

Format of Final report

FHCS ERC Proposal No:

Study title:

Principle investigator:

Sponsor:

Duration of study:

Started date:

Completion date:

Summary of study participants:

- Target no. of participants:
- Total patients to be recruited at approved study site (ERC ceiling):
- Screened:
- Screen failures:
- Enrolled:
- Consent withdrawn: Reason:
- Withdrawn by PI: Reason:
- Active on treatment:
- Completed treatment:
- Patients on follow up:
- Patients lost to follow up:
- Any other:

No. of study arms:

Results (brief) (use extra blank sheets if more space required)

Presentation/ publication related to the data generated in this trial

SAEs at approved study centre (Total number and type)

Whether all SAEs were intimated to the ERC (Yes/ No)

Protocol deviations/ violations (Number and nature)

Conclusion:

Signature of PI and Date: