

# 10. Claim of Exemption from Review by the Human Subjects Research Review Board

**United States Army Medical Research and Materiel Command  
Office for the Deputy Chief of Staff for Regulatory Compliance and Quality Human  
Subjects Protection Division**

PROTOCOL TITLE:
PRINCIPAL INVESTIGATOR'S NAME:
INSTITUTION:

**EXEMPT CATEGORIES CLAIMED:** Yes   No

1. Will existing or archived data, documents, medical records, or database records be used?
2. Will biological specimens (e.g., cells, tissues, blood) be used?
3. Indicate below the source(s) of existing or archived data or biological specimens:
 

Existing data	Publicly available?
Archived data	Publicly available?
Biological	Publicly available?
4. Will the donors of the original biological specimens be able to be identified, directly or indirectly, through identifiers linked to the donor?
5. Will data be recorded in writing?
6. Will data be recorded by audiotape?
7. Will data be recorded by videotape?
8. If survey instruments are used, will sensitive or private topics be explored?
9. Will subjects be identifiable either by name or through demographic data?

If the answer to any question 4-9 is yes, describe on a separate sheet of paper how the confidentiality of a subject's identity will be maintained. Also describe plans for maintaining or destroying identifying links to subjects after the protocol has been completed.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date