Title 21 Vacancy Announcement – Physician
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner
Office of Clinical Policy and Programs
Office of Clinical Policy (OCLiP)

Application Period: January 2, 2024 – Feb 1, 2024

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Physician (Senior Medical Advisor & Bioethics Consultant Ethicist)

Series: 602

Location(s): Remote

Salary: Table 3: $180,000-$288,365

Work Schedule: **Full Time**

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: N/A

Bargaining Unit: Bargaining Unit

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices are safe and effective.

This position is located in the Office of Clinical Policy (OCliP), within the Office of Clinical Policy and Programs, in the Office of the Commissioner. OCliP is the focal point within the FDA for human subject protection issues arising in clinical investigations regulated by FDA. Among other

things, the Office provides ethical expertise to help resolve scientific and regulatory issues involving adult human research subjects across all of FDA's Centers. As a Senior Medical Bioethicist on the Adult Bioethics Team within OCliP, the incumbent provides independent review of adult human subject research ethics issues and participates in the planning, management, and implementation of bioethics activities across the FDA's Centers. Activities will include human subject research ethics consultations, providing ethics training to interested parties within and outside the Agency, and policy development pertaining to a wide range of research ethics issues.

Duties/Responsibilities

Recognized as an agency medical expert in the protection of human subjects in clinical trials and research ethics. Spends the majority of their time providing expert consultative services to the Agency's medical product review divisions on research ethics issues that arise during review of medical products intended for adult patients, including with respect to clinical trials that have a national or international impact on public health and public health policy. Analyzes clinical studies and performs critical reviews for sufficiency according to the Agency's regulations on informed consent and human subject protections. Collaborates as a recognized expert with other members of the Adult Bioethics Team as well as colleagues on the Pediatric Bioethics Team to advise on unique, far-reaching, and previously unresolved problems involving research ethics related to FDA-regulated clinical trials. Analyzes ethical implications for research programs in areas that require extensive interpretation and provides authoritative guidance to Center leadership and staff. Helps to conceive and develop valid approaches to complex bioethical issues that become Division, Center, or Agency policy and procedure. Maintains close personal contact with the "state of the science" and research ethics literature in order to inculcate the most advanced theories and practices in the field of bioethics into premarket review activities. Keeps fully abreast of crucial and precedent-setting cases related to bioethics both within the Adult and Pediatric Bioethics Teams and under review at the Agency. Has active work on the protection of human subjects from research risks through provision of consultation services in the design, review, and monitoring of research protocols. Serves as an expert bioethics advisor in meetings with Center Division staff and other Center and Agency officials, as well as with the regulated industry, on problems related to products under review. Uses clinical, scientific, and bioethics expertise, as well as care and sensitivity, to resolve issues raised by biomedical research.

In collaboration with senior staff, serves as a resource for research ethics, provides review of research ethics issues across the FDA's Centers, and participates in the planning, management, and implementation of bioethics activities across all of FDA's Centers. Establishes and maintains communication within the Centers of the Agency to facilitate the exchange of scientific and regulatory information on human subject protections and research ethics, and to ensure that policy issues are addressed appropriately.

Contributes to regulatory standards for the ethical evaluation of the safety, effectiveness,

and quality of regulated products. Personally explains critical and significant concepts of research ethics to internal and external parties. Briefs supervisor, office director and other relevant FDA executive leadership on relevant conclusions and interpretations related to ethical matters. Coordinates and provides interpretation and guidance on overall policy and special issues related to human subject protections and research ethics. As a leading Agency authority and expert in the regulatory field of human subject protection and research ethics, integrates knowledge and experience to resolve problems, modify procedures, and develop and interpret complex policies to meet new and novel conditions. Actions taken and solutions devised cut across other functional areas within the organization. Leads task forces and work groups charged with considering problems or directions in human research protections. Leads or serves on committees charged with the review of federal policies and procedures related to human research protections that cross organization lines. Leads or serves as a member of task forces and working groups called to consider problems or direction in the field of research ethics and develop policy related to human subject protection. Delivers briefings on findings and recommendations.

As a recognized authority, expert, and leader in human subject protections and research ethics, provides information and consultation to individuals both within and outside the Office, Agency, to include, as necessary, federal agencies, private industry, universities, and/or foreign governments. Possesses specialized skill that is recognized by agency officials, other federal agencies, state, local, and foreign governments, regulated industry, and/or professional trade and citizen organizations directly affected by the program. Counsels and trains team members and other FDA staff on Agency regulations and policy related to human subject protection. Develops and implements educational programs on contemporary issues in biomedical ethics, especially as they relate to the Agency's mission in clinical research. Provides such training to external parties via attendance at professional meetings both within and outside the Federal government.

Prepares and gives presentations concerning the interpretation and analysis of regulations related to research ethics to state, local, and foreign governments, subject matter experts, upper levels of management, industry, and academia. Represents the organization before high-level national and international audiences regarding regulatory policies and programs related to research ethics. Defends Agency positions, interpretations, and policies related to research ethics before international organizations, government agencies, industry, academia, consumer organizations, and the scientific/medical community.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this

announcement.

- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement: Physician, 0602 Requirements: One-year probationary period may be required; Official transcripts required; Degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Desired Education: Ideal candidate will possess an M.D. and have completed additional formal education (e.g., a Masters degree in Bioethics) and/or certification in medical ethics or bioethics.

Desired Professional Experience:

- Recognized as an expert and leader in medical ethics and/or bioethics, with demonstrable

experience addressing complex ethical issues in a clinical setting.

- Knowledge and experience regarding FDA scientific and review policies is desirable
- Ability to independently evaluate medical and/or scientific research and/or evidence in a wide variety of disciplines for the purpose of addressing complex ethical issues.
- Extensive collaboration, and communication skills to advise on complex and nuanced ethical issues and deliver a consensus approach.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university.For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.
Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application

process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

How to Apply: Submit resume or curriculum vitae with cover letter by February 1, 2024 to: Jessica Bennett@FDA.HHS.GOV. Candidate resumes may be shared with hiring official within OCPP with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Cures position, please contact Jessica Bennett via email or 301-796-3070.

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