

Full Board Review Criteria for IRB Applications

Summary/Purpose: Criteria and decision-making processes to determine whether IRB applications need Full Board review.

Introduction: Regulatory criteria for assigning 'exempt' level review are fairly precise. However, in many cases, decisions to assign expedited versus full board review require judgments of risk and interpretation of regulations. This policy is designed to minimize judgment and interpretation and to distribute review level decision-making to a designated sub-group of IRB members under certain conditions.

The regulations allow expedited review when the following two conditions are met: 1) the research involves Minimal Risk and 2) the research is listed as one of the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" ([63 FR 60364-60367, November 9, 1998](#)).

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research 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 45 CFR 46.102(i).

Determinations of 'minimal risk' and 'minor increase over minimal risk' (for 46.406 research) for children will be based on the attached list [Attachment A] of considerations, criteria, and exemplars that have been conditionally approved by the Department Of Health And Human Services Secretary's Advisory Committee On Human Research Protections (SACHRP).

1. Examples of Studies that May Receive Expedited Review

- Deception studies using a 'confederate'
- Deception studies using misleading or deceptive:
 1. study descriptions
 2. procedure explanations
 3. survey instructions / rationales
- Subjects are children and research falls under 46.404 "Research not involving greater than minimal risk"
- Subjects are cognitively impaired and research is approved by an external committee of experts on the population (e.g., North Mississippi Regional Center)

2. Examples of Studies that Likely Require Full Board Review

- Deception studies that give subjects deceptive feedback, whether positive or negative [e.g., based on IQ or personality tests or interviews]
- Psychotherapy treatment studies with adults
- Studies involving a waiver of parental consent (permission)
- Subjects are in a subservient power relationship to investigators or to parties with an interest in the research, such as employees of the investigator.

3. Examples of Elements that Require Full Board Review

- Administration of alcohol
- Administration of non-drug dietary supplements
- Use of X-rays
- Classified research
- Administration of FDA approved drugs and use of devices presenting more than minimal risk
- Administration of non-FDA approved drugs and devices that come under FDA regulations
- Activity exceeding moderate exercise [See Attachment B for Determination of Intensity of Exercise]
- Surreptitious videotaping in non-public settings
- Surreptitious monitoring of electronic communications
- Subjects are prisoners
- Subjects are pregnant
- Subjects are children and research poses greater than Minimal Risk. Below are the relevant categories.
 - 45 CFR 46.405 “Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects” OR
 - 45 CFR 46.406 “Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition” OR
 - 45 CFR 46.407 “Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children”

Expedited or Full Board Review Determination Procedure

- A subcommittee consisting of at least these three IRB members: the IRB Chair, the Director of Research Integrity and Compliance, and the Research Compliance Specialist, will determine which protocols in categories 1 & 2 above may be reviewed as expedited. Additional Board members will substitute when there is a conflict of interest.
- Vulnerable population studies will be reviewed by an expert consultant(s) if there is no expertise with the population among the subcommittee members. The consultant's review will be considered in the subcommittee's decision-making.
- A majority of the subcommittee reviewers must agree that expedited review is appropriate; otherwise, the protocol will be reviewed by the Full Board.

ATTACHMENT A

DETERMINATION OF MINIMAL RISK FOR CHILD RESEARCH

Derived from a presentation by: Celia B. Fisher, Ph.D., and Susan Z. Kornetsky, M.P.H. [5th Report for SACHRP Consideration Clarifying 45 CFR 46 Subpart D Definitions - January 31, 2005](#)

Reference Point for Uniform Definition

- The definition of “minimal risk” at 45 CFR 46.102(i) when applied to Subpart D should be interpreted as those risks encountered by normal, average, healthy children living in safe environments in daily life or during the performance of routine physical or psychological examinations or tests.

Minimal Risk Should be Age indexed

- Evaluation of minimal risk under Subpart D should be indexed to the risks in daily life and routine medical and psychological examinations experienced by children the same age as the subject population.

Upper Limits of Risk & Harm

- The uniform, age-indexed definition of minimal risk should represent the upper not lower limits of risk to which children can be exposed under §46.404.

Rationale: Research procedures should not fall under §46.404 for children who because of health or other reasons would be at greater risk of harm from procedures which are minimal risk for normal, average, healthy children living in safe environments.

Equivalent Procedures

- Procedures that are equivalent in probability and magnitude of harm to risks of daily life or routine physical or psychological examinations or tests experienced by average, healthy, normal children living in safe environments should be considered as consistent with the definition of “minimal risk.”

Equivalence Criteria

- Is the probability and magnitude of harm equivalent in:
 - duration
 - cumulative characteristics
 - reversibility of harmto risks of daily life or routine examinations

Examples of Well-Child Procedures [From April, 2005 SACHRP presentation; IOM, 2004; 4.9-4.10]

- Physical examinations
- Measurement of height, weight, head circumference
- Assessment of obesity with skin-fold calipers
- Collection of blood or voided urine
- Measurement of heart rate and blood pressure
- Hearing and vision tests
- Modest changes in diet or schedule
- Testing of fine and gross motor development
- Non-invasive physiological monitoring
- Medical and social history
- Psychological examinations or tests
- Guidance and education (for the child, the parents, or both)

Routine Psychological Tests Indexed to Standardized Screening or Assessment Measures

- Child and adolescent intelligence tests
- Infant mental and motor scales
- Educational tests / Reading and math ability tests
- Neurological or motor disorders
- Social development

- Family and peer relationships
- Emotional regulation
- Feelings of sadness or hopelessness

DETERMINATION OF MINOR INCREASE OVER MINIMAL RISK FOR CHILD RESEARCH

Derived from a presentation by: Celia B. Fisher, Ph.D., and Susan Z. Kornetsky, M.P.H. [5th Report for SACHRP Consideration Clarifying 45 CFR 46 Subpart D Definitions - January 31, 2005](#)

Determining Minor Increase Over Minimal Risk

- Applying a uniform procedure for assessing whether a research presents a minor increase over minimal risk requires evaluating the risk along 10 different criteria.
- Rationale. Methods, compounds, instruments and other research procedures are so variable that a single quantitative unit of increase cannot be uniformly applied. However, there is a uniform process of evaluation that can be applied.

List of Uniform Criteria for Determining a Minor Increase Over Minimal Risk

1. Minimal Risk Comparison
2. Scientific Evidence of Risk
3. Certainty of Evidence
4. Documented Harms
5. Equivalence of Procedures
6. Participant Perspectives
7. Mitigating Factors
8. Inclusion/Exclusion Criteria
9. Monitoring
10. Safety & Competence

1. Minimal Risk Comparison

- The procedure does not meet minimal risk criteria
- The probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered by normal, average, healthy children living in safe environments in their daily activities or during the performance of routine physical or psychological examinations or tests.

2. Scientific Evidence of Risk

- There is peer reviewed scientific evidence of the range of risks associated with the procedure for the subject population, OR
- The procedure is sufficiently similar to other interventions with well characterized risks that prudent, informed judgments about risks can be made.

3. Certainty of Evidence

- The extent and quality of the evidence is such that there is little uncertainty about the range of risks involved.
- Lack of sufficient data for a risk profile would create a higher level of uncertainty supporting a more conservative approach to judgments that a procedure is only a minor increment over minimal risk

4. Documented Harms

- The documented harms are not serious for the subject population
- The data indicates no or an extremely small probability of risk of major complications.
- Harms associated with the procedure do not require in-patient monitoring or follow-up evaluation (for the procedure itself)
- The harms if they occur are transient and reversible

5. Transient & Reversible

- Transient: Restricted to time of procedure or short post-experimental period
- Reversible: Procedure to reverse the effect requires no more than a short-term simple clinical intervention

5. Equivalence of Procedures

- The procedures are equivalent in risk to documented risk profiles in terms of
 - a. Duration of harm or discomfort and
 - b. Cumulative effect of procedures on the probability and magnitude of harm.

6. Participant Perspectives

- Whenever possible the data includes information about the subject population's experience of the procedures (e.g., painful, anxiety producing).

7. Mitigating Factors

- The procedure reflects consideration of documented mitigating factors known to minimize or exacerbate the risk.

8. Inclusion/Exclusion Criteria

- Subject inclusion and exclusion criteria reflect consideration of documented subject characteristics that may moderate the probability and magnitude of harm of the procedure.

9. Monitoring

- There is an adequate monitoring procedure.

10. Safety & Competence

- The procedure will be performed in a safe environment by qualified personnel with experience conducting the procedure with the subject population.

ATTACHMENT B

DETERMINATION OF INTENSITY OF EXERCISE Background

OHRP's "*Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Procedure*" lists under (4)(e) "moderate exercise, muscular strength testing, body composition testing, and flexibility testing where appropriate given the age, weight, and health of the individual." There is no further detail on how to determine what constitutes moderate exercise (versus vigorous exercise). This guidance aims to meet that need.

Procedure

The "Expedited or Full Board Review Determination Procedure" described above in this policy will be used to decide whether procedures involving exercise meet the definition above. However, for protocols falling into 'gray areas,' three sources of information will be used at the discretion of the subcommittee:

1. IRB members or others with expertise in medicine and/or exercise science will be consulted.
2. Subcommittee members will have investigators run them through exercise procedures.
3. Subcommittee members will consult the guideline below from the Centers for Disease Control and Prevention and the American College of Sports Medicine (ACSM).
4. The ACSM table** (p.7) will be considered definitive, if specified parameters are measured in a study of apparently healthy adults, as determined by, for example, the PAR-Q or PAR-Q+_____

ACSM/CDC Guidelines:

- Moderate exercise consists of activities that result in a noticeable increase in breathing and heart rate, but can be comfortably sustained for ~45 minutes. The activities are commonly described as "very light" to "light" to "somewhat hard" when the level of perceived exertion is rated. During moderate intensity exercise, participants should be able to easily carry on a conversation. Examples of common moderate intensity activities include:
 - Walking at a moderate or brisk pace on a level surface ◦ Hiking ◦ Water aerobics ◦ Yoga
 - Doubles tennis ◦ Raking the lawn ◦ Moderate household cleaning (e.g. vacuuming, washing windows, sweeping).
- More than moderate exercise (vigorous) results in substantial increases in breathing and heart rate. The activities are commonly described as "hard" to "very hard" when the level of perceived exertion is rated. Carrying on a conversation is difficult during/while performing vigorous intensity exercise. Examples of common more than moderate intensity activities include:
 - Jogging or running ◦ Step aerobics ◦ Circuit weight training
 - Most competitive sports (basketball, soccer, football, etc.) ◦ Singles tennis
 - Heavy yard work (e.g. digging ditches, swinging an ax, pushing a mower).
- Note: Moderate intensity activities may, in fact, be more than moderate if the participants are sedentary, not physically fit, elderly, and/or have a known cardiac, pulmonary, or metabolic disease.

Reference:

ACSM's *Guidelines for Exercise Testing and Prescription* (2010). Baltimore, MD: Lippincott, Williams, & Wilkins.

The IRB thanks Dr. Paul Loprinzi for his efforts in compiling this guidance. (Dr. Loprinzi is an Associate Professor of Health, Exercise Science and Recreation Management, and Director of the Exercise & Memory Laboratory in the School of Applied Sciences.)

TABLE 5. Classification of exercise intensity, relative and absolute exercise intensity for cardiorespiratory endurance and resistance exercise.

Cardiorespiratory Endurance Exercise											Resistance Exercise	
Intensity	%HRR or % $\dot{V}O_{2R}$	Relative Intensity			Intensity (% $\dot{V}O_{2max}$) Relative to Maximal Exercise Capacity in METs			Absolute Intensity		Absolute Intensity (MET) by Age		Relative Intensity
		%HR _{max}	% $\dot{V}O_{2max}$	Perceived Exertion (Rating on 6-20 RPE Scale)	20 METs % $\dot{V}O_{2max}$	10 METs % $\dot{V}O_{2max}$	5 METs % $\dot{V}O_{2max}$	METs	Young (20-39 yr)	Middle-aged (40-64 yr)	Older (≥ 65 yr)	
Very light	<30	<57	<37	<Very light (RPE < 9)	<34	<37	<44	<2	<2.4	<2.0	<1.6	<30
Light	30-39	57-63	37-45	Very light-fairly light (RPE 9-11)	34-42	37-45	44-51	2.0-2.9	2.4-4.7	2.0-3.9	1.6-3.1	30-49
Moderate	40-59	64-76	46-63	Fairly light to somewhat hard (RPE 12-13)	43-61	46-63	52-67	3.0 to 5.9	4.8-7.1	4.0-5.9	3.2-4.7	50-69
Vigorous	60-89	77-95	64-90	Somewhat hard to very hard (RPE 14-17)	62-90	64-90	68-91	6.0-8.7	7.2-10.1	6.0-8.4	4.8-6.7	70-84
Near-maximal to maximal	≥ 90	≥ 96	≥ 91	\geq Very hard (RPE ≥ 18)	≥ 91	≥ 91	≥ 92	≥ 8.8	≥ 10.2	≥ 8.5	≥ 6.8	≥ 85

Table adapted from the American College of Sports Medicine (14), Howley (173), Swain and Franklin (344), Swain and Leutholtz (346), Swain et al. (347), and the US Department of Health and Human Services (370). HR_{max}, maximal HR; %HR_{max}, percent of maximal HR; HRR, HR reserve; $\dot{V}O_{2max}$, maximal oxygen uptake; % $\dot{V}O_{2max}$, percent of maximal oxygen uptake; $\dot{V}O_{2R}$, oxygen uptake reserve; RPE, ratings of perceived exertion (48).