OMB No.: 0925-0761
Expiration Date: 07/31/2022

NIH NATIONAL CANCER INSTITUTE

Track 1: Oncology Product Research and Review for M.D. Oncology Fellows

This fellowship will train physicians in aspects of clinical trials methodology and analysis, epidemiology, clinical aspects of medical product development, and regulation, as it relates to clinical research to facilitate the movement of drugs, biologics, and devices from the basic bench science to commercialization.

*Selection of fellows will be dependent upon the availability of funds.

Training Goals and Outcomes

- Clinical training in an oncology subspecialty to meet the requirements for board eligibility in that subspecialty
- Understanding of the various legal and regulatory aspects of cancer product development
- Understanding the review process for regulatory pathways
- Understanding of critical ethical issues and requirements in product research, development, and review, including protection of human research subjects and conflict of interest
- Training and experience in clinical trial design, clinical pharmacology, pharmacoepidemiology, and the product development process in the context of clinical research

Eligibility Requirements

- Board-certified or board-eligible in internal medicine, pediatrics, surgery, and/or radiation oncology
- U.S. citizenship or permanent residents, who have resided in the US for a total of three of the past five years.

NOTE: In order to be approved for logistical and physical access to NIH facilities and systems, candidates must be able to pass a Federal background check using Standard Form-85 (read-SF-85). Section 14 of the Form asks, "in the last year, have you used, possessed, supplied, or manufactured illegal drugs?" The questions pertain to the illegal use of drugs or controlled substances in accordance with Federal laws, even though permissible under state laws. Federal laws supersede all state laws.

Curricula and Responsibilities

First Year

Fellows will train in the participating oncology training programs of the NCI. During this year, fellows will undertake the primary care of both inpatients and outpatients entered into clinical trials and develop expertise in cancer treatment as well as the specifics of clinical trial design.

Second and Third Year

During the second and third years, course work and practical experience will be provided at both agencies in a wide variety of topics such as clinical trial design, clinical pharmacology, pharmacoepidemiology, and the legal and regulatory aspects of new product development. At both NCI and FDA, fellows will have the opportunity to become involved in medical product development research projects, including such topics as clinical trial design and analysis, drug regulation and post-marketing surveillance, and the basic science, epidemiology, and clinical aspects of the new agents. There will also be the opportunity to spend approximately one day per week in continued clinical activities at NCI.

How to Apply

Applications are due January 31, 2020 for an earliest start date of July 1, 2020.

Please submit:

- Curriculum Vitae
- Personal statement of research goals
- Three letters of reference

For more detailed information and application guidelines view the NCI-FDA Research and Regulatory Review Fellowships Guidelines for Application (PDF)

Send application materials to:

Chanelle Case Borden, Ph.D.
IOTF Program Manager
9609 Medical Center Dr.
Rm. 2W234, MSC 9707
Bethesda, MD 20892-9707
Office Phone: 240-276-5956
Email: casec@mail.nih.gov

Mentors

While at FDA, fellows will each be assigned a mentor who will be a senior member of FDA scientific review staff.

Review list of mentors and projects here.

Burden Statement

OMB No.: 0925-0761
Expiration Date: 07/31/2022

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing he collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0761). Do not return the completed form to this address.

Updated: January 16, 2020

NIH NATIONAL CANCER INSTITUTE

Track 2: Oncology Product Research and Review for Board Certified Oncologists

This fellowship will train physicians in aspects of the drug, biologic, or device development and related issues and standards for assessing medical product safety and efficacy, to facilitate the movement of drugs, biologics, and devices from basic bench science to commercialization.

Fellows will receive formal training and mentoring in the relevant federal statutes, regulations, principles and practices of FDA medical review, including issues related to the assessment of safety and efficacy, for limited human exposure in clinical trials, and later potential exposure to the broader patient population postmarketing approval.

*Selection of fellows will be dependent upon the availability of funds.

Eligibility Requirements

- Applicants must be Board Certified in Oncology
- Completion of clinical residency or clinical fellowship
- U.S. citizenship or permanent residents, who have resided in the US for a total of three of the past five years.

NOTE: In order to be approved for logistical and physical access to NIH facilities and systems, candidates must be able to pass a Federal background check using Standard Form-85 (read-SF-85). Section 14 of the Form asks, "in the last year, have you used, possessed, supplied, or manufactured illegal drugs?" The questions pertain to the illegal use of drugs or controlled substances in accordance with Federal laws, even though permissible under state laws. Federal laws supersede all state laws.

Training Goals and Outcomes

- Training and experience in clinical trial design, clinical pharmacology, pharmacoepidemiology, and the drug development process in the context of clinical research
- Understanding the review process for regulatory pathways
- Understanding of the various legal and regulatory aspects of cancer product development

- Understanding of critical ethical issues and requirements in product research, development, and review, including protection of human research subjects and conflict of interest
- Understanding of mechanisms of pathogenesis and cancer biology

Curricula and Responsibilities

This is a one-year program for up to three fellows per year.

Fellows will choose one of the product or clinical divisions in FDA Centers for supplemental training. In a particular product or clinical division, these fellows will be matched to a pre-screened pool of principal investigators for regulatory research and review or to a branch chief for regulatory review and policies. These fellows will have the option to participate in translational research in the participating division.

Fellows will undertake and participate in various regulatory activities of the chosen division. The division director or their designee will oversee these activities.

Regulatory activities include but are not limited to training courses and reviews of files to become proficient in the process of product, pharmacology/toxicology or clinical reviews; and policy and guidance document development. Fellows will also participate in branch, lab, division, and office meetings; grand rounds; and regulatory presentations offered at the participating Center. They will also participate in regulatory meetings with investigators and sponsors.

During the training program, these fellows will be expected to attend and take and pass required tests in reviewer training and various courses offered by participating FDA Centers.

How to Apply

Applications are due January 31, 2020 for an earliest start date of July 1, 2020.

Please submit:

- Curriculum Vitae
- Personal statement of research goals
- Three letters of reference

For more detailed information and application guidelines view the NCI-FDA Research and Regulatory Review Fellowships Guidelines for Application (PDF)

Send application materials to:
Chanelle Case Borden, Ph.D.
IOTF Program Manager
9609 Medical Center Dr.
Rm. 2W234, MSC 9707
Bethesda, MD 20892-9707
Office Phone: 240-276-5956
Email: casec@mail.nih.gov

Mentors

While at FDA, fellows will each be assigned a mentor who will be a senior member of FDA scientific review staff.

Review list of mentors and projects here.

Burden Statement

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Expiration Date: 07/31/2022

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Updated: January 8, 2020

NIH NATIONAL CANCER INSTITUTE

Track 3: Oncology Product Research and Review for Postdoctoral Research Fellows

This fellowship will train individuals in the aspects of research and review of medical product development process to facilitate the movement of drugs, biologics, and devices from the bench to the bedside.

Fellows will receive formal training and mentoring in the relevant federal statutes, regulations, principles, and practices of FDA medical product review, including issues related to product development, e.g., manufacturing processes, production, purification, characterization, testing, quality control, and quality assurance, understanding the biology, chemistry, pharmacoepidemiology, manufacturing, postmarketing surveillance, and mechanism of action/pathogenesis of disease.

*Selection of fellows will be dependent upon the availability of funds.

Training Goals and Outcomes

- Understanding of cancer biology relevant to molecular targeted therapy
- Understanding of regulatory requirements for product development and approval process and participation in the review of regulatory files (e.g. IND, NDA, BLA, 510k, PMA) for chemistry, manufacturing control, pharmacology/toxicology and clinical trial design
- Participation in the development of product standards and guidance document development
- Understanding of critical ethical issues and requirements in product research, development, and review, including protection of human research subjects and conflict of interest
- Understanding the manufacturing processes, e.g., production, purification, characterization, testing, quality control, and quality assurance
- Participation in and understanding of product-related research, i.e. understanding the biology, chemistry, pharmacoepidemiology, manufacturing, post-marketing surveillance, and mechanism of action/pathogenesi

Eligibility Requirements

- Ph.D., M.D., or M.D./Ph.D.
- Minimum of 3 years of postdoctoral training

- Must be within 5 years of the applicants most advanced degree
- U.S. citizenship or permanent residents, who have resided in the US for a total of three of the past five years.
- Experience and interest in molecular targets or product development and/or design
- Fellows finishing their fourth or fifth year may qualify for a sixth year CRTA extension

NOTE: In order to be approved for logistical and physical access to NIH facilities and systems, candidates must be able to pass a Federal background check using Standard Form-85 (read-SF-85). Section 14 of the Form asks, "in the last year, have you used, possessed, supplied, or manufactured illegal drugs?" The questions pertain to the illegal use of drugs or controlled substances in accordance with Federal laws, even though permissible under state laws. Federal laws supersede all state laws.

Curricula and Responsibilities

The program time frame will be for up to two years and include up to six fellows per year.

First Year

Fellows will choose one of the product or clinical divisions in FDA Centers for supplemental training. In a particular product division, these fellows will be matched to a pre-screened pool of principal investigators or to a branch chief for regulatory research and regulatory experience. Fellows with a Ph.D. degree will be matched to a product division or pharmacology/toxicology branch in a clinical division.

Fellows will have the option to perform translational research in the participating division or office. These fellows will undertake and participate in various training activities of the chosen division. The division director or their designee will oversee these activities.

Fellows will spend approximately 40% of their time in training to become proficient in the process of product or pharmacology/toxicology reviews; and policy and guidance document development. Fellows will also participate in branch, lab, division and office meetings, grand rounds, and regulatory presentations offered at the participating Center. They will also participate in regulatory meetings with investigators and sponsors.

Fellows are expected to conduct research activities under the guidance of principal investigators in ongoing projects in the lab. These fellows will have option to choose their principal investigator at the beginning of program.

During the training program, fellows will be expected to attend and take and pass required tests in reviewer training and various courses offered by participating FDA Centers.

Second Year

The first-year curricula and activities may be continued in the second year of the program based on the fellow's performance evaluated by PI, branch chief, division director and associate directors of research at both institutions.

How to Apply

Applications are due May 31, 2020 for an earliest start date of October 1, 2020.

Please submit:

- Curriculum Vitae
- Personal statement of research goals
- Three letters of reference

For more detailed information and application guidelines view the NCI-FDA Research and Regulatory Review Fellowships Guidelines for Application(PDF)

Send application materials to:
Chanelle Case Borden, Ph.D.
IOTF Program Manager
9609 Medical Center Dr.
Rm. 2W234 MSC 9707
Bethesda, MD 20892-9707
Office Phone: 240-276-5956
Email: casec@mail.nih.gov

Mentors

While at FDA, fellows will each be assigned a mentor who will be a senior member of FDA scientific review staff.

Review list of mentors and projects here.

Burden Statement

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Expiration Date: 07/31/2022

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Updated: January 16, 2020

NIH NATIONAL CANCER INSTITUTE

Track 4: Cancer Prevention Product Research and Review for Postdoctoral Research Fellows

This fellowship will provide training in cancer prevention (e.g., chemoprevention, vaccination, and early detection). Individuals will be trained in the drug, biologic, or device development and approval processes and their application to study populations (including healthy subjects) to facilitate the movement of novel approaches from the bench to the community. Combining training in public health, cancer prevention research, and research-related regulatory overview will allow individuals to develop expertise across these disciplines.

*Selection of fellows will be dependent upon the availability of funds.

Training Goals and Outcomes

- Understanding the design and analysis of clinical trials, familiarity with the IRB approval process, and determining appropriate clinical endpoints in cancer prevention and early detection trials.
- Participation in multidisciplinary cancer prevention research
- Understanding the review process for regulatory pathways
- Understanding and participation in the development of product standards and guidance documents, particularly with respect to regulations for use of agents with limited preclinical data in humans
- Understanding of critical ethical issues and requirements in product research, development, and review, including protection of human research subjects and conflict of interest
- Understanding and developing guidelines for use of agents in chemoprevention trials that have approved indications only in the treatment setting
- Understanding and developing criteria for "acceptable drug toxicity" in chemoprevention trials, where study subjects are often healthy volunteers
- Understanding and developing criteria to determine acceptable surrogate clinical endpoints unique to cancer prevention trials (in contrast to treatment endpoints: e.g., tumor response, survival)

Eligibility Requirements

- Doctoral degree (M.D., Ph.D., or equivalent)
- U.S. citizenship or permanent residents, who have resided in the US for a total of three of the past five years (September 1)
- Applicants must have less than 5 years relevant postdoctoral training at the time of appointment

NOTE: In order to be approved for logistical and physical access to NIH facilities and systems, candidates must be able to pass a Federal background check using Standard Form-85 (read-SF-85). Section 14 of the Form asks, "in the last year, have you used, possessed, supplied, or manufactured illegal drugs?" The questions pertain to the illegal use of drugs or controlled substances in accordance with Federal laws, even though permissible under state laws. Federal laws supersede all state laws.

Curricula and Responsibilities

First Year

Individuals will pursue a master's degree in clinical investigation (M.S.) or in public health (M.P.H). Those already possessing a master's degree, will come directly to the NCI/FDA and begin the activities described below.

Second Through Fourth Year

At the NCI fellows will participate in the NCI's Summer Curriculum in Cancer Prevention, Molecular Prevention Laboratory, weekly Fellows Research Meetings and Colloquia series, Grants and Grantsmanship Workshop, Effective Presentations Workshop, and other professional development activities.

At the FDA, depending upon research interests, fellows will choose from among the product or clinical divisions of the participating FDA Centers. In a particular product division, fellows interested in regulatory research and related regulatory experience will work with a principal investigator or branch chief (or designee) selected through mutual agreement. Fellows may elect to work in a product division or in a pharmacology/toxicology branch in a clinical division. Both clinical and non-clinical fellows will have the option of performing translational research in the participating division, branch, or office.

Fellows will participate in various regulatory activities of the division at the FDA where they undertake their research. Fellows will spend approximately 40% of their time in product, pharmacology/toxicology, or clinical reviews and policy and guidance document development. They will participate in grand rounds and meetings related to regulatory activities. Additionally, fellows will attend courses offered by the participating FDA Centers and pass required testing in reviewer training.

Fellows' performance will be evaluated by Fellowship Program staff at the NCI and FDA, research mentors, and scientific staff overseeing fellows' activities at either institution.

How to Apply

Applications are due August 25, 2020 for an earliest start date of July 1, 2021.

Please submit:

- Curriculum Vitae
- Personal statement of research goals
- Three letters of reference

For more detailed information and application guidelines view the NCI-FDA Research and Regulatory Review Fellowships Guidelines for Application (PDF)

Where To Submit:

- Application guidelines and further information are available at Cancer Prevention Fellowship Program.

Mentors

While at FDA, fellows will each be assigned a mentor who will be a senior member of FDA scientific review staff.

Review list of mentors and projects here.

Burden Statement

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Expiration Date: 07/31/2022

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Updated: January 16, 2020

OMB No.: 0925-0761
Expiration Date: 07/31/2022

NCI-FDA Research and Regulatory Review Fellowships Guidelines for Application

Application Materials

The following application materials are required, as described below:

- Personal statement of research goals
- *Curriculum vitae*
- Three letters of reference
- Academic transcripts
- Other documentation

Personal statement of research goals. In narrative form describe your research interests and goals and how these relate to the field of cancer research and regulatory review. Please also provide insight into your short-and long-term career goals, and explain how the IOTF will help you in achieving those goals. Limit your personal statement to two typed, single-spaced pages and use 12-point font and 1" margins (approximately 1,000 words).

Curriculum Vitae. Please refer to *Guidelines for Application/Information to Include in Curriculum Vitae* section.

Letters of Reference. Three current and original letters of reference must be sent directly to the CCT Office of Training and Education by individuals in the scientific/academic community who have knowledge of your scientific accomplishments, motivation, and skills. Letters should be addressed to the Program Director, Dr. Chanelle Case Borden; typewritten on official letterhead; written in English; and contain an original signature. A faxed copy is acceptable provided that the original letter is sent by mail and postmarked on or before the deadline for the appropriate program. Photocopies and electronic copies are *not* acceptable.

AcademicTranscripts. Copies of all graduate and undergraduate transcripts (and/or translations, if applicable) must be submitted directly to the CCT Office of Training and Education.

Other Documentation. Permanent residents of the United States must submit proof of eligibility for citizenship. The I-551 stamp in a passport is acceptable; "Employment Authorization" documents are not acceptable.

Information to Include in *Curriculum Vitae*

- Applicants are encouraged to use their current curriculum vitae and to add any necessary information.
- Please include your name on each page of the curriculum vitae.
- Some of the information requested below will not be applicable to all individuals.
- Please do not print or type your information on this page.

Date Prepared

_____

Personal Information

_____

Name (First middle last)
Gender (*optional*)
Race (*optional*)
Date of birth
Place of birth (city, state, country)
Home address
Work/school address
Telephone (*if more than one telephone number is provided, please indicate preferred contact*)
Fax
E-mail (*if more than one e-mail address is provided, please indicate preferred contact*)

Citizenship

_____

Country of citizenship
U.S. permanent resident number, if applicable

Education

_____

Please list all colleges and universities attended and any other relevant training. Include the following information for each institution:

School, department, city and state, country
Dates attended, academic major, degree, year degree awarded/expected

Work Experience

_____

Please list current and past employment. Include the following information for each position:

Title, employer's name, address, and telephone
Dates of employment, hours per week
Brief description of duties and accomplishments

Other Information

_____

Please note that the items requested below may not be relevant to all applicants.

Board certification
Committees
Grants awarded
Honors and awards
Patents
Peer-review service
Professional licenses
Professional society memberships
Scientific presentations
Teaching

Research Interests

_____

Please provide a few key words that describe your research interests.

Bibliography

_____

Please list all publications and indicate whether they are "published," "in press," "submitted," or "in preparation." Please list full-length manuscripts and abstracts separately.

How to Submit Application Materials

If you are interested in applying to the IOTF and meet the eligibility requirements (refer to *Eligibility* section), you may submit your application either:

• Email: send materials to chanelle.case@nih.gov
• Via postal mail

Please select only one method by which to submit your application. If more than one application is received for an applicant, only the first application received will be considered.

Applying By Email

Personal Statement of Research Goals and *Curriculum Vitae*. Please send our Application to chanelle.case@nih.gov. And provide your personal statement of research goals and *curriculum vitae* as two separate documents. The application must be submitted on or before the appropriate deadline for the desired program.

Letters of Reference, Academic Transcripts, and Other Documentation. Three letters of reference, academic transcripts, and other documentation materials should be sent directly to Dr. Case Borden (refer to *Contact Information* below). All application materials must be postmarked on or before the appropriate deadline for the desired program.

Application Deadline: As Appropriate for Each program

Contact Information

Send application materials to:

Chanelle Case Borden, Ph.D.
IOTF Program Director
Center for Cancer Training
Office of Training and Education
National Cancer Institute
9609 Medical Center Drive
Rm. 2W234
Bethesda, Maryland 20892-9707

Selection for these positions will be based solely on merit, with no discrimination for non-merit reasons, such as race, color, gender, national origin, age, religion, sexual orientation, or physical or mental disability. NIH and FDA provide reasonable accommodations to applicants with disabilities. If you need reasonable accommodation during any part of the application and hiring process, please notify us. The decision on granting reasonable accommodation will be handled on a case-by-case basis.

THE NIH/NCI AND FDA ARE AN EQUAL OPPORTUNITY EMPLOYER.