

FELLOWSHIP IN CLINICAL BIOETHICS AND ETHICAL TRANSLATIONAL RESEARCH: A Full Description

Introduction

The **Columbia University Center for Bioethics** and the **Irving Institute for Clinical and Translational Research (ICTR)**, offers an innovative **Fellowship in Clinical Bioethics and Ethical Translational Research (CBETR)** that is helping to create the new generation of clinicians who have expertise in both clinical consultation and translational research. The need for such a program is great and we are uniquely positioned to fill this need. The CBETR Fellowship takes place at Columbia University Medical Center (CUMC) where clinical care, teaching, and research are closely integrated and mutually reinforcing.

The practice of medicine has become extraordinarily sophisticated, with novel technologies and therapies requiring ever more expertise. As a result, clinical specialties have given rise to subspecialties and sub-subspecialties, each with its own fellowships and certification requirements. Accompanying this growth in technical complexity, equally complex ethical dilemmas have arisen. Our ability to intervene in ways previously unthought-of induces us to question not what can be done but rather what should be done. To keep pace with the ever-advancing technical and scientific aspects of medicine, Bioethics too has developed subspecialties, including Clinical Bioethics and Research Ethics. Mastering the practice of these domains requires dedicated education and training that Columbia offers. [1-7]

Aims

The Columbia University Center for Bioethics and ICTR developed a two-year Clinical Bioethics and Ethical Translational Research (CBETR) Fellowship program for physicians and other health professionals. At the conclusion of the Fellowship, the Fellows will be skilled Bioethicists, competent in identifying, analyzing, and resolving bioethical issues, both in the clinical and in “the bench to bedside” translational research settings. They will provide consultations to clinical and translational investigators. It is expected that Fellows will become clinical educators as well as researchers and academic scholars, and ultimately leaders in the field who will direct centers and departments of Clinical Bioethics at medical schools and hospitals throughout the country. Columbia University will thus continue its tradition of producing clinical and academic leaders that will contribute to a higher ethical standard nationally and worldwide.

Significance

While there is a growing literature on the role of education and training in the development of the clinical ethicist, there are relatively few post-doctoral fellowship programs designed to educate and train clinical ethicists. A web-based national search identified sixteen such programs, including Johns Hopkins, University of Chicago, Harvard, M. D. Anderson, NIH, the VA, The Cleveland Clinic, and Universities of Indiana, Pittsburgh, Minnesota, and Case Western Reserve. However, many of these remain focused on theoretical ethics, research, or a specific specialty (e.g., genetics), and are not designed specifically for consultation. None has a focus on Translational Research despite this burgeoning field. Few programs are structured on the traditional clinical teaching model that gives physicians in-depth exposure to the full range of issues and scenarios contemporary Clinical and Research Bioethicists face. Clinical exposure, however, is the key to mastering any field of medicine, including Clinical and Research Bioethics. As a result of this lack of clinical and translational research exposure, there is a dearth of expert clinical bioethicists to provide Bioethics training to new physicians and guidance to clinicians and researchers involving complicated issues.

Translational Research is an evolving field that presents many brand-new and exquisite ethical issues. Gaining expertise in this field will provide the Fellow a skill set that few others possess. Many questions will challenge the learner: What kind of criteria will basic research discoveries have to satisfy in order to uphold a clinician's fiduciary obligations to clinical trial participants? Is there a consensus on when preclinical data are sufficient to justify translation into phase I trials? What are safe clinical trial designs for novel therapeutic techniques (e.g., gene transfer therapy, RNAi, stem cell implants)? How much communication is there between basic, preclinical, and applied researchers and how can the Translational Researcher serve as the consultant to promote constructive communication? This Fellowship will pave the way for a new and singular expert who will be prepared to flourish in the challenges that translational research presents.

Institutional Resources

As one of the premier academic medical centers in the world, Columbia University has a long tradition of educating clinical fellows as well as post-doctoral research fellows. The CBETR Fellowship will extend this tradition in a new direction while drawing strength from the vast experience this tradition provides. Columbia University is one of twenty-four sites awarded a Clinical and Translational Science Award (CTSA) by the NIH to support a comprehensive program of clinical and translational research. This award, which resides in the

IICTR, enables CUMC to promote a coordinated structure and collaborative environment within which multi- and inter-disciplinary clinical and translational research can flourish. Furthermore, as an international leader in so many different areas of medicine and clinical care, CUMC attracts some of the most interesting and complex medical cases from around the world. With complex medicine comes complex ethical dilemmas, and just as in clinical medicine, Clinical Bioethics is best learned by a heuristic process, learning from encountering and resolving difficult cases repeatedly. CBETR Fellows will participate actively in this environment, gaining expertise in consultation and research issues.

Columbia University has both the institutional resources and personnel to meet the challenges educating well-rounded bioethicists will present. The CBETR Fellowship is based at the Columbia University Center for Bioethics that has an established record of being a leader in Bioethics education at the University and national levels. Supplementing this educational expertise, and providing the core of the clinical experience so necessary for the success of the program, will be our broad-based, highly-active ethics consultation services at the NewYork-Presbyterian (Milstein) Hospital, Children's Hospital, and the Allen Pavilion. Further notable resources adding to the Fellows' experiences in Research Ethics are the many skilled members of the CTSA Regulatory Knowledge, Support, and Ethics Resource Consult Service. Finally, the University's world-class graduate schools and departments including the Mailman School of Public Health, the Law School, and the Graduate School of Arts and Sciences provide unmatched opportunities for the academic instruction that supplement the CBETR Fellows' clinical and research experiences.

The faculty affiliated with these programs and other departments of the Medical Center are equally impressive. The CBETR Fellowship will be directed by **Ruth Fischbach, PhD, MPE**, Director of the Center for Bioethics and Co-director of the Clinical Research Ethics (CRE) efforts in the Regulatory Knowledge, Support, and Ethics Resource (RKSR) of the IICTR. Dr. Fischbach, a noted Bioethicist and educator, serves on numerous ethics and research committees at Columbia University and beyond. **Kenneth Prager, MD**, Director of Clinical Ethics at the Center for Bioethics, is also the Director of the Clinical Ethics Department and the Ethics Consultation Service at NYPH (Milstein Hospital) as well as the Chair of the Columbia University Medical Center's Ethics Committee. Widely recognized for his supreme skill in bedside consulting, he will serve as Director of Clinical Consultation for the Fellowship. Further Clinical Bioethics experience in Pediatrics will be overseen by **John Lorenz, MD**, a leading pediatrician and Chair of the Children's Hospital Ethics Committee. In addition to vast experience in Clinical Bioethics, both of these physicians have been active in fellowship training in their respective specialties (pulmonology and neonatology) and thus are experienced clinical educators. **Paul Appelbaum, MD**, one of the world's leading experts on informed consent, decision-making capacity, and the intersection of law and psychiatry, and Co-director of the Clinical Research

Ethics (CRE) efforts in the Regulatory Knowledge, Support, and Ethics Resource (RKSR) of the IICTR, will serve as Director of the Ethical Translational Research Program for the Fellowship. **Henry Ginsberg, MD**, Principal Investigator of the CTSA and Director of the IICTR will serve as Senior Advisor, Ex Officio, to the Executive Committee. See the Appendix for a description of the Executive Committee.

The Medical Center and University are also well known for other outstanding faculty who, as a cadre of multi-disciplinary experts, will enhance the education and training of the CBETR Fellows. This group of Core Faculty includes: **Elaine Abrams, MD**, noted for her work in the inner-city on infectious disease and epidemiologic research, particularly maternal-infant HIV transmission, **Michelle Ballan, MSW, PhD**, professor of Social Work and highly regarded course director for the *Ethics for Social Workers* course, **Ron Bayer, PhD**, an expert in ethical and policy issues in Public Health, **Tim Fauvell**, Chief Chaplain of Children's Hospital, **Mindy Fullilove, MD**, award-winning researcher with expertise in the relationship between the collapse of communities and decline in health, **Evelyn Granieri, MD**, Chief of the Division of Geriatric Medicine and Aging, **Robert Klitzman, MD**, noted author and expert on HIV, gender issues, and genetic privacy, **Elaine Larson, RN, PhD**, widely regarded professor of nursing, IRB Chair, and successful researcher, **Carol Liebman, JD**, distinguished Law professor noted for her work in bioethical conflict resolution, **Barron Lerner, MD, PhD**, a practicing internist and celebrated medical historian with particular interest and expertise in medical ethics, **John Loike, PhD**, active researcher and eminent bioethics educator, **Jeremy Simon, MD, PhD**, a notable trained philosopher working in medical ethics and philosophy of medicine, and **David Strauss, MD**, widely acknowledged expert in research ethics and leader in IRB issues. There are, in addition, some sixty other Faculty Associates of the Center for Bioethics at Columbia who are available to contribute their full range of expertise to the CBETR Fellowship.

Fellowship Design

Because the CBETR Fellowship aims not just to train ethically competent Clinical Bioethicists, but to produce academic leaders, the work of the CBETR Fellows will not be limited to clinical consultation and research experiences. Over the course of two years, the Fellows will receive education in all aspects of Clinical Bioethics and Translational Research. They will learn a systematic approach to **clinical consultation** including ethical reasoning and analysis, clinical decision-making, and communication skills. In the education component in Translational Research, provided by the IICTR Ethics Resource, CBETR Fellows will be **educated** in regulatory issues and will explore ethical aspects of clinical and translational research. This aspect of their education will include informed consent, study design, conflicts of interest, roles and responsibilities of research

staff, and issues in emerging areas of research. Some of these topics will be covered in online courses. Fellows will learn **consultation** skills, first by observing Drs. Appelbaum, Fischbach, and Klitzman (who compose the Clinical Research Ethics Consultation Service of the IICTR), and later by providing the service independently. IICTR investigators will be assisted by the CBETR Fellow with both IRB submissions and consultation on ethical dilemmas that arise during and after their research studies. Fellows will also assist with **research** on original projects that have been proposed in the CTSA grant submission. These involve projects to improve the informed consent process, reduce therapeutic misconception, standardize assessment of constraints on voluntariness, and increase research subjects' understanding of conflicts of interest.

The Fellows will also meet with each member of the Core Faculty. In these sessions, Core Faculty will discuss the ethical, legal, and social issues that are endemic in their field of endeavor. In addition, Core Faculty will invite Fellows to attend relevant presentations they will be offering to the Medical Center and University during the two years of the Fellowship. In some cases, Fellows may ask a Core Faculty member to serve as a tutor or mentor for their research project. Fellows will benefit from the panoply of diverse perspectives that this select group of Faculty will provide. In the Evaluation Report that Fellows will submit quarterly, they will discuss how the varied experiences with Core Faculty have enriched their perspectives on Clinical Bioethics and Translational Research.

Each year CBETR Fellows will spend nine months on the adult clinical and research services of the Milstein Hospital. They will also have a two-month rotation in Pediatrics at the Children's Hospital of New York and one month at the Allen Pavilion to provide a comprehensive, "hands-on" experience in Pediatrics and inner-city ethical issues and experience in geriatric inpatient and nursing home settings.

During the **First Year**, in addition to observing and participating in Clinical Ethics consultations in the three hospitals, CBETR Fellows, taking at least one course each semester, will complete course work in relevant academic disciplines including Philosophy, Humanities, and Public Health. These courses will provide grounding in ethical theory, principles, medical humanism, and concepts of Bioethics. Courses in the School of Public Health will provide knowledge in research design, biostatistics, and epidemiology, all necessary for the Fellows' own empirical work and for assisting clinical investigators. Attending clinical seminars, journal clubs, Ethics Committee meetings, appropriate sessions sponsored by the Regulatory Knowledge, Support, and Ethics Resource of the IICTR, and participating in relevant activities at CUMC will add to their expertise. They will also complete the highly regarded **Certificate Program in Bioethics and Medical Humanities at Montefiore Medical Center**, directed by **Nancy Dubler, LLB**. Graduating from the Fellowship with a Certificate in Bioethics and Medical Humanities, as well as with a Certificate in Clinical Consultation and

Translation Research, will distinguish this group of Fellows and add to their marketability and leadership qualifications. In addition, they will be involved in first learning, and then teaching, courses in the responsible conduct of research and regulatory knowledge and compliance. Finally, CBETR Fellows will begin work on the capstone of the CBETR Fellowship, the production of a publishable independent empirical research project, by designing the project and obtaining IRB approval to facilitate the completion of their study in the Second Year of the Fellowship.

During the **Second Year**, CBETR Fellows will take the course in **Bioethics Mediation** directed by **Carol Liebman, JD**, the Columbia Law School. CBETR Fellows will take on greater independent responsibilities, including conducting primary ethics consultations for both the IICTR and the hospitals, mentoring the First-Year CBETR Fellow as well as the participants in other IICTR training programs, including students in the Master's in Patient Oriented Research and the IICTR K12 Scholars. The Second-Year Fellow will also participate in activities aimed at educating medical, nursing, dental and public health students, house staff, fellows, and research personnel in clinical consultation and translational research issues. A major goal of the Second-Year Fellow will be completion of his or her empirical research project. The CBETR Fellow will make a formal presentation of his or her research project at a jointly sponsored Center for Bioethics and IICTR Seminar.

In future years, we hope to coordinate with Columbia's Mailman School of Public Health to give CBETR Fellows the opportunity to obtain a Masters degree in Public Health (MPH).

See **Appendix** for a detailed outline of the two years of the CBETR Fellowship.

Compensation

CBETR Fellows will hold the title of "**Postdoctoral Research Scientists**" and will receive a salary comparable to other fellowships at Columbia and commensurate with their years of experience. In addition, other costs will be covered including tuition for courses, health care, travel to meetings, computer, and library fees.

Eligibility Requirements

Applicants must have obtained their doctoral degree (MD) and completed their residency by the starting date of the fellowship. Preference is given to applicants with prior exposure to Clinical Bioethics and translational research including consultation, teaching, and human subjects research experience. The CBETR Fellowship is best suited to applicants with interdisciplinary research interests and a background in the humanities.

Recruitment of Fellows

The availability of this two-year CBETR Fellowship will be widely publicized in medical and Bioethics journals, and medical schools will be sent a notice informing them of the Fellowship. Each year, one CBETR Fellow will be accepted for the two-year fellowship.

Application Process

Applicants should submit materials electronically or in hard copy:

1. Completed Fellowship Application form (link to PDF form)
2. Official transcripts from both undergraduate school and medical school
3. Current curriculum vitae including list of publications
4. Two writing samples, including a brief professional writing sample, preferably in the form of a research proposal that the applicant would be interested in completing during the Fellowship
5. A cover letter of not more than 500 words describing reasons for interest in the Fellowship, research experience, and qualifications for the Fellowship
6. Three letters of recommendation, at least one from a former or current faculty advisor or training director

Completed applications must be received by January 31, 2008. A panel composed of Core Faculty will screen the applications. The CBETR Fellowship's Executive Committee (Drs. Fischbach, Appelbaum, Lorenz, and Prager) will interview the most highly qualified candidates. The Fellowship will begin July 1, 2008.

Evaluation of the Fellowship

To ensure successful completion of the CBETR Fellowship, the following activities are required:

1. a minimum of a B average in academic courses
2. successful completion of the Montefiore/Dubler Certificate Program
3. successful completion of the Bioethics Mediation Program
4. successful performance appraisal every six months by Drs. Prager and Lorenz (clinical consultation), Dr. Appelbaum (research ethics), and Dr. Fischbach (education).
5. completion of an independent empirical research study
6. completion of a publishable manuscript
7. presentation at a national meeting (paper or poster) is desired

There will be a monthly meeting of the CBETR Fellowship's Executive Committee (Drs. Fischbach, Prager, Lorenz, and Appelbaum) to counsel and guide the Fellows if necessary and to evaluate and to improve the progress of the Fellowship. The Committee will use the Fellows' Quarterly Reports to aid in evaluating the CBETR Fellowship.

Deliverables

An Annual Report will be completed and sent to the supporters of the Fellowship.

Each year, one well-educated and well-trained Fellow will complete the CBETR Fellowship Program to assume a leadership role in clinical consultation and translational research.

Conclusion

The **Fellowship in Clinical Bioethics and Ethical Translational Research** will educate and train a unique and highly valued cadre of Clinical Bioethicists skilled in Clinical Consultation and Translational Research. Given the synergy of the Center for Bioethics, the Irving Institute for Clinical and Translational Science, and a renowned academic medical and research center as the educational setting, CBETR Fellows will be the new generation of clinicians who will have significant expertise in much needed areas of practice. The combination of consultation and research skills will be increasingly in demand as we continue to move our state-of-the-art research findings from bench to bedside and grapple with the complex ethical issues generated by the ever-advancing technical and scientific aspects of medicine.

References

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Appendix

Fellowship Curriculum:

First Year

Academic Education and Training:

1. Complete Academic Courses
 - a. Fall Semester: Philosophy
 - b. Spring Semester: Humanities or Social Science elective
Summer term: Epidemiology and Biostatistics
2. Complete the Certificate Program in Bioethics and Medical Humanities at Montefiore Medical Center (course meets one evening per week for two semesters)
3. Attend monthly seminars and symposia of the Center for Bioethics
4. Meet with Core Faculty and attend relevant presentations
5. Participate in a weekly Bioethics Journal Club
6. Attend monthly pastoral care meetings
7. Participate in both local and national Bioethics conferences {e.g., national meeting of the American Society of Bioethics and Humanities (ASBH)}
8. Complete a written quarterly report, 4-6 pages in length, which includes a summary of activities and meetings with Core Faculty, identification of significant issues or dilemmas encountered, and insights and reflections related to personal and professional identity

Clinical Consultation Education and Training:

1. Attend monthly meetings of the NewYork-Presbyterian Hospital Ethics Committee and Morgan Stanley Children's Hospital Ethics Committee and serve on subcommittees of interest
2. Gain expertise in Clinical Consultations (both adult and pediatric) with Drs. Prager and Lorenz, and in Research Ethics Consultations for the IICTR with Drs. Appelbaum, Fischbach, and Klitzman (Clinical Research Ethics Consultation Service)
3. Accompany the NYPH Palliative Care Service team on rounds once per month
4. Attend weekly meetings with Dr. Prager to discuss case consults
5. Volunteer in a relevant agency once a month for half a day (e.g., a Free Medical Clinic)
6. Complete consultation experience at Milstein, Children's Hospital, and the Allen Pavilion.

Translational Research Education and Training:

1. Attend seminars and other educational events developed by the Regulatory Knowledge and Support Group of the IICTR
2. Develop an independent empirical research project to be completed during the Second Year that will result in a publishable manuscript (submit proposal to the IRB in Month 3)
3. Attend *Research in Progress* seminars monthly
4. Attend four IRB meetings annually (two at CUMC and two at New York State Psychiatric Institute (NYSPI))
5. Participate in the development and teaching of courses in the Regulatory Knowledge, Support, and Ethics Resource of the IICTR
6. Participate in the IICTR research projects

Second Year

Academic Education and Training:

1. Complete Bioethics Mediation course at Columbia Law School
2. Attend Center for Bioethics monthly seminars
3. Attend and present at weekly Bioethics Journal Club
4. Attend monthly pastoral care meetings
5. Teaching responsibilities (e.g., present seminars to medical, nursing, public health, dental, and social work students and faculty)
6. Complete a written quarterly report, 4-6 pages in length that includes a summary of activities, identification of significant issues or dilemmas, and insights and reflections related to personal and professional identity

Clinical Consultation Education and Training:

1. Take an active, independent role in Clinical and Research Ethics Consultations
2. Volunteer in a relevant agency once a month for half a day
3. Complete consultation experience at Milstein Hospital, CHONY, and the Allen Pavilion.
4. Tutor and mentor the First Year Fellow

Translational Research Education and Training:

1. Complete the empirical independent research project
2. Submit a manuscript for publication based on research project
3. Participate in the development and teaching of relevant courses and seminars developed by the Regulatory Knowledge, Support, and Ethics Resource of the IICTR
4. Attend *Research in Progress* seminars monthly
5. Attend the national meeting of the American Society of Bioethics and Humanities
6. Submit an abstract to a national meeting to share research results, research projects, and to plan future collaborations

Illustrated Timeline of the CBETR Fellowship – YEAR 1

Summer (July/Aug)	Fall (Sept-Dec)	Winter/Spring (Jan-June)
Academic course: Epidemiology and Biostatistics (Mailman School of Public Health)	Academic course: Philosophy (ethical theory, principles, and concepts; history of bioethics)	Academic course: Humanities or Social Science elective
	Present research proposal to the CUMC IRB	Continue Certificate Program in Bioethics and Medical Humanities c/o Montefiore Medical Center
	Begin the Certificate Program in Bioethics and Medical Humanities c/o Montefiore Medical Center (1 evening per week)	
	Attend the American Society of Bioethics and Humanities (ASBH) Annual Conference	
Clinical consultations with Drs. Prager and Lorenz		
Translational ethical consultations with Drs. Appelbaum, Fischbach, and Klitzman		
Weekly meeting with Dr. Prager to discuss case consults		
Meet with Core Faculty and attend relevant presentations		
Attend seminars and educational events of the Regulatory Knowledge and Support Group of the IICTR		
Observe the monthly meetings of the NYPH Ethics Committee and the CHONY Ethics Committee, and serve on subcommittees of interest		
Attend four IRB meetings (two at CUMC and two at NYSPI)		
Participate in the development and teaching of courses in the Regulatory Knowledge, Support, and Ethics Resource of the IICTR		
Participate in IICTR research projects		
Participate in weekly Bioethics Journal Club sessions		
Participate in the monthly <i>Research in Progress</i> seminars		
Attend the Center for Bioethics monthly seminars and symposia		
Participate in monthly rounds with the NYPH Palliative Care Service team		
Attend monthly pastoral care meetings		
Serve as a monthly half-day volunteer in a relevant agency (e.g., a Free Medical Clinic)		
Develop an independent empirical research project to be completed during Year 2 that will result in a publishable manuscript. Submit proposal to the IRB in Month 3.		
Written quarterly report (4-6 pages): summary of activities, meetings with Core Faculty, identification of issues and dilemmas encountered, and additional personal and professional reflections		

Illustrated Timeline of the CBETR Fellowship YEAR 2

Summer (July/Aug)	Fall (Sept-Dec)	Winter/Spring (Jan-June)
Complete one-month rotation at the Allen Pavilion, Division of Geriatrics and Aging	Bioethics Mediation course at Columbia Law School	Independent Empirical Project
History/Gender/Culture elective course	American Society of Bioethics and Humanities conference	Independent Empirical Project
		COMPLETE FELLOWSHIP
Take an active, independent role in clinical consultations		
Take an active, independent role in translational ethical consultations		
Tutor and mentor the first-year fellow		
Complete empirical independent research project, and submit manuscript for publication based on the project		
Submit an abstract to a national meeting (e.g. PRIM&R, ASBH) to share research results and plan future collaborations		
Weekly meeting with Dr. Prager to discuss case consults		
Meet with Core Faculty and attend relevant presentations		
Attend seminars and educational events of the Regulatory Knowledge and Support Group of the IICTR		
Teaching responsibilities (e.g., present seminars to medical, nursing, public health, dental, and social work students and faculty)		
Participate in the development and teaching of courses in the Regulatory Knowledge, Support, and Ethics Resource of the IICTR		
Participate in IICTR research projects		
Participate in weekly Bioethics Journal Club sessions		
Participate in the monthly <i>Research in Progress</i> seminars		
Attend the Center for Bioethics monthly seminars and symposia		
Serve on the NYPH Ethics Committee and the CHONY Ethics Committee, and serve on subcommittees of interest		
Participate in monthly rounds with the NYPH Palliative Care Service team		
Attend monthly pastoral care meetings		
Serve as a monthly half-day volunteer in a relevant agency (e.g., a Free Medical Clinic)		
Written quarterly report (4-6 pages): summary of activities, meetings with Core Faculty, identification of issues and dilemmas encountered, and additional personal and professional reflections		

Executive Committee

Members of the Executive Committee are well known and together will ensure a uniquely diverse and comprehensive learning experience. Members include:

Ruth L. Fischbach, PhD, MPE is Professor of Bioethics and Director and Co-founder of the Center for Bioethics. She is a faculty member both in the Department of Psychiatry at the Columbia University College of Physicians and Surgeons and the Department of Sociomedical Sciences at the Columbia University Mailman School of Public Health. At Columbia, Dr. Fischbach is a member of the Columbia University Medical Center (CUMC) Institutional Review Board (IRB), the CUMC Ethics Committee, the Children's Hospital of New York (CHONY) Ethics Committee, the University Stem Cell Consortium, the University's Stem Cell Oversight Committee, the Ethics, Policy, and Human Rights Core of the HIV Center at Columbia and the NY State Psychiatric Institute, and the Advisory Board for the Center for the Study of Science and Religion. Beyond Columbia, Dr. Fischbach serves on the [Arnold P. Gold Foundation](#) Medical and Professional Advisory Council and Gold Foundation Honor Society, and the [Population Council](#) IRB. Additionally, she is the ethics member of two DSMBs. Dr. Fischbach is a member of the Board of Directors of [PRIM&R \(Public Responsibility in Medicine and Research\)](#) and is a Fellow of the AAAS and the elected Member-at-Large for Section X (Societal Impacts of Science and Engineering) of the AAAS.

Prior to arriving at Columbia, Dr. Fischbach served from 1998 to 2001 as Senior Advisor for Biomedical Ethics in the Office of the Director of Extramural Research at the National Institutes of Health. Here she participated in many federal interagency committees designed to protect the rights and welfare of research participants. Preceding her service at the NIH, Dr. Fischbach was a bioethicist/medical sociologist at Harvard Medical School in the Department of Social Medicine and the Division of Medical Ethics from 1990 -1998 where she directed the *Program in the Practice of Scientific Investigation*. At Washington University from 1983 - 1990, as an Assistant Dean, she headed the Ethics Program and founded the Humanities in Medicine Program.

Dr. Fischbach's research interests and scholarly publications have focused on decisions around the end of life, autonomy of the elderly, communication between patients and healthcare professionals, pain assessment and management, and the experiences of research participants, particularly as they relate to privacy and informed consent. Current work focuses on research ethics and contemporary issues in bioethics including: neuroethics, stem cell research, and advances in assisted reproductive technology.

Kenneth Prager, MD is Clinical Professor of Medicine at Columbia University College of Physicians and Surgeons, and the Director of Clinical Ethics at the Center for Bioethics. He also serves as Director of Clinical Ethics at the New York Presbyterian Hospital and Chairman of the Medical Ethics Committee of

Columbia University Medical Center. A widely recognized expert in clinical consultation, he conducts most of the clinical consults for the hospital. He spent two years practicing general medicine on the Cheyenne River Sioux Indian Reservation in South Dakota after his medical internship. Dr. Prager held clandestine medical clinics in the Soviet Union during a visit in 1986, and later set up the first U.S. - Soviet medical student exchange program between Columbia P&S and the First Moscow Medical Academy.

In addition to his pulmonary practice, Dr. Prager is heavily involved in teaching pulmonology and medical ethics to medical students, house officers and nurses. His writings on medicine and medical ethics have appeared on the Op-Ed pages of The New York Times and The Wall Street Journal as well as in medical journals and textbooks. He lectures extensively on medical ethics.

Dr. Prager is on the admissions committee of, and is a regular guest lecturer for, the Ben Gurion University MD Program in International Health and Medicine in collaboration with Columbia University Health Sciences. He is on the Board of Directors of the American Council on Science and Health.

John Lorenz, MD is Professor of Clinical Pediatrics at Columbia University Physician and Surgeons and Chair of the Children's Hospital of New York Ethics Committee. His research interests are developmental renal and fluid and electrolyte physiology, long-term newborn intensive care outcomes and decision making in the NICU. Dr. Lorenz clinical specialties are thermal management, hyperbilirubinemia, and biomedical ethics.

Paul S. Appelbaum, M.D. is the Professor of Psychiatry and Director, Division of Psychiatry, Law, and Ethics, Department of Psychiatry, College of Physicians and Surgeons of Columbia University. He is the author of many articles and books on law and ethics in clinical practice, including four that were awarded the Manfred S. Guttmacher Award from the American Psychiatric Association and the American Academy of Psychiatry and the Law: (with Thomas G. Gutheil, M.D.) *The Clinical Handbook of Psychiatry and the Law* (3rd ed., 2000); *Almost a Revolution: Mental Health Law and the Limits of Change* (1994); (with Thomas Grisso, Ph.D.) *Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Healthcare Professionals* (1998); and (with John Monahan, Ph.D., et. al.) *Rethinking Risk Assessment* (2001).

Dr. Appelbaum is Past President of the American Psychiatric Association, the American Academy of Psychiatry and the Law, and the Massachusetts Psychiatric Society, and serves as Chair of the Council on Psychiatry and Law for the American Psychiatric Association. He was previously Chair of the Commission on Judicial Action for the American Psychiatric Association and a member of the MacArthur Foundation Research Network on Mental Health and the Law. He is currently a member of the MacArthur Foundation Network on Mandatory Outpatient Treatment. He has received the Isaac Ray Award of the

American Psychiatric Association for "outstanding contributions to forensic psychiatry and the psychiatric aspects of jurisprudence," was the Fritz Redlich Fellow at the Center for Advanced Study in the Behavioral Sciences, and has been elected to the Institute of Medicine of the National Academy of Sciences.

Henry N. Ginsberg, MD, is Irving Professor of Medicine at Columbia University College of Physicians and Surgeons where he serves as Program Director of the General Clinical Research Center and Director of the Irving Center for Clinical Research at New York–Presbyterian Hospital where he is the Principal Investigator for the CTSA Award.

A fellow of the Council on Arteriosclerosis and the American Association for the Advancement of Science, Dr. Ginsberg is a member of several professional organizations, among them the American Association of Physicians, American Society for Clinical Investigation, American Heart Association, and American Diabetes Association. Dr. Ginsberg's recent research efforts have focused on the regulation of apoprotein B metabolism in humans and the relationship of insulin resistance with dyslipidemia and cardiovascular disease.

Dr. Ginsberg is an editorial board member of the Journal of Lipid Research, Metabolism, Journal of Biological Chemistry, and Journal of Clinical Investigation. He is a reviewer for Circulation, The New England Journal of Medicine, Diabetes, and Atherosclerosis, among others. Dr. Ginsberg has also authored or coauthored more than 170 peer-reviewed papers, invited reviews, and book chapters.