date of start. Any extension shall be subject to review and approval of the Annual Progress Report by the Single EC.
- The study shall be conducted strictly in accordance with the Single EC- approved protocol, informed consent documents and applicable ethical guidelines/regulatory requirements.
- This approval letter applies to all participating study sites as listed above.
- The Coordinating PI (c-PI) shall communicate the approval and related instructions to all Site PIs who shall share a copy of this approval letter with the institutional authorities.
- Serious Adverse Events (SAEs), protocol deviations/ violations, non-compliance, and any unexpected events shall be promptly reported to the Single EC as per applicable timelines.
- Copy of the final study report shall be submitted within 30 days of completion.

Signature & Date

Chairperson/Member Secretary
(Official seal/ stamp of the Single EC)

Contact details of Single EC Secretariat:

_____
_____
_____