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 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, Wadhwani, 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...
by stakeholder groups, was approved as a hospital-wide goal for 2016–2017. An interprofessional work group convened in December 2015 and met biweekly, following the Six Sigma process improvement methodology of define, measure, analyze, design, and verify, to arrive at a comprehensive solution. This allowed for improved understanding of the overall problem using data, process mapping, and prioritization surveys.

This work group focused on amendments affecting the treatment plan (i.e., drug, vital sign, and other monitoring) and clinical and research laboratory changes to be completed by the nursing staff. The treatment plan changes needed to be made manually for patients already enlisted in a trial. The changes were made to the chemotherapy computerized physician order entry (CPOE) for future patients enrolled in a study. A written standard operating procedure was developed and piloted within the lymphoma/chronic lymphocytic leukemia (CLL) clinical trials in the fall of 2016.

**Implementation**

The created policy statement focused on the systematic communication of clinical trial amendments and the consistent execution of treatment plan changes related to the amendments. Standard email communication, using an online collaborative research environment template, was generated from the regulatory compliance officer. This established a clear method for communicating the clinical trial amendments, both before and after IRB approval, and allowed for the timely identification of treatment-related changes and a regimented timeline for making changes in CPOE. The clinical team, responsible for making manual changes, was promptly notified. The goal for all treatment plan changes to be completed was 10 days from IRB approval of the amendment (see Figure 2). This process decreases potential deviations and the risk of patient safety events related to trial amendments.

The SMART (specific, measurable, attainable, relevant, and time-related) goal-writing guidelines are commonly used with formal goal setting in health care (Bowman, Mogensen, Marsland, & Lannin, 2015). The policy was piloted in the lymphoma and CLL group from September to November 2016 using the following SMART goal: 60 days following IRB approval. This defined, rigorous process decreased potential deviations and the risk of patient safety events related to trial amendments.

The created policy statement focused on the systematic communication of clinical trial amendments and the consistent execution of treatment plan changes related to the amendments. Standard email communication, using an online collaborative research environment template, was generated from the regulatory compliance officer. This established a clear method for communicating the clinical trial amendments, both before and after IRB approval, and allowed for the timely identification of treatment-related changes and a regimented timeline for making changes in CPOE. The clinical team, responsible for making manual changes, was promptly notified. The goal for all treatment plan changes to be completed was 10 days from IRB approval of the amendment (see Figure 2). This process decreases potential deviations and the risk of patient safety events related to trial amendments.

The SMART (specific, measurable, attainable, relevant, and time-related) goal-writing guidelines are commonly used with formal goal setting in health care (Bowman, Mogensen, Marsland, & Lannin, 2015). The policy was piloted in the lymphoma and CLL group from September to November 2016 using the following SMART goal: 60 days following IRB approval. This defined, rigorous process decreased potential deviations and the risk of patient safety events related to trial amendments.

The created policy statement focused on the systematic communication of clinical trial amendments and the consistent execution of treatment plan changes related to the amendments. Standard email communication, using an online collaborative research environment template, was generated from the regulatory compliance officer. This established a clear method for communicating the clinical trial amendments, both before and after IRB approval, and allowed for the timely identification of treatment-related changes and a regimented timeline for making changes in CPOE. The clinical team, responsible for making manual changes, was promptly notified. The goal for all treatment plan changes to be completed was 10 days from IRB approval of the amendment (see Figure 2). This process decreases potential deviations and the risk of patient safety events related to trial amendments.

The SMART (specific, measurable, attainable, relevant, and time-related) goal-writing guidelines are commonly used with formal goal setting in health care (Bowman, Mogensen, Marsland, & Lannin, 2015). The policy was piloted in the lymphoma and CLL group from September to November 2016 using the following SMART goal: 60 days following IRB approval. This defined, rigorous process decreased potential deviations and the risk of patient safety events related to trial amendments.
resulting in 12 fewer tubes of blood. The new policy ensured manual changes were completed quickly, improving the experience for the bedside nurse and patients.

Conclusion
A staggered rollout and implementation of the clinical trials amendments process took place in eight months (September 2016 to April 2017) across all of The James. During this time, 24 amendments were identified to have changes affecting patient treatment plans. Of those 24 amendments, 14 clinical trials had patients enrolled, requiring manual changes to existing treatment plans. Ten manual changes were completed within 10 days; four were completed after a reminder was provided as part of the month-end audit process. The number of patients requiring manual changes generally ranges from 1–14. The amendments with treatment plan changes have occurred within seven different disease groups to date. Of note, individual research coordinators and even individual disease group managers will possibly have a significant time lapse before having to follow this process. With that, one consistent person will routinely manage a month-end audit to provide education and to make sure needed changes have been made. Ultimately, having this policy and procedure in place will enable consistent communication and individual accountability to ensure accurate and timely implementation of clinical trial amendments.

Gretchen A. McNally, PhD, ANP-BC, AOCNP®, is a nurse practitioner, Amanda K. Hrnicek, MBA, LBHH, is a service line administrator, and Hallie Barr, PharmD, BCOP, is a hematology/oncology clinical specialist pharmacist, all at the Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute in Columbus. McNally can be reached at gretchen.mcnelly@osumc.edu, with copy to CJONEditor@ons.org.

The authors take full responsibility for this content and did not receive honoraria or disclose any relevant financial relationships.

REFERENCES

DO YOU HAVE AN INTERESTING TOPIC TO SHARE?
Quality & Safety provides readers with an update on innovative work in the area of practice and safe care delivery. Length should be no more than 1,000–1,500 words, exclusive of tables, figures, inserts, and references. If interested, contact Associate Editor Barbara Jagels, RN, MHA, CPHQ, at bjagels@seattlecca.org.