MCW Office of Research
Standard Operating Procedure

USE AND STORAGE OF INVESTIGATIONAL DRUGS AND BIOLOGICS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
It is the policy of the Medical College of Wisconsin (MCW) HRPP office and Institutional Review Board (IRB) that the use and storage of investigational drugs, and/or biologics be reviewed and approved in accordance with the Federal regulations.

DEFINITIONS:
Clinical Trial: a research project in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Investigational Drugs/Investigational Biologics (Test Articles): A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes. Investigational drugs or biologics may include:

- Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the Food and Drug Administration (FDA); or
- Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).

Investigational New Drug (IND): Food and Drug Administration (FDA) granting of permission that a new drug, agent, or biologic may be used in humans prior to FDA review of clinical data to determine that a particular product is safe and effective for a specific use. The FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

FDA regulations allow certain individuals not enrolled in clinical trials to obtain expanded access to investigational drugs, agents, or biologics through the following methods:

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- Group C Treatment Investigational New Drug (IND): A means for the distribution of investigational drugs, agents, or biologics to oncologists for the treatment of cancer under protocols outside controlled clinical trials. Group C drugs, agents, or biologics usually have shown evidence of relative and reproducible efficacy in a specific tumor type. Although the FDA typically grants a waiver for most drugs used in Group C Treatment IND protocols. IRB review and approval is required

a. MCW IRB is responsible to conduct initial reviews, grant approvals and maintain ongoing monitoring of all investigational drugs, and biologics used in human subjects under its jurisdiction.

Determining if an IND is required

1. All drugs, biologics and/or agents as defined above are regulated by the FDA. Investigators should determine if a drug, biologic or agent to be used in a project requires an IND. INDs must be filed by Sponsor of a project, or the Sponsor must be able to demonstrate the use of the drug, biologic or agent is exempt from IND requirements. The IRB will make a formal determination regarding the exemption from IND requirements.
2. Investigators may encounter projects with the use of a drug, or biologic that is lawfully marketed in the United States. In some cases, the drug or biologic may be exempt from the requirements of an IND, <u>if all of the following conditions are met</u> as outlined in the federal regulations:
    a. Use of the investigational drug, or biologic is not intended to be reported to the FDA in support of a new indication for use nor support any significant change in labeling for the product;
    b. The use of the investigational drug, or biologic is not intended to support a significant change in the advertising of the product;
    c. The use of the product does not involve a route of administration, dosage level, and/or use in a subpopulation, or other factors that significantly increase the risks, or decrease the acceptability of the risks associated with the use of the drug, agent, or biologic;
    d. The use will be conducted in compliance with the IRB approval and informed consent procedures;
    e. The use will be conducted in compliance with the requirements concerning the promotion and sale of the drug, agent, or biologic as described in FDA regulations 21 CFR 312.7; and
    f. The use does not intend to invoke exception from informed consent requirements for emergency use.
3. For Investigators who investigate the use, efficacy, or safety of an in-vitro diagnostic biological product, the following may apply:
    a. A clinical investigation involving an in vitro diagnostic biological product (as listed below) is exempt if the diagnostic test was intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established diagnostic product or procedure and the diagnostic test was shipped in compliance with 21 CFR 312.60.
    b. Clinical investigations of an in vitro diagnostic biologic product that involves one or more of the following are exempt from the requirements of an IND: blood grouping serum; reagent red blood cells; anti-human globulin.
4. For some projects or clinical investigation involving the use of placebo may be considered exempt if it does not otherwise require IND submission.
5. If the project involves combinations of FDA approved drugs, agents, or biologics that are currently approved as single use, the combination may not require an IND. However, use of these drugs, agents, or biologics in research must still be prospectively reviewed and approved by the IRB.

Sponsor-Investigator responsibilities

1. When an Investigator serves as the sponsor for a project, the Sponsor-Investigator must comply with MCW Corporate SOP: Early Stage Research Regulatory Requirements (RS.GN.170). This process will ensure Sponsor-Investigators are aware of their regulatory requirements, provide support with submissions and annual reports.
2. Sponsor-Investigators will assure that research will not begin until a valid IND is in effect. This includes recruiting, obtaining consent, and screening subjects for a specific project subject to the IND.

3. The Sponsor-Investigators will assure that manufacturing, handling, and storage is conducted in accordance with applicable good manufacturing practice.
4. The IND goes into effect 30 days after the FDA receives the IND, unless the Sponsor-Investigators receives earlier notice from the FDA.

REFERENCES:
45 CFR 46
21 CFR 312.60
21 CFR 312.7

SUPPORTING DOCUMENTS:
MCW Corporate SOP: Early Stage Research Regulatory Requirements (RS.GN.170)
FH Corporate: Clinical Research & Investigational Drugs (CPM.0152)
IRB SOP: Expanded Access Use of An Investigational Drug, or Biologic
IRB SOP: Emergency Use of Investigational Drugs, or Biologics
IRB SOP: Submitting New Projects
IRB SOP: Advertisements
IRB SOP: Informed Consent for Human Subject Research

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