**** *Early Career Award***

***General Instructions***

### INSTRUCTIONS FOR Submission of THE Proposal

Only proposals invited after acceptance of a Concept Paper will be considered. Each section has a specified page limit. **Do not** exceed the number of pages specified in each section of the proposal. Applicants may use a Calibri or Arial typeface and a font size of 11 points or larger. Do not adjust the margins. Appendixes, including tables, charts, graphics, photographs and illustrations are not allowed. Any such illustrative material must be embedded in the text without exceeding the stated page limitations for each section.

Some of the pages in the proposal contain tables, and all the normal table commands apply. You may adjust the size of each cell to fit your needs. However, you must stay within any page limitations noted in each section.

The face page also requests the legal name of the Supervising Institution as it should appear on the award letter if a grant is made. Please check with your grants and contracts office for the official name.

The completed proposal should be returned as a Word document in an e-mail attachment to Allison Martinez at [MartinezAF@ThrasherResearch.org](mailto:MartinezAF@ThrasherResearch.org) with the words “Early Career Award Proposal” in the subject line. Please confirm that the Fund has received your application. If the file contains multiple images and/or graphics, it may be too large to be transmitted as an e-mail attachment. Typically, 10MB or less should transmit without problems. In some cases, neither the sender nor the intended receiver is notified of the failure. Signed copies of the first two pages should be returned electronically.

### Instructions for Study Content pages

### Administrative Information

Each application may have only one Principal Investigator. This individual will be responsible to the Thrasher Research Fund for the scientific and/or technical work of the project. The Mentor has responsibility for guiding the work of the Principal Investigator and includes direct supervision of all project activities and approval of minor changes in emphasis or direction of the work, as necessary. As Co-Mentors are allowed, please designate the primary Mentor.

Where applicable, the Institutional Review Board (IRB) approval, Animal Welfare Assurance and proof of registration with [ClinicalTrials.gov](http://www.ClinicalTrials.gov) or an equivalent, must be received prior to any disbursement of funds. These documents are only required if the study is funded, although inclusion may assist in the review process.

The project period may not exceed two years. The project start date may be as soon as July 1 (first cycle) or January 1 (second cycle). If your project requires a later start date, please enter that date. Enter the appropriate date on the face page of the application. If awarded, please note that all projects must receive IRB approval (and if applicable, an IND approval or waiver) within six months of the award notification date. These dates are listed for each cycle at [ThrasherResearch.org](http://www.thrasherresearch.org/sites/www_thrasherresearch_org/Default.aspx?page=168). All projects must begin within six months of the award notification date. Please plan accordingly.

**Protection of Human Subjects Assurance/Certification/Declaration**

*Investigational New Drug (IND)*

If the study involves the administration of a medication, provide IND approval and FDA correspondence, an IND waiver, plans to pursue the IND approval, or a justification why an IND is not required. Include this information within the Experimental Design. [Click here](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm) for IND application instructions. If eligible for an IND exemption according to [21 CFR 312.2b](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2), provide proof of the IND waiver from the FDA.

Examples of research requiring an IND may include studying an unapproved drug, or an approved product for a new indication or in a new patient population. ***If there is any question about whether an IND is needed, please contact the Fund.***

*Health and Human Services (HHS) Assurance Status*

Contact your Supervising Institution to determine HHS Assurance Status. The Assurance identification number is the Supervising Institution’s Federal-wide Assurance number (FWA). If your institution does not hold an FWA, HHS Assurance may be obtained by visiting the [HSS website](http://www.hhs.gov/ohrp/assurances/assurances/file/index.html) and applying for an FWA.

*Institutional Review Board*

If funded, Institutional Review Board (IRB) approval must be received from each participating institution and study site prior to any disbursement of funds.

### Mentor(s) Evaluation of Applicant

The Mentor(s) Evaluation Letter should be no more than two pages. A Co-Mentor may contribute to the letter or write a separate letter. However, if a Co-Mentor provides a separate letter, this must be included within the two-page limit.

1. Describe your prior experience working with the applicant. Evaluate the applicant’s potential for conducting research, quality of research endeavors and publications to date, commitment to pediatric research, and need for further research experience and training.
2. Evaluate the applicant’s application with reference to evidence of originality, the significance of the problem, and the potential to impact children’s health. Describe what the applicant’s role has been in developing this project and what their role will be throughout the project.
3. Describe the research training plan that you have developed specifically for the applicant. Indicate the relationship of the proposed research training to the applicant’s career goals. Describe the skills and techniques that the applicant will learn, and how they will contribute to the applicant’s career goals.

### Scientific Summary

Summarize the proposal’s objectives and specific aims, making reference to how the project relates to pediatric health, and describe concisely the methodology for achieving these goals. The summary serves as a succinct and accurate description of the proposed work when separated from the application. You may use or modify the Scientific Summary from your concept paper, as the sections are the same. Further instructions are in the application template. ***Do not exceed one page****.*

### Significance of the Proposed Research and Supportive Preliminary Data

Concisely explain the significance of the proposed research project. Describe research conducted by the investigator(s) or by others that leads to the present proposed research project. Include literature references in the Literature References section. ***Do not exceed one page.***

### Experimental Design and Methodology

This section should include information pertinent to your specific study and information necessary for the reviewers to determine the scientific merit of the proposal. ***Do not exceed two pages****.* Include literature references in the Literature References section. As applicable, address the following:

*Parent Study*

* Please briefly describe the hypothesis, aims, and design of the parent study, if applicable
* State the additional aims supported by Thrasher funding.
* Describe the benefit of the additional aims.

*Study Design*

* State the study design.
* Describe the study site(s).
* Describe the population to be studied and clearly state inclusion and exclusion criteria.
* Describe the control group, justifying why this population would serve as an appropriate control.
* Describe the intervention(s).
* Describe measurements and data to be collected.
* Describe the plan for recruitment, enrollment and retention of the proposed sample size within the projected timeline of the study. Include resources, facilities and staff available to the researcher. Cite the number of patients expected to meet inclusion criteria at each site, the expected “drop-out” rate, and any other potential limitations that may affect enrollment or retention.
* Provide the sample size and power calculations for ***each specific aim*** of the study. Include the effect size estimates using the calculations and associated justification.

*Methodology*

* Discuss the procedures and protocols to be used to accomplish the project.
* Include a description of the statistical analysis plan to be used.
* Describe how potential confounders will be measured and controlled for in the analysis.
* Discuss potential difficulties and limitations and propose alternative approaches to achieve the specific aims.
* Discuss the potential ethical concerns with the design or conduct of the study and describe the precautions to be taken.
* Provide a timeline for the study.

*Human Subjects/Investigational New Drug*

* Discuss the potential ethical concerns with the design or conduct of the study. If applicable, describe the precautions to be taken, including comments on the planned use of an Institutional Board Review or comparable ethics board, a Data Safety Monitoring Board, and the informed consent/assent protocol to protect human subjects within the proposed study.
* If the study involves the administration of a medication, provide IND approval and FDA correspondence, an IND waiver, or a justification why an IND is not required.

### Literature References

There is no page limitation on references.

### Instructions for Budget Page

**\*\*The total Direct Costs cannot exceed $25,000****. In addition, 7% of Direct Costs are allowed as Indirect Costs (split proportionally between supervising institution and contractual institution(s), making the total maximum budget $26,750.**

### Personnel Costs

Up to $12,500 of the award may be used for salary (including fringe) of the applicant. In addition to any salary requested for the applicant, salary for technical personnel is allowed. Salary support for the mentor is not allowed.

### Consultant Costs

### Provide the name, institutional affiliation, and cost of consultants who have agreed to participate in the project. A consultant is an individual that provides professional advice or services on the basis of a written agreement for a fee. A consultant is not normally an employee of the supervising institution and should provide services that are clearly outside the scope of the consultant’s salaried employment.

### Supplies

Itemize by category supplies such as glassware, chemicals, radioisotopes, medical supplies and animals.

### Travel

Research-related travel costs are permitted with adequate justification. Up to $2,000 of the budget may be used for the Applicant to attend one conference, but only for the purpose of reporting findings resulting from Thrasher-supported research.

### Patient Care Costs

These costs are directly related to the patient, such as a hospital stay and testing.

### Other Expenses

Itemize other expenses not previously listed. Include items such as communication expenses, postage, printing of publications, shipment costs, and participant incentives. Include outside laboratory services. Tuition is allowed with prior fund approval. The course must be directly related to the project and should not exceeded $2,000.

### Indirect Costs

The Fund will participate in the payment of Indirect Costs up to 7% of the Direct Costs.

#### Equipment

Equipment (single items over $4,000) is highly discouraged and must be approved by the Fund prior to submission of the application. Indirect Costs may not be claimed for Equipment. Equipment purchased with money awarded by the Fund shall be the property of the Fund, which has authority to determine the disposition of the equipment at the conclusion of the project after consultation with the Principal Investigator.

#### Contractual Costs

Contractual arrangements are for major support services, such as additional project sites. Additional project sites will split the indirect costs proportionally with the supervising institution.

#### Budget Justification

Include the following in the Budget Justification section.

* For each of the professional and non-professional personnel involved in the project ***who would receive Fund support***, list the following:
  + - Name and position
    - Percentage of time and hours per week on the project
    - Dollar amount for combined salary and fringe benefits
* If salary for the applicant is requested, describe the applicant’s current salary amount and source.
* For current and pending grant awards of the Applicant, list sources, amounts, and percentage of time commitments.
* Provide a brief justification of expenditures in the other budget categories.

### Biographical Sketch

### Applicant

Provide a current CV or NIH-format biographical sketch. Include your education training, a personal statement, positions and honors, contribution to science, and research support (both received and pending). eRA commons name is not required.

[Click here](https://grants.nih.gov/grants/forms/biosketch.htm) for a link to the general NIH biographical sketch template, instructions, and sample.

### Mentor(s)

Provide a current CV or NIH biographical sketch for each mentor and co-mentor. eRA commons name is not required. A mentor may have only one Thrasher Research Fund Early Career Awardee at a time.

### Mentor Instructions

### Pre- and Post-Trainees of Mentor

Our reviewers appreciate having examples of past and current trainees to help as they evaluate the ability of the mentor to train the ECAP applicant. There are several ways to provide this information to the fund, please choose what works best in your situation. 1) Use the form provided (below), 2) use similar forms required by the NIH or other funding groups, 3) Provide a freeform letter detailing mentoring history

Ideal information to include is:

* Past and current pre-doctoral and postdoctoral trainees for whom the faculty member was/is the thesis advisor or sponsor (past 10 years, at least 5-10 persons).
* Where the pre- or postdoctoral training with the faculty member occurred, if at a different institution
* Training level (pre-doctoral or postdoctoral level)
* Training period
* Title of the research project
* Current positions or current source of support
* Exclude medical interns and residents unless they are heavily engaged in laboratory research

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| **Thrasher Research Fund**  ***Early Career Award Proposal Application*** | |
| **Title (**Limit the title to 100 characters including spaces.) | |
| **Principal Investigator** (Name, degree, title and address) | **Mentor(s)** [Name, degree, title, institution, address and email] |
|  | Primary Mentor:  Co-Mentor(s): |
| Telephone |
| E-mail |
| **OPTIONAL:** Underrepresented Minority  Yes  No  Definition at <https://www.thrasherresearch.org/diversity> |

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| **Human Subjects?** If yes, complete the enclosed Protection of Human Subjects form. | IRB Approval |
| Yes  No | Included  Pending  NA |
| **Animals Used?** If yes, document compliance with Animal Welfare Assurance laws. | Approval Status |
| Yes  No | Included  Pending  NA |

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| **Project Period The** entire project may not exceed 2 years. | | | | | |
| Start date (month and year) | | | End date (month and year) | | |
| Total Budget Request – may not exceed $25,000 in Direct Costs, plus 7% Indirect Costs. | | | | | |
| $ | | | | | |
| **Performance Site(s)** | Indicate where the work described in the “Experimental Design and Methodology” section will be performed. Provide specific organization names and their location. | | | | |
| Organization name and address | | | Organization name and address | | |
| **Supervising Institution** | | Name the *one* organization that will be legally and financially responsible and accountable for the use and disposition of any funds awarded on the basis of this application. | | | |
| Supervising institution name and address | | | | Name of Financial Contact :  Address :  Phone :  Email : | |
| **Official Signatures for Supervising Institution** | | | | | |
| We, the undersigned, certify that the statements herein are true and complete to the best of our knowledge, that facilities are available for the proposed research and that the Principal Investigator is the primary author of all application sections with the exception of mentor-related documents. We will comply with the Thrasher Research Fund's Early Career Award Conditions of Grant that are in effect at the time of the award. | | | | | |
| Name and title of Principal Investigator | | | Signature | | Date (mm/dd/yy) |
| Name and title of primary Mentor | | | Signature | | Date (mm/dd/yy) |
| Name and title of official from Supervising Institution | | | Signature | | Date (mm/dd/yy) |
| **Protection of Human Subjects Assurance/Certification/Declaration**  Thrasher Research Fund | | | | | |
| **Policy** Aresearch project involving human subjects sponsored by a U.S.-based institution that is not exempt from HHS regulations may not be funded unless an institutional review board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45. Part 46, of the Code of Federal Regulations (45 CFR 46-as revised). The applicant institution must submit certification of IRB approval to the Thrasher Research Fund unless the applicant institution has designated a specific exemption under Section 46.101(b) that applies to the proposed research project. Institutions with an assurance of compliance on file with HHS that covers the proposed project should submit certification of IRB review and approval with each application. In the case of institutions that do not have an assurance of compliance on file with HHS covering the proposed project, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification. Documentation of IRB approval from all project-related participating institutions must be included. | | | | | |
| **Title of Application** | | | | | |
| **Principal Investigator** | | | | | |
| **Investigational New Drug Application** | | | | | |
| **Food and Drug Administration required information** In accordance with 21 CFR 312, if an application is made to HHS requiring certification and involving use of an investigational new drug or device, additional information is required. Thirty (30) days must elapse between date of receipt by FDA of Form FDA-1571 and use of the drug, unless the 30-day delay period is waived by FDA (21 CFR 312.40 b.2). | | | | | |
| **Sponsor name** | | | | | |
| **Drug name** | | | | | |
| **Date of end of 30-day expiration or waiver** | | | | **Number issued** | |

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| **HHS Assurance Status** | | |
| This institution has an approved assurance of compliance on file with HHS which covers this activity. | Assurance identification number | IRB identification number |
| No assurance of compliance which applies to this activity has been established with HHS, but upon request the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46. | | |
| **Certification of IRB Review or Declaration of Exemption** | | |
| This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant subparts. This certification fulfills, when applicable, requirements for certifying FDA status for new investigational drug or device. | | |
| **Date of IRB approval or Pending**:  Pending | Full Board Review  Expedited Review | |

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| This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated, and that appropriate further certification will be submitted. | Human subjects are involved, but this activity qualifies for exemption under 45 CFR 46.101(b) in accordance with paragraph\_\_\_\_\_\_ [insert paragraph number of exemption in 46.101(b), 1 through 5], but the institution did not designate that exemption on the application. |

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| The official signing below certifies that the information provided on this form is correct and that the supervising institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification. As determined by the Supervising Institution, the authorizing official may be from the offices of sponsored grants, contracts or the administrating school/department such as the Dean or Chair. | | |
| **Supervising Institution Official** | | |
| Name | Telephone | |
| Address | Email | |
| Title of official | | |
| Signature of official | | Date |

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| **Mentor(s) Evaluation of Applicant** *(Do not exceed two pages, including any co-mentor letters)* |

*Please include Mentor Evaluation here*

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| **Scientific Summary** *(Instructions are in italics and should be deleted prior to submission - Do not exceed one page)* |

*Please note that this summary, except the final section on “Other considerations”, will serve as the website abstract if the project is funded and be published on the ThrasherResearch.org website.*

Background:

*A sentence or two describing the significance of the medical problem under study. Many applicants allocate too much space describing background that is not directly relevant to their research question*.

Preliminary Data:

*Present any preliminary data or findings that lead you to the hypothesis. This can include pilot studies, early results, or any relevant data that supports your research direction. Make sure to highlight if the applicant had a role generating or analyzing this data.*

Research Gap:

*A sentence describing the gap in the field that your proposal seeks to address.*

Hypotheses and Specific Aims:

*State each hypothesis in a single sentence. Briefly describe the related aims.*

Design:

*Outline the basic design of the study. Indicate the primary outcomes and how they will be measured. As applicable, include information about study subjects, sample size, or other sample material to be used in the study.*

Potential Impact:

*Highlight the potential significance for the field of study and child health. This section should be no more than two sentences.*

Other considerations:

*Anything else you think the reviews should know about the project or application. This could include how the work fits into the larger scope of your projects or your mentor’s work, what the Thrasher grant adds to the applicant’s research skills, or how the work will allow for future funding opportunities.*

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| **Significance of the Proposed Research and Supportive Preliminary Data (***Do not exceed one page)* |

*Please include Significance of the Proposed Research and Supportive Preliminary Data here*

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| **Experimental Design and Methodology** *(Do not exceed two pages)* |

*Please include Experimental Design and Methodology here*

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| **Literature References** *(There is no page limitation on references)* |

*Please include references here*

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| **Budget and Justification** *(Do not exceed one page)* | | | |
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| **Supervising Institution** | | | |
| **Budget Category Totals** | **First 12 mo. budget period** | **Second budget period, up to 12 mo., if applicable** | **Total** |
| **Personnel costs** (including fringe) |  |  |  |
| **Consultant Costs** |  |  |  |
| **Supplies** |  |  |  |
| **Travel** |  |  |  |
| **Patient Care Costs** |  |  |  |
| **Other Expenses** |  |  |  |
|  | **Direct Costs to Supervising Institution:** | | *Total of cells above* |
|  | **Indirect Costs to Supervising Institution** | | *7% of Supervising Institution costs* |
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| **Contractual** **Costs** | | | |
| **Budget Category Totals** | **First 12 mo. budget period** | **Second budget period, up to 12 mo., if applicable** | **Total** |
| **Contractual Costs** |  |  |  |
|  | **Indirect Costs to Contractual Institution(s)** | | *7% of Contractual Institution costs* |
|  | **Total Contractual Costs** | | *Total direct and indirect Contractual* |
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| **Total for entire proposed project:** *Supervising Institution costs, Indirect costs to supervising institution, and total contractual costs. Budget will not exceed $26,750* | | |  |

**Budget Justification:**

*Please include Budget Justification here*

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| BIOGRAPHICAL SKETCH - APPLICANT **DO NOT EXCEED FIVE PAGES** | | | | |
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| NAME | | POSITION TITLE | | |
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| EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)* | | | | |
| INSTITUTION AND LOCATION | DEGREE  *(**if applicable)* | | MM/YY | FIELD OF STUDY |
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[*Click here*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html) *for the general NIH biosketch template, instructions and sample.*

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| BIOGRAPHICAL SKETCH - MENTOR **DO NOT EXCEED FIVE PAGES** | | | | |
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[*Click here*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html) *for the general NIH biosketch template, instructions and sample.*

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| **Pre- and Postdoctoral Trainees of Mentor Mentor’s Name:** |

| Mentor’s Past and Current  Trainees | Pre or Post | Training Period | Prior Academic Degree(s) | Prior Academic Degree Year(s) | Prior Academic Degree Institutions(s) | Title of Research Project | Current Position (past trainees) Source of Support (current trainees) |
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