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OPTIONS PAPER

The Fullest Possible Participation of Former Ranch Hands and Their Controls

It has been recognized by the various peer review groups and our own study designers that all surviving Ranch Hands must participate in order to maximize the statistical power of the study. No other techniques (such as adding the Marines to the Ranch Hand population as suggested by the National Academy of Sciences) will improve the power of the study. This fact of study, coupled with the requirement for assuring public safety, creates a unique set of circumstances calling for perhaps some extraordinary solutions. The set of circumstances involve voluntary participation of all subjects, disposition of medical findings, and incentive and lost pay compensation. Each of the three topics will be examined separately while recognizing their interdependent nature.

Voluntary Participation - It is known that 239 of the former Ranch Hand participants are presently on active duty. These individuals, comprising approximately 20 percent of the Ranch Hand surviving population, could be directed by the Air Force to participate. However, it might be questionable as to whether they would continue to participate in the study after retirement if initially forced to do so. Since the remaining portion of the Ranch Hand population, approximately 80 percent, cannot be directed to participate, the sense of fairness or equal treatment of participants in the eyes of those still on active duty

may be of paramount importance in the initial phases of the study. Equal treatment of active duty, retired and separated personnel would minimize the development of a negative attitude of active duty individuals after they retire. An estimate of the number of individuals eligible for retirement by year is not presently available but for most, retirement will occur over the next several years. Participation in the study by active duty individuals might be maximized over the 20 year study period if they are allowed to volunteer. Should inadequate participation be achieved, then the option of directing active duty personnel to study could be exercised, fully recognizing the likely result that a good number of these individuals would be lost to study upon retirement. At minimum, a baseline physical would be achieved for future reference should any given individual die during the 20 year examination period.

Disposition of Medical Findings - Medico-legal considerations require that all volunteers be informed of potential adverse effects on their health and livelihood. Respective to this, the potential subject for the study must be informed prior to volunteering for the study that his occupational status might be changed if he is presently required to have a certain physical profile, i.e., flyers, air traffic controllers, policemen, firemen, etc., in order to pursue his occupation. The number of individuals within the Ranch Hand and the control group whose jobs require specific physical and mental profiles is unknown. However, it is felt that the rate of identification of disqualifying defects will be exceedingly low compared to the number of individuals

in the required physical/mental profile category. Using the practice of having the study participant first see his usual examiner for purpose of physical profile status and recertification may allow the use of confidentiality during the study while assuring public safety. Also this practice may greatly alleviate the nagging fear of the Ranch Hand that the examination results could impact his occupational status: Thus enhancing participation. However, even this leaves the remote possibility that a disqualifying defect may be discovered. This possibility in the mind of the potential participant may be an overriding concern. The necessity of protecting the public safety and discovery of a disqualifying defect, places the government in a situation which would appear to require disclosure and appropriate disposition of the impacted subject. This would have a direct negative effect on the volunteer status of those individuals requiring occupational physical profiles. One alternative would be to assure confidentiality which would assuage the concerns of the participant but leave the problem of public safety. A second alternative would be to indemnify the participants against such potentialities. Such a governmental risk was assumed once before with regard to Herbicide Orange. The indemnification of the incinerator ship Vulcanus against all claims. If the government were to deem this necessary for the purpose of maximizing participation and protecting the public safety, the General Counsel could be requested to write appropriate language which would provide indemnification but still limit the scope liability.

Incentive and Lost Wage Compensation - Individuals separated or retired from the Air Force who are now employed will likely suffer lost income when participating in the study during the physical examination phase. Indications are that the initial physical examinations will require 23 patient contact hours alone. This suggests the initial loss of one week if two days of travel are required. Although their travel expenses will be reimbursed in accordance with joint travel regulations, one can anticipate reluctance on the part of many individuals to lose wages or dedicated vacation time as a result of their voluntary participation in this study.

For the presently and previously enlisted personnel, approximately one-half of the Ranch Hands, this consideration may be of prime importance. The practice of paid volunteers in the civilian and military sectors has been successfully used to encourage participation in human use studies. Again, continued participation of all participants would suggest equal treatment of retired, separated and active duty individuals. An alternative would be to pay all volunteers a set fee based on condition of employment. One could envision employed individuals taking leave during the period of time required for physical examination. Like civilian and military personnel, some would take leave in a paid salary status while others may be required to participate in a leave without pay status, i.e., a self-employed person. One method for determining status would be to require a responsible company or government pay officer certification, i.e., paid vacation, leave without pay, self-employed, etc. It would seem that an individual in a lost wage situation

would require more than an individual with a paid leave condition. An unemployed individual would receive the same pay as an individual in a paid vacation status. Election of this methodology would again require the General Counsel and the Comptroller to write appropriate language. The legality of active duty personnel participating in a paid leave status would require exploration by the General Counsel. A second alternative for active duty personnel would be to designate the study a human use experiment and to pay accordingly. A possible method which would combine indemnification and incentive pay is the use of a contract with each individual. In addition to the above described inducements for participation, there is at least one other method that can be used. That is to develop a letter of introduction for the study which enhances the esteem of the individual and appeals to his patriotism, the most optimal signature on the letter being the President. To develop such a letter of introduction would require the support and active participation of the White House Domestic Policy Staff. A second letter would be required which provides essential information regarding risks and benefits, compensation, medical findings disclosure, time commitment and location of examination. The second letter would serve as the basis for obtaining the informed consent of the participants.

Given the above discussion, the following questions need to be answered:

1. Can confidentiality of study results be given to participants, given the issue of public safety?

2. How can occupational indemnification be provided to participants, given that the study is in the national interest?

3. How can a stipend (special payment to study participants) be paid to participants, particularly Federal/civil servants and active duty military personnel?

4. Can a contract be used to obtain the informed consent of each participant while providing for compensation and indemnification?