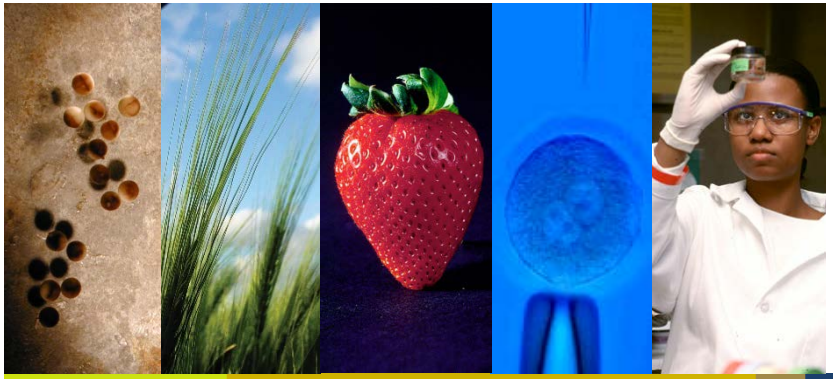

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# Choosing Determinations for New Studies, Modifications, and Renewals

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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

# Checklists, Be Sure To:

Compare the study to the criteria of the checklist

Check each appropriate box on the checklist

Write justifications where specified

Upload Your Completed Checklist to Your Reviewer Comments in IRBNet

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# And if you forgot to upload your checklist:

Please be sure to sign and date the completed checklist at the full committee meeting.

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# Your Placemat:

# A Guide to In-Committee Deliberations and Determinations

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## Devices
21 CFR 812

- Significant Risk (SR)

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

- Non-Significant Risk (NSR) Abbreviated IDE (Checklist 418 Required)

- IDE exempt (no Checklist required)

## Is an IND Required?

- Is drug FDA approved? If "No"– IND required
- If "yes" Is the drug used off label? If no – No IND
- If "yes" Does the investigation 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;

## Studies with/of Supplements

- Supplement breakdown
- Where is the supplement coming from: Company or OTC
- Statement of Ingredients
- Check inclusion/exclusion criteria & ICF for Food Allergies or considerations
- Composition and microbial analysis report
- Is an IND required?
- Following Current Good Manufacturing Practices (cGMP) for dietary supplements being followed

## Waiver of Documentation of Consent

- Minimal risk
- No procedures that usually require consent

Or

- Not under FDA.
- Principle risk is breach of confidentiality.
- Only record linking subject to research would be the consent document

## Criteria for Approval
45 CFR 46.111 and 21 CFR 56.111

1. Risks to subjects are minimized by (1) using procedures, consistent with sound research design; using procedures already being done on the subjects for other purposes; and (2) without exposing subjects to unnecessary risk. Ask: Is there any way to minimize risk?
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Additional safeguards have been included in the study to protect the rights and welfare of subjects who are vulnerable to coercion or undue influence.
5. The research plan has adequate provision for monitoring the data collected to ensure subject safety.
6. There are adequate provisions to protect the privacy of subjects.
7. There are adequate provisions to maintain the confidentiality of data.
8. The informed consent process is adequate.
9. The documentation of informed consent is adequate.

## Definition of Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

## Determinations

Approval
Approval with Minor Modifications
Deferred
Disapproval

## RNI Determinations

Non-Compliance: Failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.

Continuing Non-Compliance: A pattern of noncompliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

Serious Non-Compliance: Noncompliance that adversely affects the rights or welfare of participants. Note special standard for DoD funded research.

Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) – Indicates subjects or others are at an increased risk (Serious, Unexpected, Probably Related)

None of the Above (Acknowledge)

## Conflicts of Interest as a Reviewer

The following would fall under financial conflicts of interest as a Reviewer (including subsidiaries and parent companies):

Consultant/Speaker bureau
Advisory board membership
Honorarium recipient
Stockholder
Editorial board involvement
1571/1572 investigator/collaborator

## Investigator Conflict of Interest Management Plans

- Disclosure
- Conflicted party cannot obtain consent
- Conflicted party cannot recruit
- Conflicted party cannot analyze data
- Conflicted party cannot be associated with the research

## CAPA

What was the error?

Who was responsible, and how does PI responsibility relate?

How did the error occur?

Why did the error occur?
(ask how and why five times!)

What are the corrective actions?
- Disclosure
- Reconsent
- Redoing procedures
- Excluding data

What are the preventive actions?
- Checklists
- Independent Monitoring
- Subject specific documentation

Is new training needed?

Is re-evaluation needed within a timeframe (6-9 months)

Document Everything

## Criteria for Minors

Subpart D Categories 45 CFR 46

404 – Level 1
- Minimal Risk
- Benefit or no direct benefit
- 1 Parent Signature

405 – Level 2
- Greater than minimal risk
- Risk is justified by anticipated benefit
- Risk/benefit at least as favorable as alternative approaches
- 1 or 2 Parent Signatures

406 – Level 3
- Minor increase over minimal risk
- Commensurate
- Likely to yield generalizable knowledge of vital importance
- 2 Parent Signatures

407 – Level 4
DHHS Review and approval required

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## Waiver or Alteration of the Consent Process

- Not FDA regulated
- Does not involve non-viable neonates
- Does not meet the state of CA definition of a medical experiment

You must be able to say "YES" to all of the following

- The research involves no more than Minimal Risk to the subjects.
- The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.
- The research could NOT practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Or

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.
- The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. One must be checked)
  - o Public benefit or service programs.
  - o Procedures for obtaining benefits or services under those programs.
  - o Possible changes in or alternatives to those programs or procedures.
  - o Possible changes in methods or levels of payment for benefits or services under those programs.
- The research could NOT practicably be carried out without the waiver or alteration.

## International Research

The research involves only minimal risk

The reviewer has materials necessary about the local research context through:
Written materials such as
(1) previous consultations;
(2) information from the Department of State website :or
(3) information from the OHRP Compilation of Human Research Standards; and/or
Discussions with or written material from appropriate consultants with expertise in the local context where the research is being conducted.
The research appears to be acceptable in terms of institutional commitments, regulations, applicable law and standards of professional conduct and practice.

One of the following must apply:
Approval will be/has been obtained from a local ethics committee; and/or
Approval will be/has been obtained from a local authority

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The research involves greater than minimal risk

The reviewer has obtained necessary information about the local research context:
1. The types of subject populations likely to be involved;
2. Applicable law;
3. Local culture and norms related to the research, the research procedures, subject matter being researched, and informed consent (if applicable),
1. Method for protection of privacy of subjects;
2. Method for maintenance of confidentiality of data;
3. Language(s) understood by prospective subjects and methods for effectively communicating with them;
4. Method for minimizing the possibility of coercion or undue influence in seeking consent; and
5. Safeguards to protect the rights and welfare of vulnerable subjects.

The information was obtained by:
1. Personal knowledge of the local research context on the part of one or more IRB members;
2. Participation (either physically or through conference) by one or more appropriate consultants with personal knowledge of the local context in convened meetings of the IRB.
3. Prior written review of the proposed research by one or more appropriate consultants in conjunction with participation (either physically or through audiovisual or telephone conference) by the consultant(s) in convened meetings of the IRB, when such participation is deemed warranted either by the consultant(s) or by any member of the IRB

One of the following must apply:
Approval will be/has been obtained from a local ethics committee; and/or
Approval will be/has been obtained from a local authority

Applicable to each site conducting research

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