DoD Human Radiation Experiment Command Center

Comments Prepared by the Armed Forces Radiobiology Research Institute (AFRRI) 24 January 1994

As described in the draft (18 January 1994 text) testimony for Dr. Smith to the Committee on Government Affairs, there are two basic assignments to the Command Center. The first, involving the role of the Center as the collection point/clearinghouse for information, involves three sub-tasks: receive, catalog, and review the incoming information. The second assignment is to collect and review the policies and procedures that DoD has established in regard to human experimentation. The comments below are organized around these assignment/sub-task areas.

As of now, the scope of the collection of information remains quite broad. Until it is narrowed, we have assumed that any research involving ionizing radiation and humans will be included. This assumption has led us to include epidemiology studies of exposed populations and studies involving exposure of tissue samples of human origin. It is hoped that these types of studies could be eliminated from consideration at the earliest possible opportunity.

Collection/Clearinghouse

Receipt

1. There are two sources of information that will be coming to the Center. The first will be via the DoD "hotline", the second will be via each of the Services or other DoD elements.

   A. Hotline. The experience of both the NTPR program and DOE will be helpful in establishing procedures and policies for this function. The components of this phase should include the creation of a questionnaire to prompt the interviewer to get basic information such as: name, address and phone number of caller; identification of the individual involved in the experiment; a brief outline of the nature of the experiment or circumstances of the exposure including the locations of the events and names of other participants or persons directing the studies; and other relevant information such as health effects that the caller attributes to the studies. Each caller should be told what to expect (e.g., follow-up phone call or written correspondence). Discussion of the significance of the information in this initial phone call is not appropriate. The caller should be thanked for the proffered information.

B. Service-supplied information. We assume this information is already being collected by the Services. Contacts should be made with each of the services to establish appropriate liaisons with committees/individuals collecting this information. These contacts will be useful in ensuring that the scope of the effort is consistent throughout DoD and in establishing a consistent reporting format. On a periodic basis, the Services should be expected to report the status of the effort to the Center. We recommend that source material for all of the following be included:

Research protocols
Documentation of participants, scientists
Documentation of scientific reviews/oversight activities
Documentation of ethical review/oversight
Documentation of information supplied to participants--consent forms/study information
Logbooks/laboratory records
Health records of participating individuals
Death certificates/tumor registry information
Dosimetry records/assessments

Cataloging Function

Records for specific experiments or exposure scenarios should be grouped together. These groupings could then be organized in several ways. One possibility is to classify these by the intended purpose: clinical research (i.e., the study was conducted to develop new diagnostic or therapeutic approaches involving the use of radiation sources) or radiobiology (i.e., the study was conducted to understand the effects of the source of the radiation on humans). The clinical studies could be further classified by whether or not the sources of radiation were simply tools to monitor the biomedical status of the subject (e.g., a periodic chest X-ray to evaluate the efficacy of a treatment for tuberculosis).

A second approach is to organize the information by the type of study: human external exposure; human internal exposure (i.e., involving intake of radioactivity); human tissue studies (i.e., studies involving irradiation of tissues such as blood samples, after they have been removed from the subject/patient); retrospective studies such as epidemiology studies of exposed populations; and studies in which the exposure was entirely incidental to the objective of the study (i.e., radiation was used only as a tool to elucidate relevant biomedical parameters).

Review/Analysis Function

Review of the collected material is the area of greatest challenge. The Services will have already conducted a review of submitted material and will be a major help in this area. The objectives of these reviews will be to establish the following information:

1. Is the material within the scope of the DoD effort?
2. Did the study meet contemporaneous scientific standards (adequacy of controls, procedures, analysis of data, conclusions)?
3. Did the study meet contemporaneous ethical standards?
4. Is there sufficient information available to make an evaluation of a credible causal relationship between the study and health status or cause of death for the individuals involved?
5. Was there a benefit to the participant?
6. Was there a good reason to do the experiment?
7. What effort was made by the research team to assess the risk to participants?
8. What precautions were taken to minimize risks to participants? Were these reasonable in view of what was known at the time?
9. What health care or other follow-up activities were planned? What follow-up occurred?
10. Based on information provided, what additional detective work is required?
11. What is the best assessment of the harm to the participants that is attributable to the research study?

DoD Policy and Procedures Review

The Center should collect information from the Services or DoD laboratories regarding the nature of current policies in this area, procedures that are followed to carry out these policies, and mechanisms for evaluating the effectiveness of these policies and procedures.

Other Issues

DoD Working Group The relationship of the Command Center and the DoD Working Group remains unclear. We would suggest that the Center Commander should report directly to Dr. Smith. The Working Group should be largely responsible for liaison with the Interagency Task Group and for the formulation of DoD policy on this matter. The Center Commander should be a member of this group and should be the conduit of information to it.

Public Affairs Public Affairs issues need to addressed. We would recommend that the Command Center should be given this function as well.

Close-out Report The Command Center should be assigned the task of preparing final reports to Congress outlining lessons learned and providing recommendations based upon their findings.

Command Center Organization The draft organization chart and planned staffing levels seem reasonable to accomplish the tasks as we see them with one exception. It would be advisable to either create a branch for "Analysis" or augment the "Data Review" group. The bulk of the effort we described in the Review Section above would be done by this group.

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AFRRI Role

AFRRI can provide any assistance you require in this endeavor. Perhaps the most likely role for us would be to work closely with Dr. Auton's group to complement their expertise on NTPR matters. We would be able provide additional technical assistance throughout the project. Specific areas that come to mind include: scientific review/evaluation of incoming data, preparation of press releases related to technical matters, on-the-spot technical advice, preparation of risk assessment analyses, dose assessments based on records, dose assessments based on tissue analyses (if necessary), and independent audits of activities of the Center.