Recommendations for safely dispensing investigational medications for clinical cancer trials

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The National Comprehensive Cancer Network (NCCN) today announced the publication of new expert consensus recommendations to

address routine problems that can occur during prescribing, receiving, storing, preparing, and delivering investigational drugs. These new recommendations come from an Investigational Drug Services (IDS) work group that arose out of the NCCN Pharmacy Directors Forum. They are intended to build on existing resources to help improve the safety and efficiency of research studies.

"Clinical trials provide vital treatment options for many of our cancer patients," said Stephen Polley, PharmD, Assistant Director—Cancer Pharmacy Services, The Ohio State University Comprehensive Cancer Center—James Cancer Hospital and Solove Research Institute, Co-Lead for the NCCN Work Group. "Promoting standardization and establishing robust IDS policies and procedures will help improve the feasibility of opening and successfully operating clinical trials. We hope these recommendations will be a helpful resource for IDS pharmacy leaders and pharmacists when creating or updating their policies and procedures."

"Clinical trials are increasing in complexity and logistics," agreed NCCN Work Group Co- Lead Sapna Amin, PharmD, Manager, Investigational Pharmacy Services, The University of Texas MD Anderson Cancer Center. "Understanding pharmacy workflows and collaboration with sponsors is key to ensure their success. IDS plays a critical and intricate role in the clinical trial. Having a standardized approach across institutions benefits the patients, institutions, and the trial sponsors."

The IDS recommendations were published in the *American Journal of Health-System Pharmacy*. They focus on seven areas of need identified by the work group:

1. Investigational product (IP) labeling from supplier
2. Building and validating research-specific treatment plans in the medical record

3. Restrictions on retained IP materials
4. IDS technician roles and training
5. Hazardous drug handling, and use of closed-system transfer devices
6. IDS participation in interactive response technology (IRT)
7. Temperature monitoring while IP is stored in institutional assets

The work group also suggests involving IDS pharmacists earlier in the development of research to capitalize on their unique expertise in order to improve study design and planning and mitigate many potential issues that arise during study treatment.

"If these recommendations can help improve how quickly and safely we can set up a clinical trial at our local institutions, then everyone wins," said Polley.

More information: Sapna Amin et al, National Comprehensive Cancer Network investigational drug service consensus recommendations, *American Journal of Health-System Pharmacy* (2021). DOI: 10.1093/ajhp/zxab455

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