



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

Policy Guidance

PG-06-002

R2O2

SUBJECT: Policy for Requesting Modifications to the Electronic Institutional Review Board (EIRB)

References: See References in Enclosure 1.

Guidance History:

Document Number	Document Version	Effective Date	Lifecycle Review Date
PG-06-002	1.0	11/10/16	11/9/2019

1. PURPOSE. This Policy Guidance Document explains the process by which EIRB Users at OUSD(P&R) institutions may request modifications to the EIRB system. Policy Guidance documents are promulgated by the Research Regulatory Oversight Office (R2O2) within the Office of 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 are using the EIRB system, as required by Reference (a) and (b).
3. POLICY. OUSD(P&R) institutions using the EIRB system will request changes to the system only via the R2O2 EIRB inbox (dha.ncr.rsrch-reg.mbx.ousd-pr-eirb@mail.mil). The Executive Steering Committee (ESC) must approve changes to the EIRB system. OUSD(P&R) institutions using the EIRB system are encouraged to make recommendations to improve the functionality and effectiveness of the EIRB:
 - a. Requests for changes to EIRB from OUSD(P&R) institutions must be submitted to the R2O2 EIRB-dedicated inbox via email routed through the local HRPP or IACUC personnel.
 - i. Users should submit change requests when they believe the design or functionality of the system could or should be modified in a specific way to better suit Users' or institutions' needs.

- ii. Users should refer to the R2O2 EIRB Inbox Rules of Engagement for information about what should be included in a change request.
 - iii. Change requests may be submitted for system functionality as well as for form design, form content, and any other aspect of the system.
- b. R2O2 will meet regularly to review the submissions and assign relative priorities to the recommended changes.
- c. Prior to each Sprint by Aderas and iMedRIS, the ESC will meet to compile the changes requested by each Component and vote on the final prioritization of items to be addressed during the upcoming Sprint.
 - i. Any requests not addressed at a Sprint will be flagged and re-prioritized for the next Sprint.
 - ii. It is anticipated that Sprints will occur approximately every 60 days, but the timing may be accelerated based on the number of requests and the level of effort it will require for the vendors to implement the changes.

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 the HRPP and IACUC personnel at each of the OUSD(P&R) institutions to create and implement Standard Operating Procedures (SOPs) in a manner that ensures consistency and standardization across all OUSD(P&R) institutions.
 - iii. Compiles EIRB change requests and recommendations submitted by the OUSD(P&R) EIRB user community into a single list.
 - iv. Evaluates and prioritizes the EIRB change requests submitted by the OUSD(P&R) EIRB user community.
 - v. Submits the prioritized list of OUSD(P&R) EIRB change requests to the ESC for consideration, prioritization, and vote.
 - vi. Advocates to the ESC for the requests made by the OUSD(P&R) EIRB user community that R2O2 has determined to be high priority.
 - vii. May delegate the authorities listed above to appropriate R2O2 staff.
- b. CO-CHAIR, EIRB EXECUTIVE STEERING COMMITTEE (ESC).
 - i. Set the agenda for ESC meetings, to include compiling and prioritizing EIRB change requests submitted by individual Components.
 - ii. Ensure the ESC votes on the prioritization of change requests with sufficient time to provide the prioritized list to the Program Management Office prior to each Sprint.
 - iii. Ensure appropriate consideration is given to change requests made by each Component.
- 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 of this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution.
 - ii. Monitor institutional compliance with this Policy Guidance, and provide direction on steps to become compliant when necessary.
 - iii. Provide institutional guidance on achieving and maintaining compliance with the requirements in this Policy Guidance and their respective institutional SOPs.
 - iv. Notify respective institutional leadership if violations of guiding policies are found.
 - v. Notify Component HQ Office of repeated violations or continuous non-compliance with the guiding policies.
 - vi. Establish appropriate processes with respect to institutional needs and this policy.
 - vii. Submit change requests to the R2O2 EIRB inbox individually and on behalf of the institution's EIRB user community.
- d. OUSD(P&R) EIRB USER COMMUNITY. The OUSD(P&R) EIRB Users:
- i. Use the EIRB system for the submission, review, clearance, and approval of research protocols and life-cycle actions, and publications and/or to conduct reviews of submissions.
 - ii. Submit requests for technical support to the DHA Global Service Center Help Desk either via email (dhagsc@mail.mil) or by phone at 800-600-9332.
 - iii. Submit all change requests or recommendations for EIRB to the local HRPP or IACUC personnel for submission to the R2O2 Inbox, in accordance with institutional workflow.

5. RELEASABILITY. **Cleared for public release**. This Policy Guidance 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.

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Director, R2O2

Enclosures

1. References
2. Glossary

ENCLOSURE 1

REFERENCES

- (a) Policy Memo, "Use of the Electronic Institutional Review Board," April 25, 2016
- (b) Policy Guidance, "PG-06-001 Requirements for Use of the Electronic Institutional Review Board," Version 1.0

ENCLOSURE 2

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

EIRB	Electronic Institutional Review Board
ESC	Executive Steering Committee
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Program
IRB	Institutional Review Board
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
R2O2	Research Regulatory Oversight Office
SOP	Standard Operating Procedure

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)-(b) are not repeated here.

Change Request. Situation in which a user of the EIRB system has identified something within the system that can be improved and has asked R2O2 to bring the item to the ESC for prioritization at a Sprint.

Sprint. Part of the agile development process, by which the Vendor will continue to roll out updates to the EIRB system based on Change Requests submitted by the User community and prioritized by the ESC.