

**SWOG**  
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**Policy Memorandum No. 22**

**Subject:** Ethical and Regulatory Considerations

**Departments Affected:** All

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**ETHICAL AND REGULATORY CONSIDERATIONS**

The following must be observed to comply with Food and Drug Administration regulations for the conduct and monitoring of clinical investigations; they also represent sound research practice:

Informed Consent

The principles of informed consent are described by Federal Regulatory Guidelines (Title 21, Code of Federal Regulations, Part 50) and the Office for Human Research Protections: Protection of Human Subjects (Title 45, Code of Federal Regulations, Part 46). They must be followed to comply with FDA regulations for the conduct and monitoring of clinical investigations.

Institutional Review

A study must be reviewed and approved by an appropriate institutional review committee as defined by Federal Regulatory Guidelines (Title 21, Code of Federal Regulations, Part 56) and the Office for Human Research Protections Reports: Protection of Human Subjects (Title 45, Code of Federal Regulations, Part 46).

Drug Accountability

An investigator is required to maintain adequate records of the disposition of investigational drugs according to procedures and requirements governing the use of investigational new drugs as described in the Code of Federal Regulations 21 CFR 312. For each investigational drug supplied for a study, drug disposition (drug receipt, dispensing, transfer, return or destruction) shall be maintained on the NCI Investigational Drug Accountability Record unless specified otherwise in the protocol. Drug supplies must be kept in a secure, limited access storage area under the recommended storage conditions. These Drug Accountability Records must be readily available for inspection and are open to FDA or NCI inspection at any time.

Adverse Experiences

The timely reporting of serious adverse events (SAEs) is required by regulations of the Food and Drug Administration (Title 21, Code of Federal Regulations, Section 312). Such reporting is in the interest of patient safety and scientific communication by allowing the Division of Cancer Treatment (DCT) of the National Cancer Institute to rapidly disseminate new findings to the investigative community studying the agent. The requirement for timely reporting is specified in the Statement of Investigator, FDA Form 1572. In signing the FDA 1572, the investigator accepts the responsibility for conducting investigational agent trials, including reporting SAEs to the DCT. Any adverse experience which meets protocol-specified expedited reporting guidelines must also be reported to the Operations Office Serious Adverse Events Coordinator by submission of a CTEP-AERS report. If unable to access the online system, the event should be initially reported to the Operations Office by phone (210)614-8808, or by email [adr@swog.org](mailto:adr@swog.org), attention SAE Coordinator, followed by completion of a CTEP-AERS report. Please see Group Policy No. 23 (Serious Adverse Events) and Section 16 of specific protocols for detailed guidelines for reporting SAEs.

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Investigational New Drug Application

The investigational new drug (IND) process is described by Federal Regulatory Guidelines (Title 21, Code of Federal Regulations, Parts 312 and 314). Please see Group Policy No. 15 (Group Protocols Sponsored by Pharmaceutical Companies) for information regarding investigational new drug submissions held by SWOG.