IF2: USE OF INVESTIGATIONAL MEDICATIONS

Policy

A resident may be participating in a clinical drug trial and be receiving a medication designated as an "investigational new drug (IND)" by the Food and Drug Administration (FDA). The medication may not currently be on the market, or may be a medication currently on the market but is being investigated for a new indication. In either case, the investigational product is under the control of the principal investigator of the study. The principal investigator may be a physician who practices at the nursing home or may be an outside physician. The medication supply may be issued to the facility by either the pharmacy or the principal investigator/study coordinator. At the initiation of a clinical drug trial, it is important to determine that all facility policies related to drug administration, storage, labeling, administration, and monitoring are followed and that said policies are aligned with the protocols to be followed by the research team.

Procedures

A. If an investigational drug is used in a research study, the study must have approval from an FDA-licensed Institutional Review Board (IRB). Some states may require a research license be obtained for the facility.

B. A copy of an executed informed consent form, indicating Institutional Review Board (IRB) approval, must be kept in the resident's medical record. This consent form must include the name and the address of the facility.

C. The informed consent document may not waive or appear to waive the resident's legal rights or relieve the investigator of liability. The IRB will make this determination. An informed consent procedure includes documentation of the provision of the following information to the resident/legal authorized representative:

1) A description of discomforts and risks attendant with use of the investigational new drug and alternatives to it.
2) Information about any medications required to be used in conjunction with the investigational new drug.
3) Expected benefits from the use of the investigational new drug.
4) The potential benefits, risks, and alternatives to medications used with the investigational new drug.
5) The likelihood of success.
6) The possible results of non-treatment.
7) An offer by the investigator to answer the resident's questions about the study or the investigational treatment.
8) A statement affirming the resident's right to withdraw from participation without jeopardizing future services or treatment.
9) A statement assuring confidentiality of any information that might identify the resident.
10) The identity and professional status of individuals responsible for authorizing and performing treatments.

11) Any professional relationship of the investigator to another health care provider or institution that might suggest a conflict of interest.
12) The relationship of the investigator to educational institutions involved in the resident's care and services.
13) Any business relationship among individuals providing the investigational new drug.
14) Disclosure of any patient stipend payments.

D. The consent form must be in the primary language of the individual(s) who sign(s) it. If a consent form is needed in another language than what is available, said document must be approved by the Institutional Review Board.

E. All drug-related studies use a scientifically sound methodology that is appropriate to the study design and hypothesis. Such studies are conducted with full consideration of each subject's best interests.

F. The principal investigator or study coordinator must provide information about the study and its procedures (protocol) with facility staff prior to the initiation of the study. Emphasis should be placed on potential medication side effects, special monitoring, including possible adverse reactions and laboratory studies, medication storage and administration documentation. Printed materials must be provided with this information also be provided. A copy of the protocol, or a synopsis, must be kept in the resident's medical record.

G. An order must be written by the attending physician indicating the resident may participate in the clinical trial and receive all interventions (including study drug) outlined in the protocol.

H. Facility should ensure that all Investigation New Drugs are signed out in order to account for each dose administered (See FORMS: INVESTIGATIONAL NEW DRUG INVENTORY LOG).

I. The resident may not have participated in another clinical trial within the last thirty days.

J. All packaging from the study medication must be kept and returned to the study coordinator.

K. The facility's consultant pharmacist should be made aware of the study and which residents are participating.

L. If the resident is discharged from the facility, the investigator is informed to assure appropriate hand-off to the next heath care professional.

M. If an individual receiving an investigational new drug applies for admission to the facility, the facility (IRB/Quality Assessment and Assurance Committee) determines prior to admission whether the above conditions can be satisfied, including but not limited to:

1) Obtaining a copy of the informed consent signed by the resident or responsible party. This consent must list the name of the receiving facility.

2) Obtaining a copy of the Investigational New Drug (IND) protocol and determining the ability of the receiving facility to participate in the study.
3) Ensuring that the study drug is provided to the resident without interruption.
4) Attending physician's approval.
5) Willingness/ability of research team to conduct research at the receiving facility.
6) Facility staff should be made aware of medication side effects, possible adverse reactions, and associated lab work.

N. If the stated conditions cannot be met, the resident and/or responsible party is informed. If participation in the study is terminated by the resident and/or responsible party due to failure to satisfy the above conditions, this is documented in the individual's admission record.

O. The investigator and the resident's attending physician are informed if the resident or responsible party withdraws consent to continue participation in the investigational new drug research.

P. Investigational medications are labeled, stored, documented and accounted for in accordance with facility policies and procedures for approved medications (See Form 20: INVESTIGATIONAL NEW DRUG INVENTORY LOG).

Q. The facility/research team establishes a mechanism for ensuring that there is always a sufficient supply of the medication available for the duration of the study.

R. The facility ensures that additional costs which are not part of the resident's standard care, such as medications, laboratory tests, or procedures incurred by the resident or facility as a result of study participation, are not borne by the resident or the facility.

S. Records of the receipt and disposition of the medication are retained in the facility for **[two years]** or as required by state or federal regulation.

T. The facility must provide the consultant pharmacist with a copy of the IND protocol to be used during medication regimen review. Review should include:
1) Reviews of use of the investigational new drug in the facility;
2) The resident's response; and
3) Reported findings to the Quality Assessment and Assurance Committee.