Feasibility Study of Optimal Approaches for Assessing Bioethics Training Programs at the National Institutes of Health

Final Report

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EXECUTIVE SUMMARY

This report describes findings from a feasibility study to identify optimal approaches for assessing bioethics training programs at the National Institutes of Health (NIH). NIH funds extramural training programs designed to improve the ethical conduct of research with human subjects and to ensure that all NIH-supported research is conducted in an ethical and legal manner. "Bioethics training programs" (the program to be evaluated) are supported under a number of funding mechanisms and include three main types of programs: (1) programs to train groups of investigators, (2) programs to train an individual investigator, and (3) programs to train and educate an Institutional Review Board (IRB). Because bioethics training programs at the NIH have not been formally evaluated, the purpose of this study was to determine whether a full-scale evaluation of the program is indicated and feasible.

The feasibility study, conducted by CSR, Incorporated, examined the relevant literature, developed an inventory of bioethics training programs in the United States, and collected data from key stakeholders to identify the most appropriate methodologies, techniques, and tools to measure the relevance, effectiveness, and impact of bioethics training programs at the NIH. The main study questions were:

- In addition to the NIH, what organizations are involved in supporting bioethics training?
- Is there an operative definition of "bioethics training"?
- What are the key characteristics of bioethics training programs?
- What is the program's sustainability beyond NIH funding?
- What process and outcome evaluation methodologies are most appropriate for assessing the progress and impact of bioethics training programs at the NIH?
- Is there adequate justification to conduct a full-scale process and outcome evaluation?

The study approach involved five basic components:

- Information Gathering—including document review and discussions with key stakeholders from NIH offices and programs;
- An Inventory of Bioethics Training Programs in the United States—including programs supported through NIH funding and other U.S. organizations/centers involved in bioethics training;
- Data Collection—including interviews with key stakeholders at the NIH, directors/staff from other U.S. organizations/centers involved in bioethics training, and grantees from selected NIH bioethics programs;

- Development of Programmatic Logic Models for each of three NIH bioethics programs (T15, K01, and S07); and
- Development of Evaluation Design Options—including process and outcome evaluation methodologies and techniques.

Findings related to the six study questions are summarized below.

Organizations (in addition to the NIH) Involved in Supporting Bioethics Training

A search of nongovernmental organizations involved in supporting bioethics training identified more than 100 universities and research institutions in the United States. Bioethics training programs have a variety of disciplinary homes, including health care ethics, philosophy, and medicine. There are a wide variety of certificate, undergraduate, and graduate degree programs in bioethics, including several joint degree programs. In addition to academic degree programs, academic bioethics centers support a range of activities, including faculty research, lecture series, service on national committees and IRBs, community outreach, ethics consultation, visiting scholars, and publications and journals. Center faculty are multidisciplinary, with specialties in ethics, medicine, law, and biomedical and behavioral research. The centers receive funding from multiple sources including: the NIH, the health care system, private funding/gifts, university general funds, tuition, medical school subsidies, grants, and contracts.

Definitions of Bioethics Training

This study identified various operational definitions of "bioethics training." Although there is no common definition of what constitutes a bioethics training program, there are some common elements in the various definitions of bioethics training, which include training in **ethics**, **medical/scientific principles**, and **human subjects protections**. Some definitions contain the **legal aspects** of ethics; some mention **patients' rights**; and others refer to **social principles** and **scientific aspects.** The area where commonality breaks down is whether ethics is subsumed under bioethics or vice versa. Some argue that bioethics is much broader and encompasses life science and medical issues, while others define bioethics as a subset of research ethics.

Key Characteristics of Bioethics Training Programs

An inventory of bioethics training programs at the NIH shows that bioethics training is supported under a number of funding mechanisms, primarily the R25, S07, K01, and T15. There is considerable diversity in the types of bioethics training programs supported by the NIH, with variation in the duration, funding level, funding mechanism, purpose, activities, and scope (U.S. or international). Findings from an examination of the K01, T15, and S07 bioethics training programs were used to create programmatic logic models for bioethics training programs at the NIH. This report presents a generic logic model of the NIH bioethics training program and three separate models to illustrate how the K01,

T15, and S07 programs work to achieve their intended NIH mandate. Each model includes inputs or resources of the program, planned activities or processes to produce outputs, and short- and long-term outcomes.

Program Sustainability Beyond NIH Funding

When asked about program sustainability, most grantees express doubt or uncertainty about continuation of bioethics training activities beyond NIH funding. Reasons for lack of continuation funding included: dependency on external funding, the institution's low priority on bioethics, and funding cuts in State support. Some evidence of support for program sustainability was found through program adaptation and replication, institutional support for research ethics, and community support.

Options for a Full-Scale Outcome Evaluation

The variability of bioethics training programs supported by the NIH makes it difficult to evaluate the relative effectiveness/impact of bioethics training programs as a whole across the NIH. Although evaluations are required, there is no consistent collection of data within funding mechanism or a centralized repository of program evaluation data on NIH-funded bioethics training programs. Considering these limitations, six options were identified for evaluating bioethics training programs at the NIH: (1) a comparative case study, (2) a pre-post evaluation, (3) a mixed-methods design, (4) meta-analysis, (5) systematic comparison of programs by funding mechanism, and (6) a retrospective evaluation.

Recommendations for a Full-Scale Evaluation

Overall, the results of the feasibility study point to the need for the NIH to first more narrowly focus the overall NIH training program to be evaluated. This approach would start with adopting a common definition of "bioethics training" and a classification system with functional criteria for what constitutes a bioethics training grant. The final classification system could be uniformly applied to all Institutes to categorize bioethics training programs, regardless of their funding mechanism. Based on this approach, a rigorous evaluation design could be developed consistent with the research questions and the available resources. The proposed design would include a mixed-methods approach, incorporating qualitative case studies of funded programs and a survey of a sample of programs within each type of program identified through the standardized classification system. This approach, incorporating multiple data sources, would strengthen the reliability and depth of the findings to support informed decisionmaking regarding the future direction, funding, and management of bioethics training programs at the NIH.

1. INTRODUCTION

Under a contract awarded in September 2005 by the National Institutes of Health (NIH), CSR, Incorporated conducted a feasibility study to identify optimal approaches for assessing bioethics training programs at the NIH. This report describes our findings from the study and our recommendations for a full-scale evaluation. Following this introduction, in Section 2, we provide some background on the program, plans for evaluating it, and a review of the literature. In Section 3 we present the feasibility study design, and in Section 4, a summary of findings. Options and recommendations for a full-scale evaluation are discussed in Sections 5 and 6. Appendices are provided at the end of the report.

2. BACKGROUND

2.1 Bioethics Training at the NIH

As a public sponsor of biomedical research, the NIH funds extramural bioethics training programs designed to improve the ethical conduct of research with human subjects and to ensure that all NIH-supported research is conducted in an ethical and legal manner. These programs address the NIH mandate that all extramural researchers participate in training in the responsible conduct of research. In addition to offices that protect human subjects, the NIH includes a number of offices that address ethical concerns and appraise the potential social consequences of scientific research. For example, the Office of Science Policy and Planning (OSPP), in the Office of the Director, advises the NIH director on policy issues that affect the research community. The OSPP also coordinates the Trans-NIH Bioethics Committee (T-NBC), which is responsible for developing policies and providing a coordinated approach to the consideration of ethical, legal, and social implications of NIH-funded research.

Extramural bioethics training programs exist across the NIH and are supported under a number of funding mechanisms. Each program differs from the others in scope and intent; however, there are three main types of programs:

- Programs to train groups of investigators;
- Programs to train an individual investigator; and
- Programs to train and educate an Institutional Review Board (IRB).

2.2 Purpose of the Evaluation

Because bioethics training programs at the NIH have not been formally evaluated in the past, the purpose of this study was to determine whether a full-scale evaluation of the program is indicated and feasible. This request for a program evaluation grew out of the Extramural Activities Working Group (EAWG), a subgroup of the NIH Steering

Committee. The rationale for the study was to conduct an external assessment to determine the most appropriate evaluation methodologies, techniques, and tools to measure the relevance, effectiveness, and impact of extramural bioethics training programs at the NIH. The goal was to determine whether the NIH bioethics training programs, as currently configured, are fulfilling their intended purpose—to ensure that all NIH-supported research is conducted in an ethical manner.

2.3 Use of Evaluation Results

The findings of this study will be used to inform the full-scale evaluation of bioethics training activities supported by the NIH. The results will provide important information about the influence of the NIH's bioethics training programs, and will facilitate the development of an operational definition of "bioethics training." The results of the full-scale evaluation will influence the development and management of bioethics training programs at the NIH.

2.4 Review of the Literature of Evaluations Related to Bioethics Training

Formal evaluation of the type of training fostered by programs such as the extramural training program at the NIH has been limited. There are, however, a few examples in the literature that focus on evaluating training programs in general, and some examples of evaluations relevant to various approaches to evaluating bioethics training programs at the NIH. In addition, there is literature surveying and assessing bioethics training programs related to medical education.

2.4.1 *Evaluating Training Programs*

The John E. Fogarty International Center (FIC) serves as the organizational locus for NIH international research bioethics initiatives. The Center conducts qualitative process evaluations of its programs every 5 years. In May 2005, the FIC convened a panel of six experts in research ethics and curriculum development to review progress in the first 5 years of the international bioethics training program. The panel interviewed principal investigators (PIs), past and current program trainees, the FIC program office, NIH partners, and outside experts. The panelists noted that the trainees from the bioethics program have published papers in high-impact journals, successfully obtained NIH funding, and established national ethics review committees (FIC, 2005). The panel strongly recommended the continuation and support of the bioethics program, and suggested several modifications to strengthen it. Some of the recommendations are useful for the evaluation of bioethics training programs across the NIH:

- The program should collect better information about the trainees and other NIH-sponsored grantees and share it with other stakeholders. A comprehensive, centralized trainee tracking system should be implemented.

- Annual reports from individual sites should be integrated and an annual report for the entire program should be prepared. Accomplishments and programs should be highlighted and shared with other programs.
- Communication with other NIH programs and trainees should be improved, and trainees need to be informed about other NIH programs and researchers.
- Metrics need to be developed that will describe the success and value of the accomplishments of the trainees and programs. Metrics used to evaluate the program in the long run are: publication in high-impact peer-reviewed journals, success in obtaining ongoing research support, degrees obtained, new positions achieved, consultations and technical advice provided by trainees to clinical researchers, and invitations to participate in workshops or conferences.
- Explicit links are needed between the needs of the institutions, the needs of trainees, the objectives of the curriculum, and measures of outcome.
- Long-term tracking is critical to the program in order to provide timely and thorough information on program outcomes.
- A thorough outcome assessment should be conducted.

Another example of approaches to evaluating NIH training programs is found in the National Institute of General Medical Sciences (NIGMS) assessment of the Medical Scientist Training Program (MSTP) established in 1964 to supply research training leading to the combined M.D.-Ph.D. degree. The study of this program (NIGMS, 1998) was designed to assess the success of MSTP graduates in establishing research careers and the types of careers and research activities of these graduates compared to non-MSTP graduates. By several measures, the graduates appear to have been successful in establishing research careers, and their recent publications indicate that they continue to be productive investigators. MSTP graduates were more likely than non-MSTP trainees (1) to have received postdoctoral research training support, (2) to hold academic appointments, (3) to apply for and succeed in obtaining NIH support, (4) to have more total publications as well as recent publications, and (5) to have received research support from any source. This study is important for evaluation of bioethics training programs because it compares graduates from an NIH training program with nongraduates on outcome measures in a longitudinal fashion.

Donald Kirkpatrick (1998) provides some general guidelines for evaluating training programs that might be useful in considering options for evaluating bioethics training programs at the NIH. He recommends: (1) use a control group if possible, (2) allow time for results to be achieved, (3) measure both before and after the program, (4) repeat the measurement at appropriate times, (5) consider cost versus benefits, and (6) realize that evidence of proof may not be possible. He stresses that finding “proof” of the results of a training program is very difficult, and that “evidence” is the best we can strive for. Kirkpatrick details four levels of evaluation of training programs: Level 1—Reaction

(how participants reacted to the training), Level 2—Learning (what information and skills were gained), Level 3—Behavior (have the participants transferred knowledge and skills to their jobs?), and Level 4—Results (what effect has the training had on achievement of objectives?). The methodologies suggested are checklists, questionnaires, and anecdotal data.

Another methodological approach is found in a 1989 study conducted by Narin, who looked at the funding mechanisms supporting 13 major advances in cancer research. This approach included a systematic comparison of awards by funding mechanism in order to determine the "value added" by using one mechanism compared to another. The study used citation analysis to identify the key research papers in 13 major advances in cancer research, and used the acknowledgement of support in each paper to link it to National Cancer Institute (NCI) funding mechanisms. A disadvantage of the applicability of this approach to the current study is the variability of support, which includes institutional centers (T15) and individual investigators (R01). Therefore, researchers trained in bioethics centers might have had papers published on bioethics research that do not acknowledge their center training as a source of support.

The Institute of Medicine (IOM) recently conducted a 1-year NIH-funded study of the use of research centers at the NIH (2002). The results of this study were published in a report titled "NIH Extramural Centers Programs: Criteria for Initiation and Evaluation." Some of the goals of centers cited by the study are (1) increased basic and clinical research, (2) more multidisciplinary research, (3) more translational research, (4) increased or more effective support for independent investigators, (5) successful recruitment of established researchers, (6) development of new investigators, and (7) demonstration of state-of-the-art prevention and treatment techniques. Under each goal, the IOM report provides indicators, such as increased numbers of seminars; publications in the press, radio, and television; courses; new grants; or institutional support for center operations. The study points out that results take a long time when evaluating research centers, that centers make up more than individual center grants, that much of the value added by centers is intangible (infrastructure is hard to measure), and that evaluation must rely on expert judgment. The report recommended that every center program be given a formal external retrospective review for continued effectiveness on a regular basis (every 5 to 7 years). This review should be performed at arm's length from the program, with appropriate expertise to judge the varied activities. The report also recommended that the program be evaluated against its original objectives and with regard to any changed circumstances in its field, determining if centers are the most appropriate means of making progress in the field. The review should use multiple sources of evidence to evaluate the effectiveness of the program, and its conclusions should be evidence based. Consideration also should be given to the scientific impact of the program (publication counts, discoveries, sharing of research tools); the impact on human health; and the impact on human resources, such as career paths of postdoctoral students. The report also suggested that a program evaluation plan be developed as part

of the design and implementation of new center programs and that indicator data be collected regularly.

2.4.2 *Assessing Bioethics Training Programs Related to Medical Education*

A review of the literature on medical ethics education (Eckles et al., 2005) searched Medline and PubMed for the period 1978 to 2004 and found extensive shortcomings in the theoretical literature and in empirical studies of outcomes of medical ethics education, as well as deficits in the teaching and effectiveness of coursework. The authors found that the "field would benefit from further theoretical work aimed at better delineating the core content, core processes and core skills relevant to the ethical practice of medicine" (Eckles et al., p. 1143). Citing Lehmann and colleagues (2004), the authors listed common barriers to medical ethics instruction as lack of: (1) time in faculty schedules, (2) time in the curriculum, and (3) qualified teachers. The article discusses the goals of medical ethics education—creating "virtuous physicians" versus endowing students with a set of skills for ethical reasoning. The goals of medical ethics education are summarized as follows: (1) teaching skills for ethical analysis and decisionmaking; (2) enabling physicians to recognize the humanistic and ethical aspects of medical careers; (3) affirming physicians' own moral commitments; (4) employing this knowledge in medical reasoning; and (5) equipping physicians with the interactional skills to apply this insight, knowledge, and reasoning to clinical care (Eckles et al., p. 1145). Eckles discovered few empirical studies addressing the outcomes of medical ethics education in a field where educational goals are inadequately defined. It was unclear to the authors what measures of ethical sensitivity and moral reasoning measure, and how the factors they measure map onto the overall goals of ethics curricula. The article also discussed evaluation methods in medical ethics education. Standardized evaluation of medical students in ethics would permit methods of teaching to be evaluated and improved. Analysis of means to evaluate medical ethics curricula and student performance could lead to clearer definitions of the goals of medical ethics education.

Martinez suggests that the National Board of Medical Examiners and specialty accreditation boards require candidates to pass a separate section on ethics before board certification. This also would encourage students to take the study of ethics courses more seriously (Martinez, 2002). The authors also suggest that ethics skills should be distilled into a competency which would focus medical ethics curricula as well as provide more clearly defined outcomes (Eckles et al., 2005). They recommend studies designed to improve understanding of the validity and reliability of the existing measures. This might further efforts to bring greater standardization to medical ethics curricula and enhance comparisons of outcomes of medical education teaching across institutions. In summary, the authors believed that study of the development and improvement of moral reasoning among medical students should be undertaken using qualitative data on the outcomes of medical ethics education by means of focus groups, interviews, and narratives. These qualitative methods would be able to characterize whether outcomes were achieved in medical ethics courses, and determine, for example, (1) the goals of the education, (2) the

best methods of teaching, (3) the identification and perception of ethical problems, (4) the moral reasoning skills of new students and experienced ethicists, (5) the change in process over the course of medical school, and (6) the best ways to evaluate the outcome of medical ethics courses.

In 2001, the American Society for Bioethics and Humanities (ASBH) conducted a survey on the state of graduate-level programs that train individuals to work in bioethics and medical humanities. Information collected included the number and type of existing programs, the year they started, target student populations, types of organizations offering these programs, the disciplinary homes of those organizations, enrollment levels, types of financial aid, and the backgrounds of the faculty by discipline. The ASBH prepared a report on the responses of 47 institutions (ASBH, 2001). It was learned that bioethics graduate training programs have a variety of disciplinary homes. Salary and placement data were not kept for graduates, but this type of information would be useful to determine the long-term impact of the training programs at the NIH. Most of the data gathered, however, were too descriptive to inform this feasibility study.

The University of Buffalo conducted an "objective structured clinical examination (OSCE)" of medical students, postgraduate trainees, and practicing physicians (1994). Researchers attempted to measure the clinical-ethical ability or the ability to identify, analyze, and attempt to resolve ethical problems arising in the practice of medicine. As a result of the study, they recommended a multimethod approach to the evaluation of bioethics. The primary disadvantage of the OSCEs was the psychometric limitations of the ethics OSCE—low internal consistency and reliability. An advantage might be the focus on actual behavior of candidates in a typical clinical situation.

Silverberg (2000) assessed the current resources of U. S. medical school training in bioethics in light of the higher incidence of revocation of physician licenses. This descriptive study explored medical ethics as taught in schools that participated in the survey. The authors found a large variation in the number of hours and content of bioethics courses taught in medical schools. Approximately three-quarters of schools had a structured bioethics program, about one-eighth had an integrated or combined curriculum, and fewer than 10 percent had no programs. By using the Internet, this study had a faster return rate than would surveys done through traditional mail. The authors believe that schools emphasizing processing skills, values clarification, and daily practical issues have greater potential value in changing behavior. They found no standard bioethical experience in medical schools; the argument for standardization is made in several articles reviewed below.

Lehmann and colleagues (2004) surveyed 91 medical schools that taught medical ethics education in the United States and Canada and found significant variation in the content, methods, and timing of ethics education. Lehmann's study was limited by the number of respondents, as fewer course directors than deans responded to the survey. There is little agreement on what, when, and how medical ethics should be taught. Lehmann also found

that a majority of schools had students evaluate the course formally, but follow-up of student performance was rarely evaluated. Slightly more than half of the deans reported evaluating student moral reasoning abilities. About one-third formally evaluated students' behavior in ethically difficult situations. It also was noted that faculty development and qualified teachers were lacking in this area and were an obstacle to ethics education. In summary, Lehmann determined that the current state of medical ethics education does not ensure a common standard for this education, and there is a great deal of variation in methods, curricula content, and placement of ethics within a 4-year curriculum. Future research should "address the need for a model curriculum that responds to students' concerns in addition to providing basic training in moral reasoning and ethical decision making (p. 688)." Lehmann believes that (1) basic skills training should be taught, (2) the culture of medical schools should be examined to address barriers to the goals of ethics education, (3) all schools should provide an institutional structure for teaching ethics, and (4) increased funding for faculty and curricula should be provided.

Goldie et al. (2004) evaluated the impact of a new medical curriculum on students' proposed behaviors on encountering medical dilemmas. Their findings supported the recommendation that small-group teaching should be the method preferred over lecture and large-group teaching. Full integration of ethics and law within the rest of the curriculum is recommended, particularly during the clinical years. The assessment of ethics also should be incorporated into all formal examinations. They also found that the first year of the curriculum had a positive impact on students' potential behavior in facing ethical dilemmas, but the remainder of the curriculum did not appear to have as much of an effect.

Roberts (2005) studied 300 medical students at the University of New Mexico to assess the teaching of ethical problems in human clinical research studies. Roberts believes that clinical research poses many ethical challenges, including selecting suitable scientific questions, balancing risks and benefits, managing conflicts of interest, obtaining informed consent, including potentially vulnerable participants, and offering appropriate compensation. The author points out that little consensus exists on how to prepare individuals for the ethical conduct of human research, and regulations for the educational preparation of investigators working with human volunteers are less strict than those for animal research. Roberts's study was most likely the first attempt of a medical ethics education intervention to employ a randomized controlled design with ethically relevant outcome measures. The study developed and tested two different approaches and a control group to learning research ethics, including a criteria-based intervention and clinical research and experience-based interventions focused on clinical research participants. The criteria-focused group used the Research Protocol Ethics Assessment Tool (RePEAT) as well as vignette stimuli in which diverse ethical considerations were embedded in hypothetical protocols. The criteria-focused group perceived ethical problems as more significant than the experienced-based group or the control group.

Students in the criteria-focused group were better able than those in the control group to discern specific ethical problems, closely resembling expert assessments.

Pellegrino (1990) thinks that the educational program for medical students should recognize that the "formation of student's thinking about clinical ethics must emerge from within the discipline and its role models." In recent years, many medical schools have evaluated their ethics curricula to see whether additional emphasis should be placed on formal, organized programs of medical ethics education. The use of the Delphi technique, according to the author, holds promise in achieving consensus on curricular areas of medical ethics. Musick used it to define a core curriculum in ethics education for medical schools (Musick, 1996). Schwarz (1992) sees the challenge to those who would evaluate and accredit medical schools: "LCME will be required to grapple with the serious challenges confronting the medical profession:…the development of attitudes, ethics and behaviors in future physicians." It is important to develop standards for the teaching of ethics, as well as a more precise definition of medical ethics education, so that faculty can perform educational planning and development. Some type of "core" or model curriculum might become a basis for ethics instruction in medical schools seeking full accreditation.

2.5 Timeliness of the Evaluation

Congress enacted the Government Performance and Results Act of 1993 to focus on improving program performance and providing greater accountability for results in the Federal Government. Results of the NIH bioethics training program feasibility study will help NIH officials make important decisions about viable options for assessing bioethics training programs across the NIH to support informed decisionmaking regarding the future direction, funding, and management of bioethics training programs at the NIH. The results of a full-scale evaluation also will be available to other ICs interested in conducting similar projects.

3. FEASIBILITY STUDY DESIGN

Feasibility study data sources include both new and existing data. Existing NIH grantee (CRISP, IMPAC II), publications, and Web-based data sources were used to construct the inventories of NIH-supported bioethics training programs and other organization-supported programs/centers. New data were collected through semi-structured interviews with key stakeholders at the NIH, directors of bioethics centers/programs, and PIs of active T15, K01, and S07 programs.

3.1 Study Questions

The basic research questions for the feasibility study included the following:

- In addition to the NIH, what organizations are involved in supporting bioethics training? To what extent do these programs rely on NIH support or duplicate NIH efforts?
- Is there an operative definition of "bioethics training"?
- What are the key characteristics of bioethics training programs? What are the key curricular components? What are the competencies being taught? Are there particular credentials for the instructors?
- What is the program's sustainability beyond NIH funding?
- What process and outcome evaluation methodologies and techniques are most appropriate for assessing the progress and impact of bioethics training programs at the NIH? Will these methodologies and techniques differ when assessing the various types of programs?
- Is there adequate justification to conduct a full-scale process and outcome evaluation? If not, what would need to occur for such an evaluation to be feasible?

3.2 Study Components

The approach to the feasibility study involved the following five basic components:

- *Information Gathering.* Information gathering activities included a review of written documentation and information on the background, history, scope, and evolution of the program; and discussions with key stakeholders from NIH offices and programs to identify available data and obtain their insights into bioethics training programs at the NIH.
- *Inventory of Bioethics Training Programs in the United States.* The inventory of U.S. organizations involved in bioethics training had two parts: (1) an inventory of bioethics training supported through NIH funding and (2) an inventory of other U.S. organizations/centers involved in bioethics training.
- *Data Collection.* Data collection activities included semi-structured interviews with key stakeholders at the NIH, directors/staff from other U.S. organizations/centers involved in bioethics training, and a sample of four grantees within each of three NIH bioethics programs (T15, K01, and S07).
- *Development of Programmatic Logic Models.* The results from the information gathering and data collection activities were used to develop an overall programmatic logic model and individual logic models for the three different types of bioethics training programs.

- *Development of Evaluation Design Options.* The results from the feasibility study were used to identify various process and outcome evaluation methodologies and techniques.

The overall design of the feasibility study, including evaluation questions, data sources, indicators, and data collection methods, is shown in Exhibit 1.

Exhibit 1. Feasibility Study Design Matrix

Evaluation Question	Data Source	Indicators	Data Collection Method
1. In addition to the NIH, what organizations are involved in supporting bioethics training? To what extent do these programs rely on NIH support or duplicate NIH efforts?	• Academic bioethics training centers • Center directors and staff • Center databases	• Date center established • Types of degrees in bioethics offered • Funding sources • Faculty characteristics • Range of programs/services • Research programs • Institutional home • Collaborating institutions	• Environmental scan • Interviews with center staff • Document review
2. Is there an operative definition of "bioethics training"?	• NIH stakeholders • RFA/PAs • Centers • NIH grantees • Reports/ documents	• Supporting literature • Key words	• Interviews with NIH grantees • Interviews with stakeholders • Document review
3. What are the key characteristics of bioethics training programs?	• NIH stakeholders • NIH grantees • Centers	• Key curricular components • Program activities • Types of degrees/certificates • Instructor/mentor credentials • Trainee characteristics • Number of disciplines involved	• Document review • Interviews with grantees
4. What is the program's sustainability beyond NIH funding?	• NIH grantees • Centers	• Institutional support • Integration of the program in the institution • Extent of dissemination of training • Replication of training in other settings/ institutions	• Interviews with current grantees • Interviews with former grantees • Interviews with center directors/staff
5. What process and outcome evaluation methodologies and techniques are most appropriate for assessing the progress and impact of bioethics training programs at the NIH? Will these methodologies and techniques differ when assessing the various types of programs?			• Determined from analysis of Questions 1–4
6. Is there adequate justification to conduct a full-scale process and outcome evaluation? If not, what would need to occur for such an evaluation to be feasible?			• Determined from analysis of Questions 1–4

3.3 Inventory of Bioethics Training Programs at the NIH

A critical first step in the feasibility study was creation of a comprehensive inventory of organizations involved in bioethics training supported through NIH funding. Using the inventory conducted by National Institute on Aging (NIA) staff in 2004, project staff used an iterative process to update the previous inventory by conducting a search of the NIH CRISP and IMPAC II databases for grants active in 2005. The search was conducted using the terms "bioethics and training," "ethical, legal, and social issues," and "ethics and training" from 2000 to 2005 in CRISP. The search yielded 1,049 grants. Of these, 91 were deemed appropriate (grants active in 2005 involving research and/or training in the field of bioethics). A Microsoft Access database was created containing the following information for each funded grant identified: funding mechanism/code, grant number, project title, PI, PI contact information, lead funding IC (many of the grants are cofunded by multiple ICs; however, only the primary IC is noted), scope (international or U.S.), Request for Application (RFA)/Program Announcement (PA), start date, end date, grantee organization, funding levels (2004, 2005, and 2006), and abstract. The inventory of active extramural bioethics training initiatives supported by the NIH is provided in Appendix A.

The inventory was used as a basis for beginning to describe and understand the similarities and differences between bioethics training programs supported by the NIH. There is considerable diversity in the types of programs across the NIH, with variation in the duration, funding level, funding mechanism, purpose, activities, and scope (U.S. or international). Program activities are wide-ranging and may include curriculum development and dissemination, mentored research, individual investigator research, institutional support to strengthen oversight of human subjects research, and investigator training in bioethics.

Bioethics training at the NIH is supported under a number of funding mechanisms. Exhibit 2 shows the distribution of grants by funding mechanism. The primary funding mechanisms are R25, S07, K01, and T15, representing 65 (71 percent) of 91 active grants. Other mechanisms of research support include P50, P20, R01, D43, T32, K23, K07, R03, R13, K30, and P41, representing 26 (29 percent) of active grants.

Funding levels for individual grants also are varied, ranging from $50,000 to $1,150,000. As shown in Exhibit 3, the NIH funded bioethics training grants at an annual cost of $20.04 million in 2004 and $17.79 million in 2005, totaling $37.83 million. The distribution of funding amounts across funding mechanisms (Exhibit 4) shows funding levels are the highest for the R25, P50, P20, T15, S07, and K01 programs. (Funding data for 2006 in the IMPAC II database were not complete. Therefore, these amounts are not shown.)

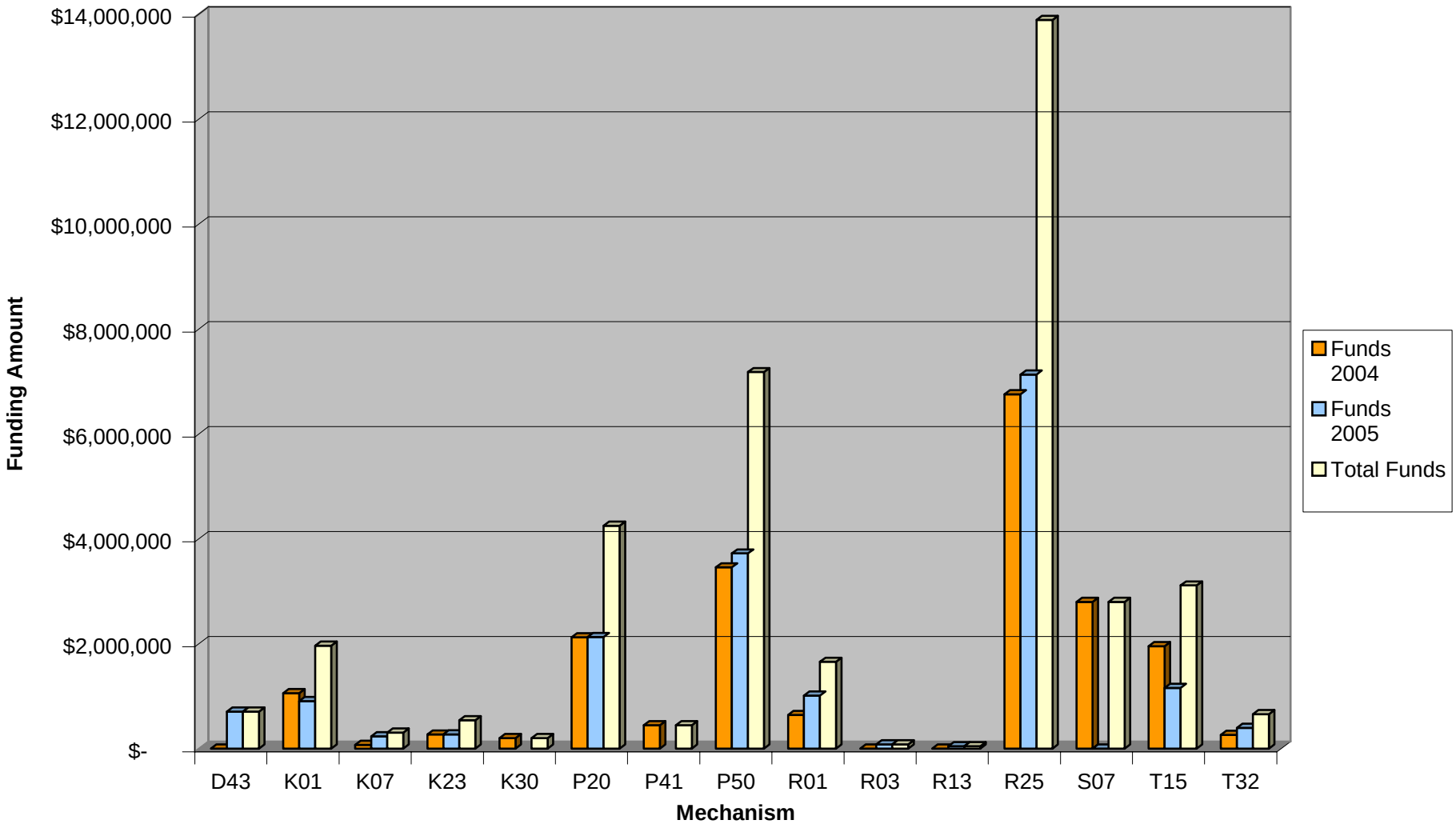
Exhibit 2. Grants by Funding Mechanism—U.S. and International

U.S. Programs			
K01	10	NHLBI (3), NHGRI (2), NIAID (2), NIMH (1), NIA (1), NCI (1)	PAR-01-144 (5) Mentored Scientist Development Award in Research Ethics PA-99-050 (5) Mentored Scientist Development Award in Research Ethics
K07	2	NCI, NIGMS	RM-04-007 Interdisciplinary Health Research Training: Behavior, Environment and Biology PAR-01-144 Innovative Toxicology Models: SBIR/STRR
K23	2	NIMH, NICHD	PA-00-004 Mentored Patient-Oriented Research Career Development Award
K30	1	NHLBI	ODOD98-007
P20	5	NHGRI (3) NCMHHD (2)	HG-03-005 MD-02-002
P41	1	NHGRI	Not Listed in IMPAC
P50	4	NHGRI	HG 03-005 Centers for Excellence in Ethical, Legal, and Social Implications (ELSI) Research (CEER)
R01	5	NINDS, NIDOCD, NHGRI (2), NINR	PA-04-050 NS-04-001 PA-96-042
R03	1	NHGRI	PA-04-051
R13	1	NHGRI	PAR-03-176
R25	12	NHGRI (4), NCRR (3), NIMH (3), NIDCR, NINDS	PA-00-134 PAR-02-087 RR03-007 PAR-97-095 PAR-00-036
S07	15	NCRR (15)	RFA OD-03-007 Human Subjects Research Enhancement Program
T15	9	NHLBI (9)	PAR-01-143 Short-Term Courses in Research Ethics
T32	2	NHLBI, NIA	PA-02-109 PA-00-103
International Programs			
D43	2	FIC	TW02-001 International Collaborative Genetics Research Training Program
R25	19	FIC	TW02-008 (10) International Bioethics Education and Career Development Award TW04-001 (9) International Bioethics Education and Career Development Award
TOTAL	**91**		

Exhibit 3. NIH Funding for Bioethics Training (2004 and 2005)

Mechanism	Funds 2004	Funds 2005	Total Funds
D43	—	$707,000	$707,000
K01	$1,056,953	$905,825	$1,962,778
K07	$72,757	$236,310	$309,067
K23	$270,116	$272,768	$542,884
K30	$200,000		$200,000
P20	$2,122,524	$2,127,439	$4,249,963
P41	$445,804		$445,804
P50	$3,456,510	$3,721,119	$7,177,629
R01	$642,416	$1,012,226	$1,654,642
R03	—	$80,500	$80,500
R13	—	$45,579	$45,579
R25	$6,755,371	$7,132,031	$13,887,402
S07	$2,799,153	—	$2,799,153
T15	$1,953,348	$1,158,110	$3,111,458
T32	$262,478	$395,766	$658,244
	$20,037,430	**$17,794,673**	**$37,832,103**

Exhibit 4. NIH Bioethics Training Program Grants Funding Amounts, by Year



The inventory illustrates the diversity and range of programs funded by the NIH to support extramural bioethics training initiatives. Given the considerable diversity across bioethics training programs, funding mechanisms, and program goals and activities, the focus of the feasibility study was narrowed to include three specific programs:

1. *Short-Term Courses in Research Ethics* (T15)—Grants to develop, conduct, evaluate, and disseminate short-term courses on ethical issues in research, particularly those involving human participants. Courses should improve the skills of biomedical, behavioral, nursing, social science, and public health researchers in identifying and addressing the ethical, legal, and social implications of their research, especially when human participants are involved.
2. *Mentored Scientist Development Award in Research Ethics* (K01)—Training in research ethics for health professionals working at academic and other health-related institutions in biomedical, behavioral, or public health research, particularly research involving human participants.
3. *Human Subjects Research Enhancement Awards (HSREA)* (S07)—Short-term interim support for institutional activities that will strengthen oversight of human subjects research at institutions that receive significant NIH support for clinical research.

3.4 Inventory of Other U.S. Organizations/Centers Involved in Bioethics Training

The inventory of bioethics training programs was expanded to the wider universe of bioethics programs, focusing on organized programs/centers that offer training beyond the requirements of the NIH. The American Society for Bioethics and Humanities (ASBH) survey cited earlier gathered information on graduate-level programs that train individuals for work in bioethics and medical humanities. This survey reported results from 42 U.S. institutions and included information on the starting year for programs; types of organizations offering these programs; the institutional and disciplinary homes of those organizations; disciplinary backgrounds of faculty; target student populations; enrollment levels; and graduate and placement information. An Internet search of the National Reference Center for Bioethics Literature at Georgetown University's Kennedy Institute of Ethics (Library and Information Services) yielded 127 nongovernmental bioethics organizations in the United States. The following criteria were applied to narrow the search to identify a smaller group of 17 established bioethics training centers/programs.

- Separate established program/center within an organization
- Program/center that offers a variety of degrees (including graduate-level programs) in bioethics
- Program/center that may have NIH funding but is not dependent on such funding for its continued existence

- Program/center that is fully integrated within the institution

Exhibit 5 shows the 17 bioethics centers/programs identified through the search of U.S. institutions. All of the centers/programs are located in academic institutions. The 17 institutions offer a variety of programs, including undergraduate and graduate degree programs, fellowships, and certificate programs. Of the programs indicating the year first offered, 2 were established in the 1970s, 5 in the 1980s, and 10 from 1990 to the present.

Exhibit 5. U.S. Centers/Organizations Involved in Bioethics Training

Center/Program	Institutional	Location	Starting	Current Bioethics
Center for Medical Ethics and Health Policy	Baylor College of Medicine	Houston	1982	Medical ethics track for undergraduate medical students; graduate program in philosophy with a specialization in bioethics
Department of Bioethics	Case Western University	Cleveland	2002	J.D./MA, MA/Ph.D. in genetics, MA/M.D. in bioethics, MA, MSN/MA
Medical Humanities Academic Program	Drew University	Madison, New Jersey		CMH (Certificate in Medical Humanities), MMH (Master of Medical Humanities), DMH (Doctor of Medical Humanities)
Duquesne University	Duquesne University	Pittsburgh		DHCE (Doctor of Health Care Ethics), Ph.D. (Doctor of Philosophy in Health Care Ethics), MA (Master of Arts in Health Care Ethics), CERT (Certificate in Health Care Ethics), Online distance learning
Center for Clinical Bioethics	Georgetown University Medical Center	Washington, D.C.	1991	M.D./Ph.D., Ph.D. in bioethics, MALS (Master of Arts in Liberal Studies)
Phoebe R. Berman Bioethics Institute	Johns Hopkins University	Baltimore	1995	Ph.D. in bioethics and health policy, MPH/J.D., undergraduate bioethics minor program
Neiswanger Institute for Bioethics and Health Policy	Loyola University	Chicago		MA in bioethics and health policy, M.D./MA program in bioethics and health policy, CME
Center for Ethics and Humanities in the Life Sciences	Michigan State University	East Lansing	1977	MA, MSN/MA, Ph.D.
Center for Health Care Ethics	Saint Louis University Hospital, Saint Louis University	St. Louis	1979	Ph.D. in health care ethics, graduate certificate in clinical health care ethics
Center for Bioethics	University of Minnesota	Minneapolis	1985	M.D./Ph.D.; Joint degree program in law, health and the life sciences; MA/MS; Ph.D. in the history of science and technology and history of medicine

Center/Program	Institutional	Location	Starting	Current Bioethics
Center for Bioethics	University of Pennsylvania	Philadelphia	1994	FEL, J.D./MA, MA, M.D./MA, MSN/MA
Center for Bioethics and Health Law	University of Pittsburgh	Pittsburgh	1987	MA in bioethics, FEL, J.D./MPH, J.D./MA, M.D./MA
University of Tennessee	University of Tennessee	Knoxville	1980	MA in philosophy with a concentration in medical ethics, Ph.D. in philosophy with a concentration in medical ethics
Institute for the Medical Humanities, Graduate School of Biomedical Sciences	University of Texas	Galveston		MA, MA/M.D., MA/J.D., Ph.D./M.D., Ph.D./J.D.
Program of Applied Ethics	University of Utah, Philosophy Department	Salt Lake City		Ph.D., MA, BA
Center for the Study of Bioethics	University of Wisconsin	Milwaukee	1982	FEL; J.D./MA; MA; M.D./MA; Ph.D.; Certificate in Clinical Bioethics; Medical student, resident, and fellow ethics education; AMA-MCW Online Fellowship
Center for Clinical and Research Ethics	Vanderbilt University	Nashville	1982	MA, M.D./MA, M.D./Ph.D.

3.5 Data Collection

Information to guide the identification of outcome measures and inform the feasibility of a full-scale program evaluation was obtained through semi-structured interviews with five groups of key informants:

- NIH stakeholders,
- Bioethics training centers staff,
- Grantees from the Short-Term Courses in Research Ethics (T15) program,
- Grantees from the Mentored Scientist Development Award in Research Ethics (K01) program, and
- Grantees from the Human Subjects Research Enhancement Awards (S07) program.

Semi-structured interview protocols were developed to guide the discussions. In developing the questions for these interviews, we had to account for the similarities and differences in the types of programs. The interviews were open-ended, although the interview questions were used to ensure that important material was covered. Exhibit 6 provides a list and characteristics of the five groups of key informants. Copies of questions asked for each group of respondents can be found in Appendix B.

Exhibit 6. Key Informant Data Collection

Informants	Number	Program Affiliation	Characteristics
NIH stakeholders	5	NIH-sponsored bioethics training programs	Current and former project officers from NHLBI, NIBIB, NIAID, and NCRR
Center staff	4	Bioethics training centers	2 centers without current NIH bioethics training grants 2 centers with current NIH bioethics training grants
PIs from active grants	4	Short-Term Courses in Research Ethics (T15)	Grants in their last year of funding
PIs from active grants	4	Mentored Scientist Development Award in Research Ethics (K01)	2 grants ending in 2006 2 grants in the third year of a 5-year grant
PIs from active and inactive grants	4	Human Subjects Research Enhancement Awards (S07)	2 active grants with carryover funds 2 grants completed in 2004

First, CSR staff conducted detailed discussions with program representatives at the NIH. These individuals included stakeholder representatives from NIH program offices involved in the K01, T15, and S07 programs, including NHLBI, NIBIB, NIAID, and NCRR. These discussions helped clarify program descriptions in the grant announcements and provided an understanding of the goals and objectives of each program. They also facilitated the identification of possible indicators and measures of the programs' impact.

Following interviews with NIH stakeholders, CSR staff conducted interviews with four grantee PIs from each of the three program types (K01, T15, and S07). The PIs interviewed were selected based on recommendations made by NIH project officers during the stakeholder interviews. They represent various characteristics, such as duration of grant, status (active/inactive), funding levels, and geographic distribution.

Finally, CSR staff conducted interviews with directors or key staff from 4 of the 17 external bioethics training centers. Information gathered included the history of the center, key components/services, degree programs offered, sources of funding, supporting or collaborating institutions, measures of impact/success, and dissemination activities.

4. SUMMARY OF FINDINGS

The findings summarized below address the first four research questions regarding (1) other organizations (outside of the NIH) involved in supporting bioethics training, (2) operational definition of bioethics training, (3) characteristics of the bioethics training program, and (4) program sustainability beyond NIH funding. The results of these findings and discussions in previous sections are then used to answer research question 5 regarding options for assessing bioethics training programs at the NIH, and question 6 regarding recommendations for a full-scale evaluation.

4.1 Organizations (in addition to the NIH) Involved in Supporting Bioethics Training

The search of nongovernmental organizations involved in supporting bioethics training identified more than 100 universities and research institutions in the United States. This report reflects the responses from semistructured interviews with staff from four of the institutions identified in Exhibit 5.

Bioethics training programs at the four centers have a variety of disciplinary homes within their institutions, including health care ethics, philosophy (two), and medicine. A wide variety of certificate, undergraduate, and graduate degree programs in bioethics are offered, including several joint degree programs (M.D./PH.D., MSN/MA, J.D./MA, and M.D./MA). In addition to academic degree programs, the centers support a range of activities, including faculty research, lecture series, service on national committees and IRBs, community outreach, ethics consultation, visiting scholars, and publications and journals. Center faculty are multidisciplinary, with specialties cutting across ethics, medicine, law, and biomedical and behavioral research. Faculty disciplinary backgrounds reported include: bioethics, law, medicine, nursing, molecular genetics, business, education, criminal justice, health sciences, history, regulatory systems, health care ethics, theology, philosophy, psychology, sociology, demography, religious education, health policy, and public policy.

Staff from one program/center refused to discuss internal and external funding sources for their programs. Of the three whose staff did, sources of funding include: the NIH, the health care system, private funding/gifts, university general funds, tuition, medical school subsidies, grants, and contracts. Three of the four centers are economically viable without NIH funding. One director reported that their center is very dependent on the university (which loses money each year) and continued funding from the NIH.

4.2 Definitions of Bioethics Training

This study identified a number of operational definitions of “bioethics training” used by stakeholders, grantees, and the NIH and its programs in the context of specific NIH programs. Exhibit 7 lists the various definitions and sources. The Belmont Report (1979) is cited as the basis of many of the human subjects and bioethics programs at the NIH.

The report includes a great deal of information about "ethical principles and guidelines for the protection of human subjects of research." It refers to "those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles are particularly relevant to the ethics of research: the principles of respect of persons, beneficence and justice."

- *Respect for persons* refers to the fact that individuals should be treated as autonomous agents, and persons with diminished autonomy (for example, children) are entitled to protection. Other examples include the involvement of prisoners in research: they may not be "subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer."
- *Beneficence* means that the research does not result in harm, and a researcher maximizes possible benefits and minimizes possible harms.
- *Justice* is defined as the balance of burdens and benefits such that each person has an equal share, "each person according to merit, and each person according to societal contribution." For example, some classes might be systematically selected for research studies simply because of their easy availability, their compromised position, or their manipulability, rather than the reasons directly related to the problem being studied (e.g., persons confined to institutions). The Belmont Report further applies these general principles to informed consent, risk/benefit assessment, disclosure to subjects, voluntariness, assessment of risks and benefits, and selection of subjects.

There are some common elements in the definitions of bioethics training, which includes training in **ethics**, **medical/scientific principles,** and **human subjects protections**. Some NIH definitions contain the **legal** aspects of ethics (the Mentored Scientist Development Award RFA and the NIH International Bioethics Education and Career Development Award Program); some mention **patients' rights** (the Human Subjects Research Enhancements Program [HSREA]—S07). Others refer to **social principles** (Mentored Scientists), and still others refer to **scientific** aspects (HSREA).

An area where commonality breaks down and areas of disagreement arise is whether ethics is subsumed under bioethics or vice versa. For example, a grantee argues that bioethics is much broader and encompasses life science and medical issues such as stem cell research and end-of-life issues, while research ethics is focused more on human subjects protections, informed consent, and protection of vulnerable subjects. The grantee thinks these are distinct "disciplines"—an investigator might be trained in one aspect and have little knowledge of others. Other grantees define bioethics as a subset of research ethics, as do some stakeholders at the NIH. In their view, ethics is a broad umbrella that covers issues like authorship and conflict of interest, while bioethics deals with protecting the welfare of subjects in the context of clinical research. The International Bioethics Education and Career Development Award Program seems to subsume the legal aspects of bioethics under "ethical considerations."

Exhibit 7. Definitions of "Bioethics Training"

	Source
The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.	The Belmont Report, 1979
"Training in research ethics." Training in the ethical, legal, and social principles guiding the responsible conduct of research, particularly focusing on scientific integrity and protection of the interests of research participants.	PAR-01-144, Mentored Scientist Development Award in Research Ethics
Training "investigative teams in the ethical as well as scientific aspects of human subjects research."	RFA OD-03-007, Human Subjects Research Enhancements Program
Training "in the ethical as well as scientific aspects of human subjects research"…"to ensure greater patient protections, to promote patients' rights and understanding of the research they are part of."	RFA OD-03-007, Human Subjects Research Enhancements Program
Imparting state-of-the-art knowledge of ethical considerations, concepts and methods in research involving human subjects such as principles of bioethics, codes and legal aspects of bioethics, ethical experimentation, informed consent, elements of study design or interventions provided to study participants, human rights, conflicts of interest, use of human biological material, vulnerable populations, and so on.	RFA TW-04-001, International Bioethics Education and Career Development Award Program, August 5, 2003
Bioethics training for research ethics is the preparation for the conduct of research that protects the rights and welfare of participants and makes sure there are no conflicts of interest and no misconduct.	Grantee
Training on research ethics enabling people to think from an ethical point of view and learn about ethics protocols.	Grantee
Delivering information about ethical principles behind all standards—professional, personal, and legal.	Grantee
There is a distinction between research ethics and bioethics. Bioethics is much broader and encompasses life sciences and medical issues such as stem cell research, end of life issues, etc., while research ethics is more focused on human subjects protections, informed consent, and protection of vulnerable subjects. It is important to distinguish the two.	Grantee
There is a clear distinction between ethics and bioethics. Bioethics is a subset of ethics focused on issues covered in the Belmont Report—things that threaten informed consent and related issues.	Grantee
"Ethics" is a broad umbrella term that covers issues like authorship, conflict of interest, tenure issues, etc. "Bioethics" is a subset of ethics that deals with protecting the welfare of subject volunteers in the context of clinical research.	NIH Stakeholder

4.3 Key Characteristics of Bioethics Training Programs

Interviews with PIs from the K01, T15, and S07 programs provided information about evaluation requirements and measures and methods employed to evaluate the effectiveness of funded programs. The findings from this data collection were then used to create programmatic logic models illustrating the common components across programs and the characteristics distinct to each funding mechanism.

4.3.1 *Individual Program Evaluations*

The program announcements for the K01, T15, and S07 programs include requirements for an impact evaluation of the programs. The K01 candidates are required to be available to provide information "helpful in evaluating the impact of the program," such as employment history, publications, research support, honors and awards, and professional activities. T15 programs are required to include "clear plans for evaluating the effectiveness of the course(s) in terms of attendees' perceptions of the material and conduct of the course." In addition, "there must be plans for assessing the longer-term impact, as measured by attendees' subsequent activities or responsibilities in their institutions in the areas of research bioethics." S07 institutions are required to include an evaluation of promising approaches to strengthening the systems of protections for research subjects, specifically, their potential usefulness, impact, and feasibility for other institutions that conduct human subjects research.

4.3.2 *K01 Program Evaluation Methods and Measures of Impact*

Interviews with K01 PIs provided a number of recommendations for possible measures to determine program impact. One PI suggested a focus on measures of types of presentations given and the venue for the presentation, rather than numbers of presentations. Another suggested that we measure how much the grantee serves "as a resource" to the NIH through participation in review groups, work groups, and workshops, as well as a resource to researcher colleagues, clinicians, and others at the grantee university. A third K01 grantee set up a Center for Ethics as a result of his grant, and suggested that data items measuring these kinds of spin-offs might be useful. This grantee also recommended that we perform qualitative analyses with open-ended questions to tap into areas such as the creation of additional centers, the impact on the community, and the reputation of researchers trained with K01 funds. Additional measures suggested were (1) invitations to speak, (2) citation impact of publications (bibliometric analysis), (3) publications and the journals in which they are published, and (4) becoming a resource in the field such that invitations to serve on advisory panels and make presentations increase.

4.3.3 *T15 Program Evaluation Methods and Measures of Impact*

Evaluations of trainings (content, competencies covered, and instructors' teaching quality) were done by almost all the T-15 programs interviewed. One program provides

its trainees with hand-held computers to score the individual evaluations of the training right after the training is given. Another method used is focus groups to assess what information should be included before the training is given. After the training, the staff assess the impact by trying to determine what knowledge has been gained and utilized in research ethics. This program also uses qualitative methods to assess impact, such as the amount of press coverage, how many telephone calls were received, and the number of computer "hits" on their distance learning coursework.

Another program developed a "sense of preparedness" scale to assess how much competency was gained as a result of the program. There also were pretests and posttests of knowledge gained. They collected course evaluations and will survey graduates in the spring of 2006. They assess the participants' knowledge of regulations and ethical issues, how well they perform a case analysis (scored using a standardized matrix and a self-report on level of preparedness to address ethical issues), and how they do on an index of confidence. They also assess how the instructors and participants would evaluate the program immediately following its completion and 1 year later. They focus on whether the course meets the objectives of increasing ethical and regulatory knowledge of the ethical issues, heightening ethical sensitivity, improving moral judgment, and fostering moral motivation. They evaluate the extent to which the trainees go on to use the program in their home institutions.

Most of the T-15 programs use outcome assessments related to longer-term impacts such as the quality of the teaching and reputation of the instructors and department. One program's evaluation process for its short-term courses on ethical issues in human subjects research includes: (1) participant evaluations of content and process, (2) interviews of selected participants 3 months after course completion, and (3) pretest and posttest course assessments of ethical knowledge, ethical behaviors, and the ethics environment of the research team.

Another program conducts the usual evaluations of the course content and instructors, but also measures the long-term impact of the program by how many "networks" of ethics committees and members are developed, how many hits are received on their Web site, and how stable the networks of committee members are.

4.3.4 *S07 Program Evaluation Methods and Measures of Impact*

The S07 grantees suggested possible measures of program impact and identified specific evaluation methods used to evaluate their individual programs. One grantee suggested that just completing the project—in this case setting up an online Institutional Review Board (IRB)—indicated the success of the project or a positive outcome. This grantee also completed user satisfaction surveys, as well as self-reports of increases in knowledge. The program tested how well trainees understood the subject matter, and computed a percentage of those who passed. Another grantee suggested a similar approach: that creating an online tool where everyone could see the IRB status on all

applications was an outcome in itself, as well as the fact that this institution received accreditation in terms of human subjects. They felt that accreditation was peer review of their entire program. For this grantee, the fact that everyone in the system can do IRB approvals online as well as updates was a long-term outcome that was substantial.

Other S07 grantees focused on the numbers trained—in one case close to 5,000 individuals, many of them new investigators. This grantee felt that the short-term outcome would be development of an IRB database, and the long-term outcome would be education of substantial numbers of investigators. Another grantee measured outcomes by how much knowledge and skill was gained. Evaluating whether people put ethical behavior in place is difficult, but at the very least, measures of knowledge gained can be determined through testing. This university responded to the query on outcomes by indicating that short-term outcomes were putting a process and procedures in place (in this case an online recertification examination, a software training program, and an online clinical newsletter which was essentially a paperless IRB system). They also measured success by how many enrolled in the certification program, whether researchers made positive comments about the internship program and the online system, and the number of articles published about the program.

4.3.5 *Program Logic Models*

The findings from the inventory of NIH programs, document reviews, and interviews with key informants at the NIH and grantee institutions were used to create programmatic logic models for bioethics training programs at the NIH. This report presents a generic logic model of the NIH bioethics training program and three separate models to illustrate how the K01, T15, and S07 programs work to achieve their intended NIH mandate (see Exhibits 8–11). Each model starts with inputs or resources of the program, and shows how the program works through planned activities or processes to produce outputs, and short- and long-term outcomes.

Exhibit 8. Generic Logic Model of the NIH Bioethics Training Program

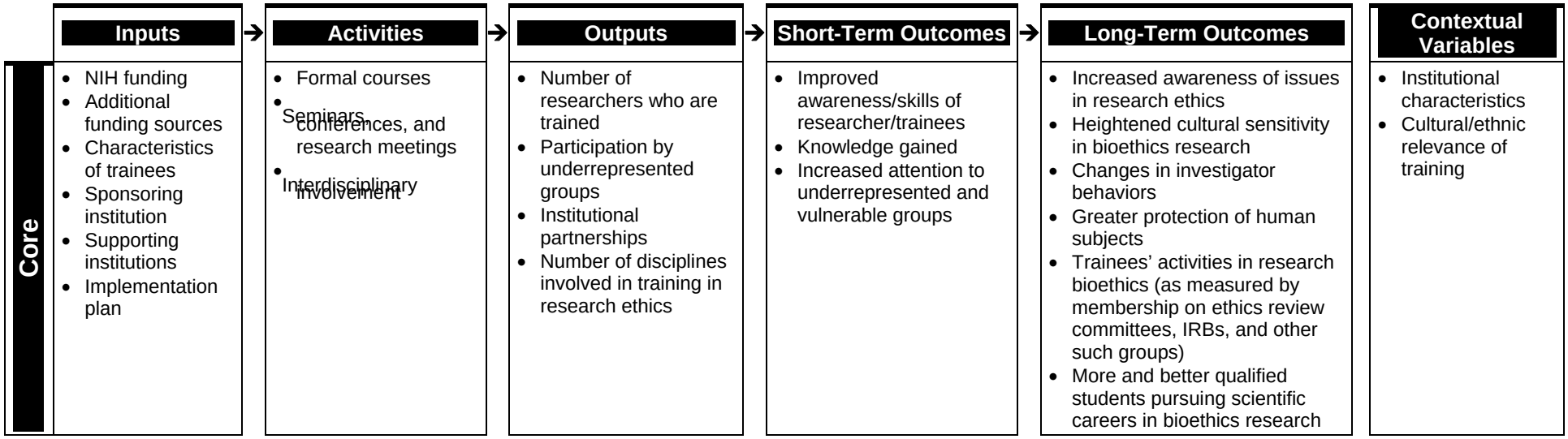


Exhibit 9. Logic Model for the K01 Mentored Scientist Development Award in Research Ethics Program

	Inputs	Activities	Outputs	Short-Term Outcomes	Long-Term Outcomes	Contextual Variables
Core	• NIH funding • Additional funding sources • Characteristics of trainees • Sponsoring institution • Supporting institutions • Implementation Plan	• Formal courses • Seminars, conferences, and research meetings • Interdisciplinary involvement	• Number of researchers who are trained • Participation by underrepresented groups • Institutional partnerships • Number of disciplines involved in training in research ethics	• Improved awareness/skills of researcher/trainees • Knowledge gained • Increased attention to underrepresented and vulnerable groups	• Increased awareness of issues in research ethics • Heightened cultural sensitivity in bioethics research • Changes in investigator behaviors • Greater protection of human subjects • Trainee activities in research bioethics (as measured by membership on ethics review committees, IRBs, and other such groups) • Increase in numbers/quality of students pursuing scientific careers in bioethics research	• Institutional characteristics • Cultural/ethnic relevance of training
K01-Specific	• Characteristics of mentors • Institutional commitment • Resources and facilities of institution • Research plan of mentee • Resources of GCRC • Career development plan of mentee	• Clinical observations • Interaction with mentors	No unique elements	• Satisfaction with training— Trainee satisfaction Mentor satisfaction • Changes in trainees' bioethics-related knowledge and skills • Changes in trainees' preparedness to identify and resolve bioethics issues	• Trainees' successful establishment of bioethics-related research careers • Trainees' publications on bioethics-related issues • Trainees' participation on IRBs and ethics review committees • Development of bioethics centers • Program sustainability	• Resources available to trainee • Type of mentor support/quality of mentors

Exhibit 10. Logic Model for the S07 Human Subjects Research Enhancement Awards Program

	Inputs	Activities	Outputs	Short-Term Outcomes	Long-Term Outcomes	Contextual Variables
Core	• NIH funding • Additional funding sources • Characteristics of trainees • Sponsoring institution • Supporting institutions • Implementation Plan	• Formal courses • Seminars, conferences, and research meetings • Interdisciplinary involvement	• Number of researchers who are trained • Participation by underrepresented groups • Institutional partnerships • Number of disciplines involved in training in research ethics	• Improved awareness/skills of researcher/trainees • Knowledge gained • Increased attention to underrepresented and vulnerable groups • Increased number of trained researchers	• Increased awareness of issues in research ethics • Heightened cultural sensitivity in bioethics research • Changes in investigator behaviors • Greater protection of human subjects • Trainee activities in research bioethics (as measured by membership on ethics review committees, IRBs, and other such groups) • Increase in numbers/quality of students pursuing scientific careers in bioethics research	• Institutional characteristics • Cultural/ethnic relevance of training
S07-Specific	• Characteristics of institution • Implementation plan/plan for activities • Resources and facilities of institution	• IRB committee observations • Interaction among investigators, administrators, and IRB members • Dissemination of educational materials • Development of tools/systems/technology for strengthening review • Collaboration with other institutions • Outreach to other institutions	• Best practices developed • Number of new educational initiatives	• Number of IRBs that have improved their certification processes through the training intervention • Number of IRBs adapting online IRB (“paperless IRB”) systems	• Fewer Code 44 (Human Subjects problems) flags on institutional grants • Increased awareness and familiarity with IRB procedures and issues among university researchers • Researcher satisfaction with IRB review process at targeted institutions	• Quality of research program • Resources and facilities of institution

Exhibit 11. Logic Model for the T15 Short-Term Courses in Research Ethics Program

	Inputs	Activities	Outputs	Short-Term Outcomes	Long-Term Outcomes	Contextual Variables
Core	• NIH funding • Additional funding sources • Characteristics of trainees • Sponsoring institution • Supporting institutions • Implementation plan	• Formal courses • Seminars, conferences, and research meetings • Interdisciplinary involvement	• Number of researchers who are trained • Participation by underrepresented groups • Institutional partnerships • Number of disciplines involved in training in research ethics	• Improved awareness/skills of researcher/ trainees • Knowledge gained • Increased attention to underrepresented and vulnerable groups • Increased number of trained researchers	• Increased awareness of issues in research ethics • Heightened cultural sensitivity in bioethics research • Changes in investigator behaviors • Greater protection of human subjects • Trainee activities in research bioethics (as measured by membership on ethics review committees, IRBs, and other such groups) • Increase in numbers/quality of students pursuing scientific careers in bioethics research	• Institutional characteristics • Cultural/ethnic relevance of training
T15-Specific	• Characteristics/qualifications of instructors • Curricula of coursework	• Online/Internet/video coursework • Biannual meeting of course developers • Dissemination of educational materials	• Number of innovative programs with new approaches to teaching • Number of new training delivery methods (e.g., videoconferencing) • Models and cases studies for ethical decisionmaking • Curricula with emphasis on cultural values, beliefs, and practices • Curricula addressing needs of junior and senior biomedical researchers • Participation by interdisciplinary investigators such as biomedical, nursing, social science, and behavioral researchers • Amount of material disseminated • Community participation	• Training participants' satisfaction with training content and experiences • Changes in participants' knowledge and/or skills in bioethics-related issues • Number of trainers trained who conduct at least one training activity at their home institutions (for train-the-trainers-type programs)	• Number of networks of ethics committees and members developed • Number of institutions using the training materials or offering the training courses	• Course duration and frequency • Course format (Internet, video, classroom)

4.4 Program Sustainability Beyond NIH Funding

NIH grantees were asked about the sustainability of their bioethics training program beyond NIH funding support—whether their university or research organization has been or will continue supporting the program after NIH funding ceases, and whether there are plans for continuing the program after the NIH funding. When asked about whether the program *should* be continued, PIs referred to the success of their program and responded that it should be continued. At least five of the PIs interviewed indicated that their programs definitely would not be continued beyond NIH funding; two indicated that program sustainability was uncertain; and five reported that there are either plans for continuation or that the program definitely will or has been continued. The reasons for lack of continuation funding include dependency on external funding (primarily the NIH), the institution's low priority on bioethics, and funding cuts in State support. The one T15 program that will be sustained is a train-the-trainer program that will continue through the use of course materials at trainee institutions. One K01 PI reported that he will continue his research through his university's increased support for research ethics. In addition, he has submitted R01 applications, written several papers, and "engaged the community." As a spin-off of his K01 grant, the community is creating a Center for Ethics in Science and Technology.

In addition to questions about sustainability, the S07 grantees (which included two active grants and two completed grants) were asked about dissemination/replication of their programs. Three of the four programs have been or will definitely be continued and either replicated as designed or adapted for others to replicate. Dissemination vehicles include published articles in peer-reviewed journals, newsletter articles, and distribution to other institutions.

5. Options for a Full-Scale Outcome Evaluation

The evaluation of bioethics training programs at the NIH presents some unique challenges:

- There is no consistent operational definition of "bioethics training."
- There is considerable diversity in the types of bioethics training programs funded across the NIH.
- There is no uniform collection of data across programs or within funding mechanisms.

The definitions of "bioethics training" across NIH-funded programs and external centers are either nonexistent or broadly defined and not uniformly applied across the various programs, making it a challenge to evaluate their impact. Given the lack of a common definition of what constitutes a "bioethics training" program, it is difficult to determine

which programs fall into this category. Also, there is no clear classification of the different types of programs within the broader category of "bioethics training" programs.

Although the inventory of active extramural training programs was developed to begin to understand the similarities and differences between bioethics training programs supported by the NIH, it actually illustrates the considerable diversity in the types of programs funded. The programs identified in the inventory are diverse in structure and purpose. This diversity also includes variation in the programs' activities, scope, duration, funding levels, funding mechanism(s), and evaluation requirements. The variability of programs makes it difficult to evaluate the relative effectiveness/impact of bioethics training programs as a whole across the NIH. This variability also makes it difficult to determine whether individual programs are duplicative of other training programs either within or outside the NIH. Therefore, a systematic approach is needed to define and evaluate bioethics training programs supported by the NIH.

Although evaluations are required as part of the RFA/PAs, there is no consistent collection of data within funding mechanisms or a centralized repository of program evaluation data on NIH-funded bioethics training programs.

Considering these challenges, the following table, Exhibit 12, lists some of the options for evaluating bioethics training programs at the NIH and presents some of the advantages and disadvantages of each option.

Exhibit 12. Options for Assessing Bioethics Training Programs at the NIH

	multiple case study research design. • Each funded program evaluated based on the programmatic logic model. • Avoids comparing one program with another. • Provides evidence to determine the replicability of the program model in different settings. • If all cases turn out as predicted, the aggregate provides compelling support for program continuation.	• If the findings are contradictory across programs (case studies), there are no outcome data to explain the differences.
2. Pre-post evaluation	• Evaluation of programs at three points, e.g., baseline (programs as planned); after full implementation; 1 year after NIH funding ends. • Addresses the short-term and long-term program goals.	• Requires a multiyear evaluation. • Requires a more labor-intensive and costly evaluation effort. • Trainees may move around in pursuing their careers, making tracking difficult after the program ends.

3. Mixed methods design	• Provides both outcome and process data. • Combines a quantitative survey of trainees and mentors with case studies on program implementation. • Outcome data collection can be standardized across program types. • Uses multiple sources of data to evaluate the program's effectiveness.	• Requires a long-term study—at least 2 years.
4. Meta-analysis	• Uses existing program evaluation results.	• Limitations as an evaluation method. • Has been no uniform or consistent evaluation of funded programs.
5. Systematic comparison of programs by funding mechanism	• Provides the "value added" by using one mechanism compared to another. • Uses citation analysis linked to funding mechanisms. • Requires no new data collection.	• Not feasible for all funding mechanisms, e.g., S07s. • Does not address the variability of support for centers vs. individual investigators. • Publications of researchers trained in bioethics centers might have carried papers on bioethics research that do not acknowledge their center training as a source of support.
6. Retrospective evaluation	• Provides a measure of the long-term impact of the program. • Data extraction from existing sources can be used for analysis.	• Institutions no longer receiving grant funding may not have an interest in participating (incentives could be offered but this would add to the study's cost). • Will need to rely heavily on NIH grantee files which may be incomplete. • May be difficult to identify and track trainees.

6. RECOMMENDATIONS FOR A FULL-SCALE EVALUATION

The results of the feasibility study point to the need for the NIH to first more narrowly focus the overall NIH training program to be evaluated. It is important to start with this step before implementing a full-scale evaluation in order to avoid conducting a full-scale study that produces little useful data to measure the effectiveness of bioethics training programs at the NIH.

First, the NIH should adopt a common definition of what constitutes a bioethics training program grant. We recommend that the NIH form and collaborate with a panel of nationally recognized experts in bioethics research to create a common definition of "bioethics training." Based on this definition, the NIH should develop a classification

system with functional criteria for what constitutes a bioethics training grant. The categories described in the inventory are one possibility: (1) programs to train groups of investigators, (2) programs to train an individual investigator, and (3) programs aimed at training/educating an IRB. The final classification system should be uniformly applied to all Institutes to categorize bioethics training programs, regardless of their funding mechanism. Based on this initial effort to clarify and state explicitly which programs the full-scale evaluation will address, we can then develop and propose the most rigorous evaluation design consistent with the research questions and the available resources. Given the diversity of bioethics training programs across the NIH, a simple one-size-fits-all evaluation approach is not feasible. The evaluation must weigh the results achieved against the goals and objectives of the various programs.

Therefore, we recommend a mixed-methods approach, incorporating qualitative case studies of funded programs and a survey of a sample of programs within each type of program identified through the standardized classification system. A study design incorporating multiple data sources will strengthen the reliability and depth of the findings. The qualitative case studies will provide contextual information to explain differences in the quantitative outcome data.

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Feasibility Study of Optimal Approaches for Assessing Bioethics Training Programs at the National Institutes of Health

Appendix A: NIH Bioethics Training Programs Grants Database

CSR Incorporated
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NIH Bioethics Training Programs Grants Database

Grant List (Active)

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
D43	5D43TW006152-04	US/Costa Rica Psychiatric Genetic Research Training	Escamilla, Michael A.	FIC	International	TW02-001	19-Sep-02	31-Aug-07	University of Texas Health Sciences Center San Antonio		$400,000.00	$400,000.00
D43	5D43TW006167-04	Training Program for Psychiatric Genetics in India	Nimgaonkar, Vishwajit L.	FIC	International	TW02-001	18-Sep-02	31-Aug-07	University of Pittsburgh at Pittsburgh		$307,000.00	$325,970.00
R25	2R25TW001599-03	South African Research Ethics Training Initiative	Ijsselmuiden, Carel B.	FIC	International	TW02-008	30-Sep-00	31-May-06	University of Pretoria	$250,000.00	$250,000.00	
R25	5R25TW001596-05	International Fellowship in Health Research Ethics	Cash, Richard A.	FIC	International	TW02-008	30-Sep-00	31-May-06	Harvard University (School of Public Health)	$147,976.00	$151,028.00	
R25	5R25TW001599-06	South African Research Ethics Training Initiative	Wassenaar, Douglas R.	FIC	International	TW02-008	30-Sep-00	31-May-06	University of KwaZulu-Natal	$250,000.00	$250,000.00	
R25	5R25TW001603-05	International Research Ethics Training Program	Loue, Sana	FIC	International	TW02-008	30-Sep-00	31-May-06	Case Western Reserve University	$247,454.00	$249,054.00	
R25	5R25TW001604-05	Bioethics Training for Developing Country Professionals	Kass, Nancy E.	FIC	International	TW04-001	30-Sep-00	30-Jun-08	Johns Hopkins University	$249,995.00	$249,890.00	$249,999.00
R25	5R25TW001605-05	A Training Program in Research Ethics in the Americas	Macklin, Ruth	FIC	International	TW02-008	30-Sep-00	31-May-06	Yeshiva University	$237,127.00	$240,897.00	
R25	5R25TW001606-05	University of Toronto MHSC in International Bioethics	Singer, Peter A.	FIC	International	TW04-001	30-Sep-00	31-May-08	University of Toronto	$250,000.00	$250,000.00	$250,000.00
R25	5R25TW006055-03	Monash Univ Master of International Research Bioethics	Loff, Beatrice	FIC	International	TW02-008	18-Sep-02	31-May-06	Monash University	$150,000.00	$150,000.00	
R25	5R25TW006056-03	Research Bioethics Training in Latin America	Lolas, Fernando S.	FIC	International	TW02-008	13-Aug-02	31-May-06	University of Chile	$309,000.00	$309,000.00	
R25	5R25TW006057-03	International Research Ethics Network, Southern Africa	Benatar, Solomon R.	FIC	International	TW02-008	09-Aug-02	31-May-06	University of Cape Town	$182,372.00	$185,315.00	
R25	5R25TW006058-03	Training on Research Bioethics (TORB)	Rashid, Harun A.	FIC	International	TW02-008	13-Aug-02	31-May-06	Bangladesh Medical Research Council	$150,000.00	$150,000.00	

Report Selection: Active grants, sorted by funding mechanism and grant number

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
R25	5R25TW006061-03	Curriculum Dev and Intensive Training in Res Ethics	DeCastro, Leonardo D.	FIC	International	TW02-008	13-Aug-02	31-May-06	University of the Philippines	$249,998.00	$250,000.00	
R25	R25TW007085	E-Education in Research Ethics: Central and Eastern Europe	Strosberg, Martin	FIC	International	TW04-001	14-Sep-04	31-May-08	Graduate College of Union University	$249,670.00	$249,994.00	$250,000.00
R25	R25TW007087	Training for Scholarships in Research Ethics	Tomlinson, Thomas	FIC	International	TW04-001	15-Sep-04	31-May-08	Michigan State University	$61,157.00	$220,174.00	$238,017.00
R25	R25TW007090	International Research Bioethics Training Program: Egypt	Silverman, Henry	FIC	International	TW04-001	03-Sep-04	30-Jun-08	University of Maryland Baltimore Prof School	$201,284.00	$234,832.00	$246,201.00
R25	R25TW007091	West African Bioethics Training Program	Adebamowo, Clement	FIC	International	TW04-001	01-Jul-04	30-Jun-06	University of Ibadan, Ibadan, Nigeria	$25,000.00	$25,000.00	
R25	R25TW007093	Centrally Co-ordinated Bioethics Education for India	Kumar, Nandini	FIC	International	TW04-001	07-Sep-04	31-May-08	Indian Council of Medical Research	$121,878.00	$150,657.00	$250,000.00
R25	R25TW007098	Strengthening Bioethics Capactiy and Justice in Health	Behets, Frieda	FIC	International	TW04-001	08-Sep-04	31-May-08	University of North Carolina Chapel Hill	$249,981.00	$249,998.00	$249,986.00
R25	R25TW007101	Bioethics for the Commonwealth of Independent States		FIC	International	TW04-001	01-Jun-04	31-May-07	Russian Academy of Sciences	$50,000.00		$1.00
K01	1K01HL072437-01A2	Ethical Issues Regarding Women in Health Research	Lyerly, Anne D.	NHLBI	National	PAR01-144	17-Dec-04	30-Nov-09	Duke University		$102,600.00	
K01	5K01AG021091-03	Ethical Aspects of Dementia Research		NIA	National	PA99-050	01-Apr-02	31-Mar-06	Johns Hopkins University	$88,602.00	$90,947.00	
K01	5K01AI001591-04	Training in Clinical Research Ethics	Kalichman, Michael W.	NIAID	National	PA99-050	01-Aug-01	31-Jul-06	University of San Diego	$84,780.00	$84,780.00	
K01	5K01AI055247-02	Vulnerable Populations and Special Protections in ACTUs	Sengupta, Sohini	NIAID	National	PAR01-144	30-Sep-03	31-Aug-08	University of North Carolina Chapel Hill	$93,848.00	$95,934.00	$98,513.00
K01	5K01HG002299-05	Concepts of Race & Ethnicity in Genetics Research	Hunt, Linda M.	NHGRI	National	PA99-050	01-Jul-00	31-May-06	Michigan State University	$156,955.00		
K01	5K01HG002883-02	Distibutive Justice in Human Genetic Variation Research	Lee, Sandra M.	NHGRI	National	PAR01-144	01-Aug-03	31-Jul-08	Stanford University	$120,876.00	$120,952.00	$121,003.00
K01	K01CA96872	Ethical Challenges in Cancer Clinical Research	Joffe, Steven	NCI	National	PA99-050	05-Jul-02	30-Jun-07	Dana-Farber Cancer Institute	$135,380.00	$157,437.00	$157,437.00
K01	K01HL72501	An Ethical Analysis of Organ Donation Policies	Fox, Mark D.	NHLBI	National	PAR01-144	01-Jul-03	30-Jun-08	University of Oklahoma Health Sciences Center	$126,800.00	$126,800.00	$126,698.00

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
K01	K01HL72530	Quality of Communication after Newborn Genetic Screening	Farrell, Michael H.	NHLBI	National	PAR01-144	01-Jul-03	30-Jun-08	Medical College of Wisconsin	$135,409.00	$126,375.00	$126,375.00
K01	K01MH001851	Competence of Human Subjects to Consent to Research	Candilis, Philip J.	NIMH	National	PAR98-006	20-Aug-99	31-Jan-06	University of Massachusetts Medical School Worchester	$114,303.00		
K07	5K07GM072884-02	PHD in Clinical Research	Harrican, Rosanne C.	NIGMS	National	RM04-007	20-Sep-04	31-Jul-09	University of Hawaii at Manoa		$161,370.00	$116,996.00
K07	K07CA108457-01	Internet use and informed consent	Simon, Christian	NCI	National	PAR01-144	01-Sep-04	31-Aug-09	Case Western Reserve University	$72,757.00	$74,940.00	$77,189.00
K23	1K23HD047634-01	Exception from Informed Consent in Pediatrics	Morris, Marilyn C.	NICHD	National	None	15-Aug-04	31-Jul-08	Columbia University Health Sciences	$102,392.00	$105,044.00	$105,765.00
K23	5K23MH066062-03	Enhancing Informed Consent in Late-Life Psychosis	Dunn, Laura B.	NIMH	National	PA00-004	25-Jul-02	30-Jun-07	University of San Diego	$167,724.00	$167,724.00	$167,724.00
K30	5K30HL004130-06	Clinical Research Training Program	Parsonnet, Julie	NHLBI	National	OD98-007	01-Jun-99	31-May-06	Stanford University	$200,000.00		
P20	1P20HG003373-01	Center on Genomics/Social Identity in African Diaspora	Royal, Charmaine D.M.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-07	Howard University	$220,091.00	$225,173.00	$231,926.00
P20	1P20HG003387-01	ELSI Scale-Up: Large Sample Gene Discovery & Disclosure	Bailey, Donald B.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-06	University of North Carolina Chapel Hill	$214,634.00	$214,503.00	
P20	1P20HG003400-01	Genetics, Vulnerable Populations and Health Disparities	Sheilds, Alexandra E.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-07	Georgetown University	$187,799.00	$187,763.00	$186,426.00
P20	1P20MD000195-01	Reducing Health Disparities in Alabama's Black Belt	Payton, Benjamin F.	NCMHHD	National	MD02-002	30-Sep-02	31-Aug-07	Tuskegee University	$1,150,000.00	$1,150,000.00	$1,150,000.00
P20	1P20MD000199-01	Reducing Health Disparities in Alabama's Black Belt	Higginbotham, John C.	NCMHHD	National	MD02-002	30-Sep-02	31-Aug-07	University of Alabama in Tuscaloosa	$350,000.00	$350,000.00	$350,000.00
P41	5P41HG001115-11	National Information Resource on Ethics & Human Genetics	Walters, Leroy B.	NHGRI	National		01-Sep-94	31-Jul-10	Georgetown University	$445,804.00		
P50	1P50HG003374-01	Genomic Health Care and the Medically Underserved	Burke, Wylie G.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-09	University of Washington	$911,748.00	$900,847.00	$911,568.00
P50	1P50HG003389-01	Center for Integrating Ethics & Genetic Research	Cho, Mildred K.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-09	Stanford University	$689,985.00	$803,537.00	$852,013.00
P50	1P50HG003390-01	Center for Genetic Research, Ethics, and Law	Juengst, Eric T.	NHGRI	National	HG03-005	01-Sep-04	31-Jul-09	Case Western Reserve University	$905,664.00	$1,040,969.00	$1,075,892.00

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
P50	1P50HG003391-01	Duke Center for the Study of Public Genomics	Cook-Deegan, Robert Mullan	NHGRI	National	HG03-005	01-Sep-04	31-Jul-09	Duke University	$949,113.00	$975,766.00	$1,004,188.00
R01	1R01DC005831-01A1	Societal Impact of Advances in Genetic Deafness	Pandya, Arti	NIDOCD	National	None	01-Sep-04	31-Jul-09	Duke University	$268,905.00	$265,720.00	$262,990.00
R01	1R01HG003891-01	Trust and Genetics Research in Diverse US Communities	Spicer, Paul G.	NHGRI	National	PA04-050	01-Sep-03	31-Aug-07	Virginia Commonwealth University		$396,437.00	$384,450.00
R01	1R01NR009357	Monitoring Fidelity to Promote Research Integrity	Santacroce, Sheila	NINR	National	NS04-001	30-Sep-04	29-Sep-06	Yale University	$266,096.00	$190,069.00	
R01	1R01NS049548-01	Defining the Learning Curve in Research Trials	Taekman, Jeffrey M.	NINDS	National	NS04-001	01-Sep-04	31-May-06	Duke University	$107,415.00	$160,000.00	
R01	5R01HG002263-03	Evaluating Use of Genetic Information: A Model Process	Burke, Wylie G.	NHGRI	National	PA96-042	01-Feb-01	31-Jan-06	University of Washington			
R03	1R03HG003682-01	The ELSI of Genetic Testing in the Workplace	Brandt-Rauf, Paul W.	NHGRI	National	PA04-051	05-Sep-05	31-Aug-07	Columbia University Health Sciences		$80,500.00	$80,500.00
R13	1R13HG003943-01	Ethics of Genetics in Research Conferences	Fischbach, Ruth L.	NHGRI	National	PAR03-176	26-Sep-05	31-Aug-06	Columbia University Health Sciences		$45,579.00	
R25	1R25DE015350-01	Genetics Education in Dentistry	Johnson, Lynn	NIDCR	National	None	08-Sep-03	30-Jun-07	University of Michigan at Ann Arbor	$161,989.00	$159,952.00	$159,676.00
R25	1R25HG002756-01	Problem-Based Learning Unit for Teaching ELSI/Genetics	Markowitz, Dina Grossman	NHGRI	National	PA00-134	15-Aug-03	30-Jun-06	University of Rochester	$433,241.00	$399,865.00	
R25	1R25HG002813-01A2	Faith Forum on Genetics: ElSI Educational Intervention	Marenco, Marc	NHGRI	National	None	22-Mar-05	28-Feb-07	Pacific University	$127,726.00	$129,527.00	
R25	1R25HG002903-01	Interactive ELSI Curriculum for Primary Care Residents	Wilkes, Michael S.	NHGRI	National	PA00-134	30-Sep-03	31-Aug-06	University of California Davis	$446,854.00	$511,797.00	
R25	1R25MH071753-01A1	US Psychiatric Genetics Research Training Program	Escamilla, Michael A.	NIMH	National	PAR02-087	12-Sep-05	31-Aug-08	University of Texas Health Sciences Center San Antonio		$237,600.00	
R25	1R25RR019488-1	Master of Science & Clinical: HLTH Disparities, Aging, CVD, Diabetes, Kidney	Yoshikawa, Thomas	NCRR	National	RR03-007	30-Sep-03	31-Jul-08	Charles R. Drew University of Medicine & Science	$536,552.00	$538,326.00	$540,000.00
R25	5R25HG001276-08	A Program for Expanding ELSI Undergraduate Pedagogy	Green, Ronald M.	NHGRI	National		01-Sep-96	31-Mar-06	Dartmouth College	$406,409.00	$353,482.00	
R25	5R25MH055929-10	Training in Professional Development for Neuroscience	Martinez, Joseph L.	NIMH	National	PAR97-095	30-Sep-95	31-May-06	Marine Biological Laboratory	$159,078.00	$158,979.00	

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
R25	5R25MH056194-09	Training Faculty to Teach Survival Skills and Ethics	Zigmond, Michael J.	NIMH	National		30-Sep-96	31-Aug-06	University of Pittsburgh at Pittsburgh	$149,751.00	$153,719.00	
R25	5R25NS046740-06	Survival Skills and Ethics Workshops for Neuroscientists	Fischer, Beth A.	NINDS	National		20-Sep-00	31-Aug-07	University of Pittsburgh at Pittsburgh	$55,449.00	$57,113.00	$58,825.00
R25	5R25RR016284-02	Collaborations to Advance Understanding Science & Ethics	Cunningham, Susanna	NCRR	National	PAR00-036	30-Sep-03	31-Aug-06	University of Washington	$321,430.00	$319,353.00	
R25	5R25RR016291-3	SEPA: Genome Science Education Program: Internet	Stark, Louisa	NCRR	National	PAR00-036	15-Jul-01	30-Jun-06	University of Utah	$324,000.00	$296,479.00	
S07	2S07RR018126-2	E-Communication between Human Subjects Compliance Offices	Shapiro, Larry J.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Washington University	$250,000.00		
S07	2S07RR018137-02	Promoting an Environment of Compliance	Chiorazzi, Nicholas	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	North Shore-Long Island Jewish Research Institute	$200,000.00		
S07	2S07RR018140-02	Computer-Based Learning for Human Subjects Protection	Chanaud, Cheryl M.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	St. Jude Children's Research Hospital	$150,000.00		
S07	2S07RR018141-02	Novel On-line Education in Protection of Human Subjects	Coller, Barry S.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Rockefeller University	$150,000.00		
S07	2S07RR018143-02	South Florida Human Subjects Benchmarking Coalition	Altman, Norman Harry	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	niversity of Miami-Medical U			
S07	2S07RR018145-02	Collaboration to Enhance Human Subjects Protections	Nebeker, Camille	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	San Diego State University	$100,000.00		
S07	2S07RR018146-02	IRB Training Through a Web-Based Protocol Review Form	Prentice, Ernest D.	NCRR	National	OD03-007	10-Sep-02	30-Sep-06	University of Nebraska Medical Center	$100,000.00		
S07	2S07RR018155-02	Enhancements to UW's Human Subjects Protection Program	Mulcahy, R.T.	NCRR	National	OD03-007	-	-	(Not on file)	$250,000.00		
S07	2S07RR018180-02	FHCRC-Human Subjects Research Enhancements Program	Storer, Barry E.	NCRR	National	OD03-007	01-Sep-02	31-Dec-05	Fred Hutchinson Cancer Research Center	$250,000.00		
S07	2S07RR018182-02	Human Research Protections Enhancement Project; Phase II	Van Dam, Andries	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Brown University	$150,000.00		
S07	2S07RR018216-02	Purdue Univ. Human Subjects Research Enhancements	Rutledge, Charles O.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Purdue University West Lafayette	$100,000.00		

Mech.	Grant Number	Project Title	Principal Investigator	Lead Funding IC	Scope	RFA_PA	Start Date	End Date	Grantee Organization	Fund (2004)	Fund (2005)	Fund (2006)
S07	2S07RR018223-02	Improving Human Subject Research by Enhancing Education	Murthy, Sreekant	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Drexel University College of Medicine	$99,965.00		
S07	2S07RR018243-02	Protecting Human Subjects in Research	Moore, Thomas J.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Boston University Medical Campus	$399,188.00		
S07	2S07RR018254-02	IRB Enhancement, Education and Training	Newell, Margaret E.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	Tufts University Boston	$250,000.00		
S07	2S07RR018274-2	SCCISARS: An E-Solution to Protect Human Subjects	Sullivan, Cornelius W.	NCRR	National	OD03-007	01-Sep-02	31-Aug-06	University of Southern California	$350,000.00		
T15	1T15HL072470-01A1	Research Ethics Training of Integrated Health Delivery	Hill, Joal M.	NHLBI	National	PAR01-143	14-Jun-04	30-Apr-07	Park Ridge Center for the Study of Health, Faith and Ethics	$173,163.00	$175,582.00	$16,524.00
T15	1T15HL072514-01A1	Valid Consent/Refusal: A Core Competency for Research	Goold, Susan D.	NHLBI	National	PAR01-143	18-Aug-04	31-Jul-07	University of Michigan at Ann Arbor	$467,945.00	$470,594.00	$516,180.00
T15	5T15HL007246-02	Ethics in Behavioral Health Services Research	Stiles, Paul G.	NHLBI	National	PAR01-143	30-Sep-03	31-Jul-06	University of South Florida	$162,184.00	$98,299.00	
T15	5T15HL069792-05	Short Courses in Research Ethics and Environmental	Quigley, Dianne P.	NHLBI	National	PAR01-143	30-Sep-00	31-Jul-06	Syracuse University	$210,160.00	$208,960.00	
T15	5T15HL070903-03	Research Ethics Course for Research Nurse Coordinators	Hamric, Ann B.	NHLBI	National	PA99-051	01-Apr-02	31-Mar-06	University of Virginia Charlottesville	$210,160.00		
T15	5T15HL072440-02	Culturally Tailored Ethics Training for the Latino Comm	Nebeker, Camille	NHLBI	National	PAR01-143	01-May-03	30-Apr-06	San Diego State University	$233,218.00	$204,675.00	
T15	5T15HL072451-03	Current Issues in Research Ethics (CIRE)	Fischbach, Ruth L.	NHLBI	National	PAR01-143	27-Sep-02	31-Jul-06	Columbia University Health Sciences	$220,460.00		
T15	5T15HL072453-03	Ethical Issues in Behavioral Health Research	Dubois, James M.	NHLBI	National	PAR01-143	27-Sep-02	31-Jul-06	St. Louis University	$125,309.00		
T15	5T15HL072484-03	Buildiing Research Ethics Capacity in Peru and the US	Gonzalez, Jesus M.	NHLBI	National	PAR01-143	27-Sep-02	31-Jul-06	Henry M. Jackson Foundation for the Advancement of Military Medicine	$150,749.00		
T32	2T32AG000276-06	Training in Genetics of Complex Behaviors in Aging	Vogler, George P.	NIA	National	PA02-109	01-Jun-00	30-Apr-10	Pennsylvania State University-University Park		$129,180.00	$129,180.00
T32	5T32HL007948-03	Academic Research Training in Pulmonary Medicine	Rosen, Glenn D.	NHLBI	National	PA00-103	01-Aug-02	31-Jul-07	Stanford University	$262,478.00	$266,586.00	$266,586.00

Feasibility Study of Optimal Approaches for Assessing Bioethics Training Programs at the National Institutes of Health

Appendix B: Interview Protocols

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Questions for Interviews with NIH Stakeholders

1. What is the history of the program? How did the program originate? What were the factors leading to program development?
2. What need did the program address?
3. What was the intent of the program?
4. How is the program fulfilling this intent?
5. What are the key components of the program design?
6. What are the main short-term, intermediate, and long-term outcomes of the program?
7. How is the program consistent with the NIH Roadmap initiative?
8. What is the program's operational definition of "bioethics training"?
9. What data are available on the program?
10. Are the evaluation data required as part of the RFA provided to NIH? If so, how often? In what format?
11. Is there a steering committee/group of PIs and, if so, is there any attempt to collect uniform data across grantees?
12. Which PIs would you recommend for grantee contacts?
13. How is the success of the program being measured?
14. Is there evidence of program sustainability beyond NIH funding?
15. Has there been an evaluation of the impact of this program?
16. What information is needed to monitor the program in the future?
17. Is there anyone else at another Institute that we should contact for background information and/or insight into this program?
18. What are your thoughts on feasible approaches for evaluating bioethics training programs at NIH?

Questions for Interviews with External Training Center/Program Staff/Faculty

1. What year was the program established?
2. What is the history of the program/center? How did it originate? What were the factors leading to the need for such a program/center at your institution?
3. What are the key components/services of the center?
4. What types of degree programs are offered in bioethics?
5. What are the main characteristics of the center's target student population?
6. What is the program/center's institutional home (i.e., school/college of medicine, college of arts and sciences, etc.)?
7. What is the program's disciplinary home (medicine, philosophy, inter-/multidisciplinary, etc.)?
8. What are the major sources and estimated amounts of funding for the center's activities? Internal (tuition, fees, etc.)? External (grants, donations, gifts, etc.)? What is the economic viability of the center?
9. Are there additional supporting and/or collaborating institutions?
10. What is the center's operational definition of "bioethics training"?
11. What data are collected on the impact of the center?
12. How is the success/impact of the center being measured?
13. Has the center received NIH funding in the past or is the center currently receiving NIH funding?
14. Can the center be sustained without NIH funding?
15. How widely is the program disseminated to other institutions? What are the dissemination mechanisms?

Questions for Interviews with K01 Grantees

1. What is the definition of bioethics training?

2. Based on the goals of the PAR (enhance the career of the candidate so that he or she can become an independent investigator and will become a research ethics resource for the sponsoring institution and the scientific community), what measures could be applied to evaluate the program?

3. Was the investigator established in another field before moving into research ethics? Is the training any more successful with such people than with people already in the ethics field? Does the investigator who changed fields remain in research ethics long term?

4. What are the long-term career goals or expectations of the K01 mentored scientist?

5. What was the nature of the mentor relationship? How effective was it?

6. Will the university continue funding the program after funding ceases? How dependent is the program on NIH funding?

7. Are there plans to continue the innovations after the award?

8. After the completion of the program, we will contact awardees about employment history, publications, support received from research grants/contracts, honors and awards, and professional activities. Is there any other information that would be helpful in evaluating the program?

Questions for Interviews with S07 Human Subjects Research Enhancement Awardees

1. What was the main focus of your grant?
2. How would you define bioethics training?
3. Did you collaborate with other institutions and, if so, how well did the collaboration work?
4. What outcomes were achieved by the grant?
5. How would you measure whether the grant was successful? How did you evaluate your program?
6. What were short-term outcomes? What might be long-term outcomes?
7. What kinds of information in the annual report would be useful for program improvements?
8. Was program translation or replication considered or accomplished? How were the results of the program disseminated?
9. Will the university continue funding the program after NIH funding ceases? How dependent is the program on NIH funding? Are there plans for continuing the program after the grant?
10. Is there any other information you could give us which would be helpful in evaluating the program?

Questions for Interviews with T-15 (Short-Term Courses in Research Ethics) Awardees

1. There seem to be a wide variety of definitions for “bioethics training.” How would you define the term?
2. What were/are the curricular components of your short course?
3. What were/are the competencies being taught?
4. What was/is the intended audience for this course?
5. What type of recognition did/do course attendees receive? CME credits/CEUs? A certificate? A degree?
6. Were/are there particular credentials required for instructors in this course?
7. What are the training delivery methods?
8. Did/does this course have additional funding sources? What is the approximate dollar amount of this additional funding?
9. Do you think this program should be institutionalized? Do you think it will be?
10. The RFA recommended evaluating attendees at the time of the course (short term) as well as assessing the longer-term impact of the course on the subsequent activities of the attendees, such as membership on IRBs, ethics review committees, or similar groups. What is the design of your program evaluation? By that I mean, what methods were used to assess learning during the course (pretest/posttest, end-of-session questionnaires, etc.)? What measures of longer-term impact did you collect?