Inconsistencies in how clinical trial information is disseminated and what information is given can adversely affect the number of patients enrolled (Avis, Smith, Link, Hortobagyi, & Rivera, 2006; Cox, 2002; Cox & McGarry, 2003; Ellis, Butow, & Tattersall, 2002; Ellis, Butow, Tattersall, Dunn, & Houssami, 2001; Hutchison & Campbell, 2002; Stevens & Ahmedzai, 2004; Wright et al., 2004), patient compliance with trial expectations (Kornblith et al., 2002; McTiernan, 2003; Oppenheim, Geoerger, & Hartmann, 2005; Stevens & Ahmedzai, 2004), and the validity of trial results (Beskow, Sandler, Millikan, & Weinberger, 2005). Additionally, inconsistencies can compromise patients’ ability to make informed decisions about whether to participate in clinical trials (Barrett, 2005; Menikoff, 2005; Weinfurt et al., 2005). Providing clinical trial information at a major comprehensive cancer center can be a challenge. At the start of the project described in this article, the University of Texas MD Anderson Cancer Center had few clinical trial educational resources, no standard clinical trial education program, and no systematic way to communicate such information to patients, staff, and the public. Patients reported being offered clinical trials as treatment options but having no tools to help them make decisions. In this article, the authors describe a needs assessment and a process survey to determine the clinical trial education needs of patients and the education practices of nursing research staff. The authors then discuss how a standard clinical trial education program was developed and implemented.

Methods
To begin, the authors informally asked staff what resources they used to educate patients about clinical trials and what information they deemed necessary to include in their teaching materials. Using that information, the authors developed a 13-item needs assessment. With institutional e-mail groups, the authors identified all cancer center research nurses, research nurse supervisors and managers, advanced practice nurses, and research data coordinators, for a total of 262 prospective survey participants, who received the needs assessment via Lotus Notes (IBM Software Group) and a reminder two weeks later.

Although the needs assessment captured the resources staff used to teach patients about clinical trials, it did not clarify who was using them, when they were using them, or how they were using them. The needs assessment did not identify the process by which staff identified patients for a particular trial, enrolled them, or educated them about clinical trials, and it did not clarify the role of those involved in the process. Therefore, the authors developed a 12-item follow-up process survey based on the results of the needs assessment. They administered it to the same 262 individuals using SurveyMonkey™ (www.surveymonkey.com). The survey sought to elucidate which patients were educated about clinical trials and at what point they received education about clinical trials (e.g., before or after signing the informed consent). The questions addressed who introduced and matched patients to clinical trials, who educated them about clinical trials and the informed consent process, and when and how each step happened.

Results of the Needs Assessment
Of the 262 people surveyed, 109 (42%) responded to the needs assessment. Respondents included research nurses (62%), data coordinators (21%), research nurse supervisors (10%), advanced practice nurses (5%), and other personnel (3%) (i.e., two research nurse managers and one clinical research program coordinator) (because of rounding, percentages do not total 100). The needs assessment revealed that respondents came from a variety of clinical areas: blood and marrow transplantation (4%), brain and spine (6%), breast (7%), cancer prevention (7%), child and adolescent (2%), gastrointestinal (13%), genitourinary (7%), gynecologic (2%), head and neck (5%), leukemia (10%), lymphoma and myeloma (5%), melanoma and skin (5%), palliative care and rehabilitation medicine (2%), plastic surgery (3%), radiation treatment (10%), sarcoma (2%), thoracic (4%), and other (9%).

The needs assessment revealed the topics most often included when participants educated patients about clinical trials: the benefits of participating in a clinical trial (88%), where patients can find information about clinical trials (85%), the informed consent process (79%), phases of clinical trials (77%), the cost of clinical trials (70%), and placebo (29%). In addition, most of the respondents’ (72%) comments indicated that they would like all of the topics to be included in an educational booklet on clinical trials, emphasizing compliance. Most referrals for more information about clinical trials were made to the institution’s Web site (62%). Fewer referrals were made to the National Cancer Institute (48%), the cancer center’s learning centers (40%), the cancer center’s information phone line (25%), and videos available through a closed-circuit television system (6%) (see Table 1).

Results of the Process Survey
Of the 262 surveyed, 115 (44%) responded to the process survey. Survey results indicated that clinical trial information was introduced most often by a physician (87%), research nurse (82%), data coordinator (10%), other (10%), or clinic nurse (9%) (see Table 2). Respondents also reported that clinical trial...