

Clinical trials are responsible for the advancements made in cancer care. An interdepartmental work group at a major academic cancer hospital developed a process for the consistent communication and implementation of clinical trial amendments. This process ensures improved patient safety, as well as high-quality research.

**AT A GLANCE**

- Clinical trials lead to advancements in cancer care, including improvements in cancer-related morbidity and mortality.
- Standardizing communication and developing a process for applying treatment plan changes improves patient safety and decreases errors.
- The process developed and successfully implemented at a large academic cancer center ensures accurate and timely implementation of clinical trial amendments.

# Clinical Trial Amendments

Development of a process for consistent implementation

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Clinical trials are used in the prevention, detection, treatment, and management of cancer. Patients have benefited from clinical trials, with improvements in cancer-related morbidity and mortality (National Institutes of Health, 2017). Clinical trial participants are human volunteers, and protecting their rights and safety is the greatest priority. This occurs in several ways, including the informed consent process, the institutional review board (IRB), and data monitoring committees. Various federal agencies, such as the Office of Human Research Protection and the U.S. Food and Drug Administration, are also involved (ClinicalTrials.gov, 2017).

The International Conference on Harmonisation ([ICH], 1996) Guidelines for Good Clinical Practice defines protocol as “a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial” (p. 6). Protocol amendments, which are written changes to or clarifications of protocols, are numbered and dated. Throughout the guideline, the terms *protocol* and *protocol amendment* are used interchangeably (ICH, 1996). Deviations are generally unplanned and occur when study-related activities do not follow the research protocol. Often, these have insignificant outcomes; however, more serious violations may affect the research quality and integrity, as well as the safety and rights of participants (Bhatt, 2012). Identification and reporting of protocol deviations is important for recognizing

contributing factors. This allows impact to be analyzed and potential prevention strategies to be developed (Ghooi, Bhosale, Wadhvani, Divate, & Divate, 2016).

Research protocols are increasingly complex, requiring interprofessional team involvement to maximize participant safety (Ghooi et al., 2016). The importance of effective detailed communication of complicated information related to research protocols cannot be understated. Constructing a standard procedure ensures the most accurate patient and protocol data are conveyed to the research team and clinical staff, ultimately preventing errors and improving safety (Ermete, 2012).

This article discusses the experience of developing a process for the consistent implementation of clinical trial amendments at the Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (The James). The goal focused on standardizing communication and applying treatment plan changes related to amendments in a timely manner.

**Significance and Background**

The James has more than 900 clinical trials spanning from phase 1 to phase 3, enrolling about 1,200 patients annually (see Figure 1). No process existed for the communication, review, and implementation of clinical trial amendments. This was first identified as a need by The James Quality and Patient Safety committee, and, after additional input was received

**KEYWORDS**

clinical trials; amendment; implementation; process; program development

**DIGITAL OBJECT IDENTIFIER**

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