

ANNEXURE: 01

AF/IEC/01/16/V7.1

Deviation / Non-Compliance / Violation Record

Application Number:

Date...

Study Title:

Investigator

Contact No.:

Institution:

Contact No.:

Sponsor:

Contact No.:

Deviation from Protocol

Non Compliance

Major Minor

Violation

Description:

IEC Decision:

Actions taken:

Outcome:

Reported by:.....

Date.....