

RESEARCH ARTICLE

## An Audit of Protocol Deviations Submitted to an Institutional Ethics Committee of a Tertiary Care Hospital

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### Abstract

Protocol deviations (PDs) may jeopardize safety, rights, and welfare of subjects and data integrity. There is scarce literature and no guidelines for Institutional Ethics Committees (IECs) to process PD reports. The PD reports submitted to IECs from Jan 2011 to August 2014 were analyzed retrospectively. Types of studies reporting PDs, category and type of PDs, PD rate per participant, time of reporting PD since its occurrence and corrective actions stated by principal investigator (PI) for major deviations were noted. Out of 447 PDs from 73/1387 total studies received during study period, 402 were from 126 pharma studies. Investigator initiated studies and dissertations reported negligible PDs. Median number of PDs was 4 per protocol. Out of 447 PDs, 304 were related to study procedure, 87, 47 and 9 were from safety, informed consent document (ICD) and eligibility category respectively. The most common reason for PDs was incomplete ICD (22/47). Maximum study procedure related PDs were due to patient visiting outside window period (126/304). Thirty five of 87 PDs were due to missed safety assessment. The overall PD reporting rate per participant was 0.08. In 90% of reports, date of occurrence of PD was not specified. The median delay for reporting PDs after occurrence was 94 days. PDs classified as Major were 73% (323/447). The most common corrective actions stated by PI were participant counseling (85/323) and caution in future (70/323). The study findings emphasize the need for GCP training at regular interval of study team members. IEC have to be vigilant and visit sites frequently, take initiative and formulate guidelines regarding PD reporting.

### Introduction

Investigators have the responsibility of adhering to the protocol approved by the Institutional Ethics Committee (IEC). However, an investigator sometimes deviates from the study procedure approved by IEC. This is called a protocol deviation (PD), which is defined by the US

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