



DON Human Research Protection Program

Department of the Navy Human Research Protection Program

Exempt Research and Expedited Review

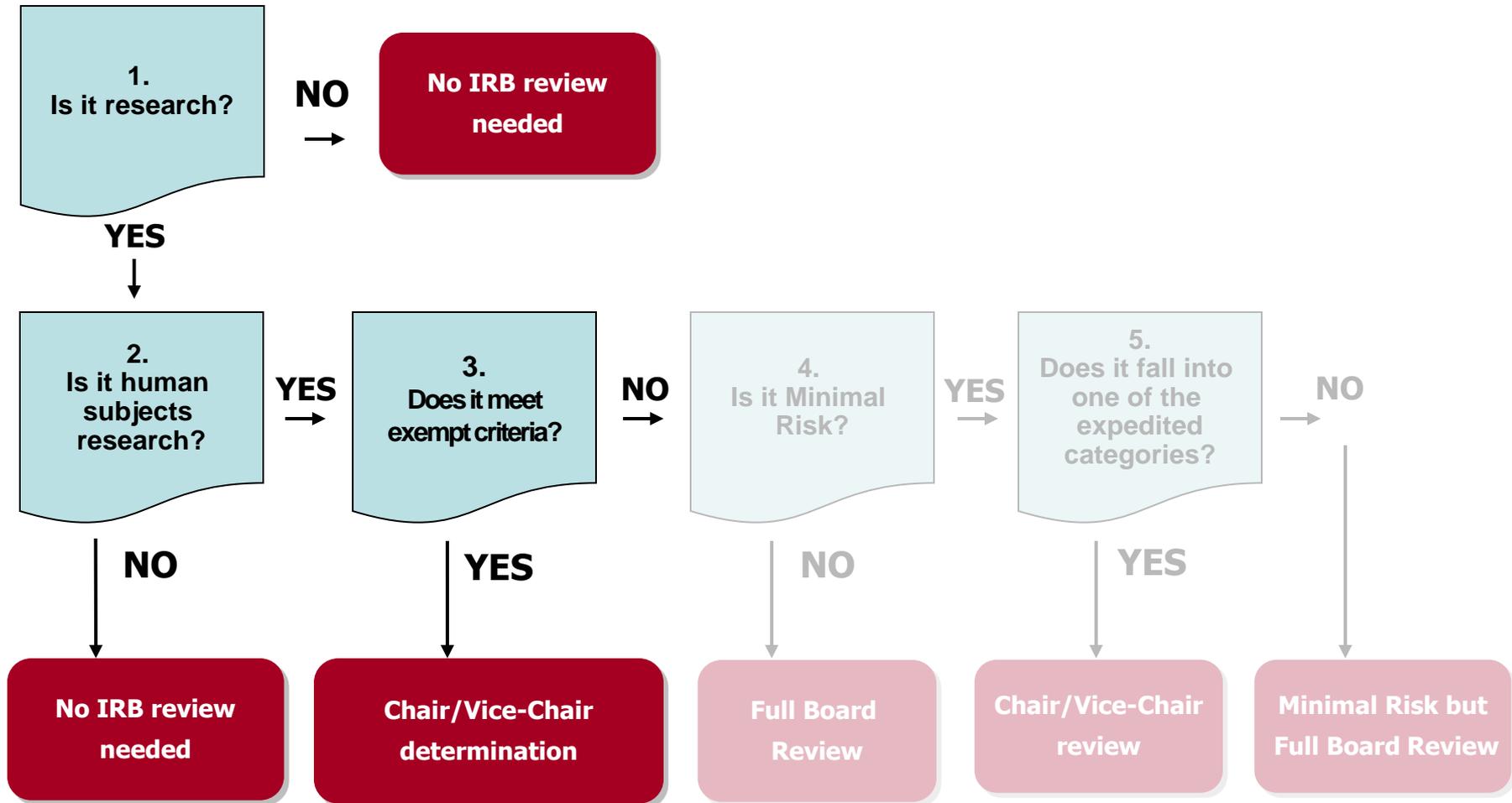
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IRB Review Decision Tree

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Exempt Research



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- Principal Investigators cannot make exemption determination
- Determination must be made by Chair or Vice Chair, designated IRB administrators, or designated officials of the DON HRPP



Does the research activity meet one or more of the six Exempt categories?



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- (1) Research in educational settings, involving normal educational practices
- (2) & (3) Research on use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, *with differences on identifying subjects and damages of disclosure*
- (4) Research with **existing*** data, documents, records, pathological specimens, or diagnostic specimens; **cannot be identified***
- (5) Research and demonstration projects
- (6) Taste and food quality tests



Exempt Research



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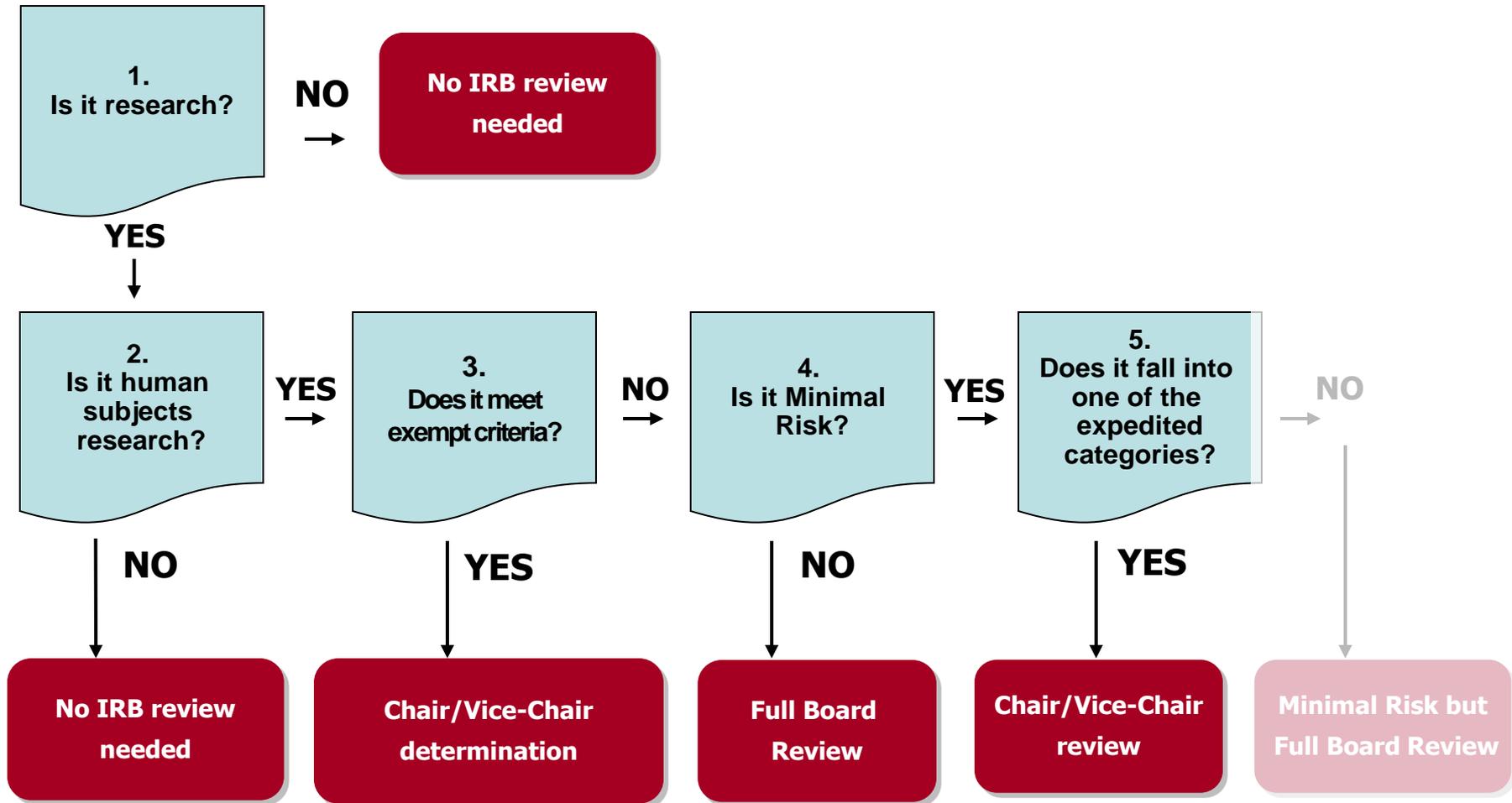
Existing* means existing before the research is proposed to the designated institutional official or the IRB for a determination of exemption.

Cannot be identified* means there is no link between the participant and participant's data



IRB Review Decision Tree

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Expedited Review



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- Only Chair or Vice Chair may review and make recommendation for approval
- May use consultants
- Chair or Vice Chair may exercise all of the authority of the IRB except disapproval
- Disapproval may only be recommended by a fully convened board
- All criteria for IRB review must be considered (criteria at 32 CFR 219.111, consent, pregnant women, children, etc.)



Two Categories of Expedited Review



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An IRB may use the expedited review procedure to review either or both of the following:

- (1) Some or all of the research appearing on the list (list of categories as published as a Notice in the Federal Register) and found by the reviewer to involve no more than minimal risk,
- (2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.



Minimal Risk



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Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research

- are not greater in and among themselves than those ordinarily encountered in daily life or
- during the performance of routine physical or psychological examinations or tests.



Minimal Risk



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Evaluating Risk

The phrase “ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life.



Minimal Risk



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Example:

If the research will involve asking a diver during a routine (already scheduled) dive to test a new fin, the IRB does NOT consider the dive in determining risk.

However, if the research will involve asking a diver to make an additional dive to test a new fin, the IRB DOES consider the dive in determining risk.



Expedited Review Categories



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1. Clinical studies of drugs and medical devices only when (a) the research is on drugs for which an investigational new drug application (21 CFR 312) is not required or (b) the research is on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.



Expedited Review Categories



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3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non research purposes (such as medical treatment or diagnosis).*

*The DoD allows the materials to have been collected for ANY purpose.

DoDI 3216.02 Enclosure 3, 3.a.(3)



Expedited Review Categories



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6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.



Expedited Review Categories



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8. Continuing review of research previously approved by the convened board where enrollment is permanently closed (all subjects must have completed all research related interventions and the research is active for only for long-term follow-up) OR no subjects have been enrolled or the only activity is data analysis.
9. Continuing review or research where categories 2-8 do not apply and the convened IRB determined that the research involves no greater than minimal risk.



Minor Changes in Previously Approved Research



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- “Minor changes” not defined in CFR, DoDI, or SECNAVINST
- Command policies should define
 - Examples of changes that might be considered minor:
 - Administrative changes to consents
 - Typographical error corrections (if they don’t change major issues like drug dosing)
 - Changes to advertisements
 - Examples of changes that are not considered minor:
 - Change in PI
 - Extending duration of exposure to test material or intervention



Documentation and Notification



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- Determination of exempt or expedited should be documented with:
 - The category into which the research falls and,
 - The justification for why the research falls into the category.
- Document findings for all IRB review criteria
- All members of the IRB must be notified of research approved under expedited procedures.



Questions

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Please contact DON HRPP with any follow-up questions or concerns.

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Email: human.research@med.navy.mil

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