

<b>RDT&amp;E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)</b>	DATE <b>February 1999</b>
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<b>BUDGET ACTIVITY</b> <b>6 - Management and Support</b>	<b>PE NUMBER AND TITLE</b> <b>0605306F Ranch Hand II Epidemiology Study</b>	<b>PROJECT</b> <b>2767</b>
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COST (\$ In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
2767 Ranch Hand II Epidemiology Study	10,216	4,273	4,510	4,554	11,434	11,014	4,903	5,033	Continuing	Continuing
Quantity of RDT&E Articles	0	0	0	0	0	0	0	0	0	0

(U) **A. Mission Description:** This RDT&E Management Support program was directed in 1980 by the Assistant to the President of the United States for Domestic Affairs and Policy upon the recommendation of the Interagency Working Group on the Possible Long-Term Effects of Phenoxy Herbicides and Contaminants. As a result of this Presidential direction, PE 0605306F was established to conduct a 20-year epidemiology investigation of approximately 1,200 Air Force personnel who were involved with aerial spraying of herbicides in Vietnam from 1962 to 1971 (Operation Ranch Hand). The objective of this investigation is to determine whether long-term health effects exist and can be attributed to occupational exposure to phenoxy herbicides and their associated dioxins. Dioxins are an unwanted by-product from numerous current manufacturing processes and a major health concern of the EPA and other government agencies.

This project involves a 20-year study, which was initiated in 1982, that compares United States Air Force (USAF) Ranch Hand personnel to a control group of USAF crew members and support personnel who were not exposed to herbicides while serving in Vietnam. Approximately 20,000 individuals (exposed personnel group plus control group) are participating in the annual mortality study, with approximately 2,200 (exposed personnel group plus control group) of these participating in the detailed morbidity study during each physical examination cycle. The detailed physical examination cycle includes follow-up health examinations at the 3-, 5-, 10-, 15-, and 20-year time periods. The study includes examination of the possible occurrence of birth defects in children as determined from children's medical records and family medical histories. The Congressionally-established Ranch Hand Advisory Committee has directed that all study findings be reported to the scientific community as peer-reviewed journal articles.

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<p>(U) <u>FY 1998 (\$ in Thousands):</u></p> <ul style="list-style-type: none"> <li>- (U) \$ 6,933 Completed fifth cycle of physical examinations, questionnaires, and participant data base.</li> <li>- (U) \$ 700 Analyzed laboratory specimens to include serum dioxin assays and initiated fat biopsy analyses as well as conducted statistical research studies to include producing a mathematical model to integrate mortality and morbidity data for analysis.</li> <li>- (U) \$ 2,583 Processed and documented examination data to include continuing to verify the physical examination database; conducted medical records coding; performed the annual mortality analysis of approximately 1,200 Ranch Hand personnel and 19,000 comparison personnel; and conducted data analysis for articles to be submitted to peer-reviewed journals as directed.</li> <li>- (U) \$10,216 Total</li> </ul> <p>(U) <u>FY 1999 (\$ in Thousands):</u></p> <ul style="list-style-type: none"> <li>- (U) \$ 1,401 Complete examination data base and conduct statistical analyses of examination data.</li> <li>- (U) \$ 229 Analyze laboratory specimens to include serum dioxin assays and completion of fat biopsy analyses as well as conduct statistical research studies to include completion of a mathematical model to integrate mortality and morbidity data for analysis.</li> <li>- (U) \$ 2,565 Continue to process and document examination data to include updating of the participant database; conduct medical records coding; perform the annual mortality analysis of approximately 1,200 Ranch Hand personnel and 19,000 comparison personnel; and conduct data analysis for articles to be submitted to peer-reviewed journals as directed.</li> <li>- (U) \$ 78 Identified as a source for SBIR.</li> <li>- (U) \$ 4,273 Total</li> </ul> <p>(U) <u>FY 2000 (\$ in Thousands):</u></p> <ul style="list-style-type: none"> <li>- (U) \$ 1,147 Complete statistical analysis of examination data. Document all analyses and findings in 4,000 page, fifth cycle final report. Conduct analyses as directed by the Congressionally-established Ranch Hand Advisory Committee. Analyses are based on current morbidity data trends and findings.</li> <li>- (U) \$ 386 Conduct other agency/university studies supporting scientific effort; start Center for Disease Control study to test for the presence of other forms of dioxin than that found in Agent Orange; conduct morbidity and mortality mathematical modeling; conduct dioxin half-life and serum dioxin analyses.</li> <li>- (U) \$ 2,977 Continue to process and document examination data to include updating of the participant database; conduct medical records coding; perform the annual mortality analysis of approximately 1,200 Ranch Hand personnel and 19,000 comparison personnel; and conduct data analysis for articles to be submitted to peer-reviewed journals as directed.</li> <li>- (U) \$ 4,510 Total</li> </ul>		
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<p>(U) <u>FY 2001 (\$ in Thousands):</u></p> <ul style="list-style-type: none"><li>- (U) \$ 1,115 Conduct analyses as directed by the Congressionally-established Ranch Hand Advisory Committee. Analyses are based on current morbidity data trends and findings. Conduct process review prior to final examination cycle to determine potential participation rates, requirements for in-house or regional examination sites and statistical, schedule, and cost implications of the aging study population.</li><li>- (U) \$ 567 Conduct other agency/university studies supporting scientific effort; complete Center for Disease Control study to test for the presence of other forms of dioxin than that found in Agent Orange; complete morbidity and mathematical modeling; complete dioxin half-life and serum dioxin analyses; start semen DNA study.</li><li>- (U) \$ 2,872 Continue to process and document examination data to include updating of the participant database; conduct medical records coding; perform the annual mortality analysis of approximately 1,200 Ranch Hand personnel and 19,000 comparison personnel; and conduct data analysis for articles to be submitted to peer-reviewed journals as directed.</li><li>- (U) \$ 4,554 Total</li></ul>		
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<p>(U) <b>B. Budget Activity Justification:</b> This program is in Budget Activity 6, Management and Support, since it includes research and development efforts directed towards support of installations or operations required for general research and development use.</p> <p>(U) <b>C. Program Change Summary (\$ in Thousands):</b></p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:40%;"></th> <th style="text-align: right;"><u>FY 1998</u></th> <th style="text-align: right;"><u>FY 1999</u></th> <th style="text-align: right;"><u>FY 2000</u></th> <th style="text-align: right;"><u>FY 2001</u></th> <th style="text-align: right;"><u>Total</u> <u>Cost</u></th> </tr> </thead> <tbody> <tr> <td>(U) Previous President's Budget/FY 1999 PB</td> <td style="text-align: right;">10,285</td> <td style="text-align: right;">4,408</td> <td style="text-align: right;">4,527</td> <td style="text-align: right;">4,570</td> <td style="text-align: right;">Cont</td> </tr> <tr> <td>(U) Appropriated Value</td> <td style="text-align: right;">10,933</td> <td style="text-align: right;">4,408</td> <td></td> <td></td> <td></td> </tr> <tr> <td>(U) Adjustments to Appropriated Value</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>    a. Congressional/General Reductions</td> <td style="text-align: right;">-451</td> <td style="text-align: right;">-135</td> <td></td> <td></td> <td></td> </tr> <tr> <td>    b. SBIR</td> <td style="text-align: right;">-198</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>    c. Omnibus/Other Above Threshold Reprogrammings</td> <td style="text-align: right;">-68</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>    d. Below Threshold Reprogrammings</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>(U) Adjustments to Budget Year Since FY 1999 PB</td> <td></td> <td></td> <td style="text-align: right;">-17</td> <td style="text-align: right;">-16</td> <td></td> </tr> <tr> <td>(U) Current Budget Submit/FY 2000 PB</td> <td style="text-align: right;">10,216</td> <td style="text-align: right;">4,273</td> <td style="text-align: right;">4,510</td> <td style="text-align: right;">4,554</td> <td style="text-align: right;">Cont</td> </tr> </tbody> </table> <p>(U) Significant Program Changes: Not Applicable.</p> <p>FY 1999: \$78 identified as a source for SBIR.</p> <p>(U) <b>D. Other Program Funding Summary:</b> Not Applicable.</p> <p>(U) <b>E. Acquisition Strategy:</b> Not Applicable.</p> <p>(U) <b>F. Schedule Profile:</b> Not Applicable.</p>							<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>Total</u> <u>Cost</u>	(U) Previous President's Budget/FY 1999 PB	10,285	4,408	4,527	4,570	Cont	(U) Appropriated Value	10,933	4,408				(U) Adjustments to Appropriated Value						a. Congressional/General Reductions	-451	-135				b. SBIR	-198					c. Omnibus/Other Above Threshold Reprogrammings	-68					d. Below Threshold Reprogrammings						(U) Adjustments to Budget Year Since FY 1999 PB			-17	-16		(U) Current Budget Submit/FY 2000 PB	10,216	4,273	4,510	4,554	Cont
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