## **EXHIBIT D**

Historical Documentation of the Agency's Role in the Human Subject Test Program at Edgewood Arsenal Research Laboratories.

21 October 1994

## ADMINISTRATIVE INTERNAL USE ONLY

28 October 1994

MEMORANDUM FOR THE RECORD

SUBJECT: Historical Documentation of the Agency's Participation in the Human Test Program at Edgewood Arsenal Research Laboratories (21 October 1994)

- 1. The subject report is a compilation of historical documentation available in the archival records of the Office of Research and Development that pertain to the Agency's participation in the human subject test program involving agent EA 3167 at Edgewood Arsenal Research Laboratories (EARL).
- 2. The Agency's association with EARL began in 1967 with the transfer of funds to support the collection of information on new drugs of interest through literature searches, conferences, etc. (Project CHICKWIT). The first reference to EARL's human test program involving EA 3167 is a memorandum written by an ORD project officer in June 1970 reviewing the results of a test conducted with nineteen test subjects (Tab 1) under U.S. Army sponsorship. Subsequent documents deal with the transfer of funds from ORD to EARL in early 1971 for the evaluation of oral percutaneous routes for the administration of EA 3167 (Tab 2). These are followed by two documents requesting time extensions, first until 30 September 1972, and then until 15 January 1973 (Tabs 5 & 6 respectively).
- 3. In January 1973 the Department of the Army was advised that the Agency program was terminated (Tab 8). While the letter of cancellation withdrew funds in the amount of \$30,000 (Project CHICKWIT), charges continued to accrue against that part of the program that involved the testing of EA 3167. About 75% of the original \$37,000 provided for this effort was expended by 31 March 1973. It should be noted that no written reports were found during the records search that document how EARL expended these funds.
- 4. While Government contracts with the private sector are quite explicit with regard to reporting requirements, it is not unusual for projects involving inter-agency transfers to provide minimal documentation. In this particular case reporting may have been verbal because of the sensitivity of the association with the Agency. According to EARL officials the final report on this project was never prepared because of the premature termination of the project (Tab 18). This same document attributes a statement to an EARL official that he was positive that no human subject testing was performed under the Agency contract. Rather the Agency contract consisted of three tasks, none of which involved human subject testing. This conclusion is reinforced by the results of a review of DoD materials prepared for submission to a Senate committee (Tab 25). Again, it is not unusual for the work that is actually done on a project involving an inter-departmental transfer to be afferent than what was originally planned.

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5. While the records are somewhat contradictory and incompavailable documentation reaffirms the conclusion that no human's of EA 3167 was conducted under Agency sponsorship.