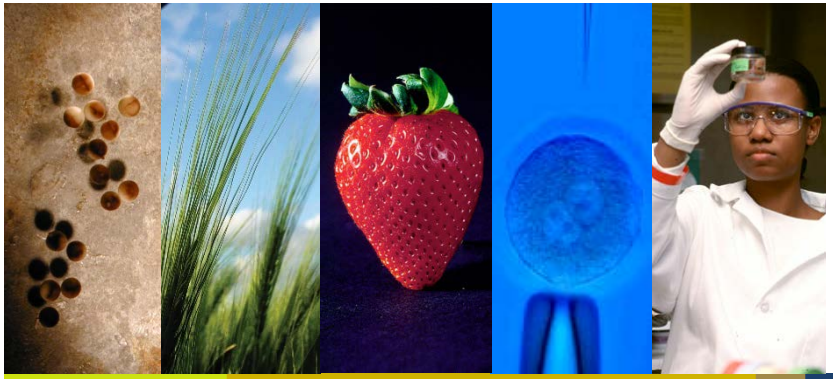

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# Choosing Determinations for New Studies, Modifications, and Renewals

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# Objectives

- Review the IRB Standard Operating Procedure for Meeting Deliberations and Determinations
- Describe Determination Options and the Applicability of Each
- Relate Determinations to Criteria of Approval

# Definition of "drug"

A drug is defined as a substance:

- Recognized by an official pharmacopoeia or formulary;
- Intended for use in diagnosis, cure, mitigation, treatment or prevention of disease;
- Intended to affect structure or any body function (if not a food).

*Biologics are included in this definition.*

# Specific Determinations for Drugs:

| Checklist | Specific Determinations |
|---|---|
| HRP-306<br>No additional IND needed<br>  | • The drug is approved and is being administered according to the label;<br>• The drug is investigational and has an approved IND.<br>• The drug is approved and<br>o Results will not be reported to FDA to support change of label or advertisement<br>o Route of administration, dosage level or population does not significantly increase risk<br>• In vitro diagnostic biologic product involving (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin. |
| HRP-306<br>An IND must be obtained | Most other investigational drugs |

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## About FDA

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# What is a medical device?

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A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

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# Specific Determinations for Devices:

| Checklist | Specific Determinations |
|---|---|
| HRP-418 Non-significant Risk Device | • The IRB determines that the device as used in a protocol is a non-significant risk device because it will not be implanted, it will not be used to support or sustain human life, it will not be used to diagnose, cure, mitigate or treat disease, and the use of this device in this clinical trial does not otherwise present a potential for serious risk to the health, safety or welfare of a subjects.<br>• Note: *Non-significant risk device studies require meeting abbreviated IDE regulatory requirements for the conduct of the study, but no prior FDA approval is required.* |
| HRP-418 Significant Risk Device | • The IRB determines that the device as used in a protocol is a significant risk device because it will be implanted, or is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety or welfare of a subject, or is for a use of substantial importance in diagnosing, curing, mitigating or treating disease.<br>• Note: *Significant risk device studies require that the investigator also function as a sponsor and to file an IDE with the FDA for approval before starting* |

# Other Device Classifications:

The IRB review processes (see Worksheet HRP-307 Devices) document other various device classifications in support of human subjects protection including:

- FDA-Approved Device
- Humanitarian Use Device (HUD)
- Humanitarian Device Exemption (HDE)
- Abbreviated Investigational Device Exemption (Abbreviated IDE)
- Investigational Device Exemption (IDE) (Note four specific sub-categories)
- Premarket Notification (510(k)) Clearance

# Checklists for Specific Determinations Regarding Waivers of Consent:

| Checklist | Specific Determinations |
|---|---|
| HRP 419 – Waiver of Consent for Emergency Research | All 29 criteria on checklist must be satisfied and confirmed in the protocol. |
| HRP 410 – Waiver or Alteration of the Consent Process | • The research is not FDA-regulated.<br>• The research does not involve non-viable neonates.<br>• The research involves nor more than minimal risk to subjects;<br>• The waiver or alteration will not adversely affect the rights and welfare of subjects;<br>• The research could not be carried out without the waiver of alteration<br>• Whenever appropriate, the subjects will be provided with additional information after participation. |
| HRP 411 – Waiver of Documentation of Consent | • The research is not FDA-regulated.<br>• The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure.<br>• That the research presents no more than Minimal Risk of harm to subjects.<br>• That the research involves no procedures for which written consent is normally required outside of the research context.<br>• Written information describing the research *(is to be/does not need to be)* provided to the subject or representative. |

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