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CONTRACTUAL OPTIONS - AGENT ORANGE PROJECTS

ISSUE:

Contractual options relating to conduct of TCDD Validation Study and decisions on conduct of Agent Orange Exposure Study.

BACKGROUND:

CDC's Health Interview Contractor, Research Triangle Institute has been maintained in a state of readiness for a period January 15, 1986 through July 30, 1986 at a cost of approximately $500,000. August 1986 will be used as a close out month for the Vietnam Experience Study and beginning September, RTI will go into a state of dormancy. Cost for this dormancy are still to be negotiated, but are estimated at $40,000 to "shut down" and $120,000 to "restart" with some minimal monthly maintenance costs.

CDC's Medical Examination Contractor, Lovelace Medical Foundation will complete the Vietnam Experience Study examinations by September 30, 1986. CDC and Lovelace have negotiated a $1.3 million settlement for the period ending September 30. This settlement is based on a two and one half month period resulting from failure of the Government to comply with the terms of the contract. Specifically, CDC has not been able to deliver the monthly lists of names as detailed in the contract due to the difficulty of determining exposure of ground troops to Agent Orange from military records alone. No negotiations have been initiated for the time period beginning October 1, 1986.

OPTION 1: MAINTAIN BOTH RTI AND LOVELACE IN A STATE OF DORMANCY UNTIL TCDD VALIDATION STUDY; MODIFY BOTH CONTRACTS TO CONDUCT VALIDATION STUDY; RETURN BOTH CONTRACTORS TO STATE OF DORMANCY AFTER VALIDATION STUDY UNTIL DECISION ON AND START (IF CONDUCTED) OF AGENT ORANGE EXPOSURE STUDY.

EFFORTS WOULD BE MADE TO IDENTIFY OTHER PROJECTS WHICH WOULD UTILIZE LOVELACE STAFF, FACILITIES, ETC., AND OFFSET THE COSTS ASSOCIATED WITH DORMANCY.

PRO:

1. Existing mechanisms/procedures could be utilized to obtain necessary interview and medical examination data for TCDD Validation Study resulting in considerably shorter start up time than if other mechanisms/procedures had to be developed.

2. Current contractors might be more willing to participate in TCDD Validation Study if they know they will do Agent Orange Exposure Study, if conducted.

3. Cost for Agent Orange Exposure Study, if conducted, would be less than obtaining new contractors.

4. Start up time for Agent Orange Exposure Study, if conducted, would be considerably shorter by avoiding a new procurement process.

5. Experience and expertise of current contractors would be utilized for Agent Orange Exposure Study, if conducted, helping to ensure consistency of data collection methods for the Vietnam Experience Study and the Agent Orange Exposure Study.

6. Provide a service to veterans participating in TCDD Validation Study by giving them a thorough health examination.

7. Possibility exists to offset costs for dormancy periods.

   - CDC's National Institute for Occupational Safety and Health (NIOSH) is negotiating a contract with Lovelace Medical Foundation for their worker morbidity study. Currently, only the pilot phase (approximately 70-80 examinations) has been approved. It is possible that some of the costs associated with dormancy related to the Agent Orange Exposure Study could be offset by this pilot phase. However, because of the scope of this pilot phase and time schedule for completion (10-12 months), it is unclear at this time how much of the dormancy costs could actually be offset.

CON:

1. The estimated costs of $2.1-$3.5 million associated with maintaining contractors in a state of dormancy before and after conduct of TCDD Validation Study.

COST – OPTION 1

Research Triangle Institute:

1.	Dormancy prior to start of TCDD Validation Study	$160,000, based on $40,000 shut down costs and $120,000 restart costs.
2.	Payment for 700 interviews at $250/interview TCDD Validation Study	$175,000
3.	Dormancy after conduct of TCDD Validation Study until decision on Agent Orange Exposure Study	$200,000
4.	Final negotiated settlement if Agent Orange Exposure Study not conducted	Unknown

Lovelace Medical Foundation:

1.	Dormancy period to TCDD Validation Study	$900,000–$1,500,000* based on 3 month dormancy (as shown in decision tree) at $300,000–$500,000/mo.
2.	Payment for 400 medical exams at $3000 per exam for TCDD Validation Study	$1,200,000
3.	Dormancy after conduct of TCDD Validation Study	$1,200,000–$2,000,000* based on 4 month dormancy (as shown in decision tree) at $300,000–$500,000/mo.
4.	Final negotiated settlement if Agent Orange Exposure Study not conducted	Unknown

*These costs can possibly be reduced if other projects are identified which would utilize Lovelace staff, facilities, etc.

OPTION 2: MAINTAIN RTI IN STATE OF DORMANCY UNTIL TCDD VALIDATION STUDY, UTILIZE RTI FOR TCDD VALIDATION STUDY, RETURN RTI TO DORMANCY UNTIL DECISION ON AND START (IF CONDUCTED) OF THE AGENT ORANGE EXPOSURE STUDY.

MAINTAIN LOVELACE IN TOTAL SHUT DOWN* MODE UNTIL TCDD VALIDATION STUDY COMPLETED AND DECISION TO START (IF CONDUCTED) THE AGENT ORANGE EXPOSURE STUDY. DEVELOP OTHER MECHANISMS (e.g. UTILIZE CDC'S FIELD STAFF OF PUBLIC HEALTH ADVISORS AND EIS OFFICERS TO MAKE ARRANGEMENTS FOR OBTAINING BLOOD SPECIMENS) TO OBTAIN BLOOD SPECIMENS AND OTHER REQUIRED MEDICAL INFORMATION.

NOTE: This Option is proposed as a possible "middle ground" between Option 1 (dormancy before and after TCDD Validation Study) and Option 3 (cancellation of contract). This Option is proposed if Option 1 is decided to be too costly. This Option has not been discussed with the contractor and might not be a viable Option.

* Shut down – a step below dormancy and includes the loss of the state of readiness to return on short notice to designated activities.

PRO:

1. Existing mechanisms/procedures could be utilized to locate and interview veterans for TCDD Validation Study. It is critical that this locating/interviewing capability be maintained.

2. Current contractors might be more willing to "participate" (as described in this Option) in TCDD Validation Study if they know they will do the Agent Orange Exposure Study, if conducted.

3. Lovelace might be willing to reduce the monthly maintenance costs associated with dormancy/shut down as described in this option.

4. Costs for the Agent Orange Exposure Study, if conducted, would be less if both RTI and Lovelace are kept under contract.

5. Experience and expertise of contractors would be utilized for the Agent Orange Exposure Study, if conducted.

CON:

1. Lovelace might not be willing to enter a total shut down mode for extended time period; could result in their requesting termination of contract.

2. Costs for Lovelace "shut down" might not be less than other options.

3. New mechanisms/procedures would have to be developed to obtain blood specimens and other required medical information. This could result in longer start up time for TCDD Validation Study and might negate any potential cost savings associated with total shut down of Lovelace.

COST - OPTION 2

Research Triangle Institute:

1. Dormancy prior to start of TCDD Validation Study	$160,000, based on $40,000 shut down costs and $120,000 restart costs.
2. Payment for 700 interviews at $250/interview for TCDD Validation Study	$175.000
3. Dormancy after conduct of TCDD Validation Study until decision on the Agent Orange Exposure Study.	$200,000
4. Final negotiated settlement if Agent Orange Exposure Study not conducted	Unknown

Lovelace Medical Foundation:

1. Monthly maintenance costs for "shut down" mode	Unknown
2. Final negotiated settlement if Agent Orange Exposure Study not conducted	Unknown

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Obtaining blood specimens and other medical information	Unknown since the new mechanisms/ procedures have not been identified/ developed

OPTION 3: TERMINATION ONE OR BOTH CONTRACTS (RTI, LOVELACE) PRIOR TO OR AFTER CONDUCT OF TCDD VALIDATION STUDY.

PRO:

1. Saves approximately $2.1-$3.5 million in costs associated with current contract(s) if cancelled prior to TCDD Validation Study. Saves approximately $1.2-$2.0 million in costs associated with current contract(s) if cancelled after TCDD Validation Study.

CON:

1. If one or both contracts were terminated now, conduct of TCDD Validation Study would require development of new mechanisms/procedures to locate veterans and obtain data and blood specimens resulting in longer time period to complete TCDD Validation Study and possible increased costs.

2. If one or both contracts were to be terminated after TCDD Validation Study, contractor(s) might not be willing to participate in Validation Study.

3. Cancellation of these contracts before conducting a TCDD Validation Study could give the perception that the health of Vietnam veterans was not important to this Administration.

4. Extensive procurement process would be required for the Agent Orange Exposure Study, if conducted.

5. Experience and expertise of current contractors could be lost since contractors might not bid for new procurement.

6. New appropriations in the amount of $21.0-$25.5 million would be necessary for the Agent Orange Exposure Study, if conducted, since any FY 1984 unused contractual funds would have to be returned to the Treasury if contracts were cancelled.

COST - OPTION 3

1. Since this option contains several sub options cost estimates are not provided. The various costs for interviews, dormancy, etc., as listed in Options 1 and 2 can also be applied here.

2. Final unknown negotiated settlement costs would have to be negotiated if one or both contracts were terminated.

3. If new contracts were let for the Agent Orange Exposure Study, new appropriations in the amount estimated below would be required:

Health Interview	$ 3-$3.5 million
Medical Examination	$18-$22 million

The estimate for the health interviews is based on inflating the FY 1984 contractual costs by 4% per year for 4 years (FY 1988 costs). It also is based on a two cohort design (12,000 interviews) as opposed to the original three cohort design (18,000 interviews).

The estimate for the medical examinations is based on two methods. Both methods resulted in approximately the same cost estimate. The first method increases the FY 1984 contractual cost by 12% per year for 4 years (FY 1988 costs). The 12% increase is used to approximate the yearly increase in medical care costs. The other method utilizes cost figures from a recent bid by Lovelace Medical Foundation on a NIOSH contract; it is important to note the requirements of this contract are different than for the Agent Orange Exposure Study.

These estimates are based on a two cohort design (4,000 exams) as opposed to the original three cohort design (6,000 exams). Since both of these approaches provide only crude estimates for the cost of a new contract for medical examinations, caution is urged in their interpretation.

POINTS FOR CONSIDERATION:

1. A TCDD Validation Study will require the locating and interviewing of veterans. RTI has the capability of performing these tasks efficiently and effectively. It would be extremely difficult to conduct the TCDD Validation Study in 4–6 months (as detailed in the Decision Tree) without the assistance of RTI.

2. Blood specimens and other medical information will need to be obtained from veterans in the TCDD Validation Study. Lovelace has the capability to complete these tasks. Development of new mechanisms/procedures could be time consuming and costly. Since specific new mechanisms/procedures have not been developed, cost estimates cannot be provided at this time. However, costs for keeping Lovelace in state of dormancy prior to and after TCDD Validation Study are also expensive — estimated at $2.1–$3.5 million.

3. Current procedures and instruments have IRB and OMB clearances. While some modifications required by the TCDD Validation Study (e.g. obtaining a certain volume of blood) might require new reviews, extensive clearance procedures should not be necessary if current contractors and procedures are utilized.

4. If current contracts are retained, funds should be sufficient to conduct the Agent Orange Exposure Study and no new appropriation for contracts would be required.

5. If current contracts were cancelled now, CDC would return about $20-$22 million in unused FY 1984 funds to the Treasury. This estimate assumes a final settlement of $4-$5 million with CDC's contractors. This $4-$5 million figure is a crude estimate since no negotiations have taken place with the contractors.

   If the current contractors are retained and an Agent Orange Study conducted, CDC would still expect to return some money to the Treasury. The exact amount that would be returned is unknown at this time. The reason for this is the original contracts are based on a three cohort design (18,000 interviews and 6,000 exams), while a "new" Agent Orange Exposure Study would probably consist of two cohorts (12,000 interviews and 4,000 exams). However, because of the change in the scope of the work to be performed, the current contractors would probably be legally entitled to renegotiate the unit cost per interview and medical examination. This increased unit cost would affect the amount of money to be returned to the Treasury and would be determined through negotiations with the contractors.

6. If new contracts were let for the Agent Orange Exposure Study, new appropriations of approximately $21-$25.5 million would be required.

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