

Annexure 04 - Application form for Waiver of consent

Title of study:

Association between early onset culture-proven neonatal sepsis and maternal genital colonisation
- A retrospective cross sectional study in a tertiary healthcare centre in South India

Principal Investigator (Name, Designation and Affiliation):

Chinua Pailoor, MBBS 3rd semester

Guide Details:

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1. Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

[1] Research involves 'not more than minimal risk'

[2] ☒ There is no direct contact between the researcher and participant

[3] Emergency situations as described in ICMR Guidelines

[4] Any other (please specify)

2. Statement assuring that the rights of the participants are not violated: Study is a retrospective study, hence there is no violation of the rights of any participant

3. State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant: Data is collected retrospectively and the case records obtained for collecting data will not be shared with anyone

4. Does the research involve vulnerable persons?

Yes ☐ No ☒

If Yes give details:

Signature of PI with date:  02-04-2024

Comments of EC Secretariat:

Signature of Member Secretary with date: