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UNSOLICITED PROPOSAL SUBMITTED

TO THE DEPARTMENT OF ENERGY

BY

NATIONAL MARROW DONOR PROGRAM

3433 BROADWAY STREET N.E., SUITE 400

MINNEAPOLIS, MN 55413

PROPOSED DURATION: 24 MONTHS

AMOUNT REQUESTED: __________

REQUESTED STARTING DATE:

TYPE OF BUSINESS: NONPROFIT

PRINCIPAL INVESTIGATOR: CRAIG HOWE, M.D., Ph.D.

PHONE: 612-627-5800

DATE OF SUBMISSION:

THIS PROPOSAL MAY BE SUBJECTED TO EXTERNAL REVIEW

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[Signature of Principal Investigator]

Draft for discussion only

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A PROPOSAL TO THE DEPARTMENT OF ENERGY

FOR FUNDING OF

INTERNATIONAL COLLABORATIVE STUDIES ON THE

HEALTH EFFECTS OF THE CHERNOBYL ACCIDENT

September 4, 1992

SUBMITTED BY:

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A PROPOSAL TO THE DEPARTMENT OF ENERGY

FOR FUNDING OF

INTERNATIONAL COLLABORATIVE STUDIES ON THE

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Proposed Activities of

The Methodist Hospital/Baylor College of Medicine

International Consortium for Research and Treatment of Radiation-Induced Injury

Specific Aims

The underlying philsophy of the proposed studies is based on three propositions. First, the effects of Chernobyl will continue to be seen for the next generation. Second, despite the rapid reduction of tensions related to nuclear war, the reality of U.S. and worldwide dependence on nuclear energy make the reality of future accidents like Chernobyl a high priority concern to the medical community. And third, as a recent emigre from the Ukraine has commented in consulting with our project staff, "radiation effects the whole body, not just the blood."

With this in mind, the broad purpose of the proposed research at The Methodist Hospital/Baylor College of Medicine will be to conduct a set of seven pilot/feasibility studies touching on various disease sites as well as psychosocial sequelae to radiation exposure following the Chernobyl accident. The studies are designed to complement the work of other consortium members. Rather than repeat the classic dosimetry studies proposed for Russia and Israel, a preliminary project will be to begin establishing a U.S. based registry of Chernobyl victims and to gradually phase in the other projects using human measures and biomarkers such as biologic dosimetry.

Background

As part of the Consortium for Research and Treatment of Radiation-Induced Injury, The Methodist Hospital and Baylor College of Medicine bring the combined resources of (1) the largest, not-for-profit, teaching/research and acute care hospitals in the United States and (2) the only private medical school in the State of Texas. Together, the two institutions have joined resources to address many specific research challenges e.g., Cardiovascular Disease, Cancer, Organ and Bone Marrow Transplantation, Cancer, Women's Health . Many of these center grants from e.g., the National Heart Lung and Blood Institue of the National Institutes of Health, was to establish a multi-disciplinary center for heart and blood vessel disease research (the first in the United States) and the first center to, by design create an integrated, program of basic and clinical research, education and demonstration projects.

With The Methodist Hospital as its primnary teaching hospital, Baylor College of Medicine has more than 40 specialty research centers, including centers for Cancer Control Research, Experimental Therapeutics, Gene Therapy, Reproductive Biology, Child Health and Nutrition, Diabetes & Endocrinology, the Human Genome Project and Human Genetics, Developmental Pediatrics, Multi-Organ Transplantation, and Child Health, plus affiliations with 17 other medical instituions and two universities in Houston.

The Methodist Hospital has developed international clinical and training affiliations with hospitals around the world. TMH//BCM bring to the Consortium a world renowned faculty and medical staff with an established commitment to international health care. Facilitated by the activities of the Texas Hadassah Medical Research Foundation, both The Methodist Hospital and Baylor College of Medicine have developed formal ties with the Hadassah Medical Organization, where some work with Chernobyl victims has already begun. In that context, Dr. Shmuel Penchas, Director General of the Hadassah Medical Organization, visited Houston twice during the past year, and ties have been established with organizations involved in resettlement in this country of immigrants from areas affected by Chernobyl. Specific to the proposed research, emigres from the former Soviet Union are on the faculty and will serve as consultants to the proposed projects.

Research Plan and Methods

Figure ___ shows the organizational chart for the propsed research site at TMH/BCM. Armin D. Weinberg, Ph.D., will serve as the Site Director and Principal Investigator and Phillip McCarthy, M.D., will serve as Co-

Principal Investigator. Dr. Weinberg will serve as the representative on the Consortium Steering Committee. In his role as Director of the Center for Cancer Control Research at TMH/BCM, Dr. Weinberg has had ongoing working relations with all the investigators. He is also a trustee of the Texas Hadassah Medical Research Foundation, in which role he co-signed the original letter of agreement to support the collaboration between Russia, Israel and the Unisted States. Dr. McCarthy is head of the Transplant Center at The Methodist Hospital. The principal investigators of the proposed projects will serve together as a research committee to coordinate activities among the studies.

Figure ___

The Methodist Hospital/Baylor College of Medicine

Chernobyl Consortium Research Site - Organization Chart

Site Directors

A.D. Weinberg, Ph.D.

P.L. McCarthy, M.D. Co-principal Investigator

Scientific Advisory Board Research Committee

W.J. Schull, M.D. E. Adam, M.D.

M. Nichaman, M.D. R. Arem, M.D.

A.M. Gotto, Jr., M.D. L.D. Cooley, M.D.

M.E. DeBakey, M.D. A. Ertan, M. D.

P.L. McCarthy, M.D.

Consulting Investigators A. I. Schafer, M.D.

W.J. Schull, M.D. G. Trey, M.P.H., M.D.

M. Nichaman, M.D. A.D. Weinberg, Ph.D.

G. Yoffe, M.D.

E.M. Vaintrub, M.D.

The Scientific Advisory Board will provide broad direction for the research as it evolves. The Board will be chaired by William J. Schull, M.D.. He is a population geneticist at the University of Texas School of Public Health and has over 40 years experience working with radiation sequelae in Hiroshima. Milton Nichaman, M.D., is an epidemiologist, also at the University of Texas School of Public Health. He has extensive experience working with the health care system in Israel. Antonio M. Gotto, Jr., M.D., is Chairman of the Department of Medicine at TMH/BCM, and is internationally known as an expert on lipid disorders. Michael E. DeBakey, M.D., is Chairman of the Department of Surgery at TMH/BCM, and is also internationally known for his pioneering work in cardiac surgery.

Working in a more ongoing fashion with the investigators a group of Consulting Investigators. Drs. Schull and Nichaman will also serve on this group. Additional consultation will be provided by Galina Yoffe, M.D., a pediatric hematologist/oncologist and native of the former U.S.S.R. who spent many years in Israel prior to coming to Houston. Elizabet M. Vaintraub, M.D., a pediatrician, will also serve as a consultant. She has immigrated within the past year from Kiev, Ukraine, and has personal knowledge of the Chernobyl accident and its after affects in the contaminated areas. Dr. Vaintraub was with the Ukrainian Ministry of Health and directed their efforts to assess the impact of Chernobyl on the children remaining in the region. Her first hand knowledge of the accident and what followed coupled with her personal relationship with many of the scientist in the former Soviet Union will certainly be an asset as we participate in the consortium's effort to establish a Bryansk research site. Dr. Vaintraub also has indicated a willingness to assist in efforts to bring the Ukraine and Byelorussia into the research efforts spawned by the agreement.

The Research Committee will be composed of the principal investigators of the various TMH/BCM studies. They will meet regularly to coordinate activities among the projects.

Proposals for the pilot research studies are found at the end of this section. The studies and investigators are as follows:

1. U.S. National Chernobyl Registry Coordinating Center (E. Adam, M.D., and A.D. Weinberg, Ph.D.)

2. A Comparative Study of Mental Health Status, Health Beliefs, and Health/Risk Behaviors Among Immigrants from the Area of Chernobyl (A.D. Weinberg, Ph.D.; L. Laufman, Ed.D.; J. Cousins, Ph.D; A. Siegel, Ph.D.)

3. Proposals for Cytogenetic Research (3.1-3.5) (L.D. Cooley, M.D.; P.L. McCarthy, M.D.; A.I. Schafer, M.D.)

4. Proposal to Study Isolated Hematopoietic Stem Cell Populations (P.L. McCarthy, M.D.)

5. Radiation Injury to Vascular Endothelium (A.I. Schafer, M.D.)

6. Epidemiology and Management of Thyroid and Parathyroid Neoplasia and Other Endocrine Abnormalities in Radiation-Exposed Populations (R. Arem, M.D.)

7. Late Radiation Injury of the GI Tract (G. Trey, M.P.H., M.D.; A. Ertan, M.D.)

As a context to the proposed pilot studies, there are several major issues facing the proposed consortion for studying the radiation effects of the Chernobyl accident:

It is important to determine the feasibility of collecting data on the number of people in the Chernobyl region and to quantitate the amount of radiation exposure to dosimetry studies. At TMH/BCM, our concern is that there is no consistently good, reliable biologic or physiologic means of measuring radiation exposure, especially this long after the original event, as noted by Dr. Schull in early conversations. While we agree that it is most important for dosimetry levels to be obtained, reconstruction of the actual dose each person has been exposed to will probably be impossible. Thus the need for historical data and reconstruction of group dose and individual dose must be evaluated.

Given these concerns, we feel that several pilot studies should proceed. The importance of initiating these can provide useful information. For instance, the first two projects regarding a U.S. National Chernobyl Registry and a comparative study of mental health status and health beliefs can be done without dosimetry readings. Indeed, establishment of a registry to locate the potential victims is a necessary first step before the other studies can proceed.

For the cytogenetic proposal (#3), dosimetry studies would be helpful to give us a better idea of who best to screen. However, cytogenetics themselves can be used as a measure of somatic cell mutation and can sometimes be the only means of determining dose rate, depending on the number of people sampled from a particular area.

Proposal #4, to study isolated hematopoietic stem cell populations could be done at all three research sites, in Russia, Israel, and the United States. Our original thinking targeted Briansk so that a leukopheresis machine would be part of the proposal and would be given to the Russians as part of the project for clinical use. We would still use the machine for isolating white blood cells for stem cell isolation and study. This again could be done in any of three research sites. It does not depend on the presence of a registry in that it is also a feasibility study to see how cost-effective this would be.

Proposal #5, to study radiation injury to vascular endothelium, can also be done in all three sites, and again does not require a database for it to take place in that a large number of studies proposed are in vitro work.

For Proposal #6, on thyroid and parathyroid neoplasia, dosimetry obviously would be important, but again this proposal can be done without dosimetry readings. Somatic cell mutation such as thyroid endocrine abnormalities could be done if you were able to screen a large enough population of people and in itself, thyroid abnormality can be a measure of radiation exposure. In fact, it may be as good as any soil sampling or water analysis in that the thyroid is readily accessible.

Proposal #7 is to study late radiation injury of the GI tract and can also be done within the context of a large number of patients. It would not be necessary to have doses of radiation if there is available a good geographic listing of where these patients came from.

On the whole, these studies are the first step in being able to understand the feasibility of whether or not biologic dosimetry would provide an alternative means to actual radiation dosimetry where dose reconstruction takes place on the basis of environmental sampling. Now that the Chernobyl explosion has taken place over six years ago, any physical reconstruction would be most difficult. A significant issue and important concern would be localizing people to a geographic location and trying to reconstruct radiation exposure on the basis of the data that have already been collected within the former Soviet Union. We can then begin comparisons to somatic cell mutation through biologic studies. That is the whole purpose of this type of endeavor and these studies may provide accurate dosimetry readings if any endocrine, GI, hematologic, cytogenetic or endothelial cell abnormalities have occurred, and are able to be quantitated.

A tentative time line for phasing in the projects is found on Exhibit "C".

Background

On April 26, 1986, the Chernobyl nuclear power plant became the site of the world's worst nuclear reactor disaster. The force of the explosion emitted radiation over a broad area of the Northern Hemisphere, with a disporportionate share of fallout centered on the western half of the Soviet Union. Estimates of the affected population included the initial exposure of several million persons to abnormally high doses of radiation. Many were later determined to have been exposed to dangerously high levels of radiation contamination. Among this population, the prevalence of leukemia, thyroid cancer, and other radiation-related illnesses is expected to rise, particularly among the exposed children. The scientific, medical, and social ramifications of the Chernobyl disaster extend far beyond the exposed population, demanding worldwide attention to a unique, albeit potentially recurring, phenomenon.

In an initial attempt to address the needs of a segment of the affected population, "Children of Chernobyl" was begun in August, 1991, under the auspices of the Hadassah Medical Organization of Israel (HMO) and Lubavitch. The program intends to facilitate the transfer of children to Israel from the Chernobyl-affected regions and to provide appropriate medical evaluations, monitoring, and treatment for the children. Though an ambitious and praiseworthy endeavor, "Children of Chernobyl" lacks the resources necessary to provide an exhaustive remedy to the affected populations. Over 100,000 exposed persons have immigrated to Israel since 1989, with children comprising 20% of this population. The subpopulation which comprises the benficiaries of the program excludes many more Russian citizens, both children and adults, who remain at risk for medical complications and, as yet, untreated.

It is in the spirit of international cooperation and collaboration in the exercise of a humanitarian and scientifically-promising endeavor that the various groups represented in this consortium have agreed to participate.

Consortium Parties

The impetus for the cooperative effort was provided by Dr. Armin Weinberg of the Texas Hadassah Medical Research Foundation (THMRF) and The Methodist Hospital (TMH), Houston, TX. In view of the wealth of scientific and medical information to be extracted for the benefit of the affected populations and potential future victims of a related nuclear disaster, Dr. Weinberg entered into agreement with the Hadassah Medical Organization (HMO) of Israel to perform mutual research programs, exchange staff members, and create a registry of the Chernobyl victims. With the rapid immigration of former Soviet Jews from Chernobyl-affected regions to the Houston area since 1986, numbering at present over 200 families, the opportunity to investigate the problems both in the United States and abroad presented itself. Clearly, there exists a compelling need to address the social and physical manifestations of this new and ever-increasing population.

The relationship of the Fred Hutchinson Cancer Research Center (FHCRC) with the Chernobyl incident is inveterately rooted. Beginning with the treatment of Russian pilots exposed to the nucelar fallout, FHCRC had dispatched a team of scientific investigators to the former Soviet Union to aid local efforts. Plans to establish a collaborative exchange effort between FHCRC and the All-Union Scientific Center for Hematology in Moscow were interrupted by geopolitical changes in the former Soviet states. Thus the groundwork laid by FHCRC in the former Soviet Union nd the world-renown status of the Center in both the exercise of cancer research and the delivery of medical care to cancer patients make their involvement in this agreement of benefit to all.

The National Marrow Donor Foundation (NMDP) brings to this forum experience in the coordination of collaborative efforts and the centralized direction necessary for the project. NMDP possesses unparalleled data management and unrelated donor tracking capabilities. With the additional capacity to create and monitor an international cell repository, NMDP will serve as the planning and integrative component of the project.

One of the largest funding bodies in the area of transplantation, the C.W. "Bill" Young Marrow Donor and Research Center (U.S. Navy) also has a vested interest in the collaborative effort. Their interest in the prevention and treatment of radiation-induced injuries stems from the exposure of a significant portion of their employees

to such potentially hazardous materials. The U.S. Navy thus provides the forum with financial backing, clinical guidance, and practical considerations.

The National Heart, Lung, and Blood Institute (NHLBI), in addition to being a major financial backer of the NMDP, is interested in the hematological aspects of this research endeavor.

Justification

The central objectives of the joint research program are twofold: (1) to facilitate the free and open exchange of data, including the long-term tracking of radiation exposure in the affected cohorts and (2) to foster research among and between scientists in the United States, Israel, and Russia, including the establishment of a research center near Chernobyl staffed by an ongoing exchange of scientists.

Both of these objectives are in concert with the interest on the Department of Energy (DOE). The Working Group 7.2 policy guidelines on the health effects of the Chernobyl incident are consistent with our efforts. This international endeavor will complement the ongoing research efforts sponsored by DOE in several ways: (1) the proposed biological and physical dosimetry projects will expand both the research cohorts and the scientific personnel and data exchanges currently underway; (2) the proposed involvement of the NMDP in donor registries and data management will vastly expand the current efforts of John's Hopkins School of Public Health and create a U.S.-based registry and unrelated donor matching program; (3) the project will create the first multi-national collaborative research efforts to address and monitor the long-term health effects of the Chernobyl accident; (4) the project will effect an opportunity for the worldwide standardization of protocols, measures, approaches, and scientific review that will portend greater opportunities for cooperative research in the developing global economy; and (5) the U.S. has a worldwide responsibility to engender humanitarian efforts that is bolstered by the ever-increasing U.S. population of former Soviet citizens from affected regions.

The information gleaned from this effort will also aid DOE's Department of International Affairs and Energy Emergencies ongoing efforts "to coordinate cooperative international energy programs with foreign governments and international organizations." Similarly, the Environment, Safety, and Health Department will be aided in its efforts to provide epidemiological expertise relating to occupational and community health.

Most significantly, this proposal offers the DOE the opportunity to be the lead organization in developing and fostering international agreements between various scientific and medical groups that are striving for mutually-beneficial goals. This agreement will emphasize the ability of such groups to coordinate often disparate responsibilities during a time of intense fragmentation both within the former Soviet Union and among the various scientific organizations within the United States. The standardization of protocols and measures will not only serve the interest of this project, but will also lay the foundation for future cooperative endeavors between global agents. An additional opportunity for coordination and long-term followup is provided by the careful tracking of the affected cohorts in Israel, Russia, and the U.S. The infrastructure of the Jewish communities in these countries is sufficiently coordinated to facilitate the monitoring of the participants.

A Comparative Study of Mental Health Status, Health Beliefs, and Health/Risk Behaviors Among Soviet Immigrants from the Area of Chernobyl

Armin D. Weinberg, Ph.D.; Larry Laufman, Ed.D.; Jennifer Cousins, Ph.D.; Alexander Siegel, Ph.D.

Specific Aims

The purpose of this project will be to assess the health beliefs and participation in health/risk behaviors among Jewish immigrants from areas affected by the Chernobyl nuclear accident. The basic research question is whether Jewish immigrants from Chernobyl and non-Chernobyl areas have different health/risk concerns and "worldviews," and if so, to what degree do such differences contribute to different health/risk behaviors. Health/risk behaviors of interest will include smoking, substance abuse, alcohol consumption, as well as preventive health behaviors such as exercise, diet, screening/well-patient medical exams.

Background and Significance.

Reported response to the Chernobyl experience has been variable. For instance, in Sweden, anxiety about radiation risk was increased, with people in more exposed areas being predictably more concerned that those farther away (Sjoberg and Drottz, 1987). In America, news of Chernobyl was reflected in increased nuclear anxiety among college students, at least in the near aftermath of the accident (Newcomb, 1989). However, in another study, concern about cancer and genetic effects actually decreased one month later (Lindell and Perry, 1990). After the accident, the rate of legal abortions increased in Denmark (Knudsen, 1991) and Sweden (Odlind and Ericson, 1991). In Sweden, the rate seems to have been part of an ongoing trend not related to Chernobyl. In the Danish study, the researchers speculate that, given the comparatively small increase in radiation, the abortions may actually have resulted in more fetal deaths than the nuclear accident itself would have. In Finland, there seemed to be no difference in rates for abortion, stillbirths, preterm births, or congenital malformations (Harjulehto, et al., 1991).

The literature on psychooncology suggests that cancerophobic reactions can range from delusional and factitious symptoms, to delay in seeking examination of real symptoms, to an extreme of suicide (Chatton, et al., 1990; Holland, 1989; Levi, et al., 1991; Storm, et al., 1992). It is not clear what the effect of an uncontrollable experience like Chernobyl would be on health locus of control, on future preventive health behaviors, or on risk-taking behaviors.

Preliminary Studies

No studies have addressed the larger psychological context of health beliefs and behaviors in general among those affected by the Chernobyl accident. Some Russian studies have looked at the immediate psychological effects of the Chernobyl disaster on its survivors (Aleksandrovskii, et al., 1991; Revenok, 1991). Katz, et al. (1991), have examined psychological distress among immigrants to Israel from the Chernobyl area. They have noted not only the normal stress of recent immigration but also increased fears of radiation, cancer, and future birth defects. Behaviorally, adolescents often participate in risk-taking activities (e.g., smoking, drinking, driving fast, or not using seat belts) as part of their normal developmental activities (Baumrind, 1987; Jessor, 1984; Shedler and Block, 1990). The present investigators have studied family patterns of disease (Iammarino and Weinberg, 1987) as well as risk taking behavior (Siegel, Parsons, and Weinberg, 1991). Their findings, in support of the larger health literature, shows that children and adolescents' health and health/risk behaviors take place in a constellation of adult health beliefs and behaviors which form part of the family context.

Research Design and Methods

Hypotheses. Specific hypotheses to be tested are that, compared with Jewish immigrants from non-Chernobyl areas, those from areas exposed to Chernobyl radiation will have a more external and/or fatalistic health locus of control, perceive themselves to be more at risk, participate more in health/screening behaviors, and participate more in risk behaviors such as smoking, alcohol consumption, etc.

Sample. In Houston, Texas, the Soviet Jewish Resettlement Office of the Jewish Family Service estimates that there are about 300 Soviet Jewish families that have immigrated thus far to Houston. Families from both Chernobyl and non-Chernobyl areas will be interviewed as comparison groups so that differences associated with immigrant status may be distinguished from those that may be associated with the Chernobyl experience. For purposes of analysis, subjects will be broken into age cohorts. For instance, in 1986 at the time of the accident, there were groups of adults, 15-19 year-olds who are now young adults, 8-10 year-olds who are now adolescents, and new-borns who are now 6-8 year-olds.

Measures. Specific measures will include a Health Locus of Control Questionnaire, the Rand Health Insurance Study Batteries (Physical Health, Mental Health, Social Health, General Health Perceptions (Bowling, 1991), the Risk Involvement and Perception Questionnaire (Cousins et al., 1992). For young children, we will use the Achenbach Child Behavior Check List (mother administered). Adolescents and young adults will be administered the Jesness Personality Inventory and the Youth Self-Report Checklist. Additional measures of peer and family relations will be reviewed during Phase 1 of the study. When possible, both parents will be recruited in addition to the children in order to form a family context for health/risk beliefs and behaviors. For young children, the interviewer will use a structured play protocol to elicit health concerns. Questionnaire administration and interviews will be conducted in the subjects' homes by bilingual interviewers.

Two individuals in particular will be of considerable help to project activities. Dr. Siegel, one of the co-principal investigators, is currently supervising Ms. Rita Shapiro, a Russian born graduate student in psychology at the University of Houston. Ms. Shapiro has been in the United States for over ten years, is fluent in both English and Russian, and can serve as an excellent liason with the participating subjects. Dr. E. Vaintrub, one of the consultants to the TMH/BCM research team, has also recently immigrated from the Ukraine and will work closely with the project.

The project will progress in three phases over 24 months:

Phase 1 -- 4 months.

Project staff will consult with Israeli and Russian researchers who have already developed base questionnaires for use with subjects from the Chernobyl areas. Where appropriate, standardized or at least overlapping protocols with common questions will be developed. During this period, questionnaires will be translated into Russian and bilingual interviewers will be recruited and trained. Contacts will be made through the Jewish Family Service, the local Jewish Federation, fraternal organizations such as B'nai B'rith and Hadassah, etc., to locate and make contact with Soviet Jews in Houston, Texas. It is anticipated that subject recruitment will proceed in tandem with activities of the Chernobyl Registry activities.

Phase 2 -- 4 months.

Pilot test and revise the questionnaires and interview protocols with a sample of ten Soviet Jewish families in Houston.

Phase 3 -- 16 months.

Data collection targeting all Soviet Jewish families in Houston.

Data analysis will be ongoing throughout this phase.

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Budget

	Year 1	Year 2
Personnel		
Project Investigators	15,000	15,600
Interviews @ $100		
Year 1 - 75	7,500	
Year 2 - 225		22,500
Data Entry $20,000 X 50%	10,000	10,000
Secretary $25,000 X 25%	6,250	6,250
Supplies		
Printing	1,000	1,000
Office supplies @ $100/month	1,200	1,200
Telephone @ $500/month	6,000	6,000
300 audiotapes @ $3	600	
Equipment		
4 tape recorders @ $75	300	
4 laptop computers @ 1,500	6,000	
1 personal computer @ 2,000	2,000	
Total	55,850	62,550
Grand Total		118,400

U.S. National Chernobyl Registry Coordinating Center

Ervin Adam, M.D.; Armin D. Weinberg, Ph.D.; Kay Dunn, Ph.D.; Milton Nichaman, M.D. (Research Site Consultant)

Specific Aims

This pilot study is a first phase in a longer term project, the goal of which is to create a national coordinating center for a registry of Jewish immigrants to the United States from areas affected by the Chernobyl nuclear accident. The major purpose of the project is to (a) create a registry of all such Jewish immigrants in the State of Texas and (b) establish contacts in the other Jewish population centers around North America where Chernobyl victims have resettled. The specific aims of this pilot project are to (a) identify the targeted immigrants around the State of Texas, (b) recruit them as subjects for Consortium research studies, and (c) collect baseline medical history data and clinical measures with a sample of Jewish immigrants in Houston, Texas, so as to establish a foundation for tracking the patients in the future. Having done so, the registry would then be able to serve as a source of subjects for the Consortium investigators. This would lay the logistical groundwork for the next phase of creating a national registry, should it be justified.

Background and Significance

In the context of Chernobyl research, there are two important reasons for focusing on Jewish immigrants from the affected areas:

1. Scientific Comparison. Jewish emigrants from the former USSR constitute three easily identified subpopulations which will allow comparison of both (a) long vs. short term radiation exposure and (b) psychosocial and medical experiences in three very different health care systems.

2. Sampling and Tracking. (a) In the former republics of the USSR there still remain 1,640,600 Jews, of whom 1,360,000 (83%) reside in Russia, Ukraine, and Byelorussia. The National Conference for Soviet Jewry has maintained ties with the Jewish communities in these regions, even during the considerable political changes since Chernobyl. (b) Israel has received over 400,000 Soviet Jews, of whom approximately 100,000 (25%) are from areas affected by Chernobyl. These immigrants participate in the Israeli national health care system, and physicians from Hadassah Medical Organization have already begun to treat them. (c) Since 1986, the U.S. has received over 157,000 former Soviet Jews as documented refugees (Emigration to the United States major population centers with existing jewish population eg, New York, Boston, Chicago, Cleveland, St. Louis, Houston, Dallas, Los Angeles, San Francisco.). In addition to these refugees, there are a yet to be determined number of Soviet Jewish immigrants who have also settled in the United States as a part of project "Exodus". Assuming a similar proportion to that in Israel, this would mean about 40,000 from Chernobyl areas. The Hebrew Immigrant Aid Society (HIAS) has been instrumental in helping to resettle these refugees and immigrants. In Houston and other Texas cities, the resettlement process is continued through the Jewish Family Service and local Jewish philanthropies. This often includes matching immigrant with American families, allowing an additional level of contact with the targeted population.

The present project is designed as a pilot/feasibility study both to collect baseline data and to address certain problems that must be overcome in order to establish a national registry in the future. In its inception, the proposed registry is in some ways more analogous to a census bureau than a registry in that we will not wait for patients to come in with illnesses in order to register them. This raises the difficulty of (a) identifying subjects, (b) locating them, and (c) convincing them to participate. In addition, given the political conditions and turmoil in the immigrants' republics of origin, it is not clear whether and to what degree they will want to be identified and tracked, albeit for scientific and medical rather than political purposes.

For these reasons, the project will utilize as liaisons existing local Jewish organizations with which the immigrants will have become familiar and which they trust, e.g., Jewish Family Service, HIAS, etc. Furthermore, by focusing on family clusters, we can use family contacts to reach other Jewish immigrants who

may not have resettled through the Jewish aid organizations, who may have moved since resettlement, or who may have emigrated to other countries. Finally, we will utilize bilingual Russian immigrants to conduct the data gathering interviews rather than depend on only mailed questionnaires.

Preliminary Studies

PROJECT 1

U.S. NATIONAL CHERNOBYL REGISTRY COORDINATING CENTER

Ervin Adam, M.D.

Armin D. Weinberg, Ph.D.

Kay Dunn, Ph.D.

Milton Nichaman, M.D. (Research Site Consultant)

SPECIFIC AIMS

Complementing international registry activities in Israel and Russia, this pilot study is a first phase in a longer term project to create a national coordinating center for a registry of Jewish immigrants to the United States from areas affected by the Chernobyl nuclear accident. The major purpose of the project is to (a) create a registry of all such Jewish immigrants in the State of Texas and (b) establish contacts in the other Jewish population centers around North America where Chernobyl victims have resettled.

The specific aims of this pilot project are to (a) identify the targeted immigrants around the State of Texas, (b) recruit them as subjects for Consortium research studies, and (c) collect baseline medical history data and clinical measures with a sample of Jewish immigrants in Houston, Texas, so as to establish a foundation for tracking the patients in the future. Having done so, the registry would then be able to serve as a source of subjects for the Consortium investigators. This would lay the logistical groundwork for the next phase of creating a national registry, should it be justified.

BACKGROUND AND SIGNIFICANCE:

Although a national registry of Chernobyl victims is the longterm goal of this project, there are considerable logistical problems to overcome prior to such an endeavor. Consequently, a preferable alternative is to "begin in a well-defined area where complete coverage at a reasonable cost is feasible." The essential steps are to (1) identify the potential subjects, (2) contact and recruit them to participate in the study, and (3) interview them to document historical medical and exposure history and collect clinical data.

In the context of Chernobyl research, there are two important reasons for focusing on Jewish immigrants from the affected areas:

1. Scientific Comparison. Jewish emigrants from the former USSR constitute three easily identified subpopulations which will allow comparison of both (a) long vs. short term radiation exposure and (b) psychosocial and medical experiences in three very different health care systems.

2. Sampling and Tracking. (a) In the former republics of the USSR there still remain 1,640,600 Jews, of whom 1,360,000 (83%) reside in Russia, Ukraine, and Byelorussia. The National Conference for Soviet Jewry has maintained ties with the Jewish communities in these regions, even during the considerable political changes since Chernobyl. (b) Israel has received over 400,000 Soviet Jews, of whom approximately 100,000 (25%) are from areas affected by Chernobyl. These immigrants participate in the Israeli national health care system, and physicians from Hadassah Medical Organization have already begun to treat them. (c) Since 1986, the U.S. has received over 157,000 former Soviet Jews as documented refugees. For the most part, they have settled in major population centers with existing Jewish population (e.g., New York, Boston, Chicago, Cleveland, St. Louis, Los Angeles, San Francisco, Houston, Dallas). In addition to these refugees, there are a yet to be determined number of Soviet Jewish immigrants who have also settled in the United States as a part of project "Exodus".

Assuming a similar proportion to that in Israel, this would mean about 40,000 from Chernobyl areas. The Hebrew Immigrant Aid Society (HIAS) has been instrumental in helping to resettle these refugees and

immigrants. In Houston and other Texas cities, the resettlement process is continued through the Jewish Family Service and local Jewish philanthropies. This often includes matching immigrant with American families, allowing an additional level of contact with the targeted population.

The present project is designed as a pilot/feasibility study both to collect baseline data and to address certain problems that must be overcome in order to establish a national registry in the future. In its inception, the proposed registry is in some ways more analogous to a census bureau than a registry in that we will not wait for patients to come in with illnesses in order to register them. This raises the difficulty of (a) identifying subjects, (b) locating them, and (c) convincing them to participate. In addition, given the political conditions and turmoil in the immigrants' republics of origin, it is not clear whether and to what degree they will want to be identified and tracked, albeit for scientific and medical rather than political purposes.

For these reasons, the project will utilize as liaisons existing local Jewish organizations with which the immigrants will have become familiar and which they trust, e.g., Jewish Family Service, HIAS, etc. Furthermore, by focusing on family clusters, we can use family contacts to reach other Jewish immigrants who may not have resettled through the Jewish aid organizations, who may have moved since resettlement, or who may have emigrated to other countries. Finally, we will utilize bilingual Russian immigrants to conduct the data gathering interviews rather than depend only on mailed questionnaires.

Pertinent Experiences

The staff of the Center for Cancer Control Research have extensive experience in patient tracking. From 1982-1987, the staff were involved in a Multiple Community Study family health education project which was funded by the National Heart, Lung, and Blood Institute. The project involved family history/health risk analysis for 5,000 families in three communities in Texas, complemented by a statewide effort in Utah. In 1988, the staff coordinated and provided computer support for a city-wide cholesterol screening effort by The Methodist Hospital and a consortium of other health care institutions in Houston. Almost 35,000 Houstonians were screened at over 80 locations, with follow-up for about 10,000 at-risk participants. The staff of the Center for Cancer Control Research also maintain ongoing tracking of 7,500 employees as part of The Methodist Hospital's employee cancer screening and education programs.

The Cancer Registry at The Methodist Hospital is approved by the Cancer Department of the American College of Surgeons and follows standard registry procedures. Since its inception in 1984, the registry has entered 19,280 cases as of August, 1992. The current case accrual is over 200 a month, with better than 94% follow-up of patients.

We also have extensive experience with recruitment, standardization of clinical examinations, and follow-up from the National DESAD study. At the end of the seven year DESAD study, 88% of the original cohort of 1,343 women in Houston remained in the study, which included regular yearly examinations. Later, the study continued with mail contact only and six years after termination of the chemical study (i.e., 13 years from the beginning) 82% of the original cohort still maintained contact with the study. Tracing and contact methods developed in the study led to this high continued participation.

Research Design and Methods

A. Targeted Population

The Soviet Jewish Resettlement office of the Jewish Family Service estimates that there are about 1,500 Soviet Jewish immigrants in Houston, Texas. Of these, at least 200 families have been resettled since 1989. Additionally, it is also estimated that there are approximately 1,000-1,500 former Soviet Jews in other localities around the State of Texas.

At this time, we anticipate conducting interviews and collecting clinical data only with the sample from Houston. In other cities, we will only register Soviet immigrants, unless the Houston data show clinically

interesting results that warrant follow-up. If so, a request ill be made for additional funds from the Development Fund for the TMH/BCM research site to continue data collection around the state.

B. Methods of Recruitment:

The strateby of recruitment efforts will be to generally convey a sense of not only the importance of the research but also the health benefit to the immigrants of being followed for potental radiation related illness. Contact with the study subjects will be made through the Jewish Family Services, local Jewish Federations, fraternal organizations such as B'nai B'rith, Hadassah, HIAS, etc., in Houston and other Texas cities where Soviet Jews have resettled. This approach will facilitate consideration of the immigrants' viewpoints and concerns about being identified, used as research subjects, and tracked over the long term. Over and beyond the normal concerns for patients' confidentiality, these are issues about which we expect Soviet immigrants to be especially sensitive.

A bilingual letter will be sent through these ogranizations to individuals and families, explaining the planned study, including its justification and objectives. At sites with a larger concentration of immigrants, the letter will invite potential participants to meetings where pertinent questions about the study can be answered. Given both the long term nature of participation we will request and the importance of cross-cultural sensitivities, we will attempt to make the meetings both pleasant and sociable. Refreshments will be served, and we will try to build on the group solidarity which any immigrant group in a new land might be expected to have.

The purpose of the meetings will thus be not only to answer the immigrants' questions but also to facilitate recruitment by putting them at ease and reassuring them about issues of confidentiality. For instance, we will make clear to the immigrants that any data that could identify them personally will be (a) kept under lock and key, (b) kept separate from the research data per se, so that scientific analyses cannot be tied directly to individuals, (c) not shared with other researchers, i.e., only grouped scientific data will be shared or published. Outside of project staff, the only persons who will be given information on individual subjects would be, with the subjects' approval, their respective physicians.

All persons agreeing to participate in the study will be considered potential enrollees. If potential subjects do not respond to the invitation, they will be contacted through the above organizations a second time. Finally, project staff will request any information on nonrespondents pertinent to the study and available through the resettlement organizations, within the limits of confidentiality. Such information (for instance: place of origin, age, gender, etc.) will allow comparison of participants and nonparticipants for evaluation of the influence of enrollees' self-selection on the outcome of the study.

C. Enrollment:

1. Standarized Forms:

Using the questionnaire already developed in Israel (see the proposal by Hadassah Medical Organization) as a starting point, standard questionnaires will be developed for collection of information related to basic demographic data as well as family and personal history, e.g.:

o residence in the USSR before, during, and after the Chernobyl accident;

o known exposure to radiation;

o health status in relation to the Chernobyl accident, with a detailed health and medical history for the periods before and after 1986;

o data enabling long term contact, e.g.: telephone numbers, Social Security numbers, driver's license numbers, addresses of friends and relatives, etc.

This documentation will contain information comparable to data collected in studies in Israel and in the Russian Republic, anticipating coordination of all studies through the consortium. In addition to the above data, information will be obtained on residence of relatives or friends who are still residing in Russia, who have emigrated to Israel, or who have settled in other cities of Texas or other parts of the U.S.A. This will allow us not only to expand the subject pool as time goes on but also, eventually, to match family members here and abroad for future studies.

2. Informed Consent:

Informed consent for participating subjects will involve three elements, to which they may conceivably consent to any one, two, or all three. One is consent to be part of the registry, which will include periodic contact by project staff, at least once a year, to maintain and update registry files and patient medical histories. The second is consent to provide a blood sample, with the understanding that future samples will be requested. The third is consent to be contacted in the future about participation in other studies.

Subjects responding to the first recruitment contact through the resettlement organizations will be requested to sign the informed consent form. At the recruitment meetings, after the project has been explained and questions answered, project staff will request those who verbally agree to participate to go ahead and sign consent forms there and then. For those who want to think about participating or who want to discuss the project with others who did not attend, consent forms and business reply envelopes will be provided to take home. For those contacted only by mail, consent forms will be included for their signature and return.

Informed consent to participate at any level of the study will be considered granted only if a subject actually signs an informed consent form. Parents or guardians may not sign for minors, who must sign independently to give their informed assent to participate, with their parents co-signing the consent form.

The consent form itself will include sections on:

o the scope of the project, including the understanding that all participation is completely voluntary

o type of interviews to be conducted and/or questionnaires to be administered

o measures that will be taken to preserve confidentiality of data.

o consent to draw blood for a basic hematologic profile including thyroid function test

20cc (approximately 7 teaspoons) for teenagers and adults

10cc (approximately 3 teaspoons) for children aged 5-12 years

5cc (approximately 2 teaspoons) for children younger than 5 years

o consent to be contacted for future studies as they are phased in

3. Interview/Data Collection

When possible, for the purpose of cost efficiency, project staff will invite small groups of participating families to come in to a centralized site for the purpose of recording all information on the standardized forms. Such a site might be the Jewish Family Service or the Jewish Community Center, which are familiar to the study population. Data collection will be scheduled for afternoon or early evening hours, or Sundays, when whole families would be available. Simultaneous with the interviews, blood specimens will be collected, as described above. The staff interviewers will be bilingual and will be properly trained for the interview process. Experienced nurses or phlebotomists will draw the blood.

Besides greater efficiency, it is hoped that focusing on small groups of families at a time will continue to build on the camaraderie which the earlier recruitment meetings attempted to engender. Alternatively, study enrollees

who cannot come in to a centralized site will be visited at home by one of the bilingual interviewers, who will record all information on the standarized form, and a phlebotomist for drawing blood.

Follow-up and preventing attrition are important to registry activities. We anticipate sending a short newsletter to all enrollees at least twice a year. At least once every twelve months, project staff will contact each participant for the purpose of maintaining and updating registry files. This will involve sending a follow-up questionnaire by mail. The questionnaire will include questions about complete medical and health history over the preceding year. Address and telephone number changes will be solicited, especially with regard to family members who may have moved, gotten married, gone to college, etc. If a follow-up questionnaire is not returned within two weeks, a bilingual interviewer will attempt to contact the subject by telephone and either mail another questionnaire, if the first has been lost, or interview the subject over the telephone.

4. Study Subjects:

a. A pilot study will be initiated in Houston, Texas, which will include 50 Soviet Jewish immigrants who have settled in Houston after 1986, preferably from areas directly or potentially affected by Chernobyl. The experience with the forms and any technical problems will be evaluated and necessary adjustments will then be made for continuation of the study.

b. Based on experience from the pilot study, the project will be extended to all Soviet immigrants in Houston, including those who may have arrived before 1986, as a comparison group.

c. Special efforts will be made to trace immigrants who arrived (a) after 1986, (b) from exposed areas, and (c) who may already have been measured for the amount of their radiation exposure (e.g., measured by Russian health authorities or by the World Health Organization). Attempts will be made to obtain all such information available from Russian resources on our subjects.

d. Enrollment will then continue in other Texas cities with large concentrations of Russian immigrants, following the same procedures developed in Houston.

e. The experience in Texas will be summarized and, if indicated after proper adjustments, registration activities will be initiated in other localities of the U.S.A. and Canada. It is anticipated that the organizational contacts and methods developed for Texas will then be used directly or modified appropriately for the expanded registry activities.

D. Handling and Evaluation:

1. Data entry and management will follow the guidelines set up by the Design and Analysis (D&A) Core, described more fully on Page ____. We will follow the protocol established by the D&A Core with regard to data entry. The D&A Core will assign a master ID number to each participant, after which personally identifying data (e.g., name, address, telephone, etc.) will be kept separate from scientific data. Only the subjects' unique identification numbers will be associated with the data in the computer master file. Forms and files will be available for authorized personnel only and will be kept in locked files when not in active use.

Internal accuracy checks, such as double entry of patient ID to minimize misassignment of data, will be followed. The D&A Core will use a 486 computer, and a Bernoulli box will be used for backup and security, with one backup copy of the data being kept in the Center for Cancer Control Research. All data entry will use IBM compatible computers and DBASE 4 software, or other software aggreed upon by the TMH/BCM and other consortium researchers.

Eventually, specific subsets of data will be shared with the consortium Coordinating Center, based on final decisions of the consortium Steering Committee and the respective researchers. Only scientific data will be shared, i.e., personally identifying data will not be shared so that the subjects' confidentiality will be maintained.

2. Statistical methods used:

Standard parametric and nonparametric statistical analyses will be used to analyze data as they come in.

E. Time Frame of the Study:

The project will proceed in four phases over 24 months:

Phase 1 (months 1-4). Project staff will consult with representatives of the Israel and Russian registries to establish standardized or at least overlapping protocols with common questions touching on the demographic, medical history, therapy, and follow-up data for survivors in the respective locations. The National Bone Marrow Donor Program will also be consulted with regard to software and policies based on their experience. Records and questionnaires will be designed and translated into Russian. Bilingual interviewers will be recruited.

Phase 2 (month 5-8). Contact 50 Soviet immigrants through the different Jewish organizations in Houston, Texas, as specified in Section B. Pilot test and revise software and bilingual materials with this sample. Contacts will be made through Jewish Family Services, local Jewish Federations, fraternal organizations such as B'nai B'rith and Hadassah, HIAS, etc., in other Texas cities to establish where Soviet Jews have resettled elsewhere.

Phase 3 (months 9-16). Data collection targeting all Soviet Jews in Houston. It is anticipated that more than one visit will be required in order to interview all members of a family. Staff will coordinate and train volunteers in other Texas cities to register Soviet Jews in their communities.

Phase 4 (months 17-24). Registration activities elsewhere in the State of Texas. Contacts will be made with Hadassah Organization chapters, local Jewish Federations, HIAS chapters, etc., in other Jewish population centers where these immigrants have settled around the USA and Canada. This will lay the groundwork for expanding the registry to a national level.

F. Reporting Schedule:

A written report will be prepared at the end of each phase and submitted to the Site Director of the Methodist Hospital/Baylor College of Medicine Project.

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August 28, 1992

To: Prof. Zeev Weshler

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From: Dr. Armin Weinberg

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Dear Prof. Weshler:

1. We have received both your Fax and telephone message about your travel plans. My understanding is that you will arrive at Washington National Airport from New York/Newark on September 3, at 16:45 (4:45 PM) on Continental Airlines, flight #319.

2. When you get off the plane, please stay at the gate. Either I or Ms. T.J. Dunlap will come to meet you there at the gate to take you to our hotel.

3. If for some reason we miss one another, we are staying at the Hyatt Arlington Hotel, 1325 Wilson Boulevard, Arlington, Virginia. The hotel telephone number is (703) 525-1234. Your reservation confirmation number is 20341.

4. Once you get to New York, if there is any change in your travel plans, please call my office in Houston at (713) 798-4614.