





# 2022 BRISTOL MYERS SQUIBB FOUNDATION DIVERSITY IN CLINICAL TRIALS CAREER DEVELOPMENT PROGRAM

# **Application Handbook**

Application Deadline: May 13, 2022 (11:59 PM ET)

Please visit <u>www.diversityinclinicaltrials.org</u> for more information

#### **About the Bristol Myers Squibb Foundation**

The Bristol Myers Squibb Foundation empowers partners to build innovative solutions to advance health equity and improve access to quality healthcare for patients by focusing grant making on communities most at risk of suffering the impacts of serious diseases in the regions of the world that are hardest hit.

For more information, visit <a href="mailto:BMS.COM/FOUNDATION">BMS.COM/FOUNDATION</a>

# **About National Medical Fellowships**

Seeking to empower and support aspiring physicians and health professionals underrepresented in medicine to contribute to the health of our nation, National Medical Fellowships' mission is to provide scholarships and support for students underrepresented in medicine and the health professions.

Founded in 1946, NMF is one of America's first diversity organizations. Today, as we come together to celebrate our diversity with joy and new purpose, NMF remains the only national organization solely dedicated to providing scholarships to medical and health professions students in all groups underrepresented in healthcare.

NMF is supported by a national network of Alumni who serve tens of millions of patients annually. Their experience inspires us and gives voice to our mission.

For more information, visit NMFONLINE.ORG

#### **About American Association for Cancer Research**

The American Association for Cancer Research (AACR) is the first and largest cancer research organization dedicated to accelerating the conquest of cancer. Through its programs and services, AACR fosters research in cancer and related biomedical science; accelerates the dissemination of new research findings among scientists and others dedicated to the conquest of cancer; promotes science education and training; and advances the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.

# **Table of Contents**

Purpo	se	3
Fundi	ng Available	3
Eligibi	ility Criteria	3
Profes	ssional Degree	3
Caree	r Phase Early Stage Investigator (ESI)	3
Citize	nship or Immigration Status	4
Revie	w of Applications	4
Key D	ates	4
Applic	cation Changes	4
Award	d Notification	5
Applic	cation Information Use and Sharing	5
Applic	cation Procedures	5
Applic	cation Guide	6
1.	Applicant Information (required)	6
2.	Project Information (required)	6
3.	Mentor Invite (required)	7
4.	Project Timeline Form (required; template provided)	9
5.	Personal Statement Form (required)	10
6.	Budget (required; template provided)	10
7.	Applicant's Biosketch (required)	11
8.	Research Strategy (required)	11
9.	Cited References (required)	12
10.	Institutional Letter of Support from Department Chair or Dean (required)	13
11.	Clinical Protocol (required)	13
12.	Supporting Documentation (optional)	13
13.	Institutional Approval (required)	14
14.	Review and Submit (required)	14
Applic	cation Submission Checklist	16
Apper	ndix A. Helpful Tips for Using the Application Portal	17

#### **Purpose**

The Bristol Myers Squibb Foundation (BMSF) in partnership with National Medical Fellowships (NMF) has developed the Bristol Myers Squibb Foundation Diversity in Clinical Trials Career Development Program (DCTCDP) to tackle low clinical trial recruitment of diverse patients by intentionally training clinical investigators committed to increasing diversity in clinical trials. This program provides early stage clinical investigators with distinct training, skills, and support to initiate and conduct clinical trials that support the recruitment of underrepresented patients.

#### **Funding Available**

Awards are \$120K/year for 2 years to garner at least 40% of the participant's time for program participation during the award period. View BMSF DCTCDP program requirements.

Awards will be made to organizations, not to individuals.

Guidance for the award: It is expected that the award will cover a percentage of the Scholar's salary to garner 40% of their time. The budget guideline is to allocate \$100,000 per year to salary support to protect the Scholar's time, although institutions may allocate the full \$120,000 to the Scholar's salary. Funds not allocated to the Scholar's salary may be used toward a portion of a research assistant/navigator salary. If funds are used for indirect costs, the amount cannot exceed \$10,000 or 10% of the recommended salary offset.

# **Eligibility Criteria**

#### **Candidate Profile**

Eligible candidates will reflect the National Science Foundation (NSF) definition of underrepresented populations in the US Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise:

- African Americans or Blacks
- Hispanics or Latinos
- American Indians or Alaska Natives
- Native Hawaiians or Other Pacific Islanders
- Other Pacific Islanders

OR have a demonstrated commitment to increasing diverse patient participation in clinical trials

#### **Professional Degree**

Eligible candidates will hold the degree of MD, MD/PhD, DO or DO/PhD

#### **Career Phase**

<u>Early Stage Investigator</u> (ESI): As defined by NIH, a new investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant. (Applicants with an RO1 or RO1 equivalent are ineligible.)

Applicants who hold concurrent career development awards (e.g., K23, K08, or any other type of career development award) are expected to have listed the funding in the Letter of Intent.

#### **Citizenship or Immigration Status**

Eligible candidates will be US Citizens or Lawful Permanent Residents (LPRs) as defined by the US Department of Homeland Security. Applicants who hold H-1B or O-1 Visas are eligible. The visa must be valid during the full 2-year program period.

The BMSF DCTCDP Selection Committee reserves the right to evaluate and determine applicants' eligibility based on the information and justifications included in the application materials. Applicants who are uncertain about their eligibility are encouraged to contact <a href="mailto:DCTCDPInfo@nmfonline.org">DCTCDPInfo@nmfonline.org</a> for clarification and provide their CV for evaluation.

# **Review of Applications**

The applications are reviewed by the BMSF DCTCDP Selection Committee using a multi-stage review process. Each application is assigned to at least two committee members who are leaders in their areas of expertise for independent and confidential review.

#### **Key Dates**

Online Applications Open: January 31, 2022

Full Application Due: May 13, 2022 (11:59 PM ET)

Selection Process: May 16-Aug 1, 2022 Award Notifications: August 2, 2022

Award Term: November 1, 2022 – October 31, 2024

# **Application Changes**

The applicant must notify BMSF DCTCDP immediately via email (to <a href="DCTCDPInfo@nmfonline.org">DCTCDPInfo@nmfonline.org</a>) if any of the following conditions apply, from application submission through award notification:

- 1. <u>Withdrawal of Application</u>: Inform the BMSF DCTCDP Grants and Awards team of the reason(s) for withdrawing the application. The email should include the applicant's name, the title of the proposal, and the reason for withdrawing the application.
- 2. <u>Change of Institution or Position</u>: The applicant has a career plan change, leaves his/her current position in the institution, or is unable to meet the eligibility requirements for the program.
- 3. <u>Change in Eligibility Status</u>: If the applicant is selected as a Scholar, BMSF DCTCDP has the right in its sole discretion to withdraw the award.
- 4. <u>Mentor Change of Institution</u>: The applicant's mentor leaves his/her current position or institution.
- 5. <u>Change in Proposal (Scope, Timeline, Budget, etc.)</u>: The applicant has significant changes in the submitted proposal affecting aims, research strategy, timeline, and/or budget. If BMSF DCTCDP is notified of the change in proposal after the applicant is notified of an award, BMSF DCTCDP has the right in its sole discretion to withdraw the award.

#### **Award Notification**

Applicants can expect to be notified in August 2022 via email. All communication regarding applications, including award notifications, will be sent to the preferred email address on file. If you have questions, please email DCTCDPInfo@nmfonline.org.

#### **Application Information Use and Sharing**

The BMSF DCTCDP may use and process the information submitted through this application form for several purposes, including but not limited to: 1) evaluating the application, 2) communicating with you regarding your application and other opportunities that may be of interest to you, 3) publishing information regarding BMSF DCTCDP's grants and awards program, including through third party databases, and 4) for other legitimate purposes in keeping with BMSF DCTCDP's Privacy Policy and charitable mission. Information submitted through this application form will be kept on secure servers accessible only to third parties authorized by BMSF DCTCDP to perform functions on BMSF DCTCDP's behalf.

In addition, by submitting an application to BMSF DCTCDP, the applicant grants BMSF DCTCDP the right to use all application information submitted, outside of the research proposal, for any purpose. BMSF DCTCDP is permitted to share research proposals with reviewers, third party contractors, and potential supporters, and BMSF DCTCDP will require all to maintain the confidentiality of such proposals.

## **Application Procedures**

All applications must be submitted in accordance with the requirements and instructions of this application. All application materials must be in English and must be submitted online through the BMSF DCTCDP application portal at <a href="https://nmf.smapply.io/prog/bmsf-dctcdp">https://nmf.smapply.io/prog/bmsf-dctcdp</a>. No paper applications sent by mail, email, or fax will be accepted.

Applicants are encouraged to start their application early due to the complexity of the online application process. For example, an Authorized Official representing the sponsoring institution (typically from the institution's Office of Sponsored Research) must approve the completed application before submission by completing the "Institution Approval" task. Notify your Authorized Official immediately of your intent to apply to allow them ample time to prepare for the "Institution Approval" task they must complete before the application deadline. The full application must be submitted by **11:59 PM ET on May 13, 2022.** No late applications will be accepted.

Any updated supporting documentation (e.g., a letter from a drug company that they will provide the investigational drug, a letter of collaboration from another laboratory providing expertise for this project, a letter of support for a collaboration, etc.) must be sent to <a href="mailto:DCTCDPInfo@nmfonline.org">DCTCDPInfo@nmfonline.org</a> no later than <a href="mailto:11:59pm">11:59pm</a> ET on May 13, 2022. Please note that these documents are optional, and only updates to documents submitted by the May 13th deadline will be accepted.

Helpful Tips for Using the Application Portal are included in Appendix A.

# **Application Guide**

Sections of the full application are listed below. More details about each section, including requirements and instructions, are described in the next pages.

- Applicant Information (required)
- Project Information (required)
- Mentor Invite (required)
- Mentor Biosketch (required)
- Letter of Support (required)
- Project Timeline Form (required)
- Personal Statement Form (required)
- Budget (required)
- Applicant's Biosketch (required)
- Research Strategy (required)
- Cited References (required)
- Institutional Letter of Support from Department Chair or Dean (required)
- Clinical Protocol (required)
- Supporting Documentation (optional)
- Institutional Approval (required)
- Review and Submit (required)

#### Applicant Information

- First Name
- o Middle Name
- o Last Name
- o Primary email address (all future communications about the application will be sent to this address)
- Primary phone number
- Mailing Address

After completing this form, click "Mark as Complete".

# Project Information

During the BMSF DCTCDP you are required to participate in an active clinical trial. In most cases, the project will be that of your mentor; in some cases it may be your own project. This section solicits the following information about the clinical trial you will be working on (all are required):

- o Research Focus Area(s): Select one. (Cancer, Cardiovascular Disease & Immunologic Disorders)
- Disease Focus: What specific disease or condition will your project address?

- o **Research Project Title (75 words maximum):** Provide a short descriptive title of the research project.
- Research Project Description/Abstract (750 words maximum): Provide a brief abstract of the research project.
- Lay Abstract (600 words maximum): Provide a layperson summary of the project. Describe the work in a way that would be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. It should not include confidential information. If selected to receive an award, BMSF DCTCDP may use the contents of this summary on its website and/or other public facing materials.
- Specific Aims (1250 words maximum per aim): Select the number of aims from the dropdown list. Use a separate text box for each aim. Succinctly list the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field or develop new technology). The specific aim should concisely and realistically state what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives.
- Type of Research Study: Drug Treatment Trial or Non-Drug Treatment Clinical Trial
- Assurances:
  - Human Subjects Indicate whether human subjects will be involved in the research. If yes, select the appropriate status.
    - If the status is Approved, enter the IRB Approval Date, IRB Expiration Date, and Assurance Number.
    - If the status is Pending, please provide the submission date and the expected approval date if known
    - If the status is Exempt, enter the Exemption Number.
  - Use of Drugs Indicate if the research involves the use of drugs.
    - If yes, enter the name of the drug(s) and the drug manufacturer(s). It is highly encouraged to include a letter from the manufacturer(s) or supplier(s) that they will provide the drug in the Supporting Documentation section of the application.

After completing this form, click "Mark as Complete".

#### Mentor Invite

All BMSF DCTCDP awardees must designate at least one mentor for clinical trial research and career development mentoring. If you appoint a mentoring team, you must designate a primary mentor. It is strongly encouraged that the primary mentor be from your sponsoring institution. In most cases, applicants will participate in the active clinical trial of the primary mentor.

To request a recommendation from your mentor:

- Click "Request a Recommendation".
- o Enter the First name, Last name, Email address, and a brief message (optional) to the mentor.
- Click "Send Request".

- The mentor will receive an email with an invite to complete the recommendation by submitting a Biosketch and a Letter of Support.
- When they click "Start" they will be asked if they wish to Accept or Decline the recommendation request from the applicant. Upon accepting, the mentor will be able to complete and submit the recommendation within the site.
- You will be notified by email when the mentor Accepts or Declines the recommendation.

To resend or withdraw the request, click the ellipsis (...) near the mentor's name and email and select the appropriate option from the drop-down list as shown below.

**IMPORTANT:** The mentor must complete their task and click "Submit" prior to the application deadline. The applicant will not be able to submit the application until these tasks are submitted. Once the mentor has submitted their documents, return to this task and click "Mark as Complete".

#### Form for "Mentor Invite"

# Mentor must submit the following:

- <u>Mentor's Biosketch</u>: The mentor must use the NIH Biosketch template with an expiration date of 09/30/2024. The Biosketch must not exceed five (5) pages. To complete the Biosketch, refer to these instructions.
- Letter of Support: This should include the following information:
  - Mentorship plan for the applicant, including intended structure of the mentor/scholar interaction during the 2-yr program period. This includes mentoring related to the research project as well as professional and career mentoring.\*
  - Confirmation that the applicant's project information has been thoroughly reviewed by the mentor.
  - o Description of the role of the applicant in the mentor's research project.
  - Description of the difference between the mentor's role and the applicant's role in the research project.

The applicant will be notified when the mentor submits a recommendation. The mentor must click "Submit" at the bottom of the page to trigger the email. The applicant will not be able to view the documents submitted by the mentor.

#### **Mentor Recommendation**

\*Mentorship Model and Mentor Roles and Responsibilities: Mentors must hold an MD, DO, MD/PhD, or DO/PhD. Mentors from an academic institution must hold a position as an associate or full professor. Mentors are expected to be established Clinical Investigators with an active clinical trial that the scholar can work on during the two-year program period. Note: submission of a copy of the protocol is a required component of the application. Research projects must meet the <a href="NIH Clinical Trial Definition">NIH Clinical Trial Definition</a> - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Mentorship is a critical aspect of the BMSF DCTCDP. It is estimated that clinical trial activities will comprise 75% of a mentor's activities. Mentors will engage scholars in the active conduct of an existing clinical trial and provide exposure to all aspects of CT administration and implementation. The remaining 25% of the mentor's focus will be on career, personal, and professional mentoring. The mentor will provide guidance on career and professional development, with a particular focus on challenges, opportunities, and strategies for URM researchers. Through this process, the mentor will share personal experiences that have influenced their career pathway.

The structure of the mentorship plan should be designed based on an estimated time commitment of 75% clinical trial research mentoring and 25% career (e.g., personal and professional) development mentoring. Minimum requirements for a mentorship plan include at least 4 meetings per month, of which 3 shall be inperson or live virtual meetings related to clinical trial research activities. BMSF DCTCDP program staff will provide mentorship support and resources for the mentor. Quarterly group mentor meetings are encouraged, where mentors may share experiences, concerns, challenges, and best practices. BMSF DCTCDP program staff will monitor the mentorship plan and collect quarterly mentor status reports.

The Mentor honorarium/stipend is set at \$4,800 per year and is tied to career/personal/professional development mentoring. Honoraria/stipends will be disbursed annually, and benchmarks will include the fulfillment of responsibilities articulated in the mentorship plan. There will be a formal mentor onboarding process and mentors will participate in a mentor orientation session.

# Project Timeline Form

Please use the template provided here.

Enter each major project milestone/activity, a brief description, the expected completion date, the status and if it is an associated deliverable. A deliverable is something that can be included in a progress report, such as a publication or an approval letter. You are not required to have deliverables; however, the timeline should make it clear what outcomes will be achieved during the grant award period.

Download the template, then update the following:

- Enter the name of the milestone/activity
- Enter a description of the milestone/activity
- Enter the expected date of completion
- Indicate whether the milestone/activity is a deliverable
- Select the appropriate status
- Do not enter any comments.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [yearprogram abbreviation]\_Timeline\_[last name] (e.g.,2022DCTCDP\_Timeline\_Smith)

After completing this form, click "Mark as Complete".

#### Personal Statement Form

Enter answers to the following questions. You may cut and paste from a Word document. **Each response is limited to 500 words.** 

- Your commitment to diversity. Describe your commitment to increasing diversity in clinical trials.
- Your career plan. Provide a brief description of your career plan.
- Impact of award on your career. Provide a brief explanation of how receiving this award will affect your career.
- Percentage time of research activities. Provide the percentage of time you will spend on total research activities.
- o Your role. Describe briefly your role versus your mentor's role in the proposed research study.
- o Sources of salary support. List your sources of salary support including dollar amounts and percentages.
- o Collection and support of data. Briefly describe who will collect and analyze the data.
- o <u>Clinical potential of research project.</u> Briefly describe the clinical potential of this research project.
- Other funding sources. List other funding agencies/organization where this research proposal has been or will be submitted. If none, please indicate N/A.

After completing this form, click "Mark as Complete".

# Budget

Please find the Budget Template here.

The award funds are primarily to protect a minimum of 40% of your time for required program components (clinical trial activities; virtual orientation; the 6-day intensive BMSF-AACR Design & Implementation of Clinical Trials Workshop (early November); the two-year Community-Oriented Clinical Trialist Training, including biweekly BMSF DCTCDP Scholars Forums; career development planning; BMSF CIPP student summer mentoring; Annual Convenings; and reporting). Award funds may not be applied to patient care costs that are reimbursable by a third-party payer.

### **Budget Guidelines:**

- <u>Total Award</u>: The total award amount is payable on or about November 1st in annual increments of \$120,000 over two years. The total budget requested per year must not exceed \$120,000. The total budget requested must be no more than \$240,000 for the 2 years. It is expected that the award will cover a percentage of the Scholar's salary to garner 40% of their time.
- <u>Salary support:</u> The budget guideline is to allocate \$100,000 per year to support 40% of the Scholar's time, although institutions may allocate the full \$120,000 to salary support to protect the Scholar's time.
- <u>Indirect costs:</u> Up to \$10,000 of the award, per year, may be applied to overhead or facilities and administrative costs of the applicant's institution in administering the research project.
- <u>Discretionary funds:</u> Remaining funds should be specifically allotted to essential needs related to conducting the study such as a portion of a research assistant/navigator salary or travel expenses.

<sup>\*</sup>During the award period, at least 80% of the year 1 budget must be expended by the end of each reporting year as a condition of approval for new funds.

\*Attendance at all program trainings and the BMSF DCTCDP Annual Convening is required and costs will be covered by program. Meeting requirements include:

- Day 1 Virtual Orientation
- BMSF-AACR Design and Implementation 6-day intensive workshop (typically the first two-weeks of November 2022)
- o Bi-weekly BMSF DCTCDP Scholars Forum every other Friday from 12:00-3:00PM ET
- Two 1.5 day Annual Convenings in October or early November at the end of program years 1 and 2 (Dates and locations TBD)

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year program abbreviation]\_Budget\_[Last name] (e.g., 2022DCTCDP\_Budget\_Smith)

After completing this form, click "Mark as Complete".

#### Applicant's Biosketch

Applicants should use the NIH Biosketch template provided with an expiration date of 09/30/2024. The Biosketch must not exceed five (5) pages. To complete the Biosketch, please refer to these instructions.

Click here for the Biosketch template. Click here for the Biosketch example.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year program abbreviation]\_Biosketch\_[Last name] (e.g., 2022DCTCDP\_Biosketch\_Smith)

After completing this form, click "Mark as Complete".

#### Research Strategy

Please describe the research strategy of the clinical trial you will be working on. The research strategy is limited to six (6) typewritten, single-spaced pages, with one-inch margins and using an 11-point Arial font type. ALL pertinent tables, pictures, and graphs MUST be included within the 6-page limit.

The Research Strategy must contain the following information:

# 1. Significance and Background:

- I. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- II. Explain how the proposed project will improve scientific knowledge, technical capability, and/or critical practice in one or more broad fields.
- III. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the proposed aims are achieved.

#### 2. Innovation:

- I. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- II. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- III. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

#### 3. Approach:

- I. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Describe the rationale for how the exclusionary criteria for enrolling patients was designed.
- II. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- III. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. Appropriate detail and/or documentation in the Supporting Documentation section must be included to assure a reviewer that the applicant's project is feasible in the time frame of the grant. Examples include: a letter confirming access to an experimental therapy or an approval letter from a CTEP or a cooperative group. NOTE: Applicants may send supporting letters regarding feasibility (e.g., proof of receipt of drug from a company, IRB approval, etc.) to DCTCDPInfo@nmfonline.org until May 13, 2022.
- IV. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- V. Clearly state the applicant's role in the project (e.g., writing of the protocol, performing the assays, patient recruitment strategies, etc.). When human subjects are involved, the precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.
- VI. List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials.

#### 4. Accrual of Diverse Patients

- I. Discuss your goals for accruing patients from groups underrepresented in medicine (URM).
- II. Describe your proposed strategy and methodology for enrolling and retaining URM patients.
- III. Discuss potential problems, alternative strategies, and benchmarks for success in accruing URM patients.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_ResearchStrategy\_[Last name] (e.g., 2022DCTCDP\_ResearchStrategy\_Smith)

After completing this form, click "Mark as Complete".

# Cited References (required)

Upload a bibliography of any references cited in the Research Plan.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_CitedReferences\_[Last name] (e.g., 2022DCTCDP\_CitedReferences\_Smith)

After completing this form, click "Mark as Complete".

# • Institutional Letter of Support from Department Chair or Dean

A letter from the Department Chair or Dean from the applicant's sponsoring institution where the research project will be conducted must be provided. This letter must include a statement of institutional support that will enable the applicant to perform the proposed research. This letter must be signed and on official letterhead.

### If the letter is not signed and not printed on official letterhead, BMSF DCTCDP will return the application.

Note: If the mentor is the Department Chair, the Institutional Letter of Support must come from the Dean.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_InstitutionalLOS\_[Last name] (e.g., 2022DCTCDP\_InstitutionalLOS\_Smith).

After completing this form, click "Mark as Complete".

## Clinical Protocol (required)

A copy of the clinical protocol must be uploaded.

Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_ClinicalProtocol\_[Last name] (e.g., 2022DCTCDP\_ClinicalProtocol\_Smith)

After completing this form, click "Mark as Complete".

# Supporting Documentation (optional)

This section may be used to upload any necessary additional information required to properly review the application (e.g., letters documenting the feasibility of the project, a letter from a drug company that they will provide the investigational drug, a letter of collaboration from another laboratory providing expertise for this project, a letter of support for a collaboration, etc.). Applicants are encouraged to provide a letter of support for any investigational agents and letters of support from collaborating biostatisticians. Due to the limited time given to the reviewers, upload of any documents that are not critical to the review of the proposal or any additional publications is not allowable.

Click "Attach File" and select the file to be uploaded in the application. Repeat this step to upload multiple files.

Use this file naming convention for each document: [year and program abbreviation]\_SupportingDoc\_[number]\_[Last name] (e.g., 2022DCTCDP\_SupportingDoc\_1\_Smith; 2021DCTCDP\_SupportingDoc\_2\_Smith; etc.) After completing this form, click "Mark as Complete".

# Institutional Approval

The Authorized Official representing the sponsoring institution must approve the completed application before submission by completing the "Institution Approval" task. This individual is typically from the institution's Office of Sponsored Research. The task will not be available until all the required application tasks have been completed.

Upon review, the Institution Approver must either complete the Institutional Approval Form or upload a letter on institutional letterhead indicating the following:

- Official name of the institution
- Address
- EIN/Tax ID
- Name of the Institution Approver, email, phone
- Confirmation that the Authorized Official has reviewed and approved the application for submission
- Signature of the Institution Approver
- To request a recommendation from the Institution Approver:
  - o Click "Request a Recommendation".
  - Enter the First name, Last name, Email address, and write a message (optional) to the Institution Approver.
  - Click "Send Request". The Institution Approver will receive an email notification with the message.
  - If the Institution Approver accepts or declines the recommendation request, the applicant will receive an email notification.
  - To resend or withdraw the request, click the ellipsis (...) near the Institution Approver's name and email and select the appropriate option from the drop-down list.
  - **IMPORTANT:** The Institution Approver must complete their task and click "Submit" at the bottom of the page <u>prior</u> to the deadline. An email notification will be sent to the applicant confirming that the task has been completed.
- You will not be able to submit the application until this task is submitted.
- Once the Institution Approver has submitted the task, return to this section and click "Mark as Complete".

#### Review and Submit

The applicant will not be able to navigate to this page until all required sections have been "Marked as Complete" and all tasks from the Mentor and Institution Approver have been submitted.

On the left navigation, click "**Review**" to review or "**Submit**" to submit the application.

To download a copy of the application, click "My Applications". Click the ellipsis (...) on the specific application and click "Download".

On the next screen, select the desired options and click "Download".

A new tab will open. When the download is ready, click "**Download**". The application will be downloaded as a zip file.

# **Application Submission Checklist**

Applicant Information (required)	
Project Information (required)	
Mentor Recommendation(s) (required)	
Mentor Biosketch and Letter of Support (required)	
o Mentor Biosketch	
o Mentor Letter of Support	
Project Timeline Form (required)	
Personal Statement Form (required)	
Budget (required)	
Applicant's Biosketch (required)	
Research Strategy (required)	
Cited References (required)	
Institutional Letter of Support from Department Chair or Dean (required	
Clinical Protocol (required)	
Supporting Documentation (optional)	
Institution Approval (required)	
Review and Submit (required)	

#### Appendix A. Helpful Tips for Using the Application Portal

# **Navigating the Application**

- Click "Save and Continue Editing" at the bottom of the page as you go through the application or "Next" to continue to the next section.
- When finished with a particular task (e.g., Project Information), click "Mark as Complete" at the bottom of the page to validate task completion.
- If you need to edit a task after it has been Marked as Complete, click the ellipsis (...) on the top right corner of the task as shown below. Select "Edit" to reopen the form.
  - o **IMPORTANT!** Do NOT click "Reset" as this will delete previously entered data!

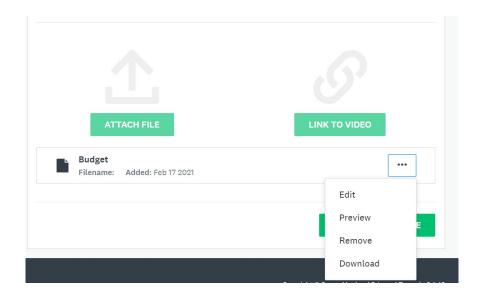


# **Receiving Notifications**

Add <u>noreply@mail.smapply.net</u> and <u>DCTCDPInfo@nmfonline.org</u> to your safe senders list to ensure you receive timely notifications associated with recommender task submissions, application submissions, etc. If you are not receiving notifications, check your junk/spam folders first, then contact <u>DCTCDPInfo@nmfonline.org</u> for additional assistance.

# **Uploading a Document**

- Documents should not be password protected.
- Documents must follow the file naming convention and requirements for page limits, margins, and fonts (see individual application sections for details). If any document you uploaded does not meet the specific criteria, BMSF DCTCDP will return your application.
- To upload a document, click "Attach File" and select the file to be uploaded.
- To edit a file name, click the ellipsis (...) next to the file name as shown below. Select "Edit" and enter the new file name based on the file naming convention.
- To remove or replace an uploaded document, click the ellipsis (...) next to the file name as shown below. Select "Remove" then click "Attach File".



#### **Inviting a Mentor**

- As part of your application process, you will need to "Request a Recommendation" from third parties such
  as a Mentor and Institution Approver. Click on the task and fill in the details of the Mentor including the
  First Name, Last Name, Email, and a brief message (optional) to send the Mentor. Once the information
  is submitted, an automated email will be sent to the Mentor letting them know that they've been asked
  to provide a recommendation. When the recommendation is submitted, you will be instantly notified.
- If the Mentor didn't receive an email invite, confirm that you sent the invite to the correct email address and there are no spelling errors, ask the Mentor to check their junk/spam folder, or resend the Invitation.
- To resend or withdraw the request, click the ellipsis (...) near the Recommender's name and email and select the appropriate option from the drop-down list as shown below.
- If the Mentor still has not received the email, please contact DCTCDPInfo@nmfonline.org.

