# Impactful Medicine Providing Access to Clinical Trials (IMPACT) Program

# Full Application Template

## Effective dates:

## June 1, 2019 – May 30, 2020

| Application Deadlines | |
|---|---|
| LOI due | August 31, 2019 |
| Full Application due: | November 30, 2019 |
| Grant Start date: | July 1, 2020 |

**Please Note:**

- **Read the Guidelines & Instructions completely before starting this form.**
- **All information must be provided. Significant deviations from the instructions may result in administrative rejection of your application.**
- **Use Times New Roman 12 point font, except figure legends, for which 10 point font may be used.**
- ***Instructions must not be deleted from this form.***

# Application Information

Provide the following information in 1 page maximum.

**IMPACT Director/Applicant Name**

**Applicant Institution**

**IMPACT Title**

**IMPACT Abstract**

## Overall Structure of Proposed IMPACT Program

Describe the proposed structure of the IMPACT Program. Include information on how the program will be set up and the key personnel running the program. This should include a dedicated coordinator as well as a brief description of clinicians involved, the latter being described more fully in the next section. Provide timelines of setting the program up as well as estimated timelines of clinical trial accrual. Include information of how patients will be accrued from the community sites. 1 page maximum.

# Cancer Center Hub Statement

Describe the overall clinical trial infrastructure of the cancer center with an emphasis on hematological cancer clinical trials. Include the number of blood cancer patients seen at the center as well as the numbers in clinical trials. 3 page maximum.

## Current Community Center Involvement

Describe the current coordination with community centers for hematological malignancy clinical trials, if any. Include the numbers of community centers that are involved in the cancer center clinical trials as well as patient numbers and characteristics. These patient characteristics should include, where available, percentage of all blood cancer patient who are minorities, lower socioeconomic status, and/or are from a rural location. 3 page maximum.

# Plan to Increase Community Center Involvement

Describe how IMPACT funding would be used to increase the community center involvement in blood cancer clinical trials. Include a discussion of which new community centers might be involved, as well as the patient characteristics (minority, socioeconomic status, and rural location), where available, of the community centers' blood cancer patients. Include a timeline for community center recruitment. 3 page maximum.

## Eligible Clinical Trials

Describe blood cancer clinical trials (currently enrolling or projected to open within one year of IMPACT funding start) that will be appropriate for community center participation. Provide the clinicaltrials.gov number (if available) and a brief description of the purpose of each trial. It is anticipated that at least 10 such eligible clinical trials will be open within two years of the IMPACT funding start date. More can be added, but there must be no fewer than 10 such trials during the IMPACT funding period. The clinical trials must have the intent to provide significant new information with high patient impact. 1,000 character limit for each trial.

## Education and LLS Resources

Describe current education outreach to community centers and how this will be enhanced with IMPACT funding. Include a discussion of how LLS resources may be used to enhance this outreach. These may include LLS's Information Resource Center and LLS's Clinical Trials Navigation Service. 2 page maximum.

# Key Clinical Personnel

There should be one cancer center clinician who oversees the IMPACT as the Program Director. There can be sub-Directors (Program Leaders) that are overseeing different aspects of the program, such as different disease focus areas. These clinicians must be the PI on at least one of the IMPACT trials. NIH biosketches for each should be attached at the end of the template. 2 page maximum.

# Institutional Commitment

A key review criteria will be the level of institutional commitment to the IMPACT Program. This commitment may be in the form of space and/or other resources, but should also be a financial commitment. The financial commitment should be described and can include salary support for non-clinical personnel. Salary support for clinical personnel may be included, but should be well justified based on new responsibilities associated with the IMPACT Program. 2 page maximum.

# Budget for Year 1 of the Award

| Personnel | | % Effort On Project | Dollar Amount Requested | | |
|---|---|---|---|---|---|
| **Name** | **Role on Project** | | **Salary Requested** | **Fringe Benefits** | **Total** |
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| | | | | | |
| | | | | Total | |

**Consultant Costs**

Total Consulting Costs

**Other Expenses *(Itemize)***

Total Other Expenses

# Summary Budget for Five Year Period

**PROJECT-SUMMARY BUDGET FOR ENTIRE FIVE YEAR PROJECT**

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total |
|---|---|---|---|---|---|---|
| **Personnel** | | | | | | |
| **Consultant Costs** | | | | | | |
| **Other Expenses** | | | | | | |
| **Total Direct Costs** | | | | | | |

| **Budget Justification** |
| --- |
| Describe how IMPACT funding would be spent to achieve the goals of increasing community center involvement. Justify each expense as to the overall goal of the IMPACT Program. Examples may include a coordinator, meetings, education/workshops, patient travel, and/or data analysis. 3 page maximum. |

## References

Use the *Blood* citation format. 4 page maximum.

# Signature Page

Signatures are required.

| **Role: Principal Investigator** | |
|---|---|
| Name | |
| Institution | |
| Title | |
| Division | |
| Department | |
| Telephone | |
| Email | |
| Signature | |

| **Role: Institutional Signing Official** | |
|---|---|
| Name | |
| Institution | |
| Title | |
| Division | |
| Department | |
| Telephone | |
| Email | |
| Signature | |

# Appendix

Attach the following materials in the order indicated. Some are required while others are optional. Refer to the Guidelines & Instructions for a complete description of each.

**IMPACT Program Director/Applicant's Biosketch** *(required)*

**Clinical Trial Leader Biosketches** *(required where applicable)*

**Collaboration Letters with Community Centers** *(optional)*

**Clinical Protocols** *(required) up to a 2 page summary for each trial and include a link to the full protocol*

**Assurances** *(required)*

- **Human Subjects**