Research Involving a Drug
Policy and Procedure

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   Clinical Investigation submitted with an IND
   Clinical Investigation submitted requiring IND, but IND pending
   Clinical Investigation submitted without an IND
References
I. Policy:
   A. The IRB reviews projects that involve drugs or biologics (referred to in this policy as drugs) to protect the rights and welfare of human subjects involved in such research/investigations as directed by DHHS (non-exempt research involving human subjects) and the FDA (clinical investigations regulated by the Food and Drug Administration under sections 505(i) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, and biological products for human use).

   B. The IRB evaluates:
      1. whether use of the drug is considered research and involves human subjects (DHHS – 45 CFR 46.101), and;
      2. whether a drug used is considered an investigational drug and involves human subjects (FDA – 21 CFR 56.102)

   C. If the IRB determines neither B.1 not B.2 above are true, the activity that includes a drug may still be reviewed. In this case, if the activity is not considered to be research (non-research) or research not involving human participants under DHHS rules the activity is reviewed following guidance in the Determining Whether an Activity is Research Involving Human Subjects Policy and Procedure.

   D. If the activity is considered Exempt research (DHHS) not constituting a clinical investigation (FDA) then it is reviewed following guidance in the Exempt Research Policy and Procedure.

   E. All research (DHHS) involving human participants (whether or not determined not to be a clinical investigation (FDA)) is evaluated following guidance in the Initial Review of Research Policy and Procedure.

   F. Clinical investigations are evaluated by the IRB to determine whether:
      1. submission to the FDA for an IND is required, and if required has been completed (as indicated by documentation provided by the sponsor) or;
      2. the use of the drug is exempt from prior submission to the FDA.

   G. It is the policy of the University of Texas Health Science Center—San Antonio that research involving a drug, other than the use of a marketed drug in the course of medical practice, must have an investigational new drug (IND) number provided by the FDA, unless the drug meets the
following exemptions (Emergency use and use under a Treatment IND are covered in the Expanded Access - Treatment Use of Drug or Biologic Policy and Procedure):

1. Exemption 1
   a) The clinical investigation is for a drug product that is lawfully marketed in the United States and all of the following apply:
      (1) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
      (2) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
      (3) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
      (4) The investigation will be conducted in compliance with 21 CFR 50 and 56.
      (5) The investigation will be conducted in compliance with the requirements of 21 CFR 312.7.

2. Exemption 2
   a) The clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
      (1) Blood grouping serum.
      (2) Reagent red blood cells.
      (3) Anti-human globulin; AND
   b) 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
c) The diagnostic test will be shipped in compliance with 21 CFR 312.160.

3. Exemption 3
   a) The clinical investigation is for a drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.

4. Exemption 4
   a) The clinical investigation involves the use of a placebo and the investigation does not otherwise require submission of an IND.
5. Exemption 5
   a) Dietary supplements, botanicals, or other substances designated as generally recognized
      as safe (GRAS) for use in food if study does NOT evaluate product’s ability to diagnose,
      cure, mitigate, treat or prevent disease (see FDA guidance for required conditions).

6. Exemption 6
   a) Radioactive drug or biological product (see FDA guidance) if
      (1) it involves basic research not intended for immediate therapeutic, diagnostic, or
          similar purposes, or otherwise to determine the safety and efficacy of the product,
      (2) the use in humans is approved by a Radioactive Drug Research Committee (RDRC)
          that is composed and approved by FDA,
      (3) the dose to be administered is known not to cause any clinically detectable
          pharmacological effect in humans, and
      (4) the total amount of radiation to be administered as part of the study is the smallest
          radiation dose practical to perform the study without jeopardizing the benefits of the
          study and is within specified limits.

II. Overview
   A. This procedure starts upon the IRB receiving a request for use of a drug.
   B. This procedure ends when the IRB approves the use of a drug in research involving human
      subjects (DHHS) or a clinical investigation (FDA)
   C. Summary of responsibilities
      1. Investigators are responsible for submitting for review all requests for use of a drug that may
         constitute research involving human subjects (DHHS) or a clinical investigation (FDA)
      2. IRB is responsible for evaluating the use of a drug in research involving human subjects
         (DHHS) or a clinical investigation (FDA) and determining if prior submission to the FDA is
         required and if required has been obtained, or if the use of the drug is exempt from such prior
         submission to the FDA.

III. Procedure
   A. When a Clinical Investigation (i.e., research proposal) is received involving a drug with an IND
      number.
      1. The OIRB documents a valid IND has been received as evidenced by:
         a) A document from the sponsor indicating the IND number or;
         b) A letter from the FDA indicating the IND number or;
         c) Other IRB approved method of validation.
   B. When prior submission to the FDA is required but has not yet been received
1. The IRB may contingently approve the study under the condition that valid proof of receipt of an IND has been obtained prior to starting the study.

C. When a study involving an investigational drug is submitted to the IRB for review without an IND number.

1. In accordance with section I.F above, the OIRB administrative pre-reviewer considers the justification for exemption provided by the investigator/sponsor in Form O. Based on this review, the OIRB administrative pre-reviewer determines whether an IND is needed or whether the use in the clinical investigation can be exempt from the IND requirements (see I.G above).

2. If the IRB agrees with the justification for exemption, then this decision is documented in the IRB files and the research is reviewed in accordance with Initial Review of Research Policy and Procedure. The IRB agreement with this determination is documented in the minutes (See IRB Minutes Policy and Procedure).

3. If the OIRB administrative pre-reviewer determines that an IND is required and the IRB agrees with this determination, the IRB staff will communicate this decision to the investigator/sponsor and approval will not be granted until an IND number is submitted to the IRB or the FDA determines that an IND is unneeded for the study.

IV. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)