APPENDIX B

UNDERSTANDING BARRIERS AND SUCCESSFUL STRATEGIES FOR FAITH-BASED ORGANIZATIONS IN ACCESSING GRANTS

IN-DEPTH TELEPHONE INTERVIEW GUIDE FOR SURVEY RESPONDENTS

Understanding Barriers and Successful Strategies for Faith-Based Organizations in Accessing Grants

In-Depth Telephone Interview Guide for Survey Respondents

INTERVIEWER INSTRUCTIONS: Before conducting the interview, review grants management administrative data and survey results for the participant, and answer any of the following questions from those sources to the extent possible. Eliminate any questions not appropriate for certain types of applicants or certain types of grant programs (such as questions in Part C), and tailor the interview to any special issues identified through the survey. Based on this review, select 12-14 of the following questions most pertinent to cover during the interview. If time permits, ask about missing or incomplete answers from the survey.

INTRODUCTION (2 minutes)

My name is NAME and I work for Mathematica Policy Research, Inc., an independent research firm. We are doing a study for the U.S. Department of Health and Human Services to learn about the experiences of faith-based organizations that apply for federal grants. You recently participated in a survey we conducted for the study. As we described in a letter you should have received in the past few days, we are contacting a few people who participated in the survey to learn more about their experiences applying for federal grants during fiscal year 2006. The interview should take about 45 minutes.

Everything you tell me is confidential. Your participation in the survey is voluntary and will not affect any grant money that you or your organization receive now or in the future.]

Is now a good time to talk?

- IF YES: Do you have any questions before we get started?
- IF NO: When would be a good time to call you back? [SCHEDULE INTERVIEW, THANK RESPONDENT, AND END CALL.]

A. RESPONDENT'S ROLE IN THE APPLICANT'S ORGANIZATION (3 minutes)

To begin, I'd like to learn about your role in ORGANIZATION NAME.

1. Your official job title [OR ROLE IN THE ORGANIZATION IF VOLUNTEER OR CONSULTANT] is [JOB TITLE FROM SURVEY], is that right?

IF NO: What is your current job title?

a. Please describe your responsibilities in that position/role. *PROBE:* Are you a grant writing specialist? Program administrator or staff member? Organization staff member? Organization leader or manager? Other?

B. PREVIOUS GRANT APPLICATION EXPERIENCE (5 minutes)

- 2. What was your role in developing the application ORGANIZATION NAME submitted to the HHS OPERATING DIVISION for the GRANT PROGRAM NAME during FY 2006 (between October 1 2005 and September 30 2006)? *PROBE: Main author? Designed or developed program to be proposed? Drafted the budget? Organized and led the proposal application process? Submitted the application?*
- 3. Prior to applying for the GRANT PROGRAM NAME in FY 2006, how would you describe your own experience, and the experience of ORGANIZATION NAME applying for grants of any type (such as from the federal or state government, foundations, or other sources), for any of your organization's activities? *PROBE:* Very experienced, grants are a common source of funding, and have used many sources; have done before on some occasions but not regularly, using a few grants but have other main sources of funds; inexperienced, just beginning to seek grant funds, may not have applied for federal grants before this.
- 4. Did any other community organizations partner with you in this program or on this grant? If so, who? Did these partners help prepare the proposal?

C. PROGRAM OR SERVICES PROPOSED FOR FUNDING (8minutes)

Let's talk first about the program or services that you proposed in your application.

- 5. Please briefly describe the program or services that you proposed in your GRANT PROGRAM NAME application. Was this an existing or new program or service? If existing, how long had it been in operation?
 - IF YES: Was the target population or group you proposed to serve through the program/services different in any way from those you were already serving?
- 6. Were any special provider or staff qualifications required, either by law or by the grant announcement, for the services you were proposing to conduct, such as certain licensing, credentials, or training? If so, how did you plan to meet these requirements?

D. PREPARING AND SUBMITTING THE GRANT APPLICATION (15 minutes)

Now let's talk about planning your application.

- 7. Besides yourself, who worked on the grant application, and what did they do? *PROBE*: Plan the program to be proposed? Develop the budget? Write the narrative? Write the evaluation plan? Write the sustainability plan? Fill out forms and documents? Submit the application?
 - a. Which ORGANIZATION NAME staff worked on the application?
 - b. Did you use any consultants to help write the grant?

- c. Did you use any volunteers to help write the grant?
- d. Did staff or members of any other organizations help write the grant? Who?
- 8. Please tell me how you OR ORGANIZATION IF RESPONDENT WAS NOT MAIN AUTHOR went about planning the grant proposal.
 - a. How did you develop the budget?
 - b. How did you develop an evaluation plan? *PROBE:* Did you consider collecting data that could be used to evaluate the program? Did you work with an evaluation committee? A consultant?
 - c. How did you develop a sustainability plan? *PROBE:* Did you propose a strategy for raising funds to continue the program after grant funding ended?
- 9. Over what period of time (total number of days, weeks, or months) did you work on the proposal, from your decision to apply to the day you submitted the application?
- 10. Did you have someone review drafts of your proposal and/or give you advice about it? If so, who was it, and how did they help?
- 11. Did you seek and/or receive assistance from OPERATING DIVISION in preparing your grant application? If so, what help did you receive, and how useful was it? *PROBE:* bidder's workshops or conference calls, individual contact with federal staff either by phone or email, webcasts, other)?
- 12. Now I'd like to talk about your experience with actually putting the grant application together and submitting it. Tell me about your experiences, both positive and negative, with completing the following steps for your fiscal year 2006 GRANT PROGRAM NAME application:
 - a. Following instructions provided in the grant program announcement for completing the application.
 - b. Determining the criteria that the government would be using for making grant award decisions.
 - c. Understanding and/or meeting federal requirements for administration, accounting, and reporting on grant activities and funds.
 - d. Understanding and/or meeting federal regulations or guidelines pertaining to charitable choice or faith-based applicants. *PROBE*: Such as separating service delivery from religious activities? Meeting hiring requirements?
 - e. Identifying costs that were allowable according to the grant requirements.
 - f. Completing the budget form.

- g. Completing the budget narrative (which explains the budget and documents costs).
- h. Completing required certifications and assurances *PROBE*: For example, certifications regarding lobbying and drug-free workplace.
- i. Registering at grants.gov on the internet.
- j. Submitting the application via the grants.gov website.

E. UNDERSTANDING WHY YOUR APPLICATION WAS SUCCESSFUL OR UNSUCCESSFUL (12 minutes)

Now I would like to ask you about what lessons others could learn from your experience.

- 13. Your 2006 application to NAME OF PROGRAM AND OPERATING DIVISION was SUCCESSFUL/UNSUCCESSFUL, is that correct?
 - a. Why do you think ORGANIZATION NAME was AWARDED/NOT AWARDED the grant? In your opinion, what made your application successful/unsuccessful?
 - b. Did you receive any feedback from OPERATING DIVISION about why your organization was AWARDED/NOT AWARDED the grant? If so, what reasons were given? How helpful was this feedback and why?
- 14. IF ORGANIZATION'S GRANT APPLICATION WAS SUCCESSFUL: Are there any special strategies or approaches you used on the application for GRANT PROGRAM NAME or that you use in general on grant applications to help ensure success? If so, what are they?
 - IF ORGANIZATION'S GRANT APPLICATION WAS NOT SUCCESSFUL: If you could write this application and submit it over again, would you do anything differently? If so, what would you do differently?
- 15. What do you think are the biggest challenges in winning federal grant funds that organizations like yours face?
 - a. In your opinion, what can organizations do to overcome these challenges?
 - b. Do you have suggestions for steps the federal government could take to help organizations overcome these challenges?
- 16. Faith-based organizations may sometimes face unique challenges in preparing and submitting federal grant applications.
 - a. Do you think that ORGANIZATION NAME has experienced any special challenges applying or being considered for this or other federal grants due to the faith-based nature of your organization or of the program for which you sought funding?

b. Do you think that OPERATING DIVISION or others in the federal government, or those who serve on the panels that review federal grant applications, have any special concerns or biases regarding certain types of organizations or providers? *PROBE: For example, very small organizations, organizations from some parts of the country, faith-based organizations?* What do you think these concerns or biases might be?

F. WRAP UP

17. Are there any other lessons learned from your experience applying for federal grants that you would like to share before we end the interview?

Thank you again for participating in the interview and survey!

APPENDIX C

UNDERSTANDING BARRIERS AND SUCCESSFUL STRATEGIES FOR FAITH-BASED ORGANIZATIONS IN ACCESSING GRANTS

FOCUS GROUP GUIDE FOR FEDERAL GRANT MANAGERS

Understanding Barriers and Successful Strategies for Faith-Based Organizations in Accessing Grants

Focus Group Guide for Federal Grant Managers

INTRODUCTION (10 minutes)

My name is [NAME] and I work for Mathematica Policy Research, Inc., an independent research firm. We are doing a study for the U.S. Department of Health and Human Services to learn about the experiences of faith-based organizations that apply for federal grants.

Thank you very much for agreeing to participate in this conversation. Your participation is very important to the success of the study. Today I'd like to learn about your experiences with the grant review process, your observations of grant quality and competitiveness, and your experiences with proposals from faith-based organizations.

- I'm going to moderate the discussion. It is really important for everyone to speak up so we can have a lively and informative conversation.
- We have many topics to cover during our discussion. At times, I may need to move the conversation along to be sure we cover everything.
- It will be helpful if you speak one at a time, so everyone has a chance to talk.
- We ask that we all respect each other's points of view. There are no right and wrong answers, and it is okay to disagree. You are the experts; we want to learn from you.
- We also ask that you not repeat any of the conversation you've heard here after you leave the room today.
- I would like to tape record today's conversation. I am taping it so I can listen to it later when I write up my notes. No one besides our research team will listen to the tape.
- We realize some things about this topic could be sensitive. We hope you will feel
 comfortable enough to be candid with us. We are not here because we suspect people
 are doing something wrong or improper. Everything you say here is confidential.
 Only our research team will have access to our notes and the tape. When we write
 our report, we will include a summary of people's ideas and opinions, but no one will
 be identified or quoted by name.
- The discussion will last about 90 minutes, and we will not take any formal breaks. But please feel free to get up at any time if you need to, such as to stretch or go to the restroom.

Once again, thank you for coming today. Let's get started.

Ice Breaker: To begin, let's go around the room and introduce ourselves. Please tell us your first name, and what you think is the most challenging aspect of reviewing and selecting grant applications, and the most rewarding aspect.

A. PROCESS OF REVIEWING FEDERAL GRANT APPLICATIONS (10 minutes)

- 1. To make sure we all have a common understanding of the grant review process, could someone please walk us step-by-step through the grant review process—that is, the process of reviewing and scoring grant applications once they have been received, and of selecting awardees?
 - AFTER ONE PERSON DESCRIBES THE PROCESS: Procedures for reviewing grants may vary somewhat by operating division and grant type. Does anyone follow a different set of steps? If so, can you please describe the differences for the group?
 - As a grant manager, what is your role in the grant review process?
 - After applications are scored by review panel members, do you make the final selection of applications recommended for funding?
- IF YES: What kinds of criteria do you typically use?
- Do the criteria vary by grant program? Can you give me some examples?
- IF NO: Who makes the final selection? What kinds of criteria are typically used?
- 2. In typical grant reviews you have managed, what proportion of review panel members are federal staff, and what proportion are external reviewers?
 - How do you select review panel members?
- How do you select external reviewers, and what qualifications do they usually have? How does this differ by grant type? Do you ever need different types of reviewers to review grants from different types of applicants? Can you give us any examples?
 - Have you ever managed a grant review panel that includes reviewers having expertise on faith-based organizations?
- IF YES: What types of organizations were they from? Can you give me some examples? Why were these reviewers selected? Was it because they were from faith-based organizations or because of their expertise in a specific area, or just by chance?

B. QUALITY OF GRANT APPLICATIONS (10 minutes)

3. Now, I'd like you to think about the applications you have received in the past two years in response to a typical program announcement. Roughly what percentage of applications are usually what you consider to be strong applications—that is, very competitive for funding?

- What is it that makes some applications especially strong or competitive? *PROBE*: Well written? Clear and concise? Demonstrated knowledge of target population? Well-qualified staff proposed? Strong community partners? Clear evaluation plans? Adequate sustainability plans?
- 4. What kinds of weaknesses or mistakes do you most often see in grant applications? *PROBE*: Not well written? Proposal does not follow format and outline described in program announcement? Staff don't meet qualifications described in the program announcement? No demonstrated experience providing the service or working with the target population? Weak evaluation plan? Weak or no sustainability plan? No consultation with community in developing the proposal? Other?
- 5. Some grant applications never get to the review process at all because they are screened out for being out of compliance with submission requirements. When this happens, what are the main reasons for being screened out? *PROBE: Failure to submit all required forms? Late submission? Ineligible applicant? Improper format? Proposal not responsive to grant announcement (in what ways)? Other?*

C. EXPERIENCE REVIEWING PROPOSALS FROM FAITH-BASED ORGANIZATIONS (25 minutes)

Applications for federal grants are received from many types of organizations. Recently, faith-based organizations have become eligible to apply for more types of grants. We would like to know what you have observed about how these applicants fare in the review process.

- 6. When reviewing grant applications as part of a review panel, are panel members able to identify applications from faith-based organizations? Are you as the grant manager able to identify applications from faith-based organizations?
 - IF YES: How do they/you usually identify applications from faith-based organizations? *PROBE:* By name of the organization? By the description of the organization in the proposal? By the narrative description of services to be provided?
 - Do you think it matters for any reason whether you or the reviewers can determine or are aware whether an applicant is an FBO or not? Why or why not?
- 7. When managing a grant review panel, have you ever received questions from reviewers about how to evaluate applications from faith-based organizations? What questions did you receive, and how did you respond?
- 8. In your role as grant manager, have you yourself ever had any questions about how to evaluate applications from faith-based organizations? What were they?
- 9. Are any additional criteria used when reviewing applications from faith-based organizations?
 - For example, do you look for evidence of separation of religious activities in time and place from service delivery?

- Do you look for evidence of nondiscriminatory hiring practices?
- 10. In your opinion, what are the typical strengths of applications from faith-based organizations? What are their typical mistakes or weaknesses?
- 11. From your observation, do you think grant reviewers ever have concerns or questions about whether faith-based organizations have the capacity to provide promised services, or whether it is appropriate for them to receive federal funds to do so?

D. PROVIDING FEEDBACK ON GRANT APPLICATIONS (10 minutes)

- 12. What is the process of providing feedback to grant applicants, including both successful and unsuccessful applicants? What kind of feedback do unsuccessful applicants automatically receive, and what do they have to request?
 - From your experience, are faith-based applicants more or less likely than other types of applicants to request feedback?
 - How helpful do you think the written and direct feedback is that applicants receive?
 Why? Do you think there are ways to make the feedback more useful to applicants?
 How?

E. RECOMMENDATIONS ABOUT THE REVIEW PROCESS (10 minutes)

Now I'd like to ask you some questions about whether there are ways to improve the review process.

- 13. Regardless of the type of application or applicant being reviewed, what are the most difficult aspects of the grant review process? Are there ways you can think of to improve the process, or make it go more smoothly?
- 14. In your opinion, would any type of additional training and/or guidance be valuable in assisting review panelists to evaluate applications from faith-based organizations?
- 15. Is there any additional training or guidance that would help grant managers in overseeing reviews of applications from faith-based organizations?

F. RECOMMENDATIONS AND ADVICE FOR FAITH-BASED ORGANIZATIONS (15 minutes)

The process of applying for and administering federal grants can be daunting to some organizations—such as small community-based groups, faith-based groups, or others.

16. Do you think faith-based organizations—especially those that might be new to the federal grant process—are able to compete for federal grants on an equal footing with other kinds of applicants? If not, what do you see as the main barriers that faith-based organizations face

- to obtaining discretionary federal grant funds? *PROBE*: Lack of information about the availability of funds? Lack of staff skills in writing grant applications? Lack of experience in service provision? Lack of qualified staff?
- 17. Federal grant funds are limited, so not every applicant can win a grant. What can faith-based organizations themselves do to improve the quality of their grant applications and their chances of winning grant awards?
- 18. In your opinion, what kinds of assistance or tools might help faith-based organizations improve the quality of their grant applications?

G. WRAP UP

We are reaching the end of the time we have for this conversation.

20. Are there any other comments related to reviewing grant applications from faith-based organizations or any other recommendations that you would like to make before we close?

Thank you so much for taking the time to participate in this discussion!

APPENDIX D

UNDERSTANDING BARRIERS AND SUCCESSFUL STRATEGIES FOR FAITH-BASED ORGANIZATIONS IN ACCESSING GRANTS

FOCUS GROUP GUIDE FOR FEDERAL GRANT REVIEWERS

Understanding Barriers and Successful Strategies for Faith-Based Organizations in Accessing Grants

Focus Group Guide for Federal Grant Reviewers

INTRODUCTION (10 minutes)

My name is [NAME] and I work for Mathematica Policy Research, Inc., an independent research firm. We are doing a study for the U.S. Department of Health and Human Services to learn about the experiences of faith-based organizations that apply for federal grants.

Thank you very much for agreeing to participate in this conversation. Your participation is very important to the success of the study. Today I'd like to learn about your experiences as federal grant reviewers, and in particular, your experiences evaluating proposals from faith-based organizations.

- I'm going to moderate the discussion. It is really important for everyone to speak up so we can have a lively and informative conversation.
- We have many topics to cover during our discussion. At times, I may need to move the conversation along to be sure we cover everything.
- It will be helpful if you speak one at a time, so everyone has a chance to talk.
- We ask that we all respect each other's points of view. There are no right and wrong answers, and it is okay to disagree. You are the experts; we want to learn from you.
- We also ask that you not repeat any of the conversation you've heard here after you leave the room today.
- I would like to tape record today's conversation. I am taping it so I can listen to it later when I write up my notes. No one besides our research team will listen to the tape.
- We realize some things about this topic could be sensitive. We hope you will feel
 comfortable enough to be candid with us. We are not here because we suspect people
 are doing something wrong or improper. Everything you say here is confidential.
 Only our research team will have access to our notes and the tape. When we write
 our report, we will include a summary of people's ideas and opinions, but no one will
 be identified or quoted by name.
- The discussion will last about 90 minutes, and we will not take any formal breaks. But please feel free to get up at any time if you need to, such as to stretch or go to the restroom.

Once again, thank you for coming today. Let's get started.

Icebreaker: To begin, let's go around the room and introduce ourselves. Please tell us your first name, and what you think is the most challenging aspect of reviewing grant applications, and the most rewarding aspect.

A. EXPERIENCE REVIEWING FEDERAL GRANT PROPOSALS (10 minutes)

- 1. To make sure we all have a common understanding of the grant review process, could someone please walk us step-by-step through the review process, as you have experienced it?
 - AFTER ONE PERSON DESCRIBES THE PROCESS: Procedures for reviewing grants may vary somewhat by operating division and grant type. Has anyone followed a different set of steps? If so, can you please describe them for the group?
 - What are your responsibilities as a grant reviewer?
 - Tell me about the instruction or training you have received on the review process—either initially or most recently? What topics were covered, and how long did the training last?
 - Have any of you ever chaired a grant review panel?
- IF YES: What were your responsibilities as chair?
- 2. In a typical grant review in which you have participated, what proportion of review panel members have been federal staff, and what proportion are external reviewers?
 - Have you ever served on a review panel with external reviewers that have expertise on faith-based organizations?
- IF YES: What types of organizations were they from? Can you give me some examples?

B. QUALITY OF GRANT APPLICATIONS (10 minutes)

- 3. Now, I'd like you to think about the applications you have reviewed for a typical federal grant announcement. Roughly what percentage of applications are typically what you consider to be strong applications—that is, very competitive for funding?
 - What is it that makes some applications especially strong or competitive? *PROBE:* Well written? Clear and concise? Well-qualified staff proposed? Strong community partners? Clear evaluation plans? Demonstrate knowledge of target population? Previous experience? Good sustainability plan?
- 4. What kinds of weaknesses or mistakes do you most often see in grant applications? *PROBE:* Not well written? Proposal does not follow format and outline described in

program announcement? Staff don't meet qualifications described in the program announcement? No demonstrated experience providing the service or working with the target population? Weak evaluation plan? No consultation with community in developing the proposal? Sustainability not adequately addressed?

C. EXPERIENCE REVIEWING PROPOSALS FROM FAITH-BASED ORGANIZATIONS (25 minutes)

Applications for federal grants are received from many types of organizations. Recently, faith-based organizations have become eligible to apply for more types of grants. We would like to understand how this might have affected the review process, and also what you have observed about how they fare in the grant review process.

- 5. When reviewing grant applications as part of a review panel, are you able to identify which applications are from faith-based organizations?
 - IF YES: How do you identify them? Are there any particular items or sections of the proposal that help you identify faith-based applicants? *PROBE: By name of the organization? By the description of the organization in the proposal? By the narrative description of services to be provided?*
 - Do you think it matters, positively or negatively, whether or not reviewers can identify faith-based applicants? Does the number of faith-based applicants seem to you to be growing?
- 6. When serving on a grant review panel, have you or others ever had questions about how to evaluate applications from faith-based organizations?
 - IF YES: What were the questions?
- Did you consult with the chair of your review panel or someone else? If so, what answers did you receive?
- 7. Are any additional criteria used when reviewing applications from faith-based organizations?
 - For example, do review panels look for evidence of separation of religious activities in time and place from service delivery?
 - Do panels look for evidence of nondiscriminatory hiring practices?
 - IF YES: Can you provide a few examples of situations in which applications have appeared not to meet these criteria? *PROBE:* What information or evidence in application directly led to the conclusion that applicant DID NOT meet these criteria?

- Can you provide a few examples of situations in which this came up, but the applications have met the criteria? *PROBE:* What information or evidence in application directly led to the conclusion that applicant DID meet these criteria?
- 8. In thinking about the applications from faith-based organizations you have reviewed, what are their typical strengths and weaknesses?
 - Do applications from different types of faith-based organizations—such as affiliates
 of large, national networks, small nonprofits or interfaith groups, and congregations
 —have different kinds of strengths and weaknesses? What are they, and can you give
 me some examples?
- 9. From your observation, do you think grant reviewers ever have concerns or questions about whether faith-based organizations have the capacity to provide promised services, or whether it is appropriate for them to receive federal funds to do so?

D. PROVIDING FEEDBACK ON GRANT APPLICATIONS (5 minutes)

- 10. Tell me about the feedback that applicants receive on their grant proposals, including both successful and unsuccessful applicants.
 - How helpful do you think the feedback is that applicants receive? Why?
- 11. Have any of you ever been involved in providing such feedback to applicants?
 - IF YES: What was your role? Have you ever spoken directly on applicants about the written feedback they received?
- 12. Do you have any suggestions or ideas about ways to make feedback to unsuccessful applicants more useful to them in improving the quality of future applications?

E. RECOMMENDATIONS ABOUT THE REVIEW PROCESS (10 minutes)

Now I'd like to ask you some questions about whether there are ways to improve the review process.

13. Regardless of the type of application or applicant being reviewed, what are the most difficult aspects of the grant review process? Are there ways you can think of to improve the process, or make it go more smoothly? *PROBE: Better or more training for review panel members? More or different information provided on applicants? Structure of review process such as time or scoring?*

F. RECOMMENDATIONS AND ADVICE FOR FAITH-BASED ORGANIZATIONS (15 minutes)

The process of applying for and managing federal grants can be daunting to some organizations—such as small community-based groups, some faith-based groups, or others.

- 14. Do you think faith-based organizations are able to compete for federal grants on an equal footing with other kinds of applicants? If not, what do you see as the main barriers that faith-based organizations face in obtaining federal grant funds? *PROBE: Lack of information about the availability of funds? Lack of staff skills in writing grant applications? Lack of experience in service provision? Lack of qualified staff?*
- 15. In your opinion, what kinds of assistance or tools might help faith-based organizations improve the quality of their grant applications?
- 16. As a previous grant reviewer, what advice would you give to faith-based organizations applying for federal grant funds about how to improve the quality of their applications? Would this advice apply to any type of applicant, or do you think there are special issues faith-based applicants will need to address?
 - What can faith-based organizations do to improve their chances of receiving grant awards?
- 17. Do you have any advice you could give to the DHHS operating division(s) for whom you have reviewed grants about how to make discretionary grant programs more accessible to faith-based organizations? Would this advice apply to any type of applicant, or do you think there are special issues faith-based applicants will need to address?

G. WRAP UP

We are reaching the end of the time we have for this conversation.

18. Are there any other comments related to reviewing grant applications from faith-based organizations or any other recommendations that you would like to make before we close?

Thank you so much for taking the time to participate in this discussion!

APPENDIX E

UNDERSTANDING BARRIERS AND SUCCESSFUL STRATEGIES FOR FAITH-BASED ORGANIZATIONS IN ACCESSING GRANTS

SECTION 301 OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C.241)

Section 301 of the Public Health Service Act (42 U.S.C.241)

TITLE 42 > CHAPTER 6A > SUBCHAPTER II > Part A > § 241

§ 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

- (1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
- (2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
- (3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
- (4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
- (6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
- (8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

- (b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation
 - (1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)

- (A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.
- (B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.
- (3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.
- (4) The Secretary shall publish a biennial report which contains—
 - (A) a list of all substances
 - (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and
 - (ii) to which a significant number of persons residing in the United States are exposed;

- (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;
- (C) a statement identifying
 - (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and
 - (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and
- (D) a description of (i) each request received during the year involved—
- (I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or
- (II) from an entity within the Department of Health and Human Services to any other entity within the Department,
 - to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.
 - (5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.
- (c) Diseases not significantly occurring in United States The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.
- (d) Protection of privacy of individuals who are research subjects The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.