

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

FAQ Topic: CRADO- Retroactive Waivers

Date: March 12, 2012

Question: If it is discovered that a study involves international research, children, or prisoners, but the required waiver from the Chief Research and Development Officer (CRADO) has not been obtained, can a retroactive CRADO waiver be obtained?

Answer: No. As a matter of policy, the CRADO and the Office of Research and Development (ORD) do not issue “retroactive” waivers for international research, research involving children, or research involving prisoners that has already been conducted.

Question: Suppose the results of the study have already been published when the lack of the required CRADO waiver is discovered?

Answer: The noncompliance should be reported to the responsible IRB, and to ORD if the research was funded by ORD. The IRB must determine (a) whether the failure to obtain the required waiver constitutes serious or continuing noncompliance reportable to ORO, and (b) whether any remedial or corrective action is warranted.

Question: Suppose data analysis has been completed when the lack of the required CRADO waiver is discovered, can the results be published?

Answer: There are no VHA policies that specifically address whether these results can be published. The IRB must determine (a) whether the failure to obtain the required waiver constitutes serious or continuing noncompliance reportable to ORO, and (b) whether any remedial or corrective action is warranted. ORD must also be consulted if the research was funded by ORD.

Question: Suppose data collection or data analysis is in progress when the lack of the required CRADO waiver is discovered, can the already-collected data be used and published?

Answer: See Response 3. In addition, any continued use of such data would need a CRADO waiver prior to the continued use. Likewise, any collection of new data for continuation of the research would require a CRADO waiver.

Question: Can data obtained without a required CRADO waiver be used in a subsequent study?

Answer: Any secondary use of data collected without a required CRADO waiver, including use in a subsequent study, requires a CRADO waiver prior to the secondary use.

References: *VHA Handbook 1200.05 §47.b, §48.a, and §56.c*
VHA Handbook 1058.01 §7.f(11) and §7.i