

6. How did the participant or legally acceptable representative (LAR) consent for collection of non-routinely recorded data?

7. Reconsenting done?

7.1 Date when the participant was reconsented?

7.2 Why consenting was not done?

Section III: Assent form

1. Did the minor give assent for collection of non-routinely recorded data?

2. Date when the minor gave assent for collection of non-routinely recorded data.

3. In case the minor refused to participate, date when minor refused

Section IV: Opt out form

1. Is the participant or LAR wants to opt out from study?

2. Who opted-out of the routinely recorded data (in-hospital)?

3. Date when participant or legally acceptable representative (LAR) opted-out.

4. Did the participant or legally acceptable representative (LAR) suggested to delete all the previously recorded data?

Any other comments?
