# A true serious NON-COMPLIANCE case: Manpower constraint that led to compromise and omission of informed consent taking

**Category: Serious Non-compliance**

**Case:**

A Principal Investigator (PI) failed to obtain informed consent from more than 85% of the research subjects in a prospective observational study. This study was not granted waiver of consent by the Domain-Specific Review Boards (DSRB). Medical data was collected during the patient's hospital stay. The failure to obtain the consent was explained to be due to manpower shortage and logistical difficulty in obtaining the consent from the inpatients or their legal representatives. The problem was also compounded by the unexpected H1N1 outbreak and a change in personal circumstance during the period of the study conduct.

## Outcome:

After reviewing the non-compliance incident, the PI was requested by the DSRB to permanently terminate any research activity, halt publications related to the research and withdraw all submissions of printed publications linked to the research. The PI was also advised to undergo retraining by attending the Singapore Guidelines to Good Clinical Practice (SG-GCP) course or completing the Collaborative Institutional Training Initiative (CITI) refresher online ethics course.

**General Lessons and Tips for PIs:**

1. The PI should first consider the potential difficulties in obtaining informed consent from the subjects. If there are difficulties conducting informed consent, the study process could be revised appropriately.

2. The PI needs to consider whether there are adequate resources (manpower, time, availability, facility etc) to conduct the trial or recruit subjects according to the stipulated regulations, guidelines and SOPs. Although there are pressures and logistical barriers to recruitment, ethical conduct of the study should not be compromised.

3. When in doubt, the PI may consult the DSRB, the clinical research unit in the institution, or governing bodies, for advice before continuing the study. Important processes which affect the patients' rights should not be compromised.

4. In the event that resources are not available, research should either be put on hold or conducted in a manner that ensures the patient's right, safety and wellbeing are being protected.