Contact

www.linkedin.com/in/jacqueline-corrigan-curay-36851336 (LinkedIn)

Top Skills

Data Analysis

Public Health

Internal Medicine

Publications

Genome Editing Technologies: Defining a Path to Clinic

The NIH Office of Biotechnology Activities Site Visit Program: Observations About Institutional Oversight of Recombinant and Synthetic Nucleic Acid Molecule Research

T Cell Immunotherapy: Looking Forward

Gene Therapy: Charting a Future Course—Summary of a National Institutes of Health Workshop, April 12, 2013

Jacqueline Corrigan-Curay

Director, Office of Medical Policy at Center for Drug Evaluation and Research, US Food and Drug Administration

Washington DC-Baltimore Area

Experience

Center for Drug Evaluation and Research, US Food and Drug Administration

Director, Office of Medical Policy

October 2016 - Present (6 years 11 months)

Silver Spring MD

As the Director of the Office of Medical Policy (OMP), oversees and manages the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP is responsible for reviewing all promotional and advertising materials in accordance with FDA regulations, and supports research on direct-to-consumer advertising and other aspects of prescription drug communications in support of policy development. OMPI develops, coordinates, and implements medical policy programs and strategic initiatives, including policy development on real world evidence, drug labeling, technology and drug development, clinical trial oversight and innovative trial design. OMP works across FDA and with external stakeholders to enhance policies to improve drug development and regulatory review processes.

Recombinant DNA Advisory Committee

Executive Secretary

October 2006 - Present (16 years 11 months)

Responsible for managing the Recombinant DNA program within OBA and supporting all aspects of the NIH Recombinant DNA Advisory Committee (RAC) activities relating to gene transfer and recombinant DNA (rDNA) research. This includes managing reviews of over 60 gene therapy protocols per year, and the planning and administering of quarterly RAC meetings and additional policy/scientific conferences related to clinical research with rDNA. Also, when required, prepare scientific presentations and communicate with the scientific community, business leaders, and the press. Other duties include:

Analysis of more than 500 serious adverse events that occur on registered gene therapy trials annually, monitoring changes in protocol design, and coordinating the review of gene transfer protocols with other federal regulatory agencies.

Supervising the staff responsible for updating and maintaining the Genetic Modification Clinical Research Information System (GeMCRIS), an NIH data base that provides the public, as well as NIH and FDA with information on more than 1000 human gene transfer trials.
Responding to queries relating to basic rDNA research and interpretation of the NIH Guidelines for Research Involving Recombinant DNA (NIH Guidelines). This includes responding to all incident reports received from basic research labs and proposing and implementing amendments to the NIH Guidelines after scientific and public review.
Overseeing Freedom of Information Requests related to recombinant DNA research.
Serving as NIH Representative on the FDA Drug Safety Board and on the Intragovernmental Select Agent and Toxin Technical Advisory Committee, and HHS Multiple Chronic Condition Task Force.
Responsible for coordinating reviews of science policy matters for the Office of Science Policy and being active in public education on rDNA and gene transfer program activities.

Internal Medicine
Attending Physician
January 2006 - Present (17 years 8 months)

VETERANS AFFAIRS MEDICAL CENTER
Attending Physician
August 2001 - Present (22 years 1 month)

Attending physician with active internal medicine practice.

VA Medical Center Washington DC
Attending Physician
2001 - Present (22 years)

Part-Time

Immediate Office of the Director, National Heart, Lung and Blood Institute, NIH
Supervisory Medical Officer
April 2015 - October 2016 (1 year 7 months)

Responsibilities include developing policies and procedures that focus on the conduct of clinical research, research oversight, programmatic planning, and new scientific initiatives. Through consultations within and outside of the Institute, develop policies and processes to enhance the stewardship of heart,

lung, and blood research with the goal of maximizing scientific impact and improving public health.

National Institues of Health
Medical Officer
October 2006 - October 2016 (10 years 1 month)

National Institutes of Health
Director, Office of Biotechnology Activities (OBA), Office of Science Policy
May 2014 - March 2015 (11 months)

Manage and office with three divisions, the Biotechnology Assessment program, the Biosafety Program and the Biosecurity program. As Acting Director, I manage activities in all of these areas and contribute to policy other cross-cutting initiatives for the Office of Science Policy. This includes representing NIH on key policy initiatives, including drug safety, research designs for subjects with multiple chronic conditions and evaluation of research on Select Agents. In addition, to my supervisory duties, I manage all clinical aspects of oversight of human gene therapy protocols, serve as the medical officer for all clinical activities in the Office and I continue to provide clinical care to patients at the VA Medical Center, one half day a week

GEORGETOWN MEDICAL CENTER
Resident Physician
June 1998 - July 2001 (3 years 2 months)

Resident, Inpatient and outpatient clinical responsibilities.

IMPACS, ROBERT WOOD JOHNSON FOUNDATION
Analyst
June 1995 - October 1995 (5 months)

Assistant to the Director of the Robert Wood Johnson Program-Improving Malpractice Payment and Compensation Systems. Developed the agenda and proposed speakers for the RWJ-sponsored conference, "Managed Care: Emerging Liability Issues

Office of Technology Assessment, US Congress
Policy Analyst
October 1990 - August 1994 (3 years 11 months)
Washington DC

Office of Technology Assessment
4 years 1 month

Senior Analyst
January 1991 - January 1994 (3 years 1 month)

, Health Program.

Researched and drafted technical reports on health policy issues for Congressional committees; briefed congressional staff; managed contracts, and organized and presented material to advisory panels.

Congressional Fellow
January 1990 - January 1991 (1 year 1 month)

OFFICE OF TECHNOLOGY
Senior Policy Analyst
January 1990 - January 1994 (4 years 1 month)

OLWINE, CONNELLY
Associate
January 1988 - January 1990 (2 years 1 month)

Provided legal counsel on all aspects of the development of independent power projects. Legislative work on behalf of National Independent Energy Producers.

DREXEL, BURNHAM, LAMBERT
Financial analyst
January 1983 - January 1985 (2 years 1 month)

Conducted financial and market analysis of companies and industries in preparation for public offerings.

Education

University of Maryland School of Medicine
M.D · (1994 - 1998)

Harvard Law School
J.D · (1985 - 1988)

Harvard/Radcliffe College
A.B, History of Science · (1979 - 1983)