



Office of the Under Secretary of Defense
for Personnel and Readiness (OUSD(P&R))
Research Regulatory Oversight Office

Policy Guidance

PG-06-001

R2O2

SUBJECT: Requirements for Use of the Electronic Institutional Review Board (EIRB)

References: See References in Enclosure 1.

Policy Guidance History:

Document Number	Document Version	Effective Date	Lifecycle Review Date
PG-06-001	1.0	November 10, 2016	November 9, 2019

1. PURPOSE. This Policy Guidance Document explains the requirements for the use of the Electronic Institutional Review Board (EIRB) system for processing, reviewing, and managing research by OUSD(P&R) institutions. Policy Guidance documents are promulgated by the Research Regulatory Oversight Office (R2O2) within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) to articulate how Department of Defense (DoD) policy will be implemented across OUSD(P&R) institutions. The intent of all implementation strategies is to ensure consistency within and among OUSD(P&R) institutions.

2. APPLICABILITY. This Policy Guidance document applies to all institutions within the OUSD(P&R) that conduct or support research involving human and animal subjects as defined in References (a) through (c).

3. POLICY. It is OUSD(P&R) Policy that:

- a. In accordance with Reference (d), OUSD(P&R) institutions conducting or supporting research involving human or animal subjects will utilize the EIRB system for processing, reviewing, and managing all research under their purview. This requirement extends to non-human subjects research determinations, administrative reviews and any other related determinations/correspondence.
- b. The R2O2 Director or their designee must approve all individuals appointed to the Senior Board Administrators role in EIRB.
- c. Any elements of EIRB (including but not limited to templates, configured language, and content) that the Executive Steering Committee (ESC) has standardized cannot be modified without prior approval from the ESC, as outlined in Reference (e).

4. RESPONSIBILITIES.

- a. DIRECTOR, RESEARCH REGULATORY OVERSIGHT OFFICE (R2O2)
 - i. Creates Policy Guidance documents that provide information on how compliance programs will be implemented across OUSD(P&R) institutions.
 - ii. Coordinates with Human Research Protection Program (HRPP) and IACUC personnel in each of the institutions to create and implement the Standard Operating Procedures (SOP) in a manner that ensures consistency and standardization across all OUSD(P&R) institutions.
- b. INSTITUTIONAL OFFICIAL (IO), DEPUTY IO
 - i. Establishes institutional-level policies and instructions for implementation and operationalization of the requirements with this Policy Guidance document.
- c. HUMAN PROTECTION ADMINISTRATORS (HPAs), EXEMPT DETERMINATION OFFICIALS (EDOs), AND INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) PERSONNEL
 - i. Create SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution.
 - ii. Configure and maintain board space and content within the EIRB system according to guidelines from OUSD(P&R).
 - iii. Monitor institutional compliance with Reference (d) and this Policy Guidance, and provide direction on steps to become compliant when necessary.
 - iv. Provide institutional guidance on achieving and maintaining compliance with the requirements in References (d), this Policy Guidance and their respective institutional SOPs.
 - v. Notify respective institutional leadership if violations of guiding policies are found.
 - vi. Notify Component HQ Office of repeated violations or continuous non-compliance with the guiding policies.
 - vii. Provide guidance and advice (orally and in written format) on steps individuals who are associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (d), this Policy Guidance document, and their respective institutional SOPs.

5. RELEASABILITY. **Cleared for public release.** This Policy Guidance document is available on the Internet at the R2O2 website (<http://www.health.mil/Military-Health-Topics/Research-and-Innovation/Research-Oversight>).

6. EFFECTIVE DATE. This Policy Guidance:

- a. Is effective on November 10, 2016.
- b. Will expire effective November 9, 2019 if not reissued or cancelled before this date.

Patrice Robinson-Haley, Sc.D.
Director, R2O2

Enclosures

1. References
2. Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Instruction 3216.01, "Use of Animals in DoD Programs," September 13, 2010
- (b) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
- (c) Office of the Under Secretary of Defense for Personnel and Readiness, Research Regulatory Oversight Office, "Operating Instruction," September 30, 2014
- (d) Policy Memo, "Use of the Electronic Institutional Review Board," April 25, 2016
- (e) Policy Guidance, "OUSD(P&R) Policy for Requesting Modifications to the Electronic Institutional Review Board (EIRB)," Version 1.0

ENCLOSURE 2PART I. ABBREVIATIONS AND ACRONYMS

DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy & Oversight
EDO	Exemption Determination Official
EIRB	Electronic Institutional Review Board
ESC	Executive Steering Committee
HPA	Human Protections Administrator
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
R2O2	Research Regulatory Oversight Office
SOPs	Standard Operating Procedures

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Policy Guidance document. Terms defined in References (a) – (d) are not repeated here.

Electronic Institutional Review Board (EIRB). Electronic system used for the submission and review of research to the appropriate oversight office(s) and for management of meetings at which research reviews are conducted.

Executive Steering Committee (ESC). The multi-Component group of experts responsible for providing input and direction regarding the functional requirements of EIRB to the Program Management Office to ensure EIRB is a useful tool for the DoD research community.

IACUC Personnel. Oversight, administrative and subject-matter-expert staff who provide management and support to the IACUCs within OUSD(P&R). This does not include members of the IACUC.

Senior Board Administrator. Individual with leadership responsibilities in research oversight at an institution who is knowledgeable about the institution's review workflow and policies and is responsible for the setup and configuration of the institution's review board space(s) within EIRB.