

## **Abstract submission number: 1198**

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Abstract Title: Improving research integrity in a hospital in the developing country by a semi-independent clinical research unit: a preliminary qualitative study

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**OBJECTIVES**

To identify the key factors in improving research integrity by developing a semi-independent clinical research unit

**METHODS**

In-depth interview was done in this preliminary study in July 2018 at Dr. Soetomo Hospital Surabaya. The participants were one person from the managerial board of Dr. Soetomo Hospital, two doctors who responsible for the Clinical Research Unit (CRU), and two users of the CRU which consist of a resident and a senior staff. The questions to all stakeholders were mostly around the story of the CRU, the strategy until today, the obstacles, and the lesson learned.

**RESULTS**

From the stakeholders, some critical factors were identified. To secure the research integrity in the academic hospital with more than 800 studies every year, a semi-independent unit should be better than the formal government units. Building and maintaining the unit required a strong commitment from all owners and stakeholders, changing pattern of recruitment of staff for the unit, new regulations for all people at the hospital in relation with research, participation from all departments and units, and continuous evaluation of programs and decisions. For the last two years some significant changes were shown. The number of studies which recruited participants before the permission from the ethical committee was almost zero on the second year, and the monitoring and evaluation for at least 90% of studies were done at least once before the study ended.

From the users, the major noted changes were the easiness of research registration and of the process for ethical committee, uniformity of regulations for one research to the other across the hospital, the opportunity for international studies, and the funding from the government for selected projects which fulfill some specific criteria including those related with the integrity aspects. All study participants mentioned the urgency for maintaining, and improving, all actual changes.

**CONCLUSIONS**

Even in the developing country, the efforts to secure the hospital research integrity could be made by the strong commitment from the stakeholders, followed by changing and strengthening the clinical research unit and the regulations, and the participation from all people in the hospital.

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