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IRB ACTION OPTIONS

A – Approved.

Acceptable as is.

NO changes are required.

M – Minor changes required.

Specific, non-substantial revisions are required.

Member comments must be directive requesting simple concurrences or specific, non-substantial changes. Upon receipt of the required changes, the IRB Chair, another member designated by the IRB Chair or an HRP colleague who is not a member but has been designated by the IRB will verify that the appropriate additions/corrections were made and will approve the study.

D - Deferred.

Substantial revisions and/or additional information (e.g., details, clarification, justifications) are required that are directly relevant to the Criteria for IRB approval.

Deferring a protocol occurs only at Committee review.[1]

D – Disapproved.

This is only done after multiple attempts have been made to resolve the issues including, at the discretion of the IRB, inviting the Investigator to the Board meeting. Disapproval occurs only at Committee review.

[1] Prior to September 15, 2025, the IRB used the term "tabled."

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Criteria for IRB Approval & Related Belmont Principle

In order to approve research covered by these regulations (45 CFR 46.111 and 21 CFR 56.111) the IRB shall determine that all of the following requirements are satisfied. Refer to the HRP-314 WORKSHEET - Criteria for Approval for additional guidance.

1. *Risks to subjects are minimized* by using procedures which are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes **(Beneficence)**.

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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research **(Beneficence)**.

3. *Selection of subjects is equitable*. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons **(Justice)**.[1]

4. *Informed consent* will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Federal regulations **(Respect for Persons)**.

5. Informed consent will be appropriately *documented* (or appropriately waived[2]) in accordance with, and to the extent required by the Federal regulations **(Respect for Persons)**.

6. When appropriate, the research plan makes adequate provision for *monitoring* the data collected to assure the safety of subjects **(Beneficence)**.

7. When appropriate, there are adequate provisions to protect the *privacy* of subjects and to maintain the *confidentiality* of data **(Respect for Persons and Beneficence)**.

   b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as *children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons*, additional safeguards have been included in the study to protect the rights and welfare of these subjects **(Respect for Persons and Beneficence)**[3].

Revised October 2025

[1] January 21, 2019: The 2018 Common Rule removes pregnant women as 'vulnerable' however Subpart B still applies.
[2] OHRP 45 CFR 46. 111 / FDA will allow waivers or alterations of consent for research no more than minimal risk as per FDA guidance document dated July 2017.
[3] Per FDA 21 CFR 56.111 pregnant women are listed as part of vulnerable populations and individuals with impaired decision-making capacity are listed as mentally disabled persons.

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IRB Member Conflict of Interest Disclosure

It is the expectation of the University that IRB members will voluntarily recuse themselves from review and discussion of research protocols if they have a conflict of interest. Members of the IRB must disclose to the IRB Chair or Administrator if a conflict of interest exists in the review of research or compliance matters for the IRB.

An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and/or dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:

1. Involvement in the design, conduct, or reporting of the research.

2. Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly traded, diversified mutual funds.

3. Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

4. Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.

5. Board or executive relationship, regardless of compensation.

6. Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

7. Any other reason for which the individual believes that he or she / they cannot be independent.

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Determining Whether Human Subject Research Can be Conducted Without an IND

The following is provided in part from this FDA Guidance. In addition, refer to HRP-306 WORKSHEET – Drugs and Biologics. The FDA states in 21 CFR 312 that human subject research studies must be conducted under an investigational new drug application if the following conditions exist:

1. **Is it a Drug is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g)(1)).?**
   a. Is it an **article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease**?
   b. Is it an article (other than food and dietary supplements, addressed in # 2 below) **intended to affect the structure or any function of the body of man or other animals?**

2. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), **a dietary supplement is not a drug if the intended use for which it is marketed is only to affect or evaluate the effect of the structure or any function of the body (i.e., not intended to be used for a therapeutic purpose).**
   a. **If the intent is to evaluate the dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease, an IND is required under part 21 CFR 312.**

3. **Is it a drug that is a Biological Product?**
   a. Is it a **virus, therapeutic serum**, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), **applicable to the prevention, treatment, or cure of a disease or condition of human beings**?

If either 1a, 1b, 3a are TRUE, go to 4!

4. **Is it a Clinical Investigation as defined in the IND regulations (21 CFR 312.3)**?
   a. Is it an experiment? i.e. any use of a drug [whether approved or unapproved] except for the use of a marketed drug in the course of medical practice?
   b. Is it an experiment in which a drug or biological product is administered or dispensed to, or used involving one or more human subjects?

If either 4a or 4b are TRUE, GO to 5 or 6!

CANCER

5. Is it exempt from IND requirements?
If ALL of the following are true, then an IND is NOT required:

a. The drug product is lawfully marketed in the United States.
b. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
c. In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
d. The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).
e. The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).
f. The investigation is conducted in compliance with the requirements of 21 CFR 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).

6. Is it exempt from IND requirements?
If ALL of the following are true, then an IND is NOT required:

a. The studies are not intended to support FDA approval of a new indication or a significant change in the product labeling
b. The studies are not intended to support a significant change in the advertising for the product.
c. Investigators and their IRBs determine that based on the scientific literature and generally known clinical experience, there is no significant increase in the risk associated with the use of the drug product.
d. The studies are to be conducted in compliance with IRB and informed consent regulations, pursuant to parts 50 and 56.
e. The studies will not be used to promote unapproved indications, in compliance with 21 CFR 312.

FDA has issued guidance to help clinical investigators studying cancer treatments determine whether the risk associated with the use of the drug in a planned clinical investigation is significantly increased or the acceptability of the risk is significantly decreased.

Determining Whether Human Subject Research Can be Conducted Without an IND

A Few Additional Points to Consider:

Off Label Use for Research: A Few Notes from Jeff Cooper, M.D.:
When considering FDA approved drugs proposed off label, a best practice would be to start with the package insert. Is there a significant difference in the proposed use versus the package insert?
Per Dr. Cooper, in a 2021 presentation to the IRB and HRP, do not rely on the FDA to understand standard of care differences, science or even common sense when considering if an IND is needed or not.

The FDA will hold the IRB responsible if an IND is needed. If anything is unclear – have the investigator go to the FDA to confirm if an IND is needed. Provide the investigator resources to assist with the process, if possible. In the past, we have worked with Center for Clinical Research to provide aid to Faculty.

UCI IRB Example of When an IND Applied (Drug):

IND Needed
IRB# 2659: Randomized, placebo-controlled study that will involve extending oral caffeine versus sterile water (placebo) treatment for at least 2-4 weeks after meeting criteria to discontinue caffeine, which is typically 5 days without significant cardiopulmonary events and at least 33-34 weeks corrected gestational age (CGA) to determine if additional caffeine will aid in better nippling tolerance / feeding. FDA determined IND required.

FDA Examples of When an IND May Apply:

No IND Needed	IND Needed
A clinical investigation designed to study the relationship between a dietary supplement's effect on normal structure or function in humans (e.g., guarana and maximal oxygen uptake) or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function (e.g., fiber and bowel regularity)	A clinical investigation designed to evaluate a dietary supplement's ability to prevent osteoporosis or to treat chronic diarrhea or constipation

UCI IRB Examples of When an IND Applied (Supplements):

IND Needed
IRB # 218: Assessing the effect of an educational prevention course, multivitamin, multi-mineral intravenous IV solution and a course of multi-ingredient dietary supplements on burnout in nurses in the emergency room. FDA determined IND required.
IRB# 20184140: Determine if the use of IBGard (peppermint oil) reduces the amount of colon spasms during colonoscopy and whether this improves the rate of polyp detection during colonoscopy. FDA determined IND required.
IRB# 20205846: The purpose of this research study is to determine what dosage of N-Acetyl-Cysteine (NAC) can be used safely in patients with ovarian cancer who are receiving a platinum-based chemotherapy. This study is also looking at whether the addition of NAC will lessen or prevent cognitive impairment due to chemotherapy, including memory and thinking skills. FDA determined IND required.

Lawfully Marketed Drugs:

The product must be legally marketed as a drug, meaning it has a New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologics Licensing Application (BLA) that was approved by the FDA. The labeling or package insert details the approved indications for use and dosage and administration. **Imported drugs, compounded drugs are not lawfully marketed drugs.** Search for FDA Approved Drugs.

Controlled Substances:

California law, pursuant to Health & Safety Code Sections §11480 & §11481, requires proposed research studies using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office. **This includes human subject research on all parts of the Cannabis sativa K. (marijuana) plant, including derivatives and extracts**[1]. Read the Guidelines. Read the UC Policy. Search for a Controlled Substance.

[1] DEA-approved source: Only the University of Mississippi is authorized to produce marijuana plant-based products for use by researchers in the U.S.

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Human Research Protections

Medical Device Assessment Guidance

The following is provided in part from this FDA Guidance, this FDA Guidance and 21 CFR 812.
If the device has already been evaluated by the FDA as part of an FDA-approved investigational device exemption (IDE) AND the device will be used as described in the IDE application, STOP HERE.
If not, proceed to Step 1 and begin the assessment. For additional guidance, refer to HRP-307 WORKSHEET – Devices.

1. **Is the device a medical device?**
   Per 21 U.S.C. 321(h), a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
   a. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
   b. **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**
   c. **Intended to affect the structure or any function of the body** of man or other animals, and which does not achieve 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 its primary intended purposes

If 1a, 1b, 1c is TRUE go to 2!

2. **Does this study collect safety and/or effectiveness data for this particular device?**
   a. If safety and/ or effectiveness are not studied for a device and that particular device is NOT the object of the investigation, a device risk determination under 21 CFR 812 does not apply.

If 2 is TRUE go to 3! If 2 is NOT TRUE, STOP HERE.

3. **Is the device approved for marketing in the United States and used in accordance with one of the following?**
   A device studied for safety and effectiveness is exempt from the requirement for an IDE if
   (1) the device is approved by any FDA approval process (a-e below), and
   (2) the device is investigated in accordance with the indications in the approved labeling.
   a. 510(k) Exempt category (no FDA application needed)
      i. The FDA has exempted almost all Class I devices.
      ii. The FDA has published a list of Class II devices considered 510K exempt.
   b. De Novo Devices (FDA application needed)
      i. The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process.
      ii. Devices that are classified into class I or class II through a De Novo classification request (De Novo request) may be marketed and used as predicates for future premarket notification [510(k)] submissions.
   c. FDA 510(k) clearance (cleared by FDA)
      i. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.
   d. Pre-Market Approval (new FDA approved devices)
      i. PMA is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the (Class III) device is safe and effective for its intended use or uses.
   e. Humanitarian Device Exemption *(HDE)*
      i. Clinical use where there is no evaluation of safety or effectiveness requires IRB review but is not considered research. HUDs evaluated for safety or effectiveness are research.
   f. Marketed Device Product Label/ Brochure

If 3 if TRUE, you can STOP HERE. Do not proceed to the next step.
If the study is using a marketed device off label OR
an investigational device with no FDA documentation of an IDE OR
otherwise, proceed to 4!

Device Assessment Guidance

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

4. Is this device exempt from IDE regulations?

a. Investigations that are exempted from 21 CFR 812 are described in Sec. 812.2(c).
b. Investigations may qualify for expedited review.
c. Do not need an IDE application approved by the FDA.

812.2(c) *Exempted investigations for these devices*	(c) Exempted investigations. This part, with the exception of Sec. 812.119 (disqualification of a clinical investigator), does not apply to investigations of the following categories of devices*: * Devices for veterinary use and used solely for research on animals have been omitted.
812.2(c)(1) *A device in commercial distribution before May 28, 1976*	(1) A device, other than a transitional device, **in commercial distribution immediately before May 28, 1976**, when used or investigated in accordance with the indications in labeling in effect at that time. **(not used)**
812.2(c)(2) *Device substantially equivalent to one in distribution before that date*	(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially **equivalent to a device in commercial distribution immediately before May 28, 1976**, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
812.2(c)(3) *Noninvasive diagnostic device* ***(MOST COMMON EXEMPTION)***	**(3) A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing:** **I. Is noninvasive,** **II. Does not require an invasive sampling procedure that presents significant risk,** **III. Does not by design or intention introduce energy into a subject (light and sound = energy), and** **IV. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.** **Under** 21 CFR 812.3(k) **Noninvasive** *when applied to a diagnostic device or procedure*, means one that does **not** by design or intention: A. Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical. B. Blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered noninvasive.
812. (c)(4) *Device undergoing consumer preference testing*	(4) A device undergoing consumer **preference testing**, testing of a modification, or testing of a combination of two or more devices in commercial distribution if **the testing is not for the purpose of determining safety or effectiveness** and does not put subjects at risk.
812.2(c)(7) *A custom device*	(7) A **custom device** as defined in Sec. 812.3(b), **unless the device is being used to determine safety or effectiveness** for commercial distribution.

If 4 is NOT TRUE, proceed to 5!

Device Assessment Guidance

5. Is the proposed use a Significant Risk (SR) device study?

a. Full Committee review is always required.

b. Must follow 21 CFR 812.

c. Under 21 CFR 812.3(m) a significant risk device means an investigational device that:

i. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

ii. 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;

iii. 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

iv. ***Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.***

d. IRBs should make the SR or NSR determination about a study by reviewing relevant information at a convened meeting. This information includes the description of the device, reports of prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria.

e. SR determination must be based on seriousness of harm that may result from the use of the device in protocol related tests and procedures in addition to the harm that may be caused by the device.

f. The sponsor should provide the IRB with a risk assessment and the rationale used in making its SR or NSR determination.

g. The convened IRB can disagree with the sponsor's determination.

h. If SR, must have an IDE application approved by FDA before they may proceed.

i. Researcher may include documentation of SR determination from the FDA, if on file.

Remember: The risk determination is based on the **proposed use** of a device in an **investigation**, and **not on the device alone**.

If 5 is NOT TRUE, proceed to 6!

6. Is the proposed use a Non-Significant Risk (NSR) device study?

a. **Initial Full Committee review required for NSR determination**.

b. A Non-Significant Risk (NSR) device is an investigational device that does not meet the definition of a significant risk device.

c. If determined NSR, future reviews may be expedited via category 9 if the research involves no more than minimal risk and no additional risk are identified. This must be documented in the minutes at time of initial full committee review.

d. The sponsor does not need to submit an IDE to FDA before starting the study.

e. Must follow the abbreviated requirements at 21 CFR 812.2(b) (IRB approval, labeling, AE reporting, records).

f. **Expedited Review: if the FDA has made an NSR determination and the research poses no greater than minimal risk, the study may be submitted for expedited review (per HRP Policy # 42).**

If 6 is TRUE, NSR- DONE!

Device Assessment Guidance

Other considerations

Clinical decision support software (CDS) for healthcare providers and patients that provide clinical decision support may be considered a device subject to 21 CFR 812 unless the following 5 criteria are met:

a. **Intended to provide recommendations to a healthcare provider** and not the patient.
b. **NOT intended** to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device (e.g., HIV tests)
c. **Intended to display or analyze** medical information about a specific patient or other generalized medical information (e.g., peer reviewed clinical studies)
d. **Intended to support or provide recommendations to a health care provider** (HCP)about prevention, diagnosis, or treatment of a disease or condition
e. **Not intended for the HCP to rely primarily on any of the recommendations to make a diagnosis** or treatment decision regarding a patient

Considerations for Physiological Research:

- Are the investigators evaluating how well the device works? If so, the IRB should consider that this a medical device.
- Do the investigators understand that the device works, and they are using the device to assess physiology or anatomy? If so, the IRB should consider that this is not a medical device. If not a medical device, IDE regulations do not apply. IRB approval and consent applies

Real IRB Examples of Non-Medical Devices:

(Data from these applications were not being used as part of treatment of patient or prevention of disease)

- Fitbit
- My Fitness Pal

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IRB Assessment of Risk & Benefit for Research Involving Children (Subpart D)

45 CFR 46.403 (HHS- Subpart D) & 21 CFR 50.50 (FDA- Subpart D)*:
The IRB must assure that all applicable criteria of this subpart have been met. Review the completed Principal Investigator (PI) Worksheet as part of making this determination. IRB determinations will be reflected in the final version/s of PI Worksheets.

Risk

Benefit	*Minimal*	*>Minimal*
Direct	**45 CFR 46.404 & 21 CFR 50.51**	**45 CFR 46.405 & 21 CFR 50.52**
Indirect	**45 CFR 46.404 & 21 CFR 50.51**	**45 CFR 46.406 & 21 CFR 50.53**

Regulatory Category	IRB Requirement
45 CFR 46.404 & 21 CFR 50.51 No more than Minimal Risk **(Expedited level research only)**	• Confirm provisions for child assent • **Confirm provisions for parental consent – If consent is required, determine whether it is acceptable for only one parent or guardian to sign the consent.**
45 CFR 46.405 & 21 CFR 50.52 Greater than Minimal Risk: Direct benefit to subjects	• Determine that risk is justified by anticipated benefit • Benefit/risk relationship is at least as favorable as alternative approaches • **Determine whether it is acceptable for only one parent or guardian to sign the consent.**
45 CFR 46.406 & 21 CFR 50.53 Greater than Minimal Risk: No direct benefit to subjects, but likely to yield generalizable knowledge about the subject's disorder or condition	• Determine there is only a minor increase over minimal risk • Determine intervention presents experiences relatively commensurate with alternative medical, dental, psychological or educational interventions • Determine the procedure is likely to yield knowledge of vital importance to understanding or ameliorating the subject's disorder • Confirm adequate provisions for child's assent and parental permission • **Permission of both parents is required**
45 CFR 46.407 & 21 CFR 50.54 Not otherwise approved in categories above	• Determine the research provides a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem • If DHHS funded refer for review by HHS secretary after consultation with a panel of experts • If non-DHHS funded not approvable by the IRB. • If FDA applies study must be submitted to the Commissioner of Food and Drugs for approval • **Permission of both parents is required**

* Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.405 & 21 CFR 50.52 and 45 CFR 46.406 & 21 CFR 50.53 only if such research is: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. If the research is approved, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis.

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IRB Assessment of Risk & Benefit for Research Involving Pregnant Women and Fetuses (Subpart B)

45 CFR 46.203 (HHS – Subpart B): The IRB must assure that all applicable criteria for this subpart have been met.

Review the completed Principal Investigator PI Worksheet/s as part of making this determination. See templates below. IRB determinations will be reflected in the final version/s of PI Worksheets.

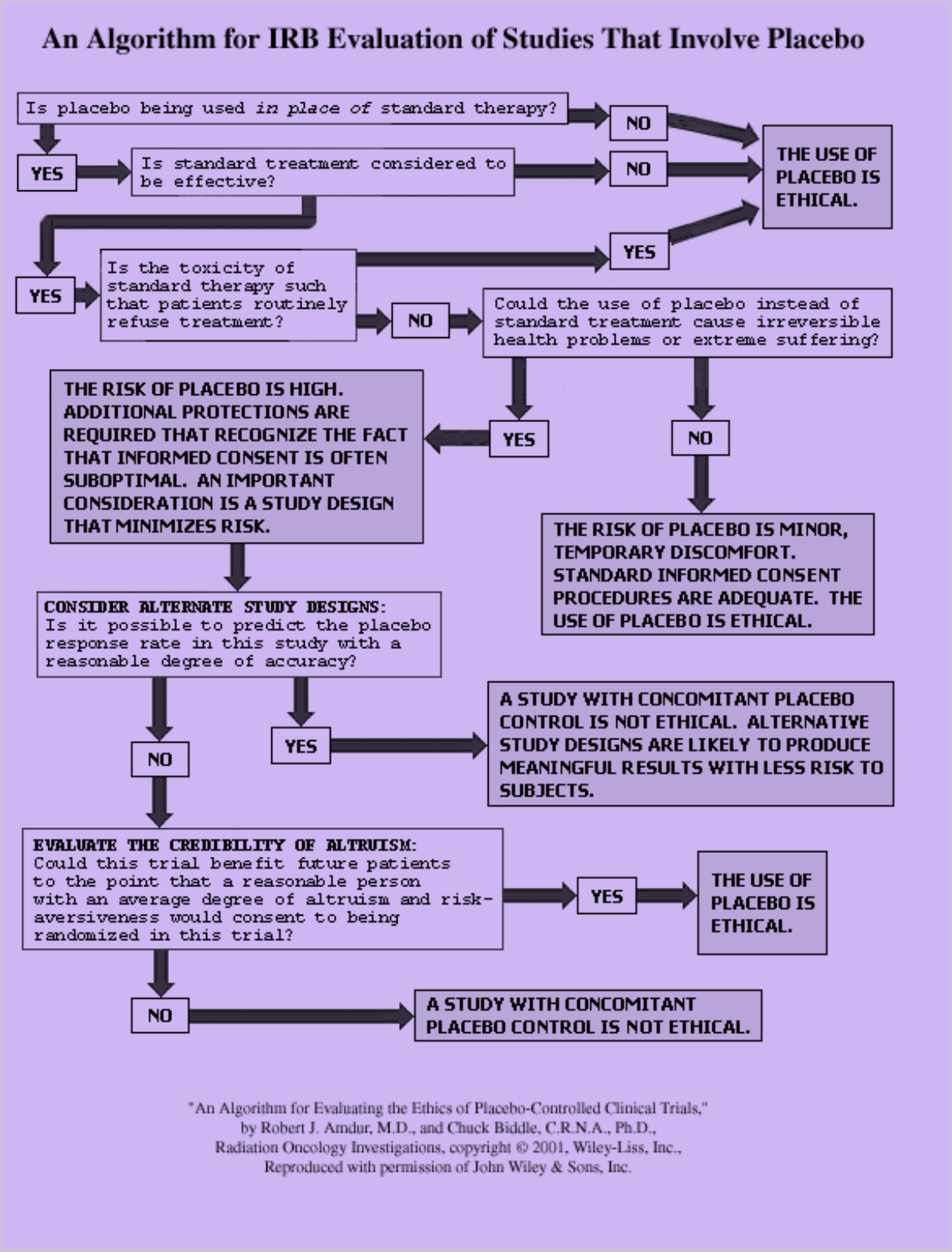
- HRP-412 PI WORKSHEET - Pregnant Women
- HRP-413 PI WORKSHEET - Non-Viable Neonates
- HRP-414 PI WORKSHEET - Neonates of Uncertain Viability

The IRB must decide which one of the regulatory categories listed below best represents the proposed research:

	Benefit to mother only	***Benefit to mother and fetus***	***Benefit to fetus only***	***No direct benefit or benefit to society only***
Risk is no more than minimal	**45 CFR 46.204 (d)** **Mother's consent only**	**45 CFR 46.204 (d)** **Mother's consent only**	**45 CFR 46.204 (e)** **Mother and father's consent**	**45 CFR 46.204 (d)** **Not approvable unless***
Risk is greater than minimal	**45 CFR 46.204 (d)** **Mother's consent only**	**45 CFR 46.204 (d)** **Mother's consent only**	**45 CFR 46.204 (e)** **Mother and father's consent**	**45 CFR 46.204 (d)** **Not approvable unless***

* The risk to the fetus is *not greater than minimal* and the purpose of the research is the development of important **biomedical** knowledge which cannot be obtained by any other means. Only Mother's consent is required. NOTE: For DoD supported research, there are exceptions (e.g., the phrase "biomedical knowledge" in subpart B shall be replaced with "generalizable knowledge" throughout the subpart). Refer to DoDI 3216.02, version November 8, 2011.

Placebo Algorithm



"An Algorithm for Evaluating the Ethics of Placebo-Controlled Clinical Trials,"
by Robert J. Amdur, M.D., and Chuck Biddle, C.R.N.A., Ph.D.,
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IRB Assessment of Risk & Benefit for Research Involving Prisoners (Subpart C)

IRB Responsibilities:

1. **Review the completed Principal Investigator (PI) Worksheet as part of making this determination. IRB determinations will be reflected in the final version/s of PI Worksheets.**
2. **The IRB must assure that all of the seven criteria have been met per 45 CFR 46.305(a)(1-7). See Table 1 below.**
   a) **The IRB may consider if research qualifies for epidemiologic research where prisoners are not a particular focus of the research** [FR Doc. 03-15580 6-19-03].
   b) Additional Guidance Document.

Table 1. Federal Requirements for Prisoner Research

45 CFR 46.305 (a)(1)	45 CFR 46.305 (a)(2)	45 CFR 46.305 (a)(3)	45 CFR 46.305 (a)(4)	45 CFR 46.305 (a)(5)	45 CFR 46.305 (a)(6)	45 CFR 46.305 (a)(7)
The research under review represents **one of the four following categories of research permissible** under 45 CFR 46.306(a)(2) which are as follows: i. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents *no more than minimal risk* and no more than inconvenience to the subjects; ii. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents *no more than minimal risk* and no more than inconvenience to the subjects; iii. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that *the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or* iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. *In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.*	Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;	The risks involved in the research are commensurate with risks that would be accepted by non prisoner volunteers;	Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;	The information is presented in language which is understandable to the subject population;	Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and	Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.