



Office of the Under Secretary of Defense
for Personnel and Readiness
Research Regulatory Oversight Office

Policy Guidance

PG-06-003

R2O2

SUBJECT: Policy Guidance for Research Conducted by Investigators without Department of Defense Common Access Cards

References: See References in Enclosure 1

Guidance History:

Document Number	Document Version	Effective Date	Lifecycle Review Date
PG-06-003	1.0	November 10, 2016	November 9, 2019

- PURPOSE.** This Policy Guidance explains the process by which research conducted by investigators without DoD Common Access Cards (CACs) shall be entered into the Electronic Institutional Review Board (EIRB) system. 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 inform how Department of Defense (DoD) policies 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.
- APPLICABILITY.** This Policy Guidance applies to all OUSD(P&R) institutions that support research conducted by non-DoD institutions and/or collaborate on research with investigators who do not have CACs.
- POLICY.** It is OUSD(P&R) Policy that:
 - In accordance with References (a) and (b), OUSD(P&R) institutions conducting or supporting research involving human or animal subjects will utilize the EIRB system for processing, reviewing, and managing research under their purview. All OUSD(P&R) human research protection program (HRPP) and animal care and use program (ACUP) reviews under the purview of References (c) and (d) will be managed within the system.
 - OUSD(P&R) institutions supporting non-DoD conducted research and OUSD(P&R) investigators collaborating on research with non-CAC holding investigators will upload and submit all research related documents that would normally be uploaded and

submitted by the non-CAC holding investigator to the EIRB system until such time as the non-CAC holding investigator obtains a CAC or until an alternative solution is identified and implemented. This policy does not absolve the non-CAC holding investigator from compliance with regulatory responsibilities and other related responsibilities as outlined in the research protocol and/or applicable agreements.

- c. OUSD(P&R) principal investigators (PIs) must use the EIRB system in accordance with References (a) and (b), and may not relegate responsibilities that are inherently the PI's (e.g., submission and submission signatures) to others unless otherwise allowed by policy.
- d. The EIRB system has the capability to accept External Certificate Authority (ECA) Certificates in lieu of a CAC as outlined in Reference (e). The ECA certificate can be requested by non-CAC holders who are on the research team for a project and are responsible for ensuring regulatory and compliance for the project. The ECA certificate will not be used by sponsors of research that desire access to the system to view or track the status of a project; it is the responsibility of the PI to communicate the necessary documents and information to the sponsor.

4. RESPONSIBILITIES.

a. DIRECTOR, RESEARCH REGULATORY OVERSIGHT OFFICE

- i. Performs the duties identified in Section 3 of Reference (f).
- ii. Creates Policy Guidance documents that directs compliance across OUSD(P&R) institutions.
- iii. Coordinates with 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 OFFICIALS (IOs) AND/OR DEPUTY IOs

- i. Establish institutional-level procedures and instructions for implementing and operationalizing the requirements with this Policy Guidance.

c. HPAs, EDOs, AND IACUC PERSONNEL

- i. Implement this Policy Guidance at their respective institutions.
- ii. Create SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution.
- iii. In cases where non-CAC investigator cannot obtain an ECA certificate, provide a memorandum to file explaining that the responsible party is a non-CAC holder who was unable to obtain an ECA certificate and, therefore, has no access to EIRB.
- iv. Provide assistance and local institutional guidance on submitting necessary regulatory documents within EIRB on behalf of the non-CAC holder investigator.
- v. Monitor institutional compliance with References (a) and (b) and this Policy Guidance, and provide direction on steps to become compliant when necessary.

- vi. Provide institutional guidance on achieving and maintaining compliance with the requirements in References (a) and (b), this Policy Guidance and their respective institutional SOPs.
 - vii. Track local institution's non-CAC holder investigators who are able to obtain an ECA certificate, and those who are unable to obtain an ECA certificate, and advise them of any policy changes affecting non-CAC investigators.
 - viii. Notify respective institutional leadership of any violations of guiding policies.
 - ix. Notify Component HQ Office of repeated violations or continuous non-compliance with the guiding policies.
 - x. Perform periodic audits of ECA certificate expiration dates, and revoke EIRB access for all ECA certificate holders when it is no longer needed.
- d. OUSD(P&R) INVESTIGATORS COLLABORATING WITH NON-CAC HOLDERS AND GOVERNMENT POCs FOR RESEARCH
- i. Use the EIRB system to submit research protocols and life-cycle actions for review and approval in accordance with References (a) and (b).
 - ii. Upload and submit all research related documents to the EIRB system on behalf of non-CAC holding investigators who are unable to obtain an ECA certificate.
 - iii. Document interactions with non-CAC holding investigators regarding t submissions and funded research.
 - iv. Provide non-CAC holding investigators who are unable to obtain an ECA certificate with required correspondence from the EIRB system.
 - v. Inform sponsors of project status and provide copies of any relevant documentation as required by the funding agreement outside of EIRB.
 - vi. Ensure the ECA expiration date is appropriate for the research.
- e. NON-CAC INVESTIGATORS AND RESEARCH TEAM MEMBERS
- i. Communicate the requirement for an ECA certificate in writing to the supporting or collaborating OUSD(P&R) institution's HRPP or IACUC, and coordinate application as outlined in Reference (e).
 - ii. Adhere to policies and instructions governing collaborative research with the DoD and OUSD(P&R).
 - iii. Inform the supporting or collaborating OUSD(P&R) institution's HRPP or IACUC of the ECA certificate application results for tracking purposes (as per item c.vi, above).
 - iv. Use the EIRB system to submit DoD-supported and DoD-collaborative research protocols and life-cycle actions for review and approval in accordance with References (a) and (b), once an ECA certificate is successfully obtained.
 - v. Upon completion of the research project for which the ECA certificate was obtained, relinquish said certificate to the OUSD(P&R) institution HRPP or IACUC.

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 Novemb

Enclosures

1. References
2. Glossary

ENCLOSURE 1

REFERENCES

- (a) Policy Memo, "Use of the Electronic Institutional Review Board," April 25, 2016
- (b) PG-06-001, "Requirements for Use of the Electronic Institutional Review Board (EIRB)," Version 1.0
- (c) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
- (d) DoD Instruction 3216.01, "Use of Animals in DoD Programs," September 13, 2010
- (e) Instructions to obtain an External Certificate Authority (ECA) for non-DoD/non-VA Researchers to use the Electronic Institutional Review Board (EIRB) System
- (f) Charter, "Electronic Institutional Review Board Executive Steering Committee"

ENCLOSURE 2

GLOSSARY

PART I: ABBREVIATIONS AND ACRONYMS

ACUP	Animal Care and Use Program
CAC	Common Access Card
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy & Oversight
ECA	External Certificate Authority
EDO	Exemption Determination Official
EIRB	Electronic Institutional Review Board
HPA	Human Protections Administrator
HQ	Headquarters
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
IRB	Institutional Review Board
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
PI	Principal Investigator
R2O2	Research Regulatory Oversight Office
POC	Point of Contact
SOPs	Standard Operating Procedures

PART II: DEFINITIONS

Terms defined in References (a) – (g) are not repeated here.