

UW-Madison Pre-Proposal Instructions The Hartwell Foundation Individual Biomedical Research Award

The Hartwell Foundation Individual Biomedical Research Award will provide financial support to stimulate discovery in early-stage biomedical research that will benefit US children. The University of Wisconsin-Madison has been selected as one of the 10 research institutions to compete for this award. The Hartwell Foundation requires each selected research institution to hold an open internal competition to identify up to three nominees, based upon application requirements set forth by the Foundation.

The following rules apply to the Hartwell Individual Biomedical Research Award:

- Proposals must describe early-stage, innovative, and cutting-edge biomedical research that is strategic or translational in nature and will benefit children in the United States.
- Proposals with high-risk hypotheses that are likely to face significant hurdles in other funding pathways are encouraged. Significant preliminary results are not required.
- Proposals should address either a specific unmet need in translational medicine or a strategic problem in applied science.
- All Nominees for the Hartwell Individual Biomedical Research Award must demonstrate they are collaborative. Each Nominee must identify at least one participating collaborator that is a practicing physician, preferably in pediatric medicine.
- The applicant may not have had significant funding from outside sources.
- The applicant should discuss thoroughly the ideas of innovation, collaboration, the deployment of technology to address the problem, and the significance or outcomes of the proposed research.
- Awards are \$100,000/year for 3 years. (No Indirect Costs)
- All recipients **MUST** be US citizens or permanent residents who hold a full-time appointment at UW-Madison and be able to serve as PI. Successful award recipients typically have been junior investigators, although occasionally senior investigators in fields some distance from children's health with ideas that could lead to a breakthrough in children's health have been considered.

Instructions for Pre-proposals:

1. On a cover page, provide only the following information regarding the applicant:

| | |
|-------------------------|--|
| Proposal Title: | Campus Address: |
| Name: | Contact Phone Numbers (office and mobile): |
| Academic Degrees: | Email Address: |
| Job Title: | Citizenship: |
| Department Affiliation: | Names and Degrees of Collaborator(s): |

2. In 2 pages or less, provide a 450-word Lay Summary, a scientific Abstract, and the Specific Aims for the project. Literature cited may be listed on additional pages as required.

3. Attach a current Biographical Sketch, including other support, for the PI only.

Submit 15 complete paper copies and one electronic copy to Tracy Cabot, 4118 HSLC, by **Noon, Wednesday, June 6, 2018**. Contact Tracy Cabot at 263-6515 or tlcabot@wisc.edu if you have questions.

THE HARTWELL FOUNDATION

INDIVIDUAL BIOMEDICAL RESEARCH AWARD 2018 COMPETITION

The Hartwell Foundation seeks to inspire innovation and achievement by offering individual researchers an opportunity to realize their hopes and dreams. Our approach is to be unique, selective, thorough and accountable. Through a unique funding process, we provide financial support to stimulate discovery in early-stage biomedical research that has not qualified for funding from traditional sources and that has the potential to benefit children of the United States. We want the research to make a difference.

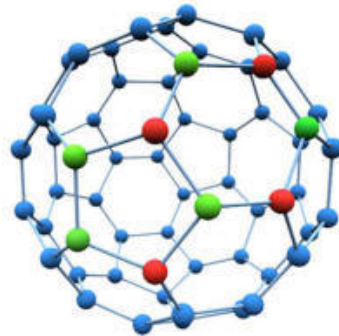


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LIMITED SUBMISSION PROCEDURE

Every year The Hartwell Foundation announces its Top Ten Centers of Biomedical Research in the United States, inviting each center to nominate individuals for a Hartwell Individual Biomedical Research Award. Selected institutions may submit up to three nominations to compete in a process that seeks to fund early-stage, innovative, and cutting-edge biomedical research. From time-to-time, the Foundation also selects institutions for limited participation, which may submit up to two nominations in each competition.

From the Nominees submitted in each competition, the Foundation selects ten investigators to receive a Hartwell Individual Biomedical Research Award, which will provide support for three years at \$100,000 direct cost per year. In addition, for *each* funded Nominee, the participating institution will receive a Hartwell Fellowship to fund one postdoctoral candidate who exemplifies the values of the Foundation. Each Hartwell Fellowship provides support for two years at \$50,000 direct cost per year.

ELIGIBILITY

Participating Institution: The Hartwell Foundation selects participating research institutions in a qualification process that takes into account the shared values the institution has with the Foundation relating to children's health, while also considering the presence of a medical school, biomedical engineering, and the quality and scope of ongoing research. The Foundation also takes into account the institutional commitment to translational approaches that promote rapid clinical application of research results, including technology transfer. Selection of an institution in any given year does not guarantee selection in a subsequent year.

Each participating institution agrees to identify Nominees by holding an internal, open competition of their design from areas of discovery and applied science related to human health, including biomedical engineering.

Each year Hartwell Top Ten Centers of Biomedical Research must submit at least one Nominee that holds a Doctor of Medicine degree (e.g., MD, MD-Ph.D., MD-DDS, etc.).

Nominee: Only researchers nominated by a participating institution selected by The Hartwell Foundation are eligible to compete for the Individual Biomedical Research Award. All nominees for the Award should be citizens of the U.S. or hold permanent residence; maintain a full-time appointment within the sponsoring institution; and must have adequate committed laboratory and office space to conduct the proposed research.

EVALUATION CRITERIA

All Nominees must submit a detailed research proposal that is consistent with the mission of the Foundation to fund early-stage, cutting-edge applied biomedical research that has the potential to benefit children of the United States. Proposals must address either a specific unmet clinical need or a strategic problem in biomedical research. Translational biomedical research targets unmet medical need by exploiting insight, discovery, or innovation derived from applied research and clinical observations; providing a guide for diagnosis, intervention, or prevention, including clinical trials. Translational research success often has the potential to impact directly healthcare outcomes. By contrast, strategic research addresses an unmet need in medicine or technology by targeting an enabling approach, which if successful will lead to essential advances and benefits that make it possible for others to broaden the systematic examination of an uncharted area of applied science or

facilitate focused development of innovation. Strategic research success has the potential to reshape a complex technical problem that may also accelerate clinical and translational research.

The Foundation will not fund basic research motivated by curiosity and a desire to extend fundamental knowledge, with long-delayed or unpredictable benefits, including research in public health, epidemiology, social science, psychology, ecology, environmental impacts, botany, or anthropology. The Foundation will not consider research in areas of medicine generally associated with adult health unless there is a particularly compelling benefit to children of the United States.

Based upon the compelling nature of the proposed research the Foundation invites a limited number of Nominees for a closed personal interview. In large measure, the selection process takes into account the extent to which funding will make a difference: the likelihood that research success will benefit children of the United States and the extent to which funding will have a positive effect on in the trajectory of the Nominee's professional career. In addition, the selection process also considers evidence that the Nominee has appropriate expertise and research facilities to conduct the proposed research, as well as the extent and nature of collaboration by the Nominee and how it will facilitate success.

The Hartwell Foundation Individual Biomedical Research Award is not a training grant, a means for incremental extension of existing research, a solution to bridge funding, or a means to provide expansion to well-funded laboratories.

Research Proposal: The Hartwell Foundation seeks to fund early-stage research that is strategic or translational in nature. We seek innovative ideas that are emboldened by discovery or distinguished by creative insight that may inspire a distinctive shift in perspective, or provide a strategic benefit to other researchers. We seek to fund new applications of existing technology, new technologic approaches to existing problems and where deficient, technology development. In all cases, we seek risk-taking innovation that addresses an unmet need and has the potential for clinical translation if successful, accepting uncertainty and deploying technology, not studying it. Proposals that already receive, or will be receiving, significant extramural funding (e.g., NIH, NSF, DOD, commercial entities, other foundations) are ineligible. *Preliminary data are not required.*

Proposals are structured as follows:

- **Glossary of Terms:** no page limitations
- **Nontechnical Description of Research:** 5 pages max
- **Technical Description of Research:** 10 pages max
- **Budget:** no page limitations
- **Status of Current and Future Funding:** no page limitations
- **Status of Existing Intellectual Property:** no page limitations
- **Research Outcomes and Vision of Project Success:** no page limitations
- **Collaborations:** no page limitations
- **References:** no page limitations
- **Appendix:** no page limitations

Personal Interview: Based upon the compelling nature of the proposed research, the Foundation will invite a limited number of Nominees for a closed personal interview. Nominees for the Individual Biomedical Research Award who do not complete the Interview will not receive further consideration in the competition. All decisions by the Foundation are final.

TIMELINE

April 15, 2018: invitation extended to institutions selected to submit nominations for a Hartwell Individual Biomedical Research Award.

April 15 – September 14, 2018: participating institutions hold their internal competition to select Nominees.

September 15, 2018: nominations for the Individual Biomedical Research Award are due at the Foundation office in Memphis, TN.

October 6, 2018: the Foundation will extend invitations to Nominees selected for interview.

October 30 – November 15, 2018: the Foundation will interview Nominees in Charlotte, NC.

April 1, 2019: the Foundation will announce Hartwell Individual Biomedical Research Awards, with funding complete in April.

REQUIRED SUBMISSION DOCUMENTS

The Foundation provides an *Official Nomination* form that the institution must complete for each candidate. The Nominee and the chief executive of the institution must both sign the nomination, acknowledging that they each read the Application Process and Administrative Guidelines provided by The Hartwell Foundation for the current competition and agree to such terms and conditions as set forth in the documents.

Participating institutions must send all required nomination documents on a portable USB drive to the central office of The Hartwell Foundation, 6000 Poplar Ave, Suite 250, Memphis, TN 38119. The USB drive should contain a single file with the Cover Letter from the Chief Executive, as well as one directory identified as < last name >, specific for each Nominee.

The Cover Letter from the chief executive (scan to PDF) should describe:

- The names and academic titles of each Nominee
- The internal selection process used by the institution in selecting Nominees
- The number of internal applicants considered in the nomination process
- What guidance, if any, was offered to applicants to prepare their proposal
- What guidance, if any, was offered to applicants to prepare for the interview process
- How the institution intends to offer recognition to both individual researchers and The Hartwell Foundation following announcement of an award
- The Individual responsible for official contact by the Foundation, including phone and email

Each directory for every Nominee must include four (4) files:

1. Official Nomination Form, complete with signatures (scan to PDF)
2. Nominee Research Proposal (*print to PDF – do not scan*)
3. Nominee Current Curriculum Vitae (*print to PDF – do not scan*)
4. *Recent* color photo head shot of the Nominee in *jpeg* format (from the shoulder up — *smiling*)

The Foundation will notify each institution by email upon receipt of their USB drive (documentation). Incomplete documentation, inclusion of unrequested materials or failure to provide an appropriate head shot photo may result in returning the submission to the institution, jeopardizing the status of the Nominee for further consideration.

NOMINEE RESEARCH PROPOSAL

*** FAILURE TO FOLLOW PROPOSAL GUIDELINES MAY RESULT IN NOMINEE DISQUALIFICATION. ***

FORMAT REQUIREMENTS

Text: 1-inch margins, single-column text, single line spacing and black 12-point Times Roman font. Do not indent paragraphs; separate paragraphs from each other by 6-point spacing. Use bold font only for section headings. Start each major Section (I-XI) on a new page. Avoid italics. Do not underline text.

Header: starting with page 1, well-spaced above the text at the top right of each page, using regular, 8-point Times Roman font, place the applicant name and highest academic degree(s) on one line.

Footer: number each page, except the Title page, at the bottom center using regular 8-point Times Roman font — use lowercase Roman numerals to paginate the Contents and Glossary of Terms, prefatory to the body of the proposal; and Arabic numerals, as p. # of n, to paginate the body of the proposal (the Nontechnical Summary must begin on page 1). Paginate only the Appendix cover page and not contents.

Proposal Title: The choice of Title should ideally identify the proposed innovation; be terse but engaging, stimulate interest and not be overly dramatic. Avoid abbreviations, acronyms, technical terms or jargon terms in the Title that are unlikely to be familiar to a lay reader.

The Title must not include any pronouns and must not begin with an adjective — such as *The*, *A*, or *An*. The Title must not include the use of *study*, *investigation*, *analysis*, or *examination*, *discovery*, or similar terms. All proposals must address potential benefits to children and therefore, the Title must not include any reference to *children*, *childhood*, *pediatric*, or similarly related terms. The Title must also not include any parentheses, or exclamation or question marks and except for a summary colon, must be free of punctuation.

Use <Title Case> format, capitalizing the first word of the title, the last word of the title, and all nouns, verbs, adverbs, and adjectives. Prepositions are only capitalized if they are used adjectivally or adverbially.

References: do not include any citations in the Lay Summary (Section I.A). Citations may however, be used to support other areas of the Nontechnical Description of Research, but *only* with the publication name and date of publication in parenthesis (e.g., US Patent, 2012; PNAS, 2014). In the Technical Description of Research (Section II), cite references using a parenthetical numerical format (i.e., (1), (2), (3) ...) in 12-point font, not as superscript. Number each citation in the Technical section numerically in sequence of appearance and as captured in References (Section X).

In-Text Abbreviations, Definitions, and Comments: within the text of the proposal the first use of any jargon should be followed by expanded identification in parenthesis and as appropriate, a detailed explanation included in the Glossary of Terms.

Uncommon abbreviations or unusual acronyms should be defined parenthetically in the text of the proposal and need not be included in the Glossary of terms unless they are essential to understanding the proposed innovation. Terms that the reader is certain to be familiar with do not require an explanation (e.g., FDA, NIH, 3-D, etc.) and must not appear in the Glossary.

Comments, explanations, or additional information relating to specific text passages may be cited as footnotes, using a numerical format in superscript font (i.e., ⁽¹⁾, ⁽²⁾, ⁽³⁾, (etc.)). Place sequentially numbered-by-appearance notations at the bottom of the same page where the citation occurs.

ORGANIZATION AND CONTENT REQUIREMENTS

**** Address explicitly all responses from *first-person point of view* – avoid the vague “we” or “our” ****

Title Page: do not number this page. Center the text and use <Title Case> format. Spaced about 3 inches below the Title provide the name of Nominee and earned academic degrees, job title(s); on separate lines provide the primary or principal department affiliation, any secondary departmental affiliation(s), name of participating institution, shipping address, contact phone numbers (office and mobile), email address and well-spaced below, the submission date. Do not include descriptors on the Title page (e.g., Title: ____, Name: ____, Degrees: ____, etc.). Center all information on the Title page for ease of reading. Do not paginate the Title page.

Table of Contents: begin on page number i — include in the Table the Glossary, major Sections I-XI and relevant sub-sections (i.e., A, B, C, etc.)

Glossary of Terms: enable the reviewer to quickly find and understand unfamiliar terms that are essential to understanding the proposed research or the innovation without creating significant interruption while reading the proposal.

- Arrange terms alphabetically and in bold font; no page limit
- Include explanations of unusual terms, technical terms, obscure or unusual abbreviations, acronyms, or jargon; and do not offer explanations with undefined terms.
- Avoid simple dictionary definitions or providing only the words that indicate what each letter in an acronym refers.
- Avoid including obvious terms that a reviewer is certain to be familiar with (e.g., FDA, NIH, etc.), which will only clutter and distract from the intended purpose.
- Provide useful explanations that will *communicate effectively* with the reviewer.
- Include useful figures, charts or photos, but only if they have explanations and are important in explaining terms; avoid the gratuitous inclusion of terms that may distract from the intended purpose of the Glossary.

I. Nontechnical Description of Research (must begin on page 1): 5-page limit

- A) **Lay Summary** – provide in a *single paragraph* a description of the proposed research (450 words or less) suitable for a nontechnical audience; do not demarcate sentences with descriptors; avoid jargon or acronyms, unless the lay reader is certain to be familiar with them; no citations are allowed; do not include the descriptors:
- **Statement of Problem** – description and magnitude of the problem in the United States; emphasize what makes it an important issue (e.g., prevalence, incidence, morbidity and mortality rates).
 - **Compelling Interest to the Foundation** – identify the unmet need and how addressing it successfully will provide a benefit for children of the United States.
 - **Innovation** – identify the novel idea(s), discovery, or creative insight that may inspire a distinctive shift in perspective, provide a strategic advantage or offer a translational benefit; identify relevant model test systems, important experiments and the technologic approach that will be used to construct or test hypotheses.
 - **Justification for Funding** – describe what will happen if the proposed research is successful (e.g. diagnosis, therapeutic intervention, prevention, clinical trials, etc.) and how successful outcomes will be deployed either translationally or strategically to benefit children.

B) Early-Stage, Innovative and Cutting-Edge Research – avoid the use of any obscure technical terms, acronyms, abbreviations, or nuanced jargon that are unlikely to be understood by a lay reader; explain explicitly in three separate paragraphs how the research is:

- **Early-Stage** – the first sentence should begin “My research is early-stage because...”

Describe the early-stage nature of the proposed research, but not from the perspective that it is a new area of interest for the Nominee. Justify how the research may be pioneering and is not simply an incremental advancement or extension of existing research by the Nominee or others; discuss the origin and timing of any discovery or first recognition of the innovation (e.g., the date of first disclosure of intellectual property) or the date of acquisition of any preliminary data.

Note: Preliminary data is not a prerequisite for funding consideration, but may provide an indication of the early-stage nature of the research.

- **Innovative** – the first sentence should begin “My research is innovative because...”

Contrast the proposed research with the state-of-the-art and how identifiable innovation(s) will overcome limitations compared to known competing approaches; describe how if the research is successful the outcome(s) may generate a dynamic tactical advantage or create paradigm-shifting strategic value. Explain how the research will be transformative: addresses an unmet need, provides an unrecognized benefit, overcomes the lack of strategic knowledge or technology, leads to a new perspective, overcomes accepted consensus, provides a valuable intervention, etc.

- **Cutting-Edge** – the first sentence should begin “My research is cutting-edge because...”

Describe how the proposed research will utilize state-of-the-art technology and/or a ground-breaking approach that will promote success of the proposed research.

C) Impediments to Success – describe:

- **Technical Risk** – identify any real or potential hazards, methodologic limitations, or unpredictability in generating expected outcomes.
- **Conceptual Risk** – discuss limitations in the working hypothesis, model test system or technology platform, etc.; contrast the magnitude of structural uncertainty with likelihood.
- **Potential Adverse Consequences** – discuss any likelihood of unintended consequences that might exceed the contemplated benefit of a successful outcome, including the translation of research outcomes to benefit children.

D) Compelling Benefits to Children in the United States – how the proposed research, if successful, will potentially benefit children of the U.S. either strategically or in translation to the bedside.

E) Laboratory and Productivity Technologies – describe:

- **Current Staffing:** identify the total number of existing lab technicians, post docs and students in the Nominee lab, irrespective of the proposed research.
- **Office and Lab Space (sq. ft):** space that will be available to administrate and conduct the research, and to what extent such facilities are under Nominee control.
- **Technologies and Core Facilities:** describe the benefit of technologies that will be deployed to maximize productivity, including those to be realized from any specialized core facilities or competencies provided by the institution, or as the result of collaboration; identify the location of technologies and core facilities.

- F) Key Collaborations** – identify all collaborators by name and highest earned academic degree(s), job title and institution or geographic location, as appropriate; succinctly describe their expected contribution: *at least one collaborator must be a practicing physician, preferably in pediatric medicine:*
- **Collaborators Essential to the Success of the Proposed Research** – may be the sole source of materials, resources or technology necessary for the proposed research; may be reimbursed for services, but generally do not take salary.
 - **Collaborators or Mentors Who Provide Guidance in Achieving Success** – receive no financial support.
- G) How Funding the Research Will Make a Difference** – describe how pursuing the proposed research could potentially benefit children of the U.S.; explain how as an independent researcher you will benefit from the proposal being funded; and explain whether or not the proposed research will be pursued if it is not funded by the Foundation.
- H) Anticipated Pathway for Translation** – describe the translation pathway leading from any strategic impacts that will exceed academic peer-reviewed publications and result directly in biomedical applications (e.g., development of enabling technology, published knowledgebase, product development, clinical trial strategy, clinical intervention, etc.) and that will ultimately benefit children of the U.S.
- I) Professional Goals** – maintaining a first-person point of view, explain your enthusiasm for the proposed research and how funding from < The Hartwell Foundation > will advance your long-term professional goals beyond peer-reviewed publications (e.g., academic promotion, future funding, recognition for your discoveries, etc.); elaborate on your passion to benefit children, include any personal experience or storyline that reveals sincerity.

II. Technical Description of Research: 10-page limit

- A) Introduction** – concise, technical overview of the proposed research; identify the unmet need that is addressed by the proposed innovation; indicate in the text one or more reference citations that provide a current general review of the state-of-the-art, identifying each citation within the text as (#, Review Article).
- B) Context** – contrast the proposed innovation with the state-of-the-art — provide reference citations that support your view:
- **Current Academic and Industry Efforts** – contrast the proposed research with any current academic and/or industry efforts in the same or similar area.
 - **Competitive Analysis** – describe presumed advantages of the proposed approach and/or technology compared to limitations of existing approaches/technologies.
 - **Supporting Evidence** – recognizing that preliminary data is not a prerequisite for funding consideration, describe any available observations or indications by you or others that support your proposed research.
- C) Aims** – in bold font, provide for each Aim:
- **Rationale** – describe in technical detail the hypotheses and assumptions; explain the reasoning for pursuing the proposed direction.
 - **Approach** – identify the priorities, objectives, technologies and desired outcomes; acknowledge potential technical issues; describe the risk vs. gain of the selected approach and why the approach is compelling and likely to succeed.

- D) Research Strategy** – for each Aim (restated word for word, exactly as in (C), above):
- **Research Design** – connection between the Aims, methodology and outcomes should be evident; integrate personnel and technology requirements sufficient to produce success within available budget and the funding period.
 - **Statistical Approach** – discuss value uncertainty and statistical methodology: if optimization is proposed for a process governed by multiple factors, the systematic method that will be used to determine the relationship between cause-and-effect relationships must be described.
- E) Backup Strategy** – offer a strategy for any technical or feasibility limitation that might potentially be encountered in the research, including possible contingencies related to personnel requirements, essential collaborations or any impediments to success.
- F) Timeline**
- **Milestones** – identify the detailed objectives required for achieving each Aim, including any potential barriers to success and any interdependence between Aims
 - **Horizontal Bar Graph** – in a single chart depict the timeline for step-wise accomplishment of each Aim, by milestone achievement (objective).

III. Budget : no page limit

- A) Budget Table (Excel template available)** – arrange the proposed use of funds for each year as depicted in the accompanying *example*; other budget formats are unacceptable. Columns in the table should consist of category line item description, expenses and % Effort. Total each column; expenses must be equal to \$100,000 for each year. Depending upon the nature of the proposed research, some expense categories may be different than offered in the example Budget Table; make adjustments based on required needs.

| Budget Expense Category | Year 1 | % Effort | Year 2 | % Effort | Year 3 | % Effort |
|---|------------|----------|------------|----------|------------|----------|
| Personnel | | | | | | |
| Nominee name, MD, Ph.D., PI | \$ - | 20% | \$ - | 20% | \$ - | 20% |
| example name, Ph.D., Post Doc | \$ 38,000 | 100% | \$ 38,000 | 100% | \$ 38,000 | 100% |
| example name, B.S., Res Asst II | \$ 20,337 | 50% | \$ 20,845 | 50% | \$ 21,367 | 50% |
| example name, M.S., Predoctoral Student | \$ - | 0% | \$ - | 100% | \$ - | 50% |
| example name, MD, Ph.D., Collaborator | \$ - | 2% | \$ - | 10% | \$ - | 2% |
| Supplies | \$ 5,227 | | \$ 5,355 | | \$ 5,433 | |
| Animals, cages, etc. | \$ 2,000 | | \$ 3,600 | | \$ 3,600 | |
| Core facilities | \$ 5,000 | | \$ 30,000 | | \$ 30,000 | |
| Equipment | | | | | | |
| example Microscope | \$ 29,436 | | \$ - | | \$ - | |
| Travel | \$ - | | \$ 1,200 | | \$ 600 | |
| Publication Costs | \$ - | | \$ 1,000 | | \$ 1,000 | |
| Total | \$ 100,000 | 172% | \$ 100,000 | 280% | \$ 100,000 | 222% |

Personnel – identify in the Budget table, even if not taking salary, the name of the Nominee (PI), all Key Laboratory Support Personnel and Collaborators Integral to Success: provide name; highest graduate academic degree(s); and job title, as appropriate (for unnamed personnel at the time of submission it is acceptable to provide job title only).

- **Salary** – personnel expenses in the Budget table must include all fringes, keeping in mind the Foundation will only agree to pay for non-discretionary government required tax deductions, social security, workman’s comp, disability insurance, and relevant medical insurance.
- **Category Line Items** – acceptable line items in the Budget table may include, but are

not necessarily limited to supplies; animals, cages and related expenses; core facilities; equipment; travel; and publication costs (show only required items).

B) Justification of Expenses – explain why funding of each line item in the Budget table is essential to achieve the Aims (unjustified items will not be funded).

- **Nominee (PI)** – provide name and earned graduate academic degree(s); and the *actual* contemplated percentage effort to manage the proposed research; describe explicitly in first person singular tense the expected benefits derived from the contribution of the Nominee in the proposed research.

It is the preference of the Foundation not to fund any salary of the Nominee. However, if salary is contemplated by the PI, justify why it is necessary to do so and why no other options are available (percentage effort is not a justification): begin “Salary must be taken because...” In addition, describe explicitly any fringe benefits.

- **Key Laboratory Support Personnel** – whether funds are requested or not, provide name, earned graduate academic degrees and job title of all lab personnel in the research; include the expected benefits from their contribution, their percentage effort to the research and where applicable, justify the necessity of funding salary (percentage effort may not be used as a justification); describe explicitly any fringe benefits.
- **Collaborators Integral to Research Success** – whether funds are requested or not, provide name, earned graduate academic degrees and job title of all relevant collaborators listed in the Budget table; include the expected benefits from their contribution and their percentage effort to the research; if applicable, justify the necessity of funding salary (percentage effort may not be used as a justification); describe explicitly any fringe benefits.
- **Specific Line Items** – offer a succinct explanation of how each budgeted item, including equipment, core research facilities, etc. would make a difference in facilitating the proposed research and why no other options are available; an explanation of how funds will be used is not a justification.
- **Travel** – describe contemplated travel and justify the necessity, explaining why other sources of funding are unavailable. Do not budget for travel to the Hartwell Annual Meeting of Biomedical Research, as expenses are paid by Foundation.
- **Publication Costs** – describe contemplated publications and explain why other sources of funding will be unavailable to cover costs.

C) Student Expense – the Individual Biomedical Research Award is not an educational training grant and Hartwell funds cannot be used to support student tuition.

Identify each student by name and earned academic degrees, regardless if they will take financial support; if degree is pending, provide the extent to which each student has completed class work and the years remaining until graduation; describe the estimated percentage effort of each student in the proposed research; describe the source of any other student financial support; and explain any fringe benefit expense.

Provide the expected benefit derived from student participation in the research and explain why the project cannot succeed without their participation.

Note: If citing institutional requirements that dictate the amount for student expenses, then provide verbatim the institution policy statement, not rate tables, in the Appendix (Section XI).

D) Sufficient Funding – state explicitly whether funding provided by The Hartwell Foundation will be sufficient to achieve the proposed Aims. Use this response to identify any assumptions you are making regarding extent and benefit of collaboration, access to institutional core or service facilities, costs that you are assuming will be covered from other sources, or other relevant considerations.

- IV. Existing Sources of Research Funding Available to the Nominee** (no page limit): identify all sources
- A) Funding Source** (including start-up funds)
 - B) Funded Project Title** (include any identification number, as appropriate)
 - **Funding Initiation and Expiration Dates**
 - **Identify the PI**
 - **Role of Nominee If Not the PI**
 - **Nominee Committed Percentage Effort**
 - **Total Amount of Funds Available to Nominee** – direct cost
 - **Technical Aims** – discuss any overlap with the Hartwell proposal
 - **Link to Website of Funding Agency** – to enable confirmation of existing research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>
- V. Future Sources of Research Funding Involving the Nominee** (no page limit): all grant requests submitted and waiting evaluation, including those where Nominee is not the PI:
- A) Funding Source**
 - B) Project Title** (include any identification number, as appropriate)
 - **Funding Agency Review Status**
 - **Expected Funding Initiation and Expiration Dates**
 - **Identify the PI**
 - **Role of Nominee If Not the PI**
 - **Nominee Committed Percentage Effort**
 - **Total Amount of Funds That Will Be Available to Nominee** – direct cost
 - **Technical Aims** – discuss any overlap with the Hartwell proposal
 - **Link to Website of Funding Agency** – to confirm pending research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>
- VI. Intellectual Property:** no page limit
- A) Status:** describe in non-confidential terms any existing or contemplated intellectual property disclosures related to the proposed research.
 - B) Patent(s) Received or Application(s) Filed:** offer a non-confidential description, including reference number(s); do not include the actual patents.
Provide a direct link to the U.S. PTO or WTO website specific to patent or patent pending applications, not simply a link to the main webpage.
- VII. Research Outcomes and Vision of Project Success:** no page limit
- A) Definition of Project Success:**
 - **Define Succinctly What Will Constitute Project Success**
 - **Explain How Outcomes Will Benefit Children in the U.S.**
 - B) Sharing Research Results:** describe your approach to share research results with others (specific meetings, publications, or other forms of disclosure).

- C) Translation of Results:** describe contemplated approach and timing for translation of research success to biomedical applications (e.g., published knowledgebase, product development, clinical trial strategy, and/or clinical intervention) that will benefit children in the U.S.
- D) Technology Transfer:** outline a general plan for technology transfer to enable licensure and/or commercialization of intellectual property.
- VIII. Collaborators Contact Information** (do not submit CVs): no page limit
- Name and Academic Degrees
 - Job Title, Departmental Affiliation, Institution and Geographic Location
 - Contact Phone Number(s) and Email Address
- IX. Follow-on Funding** (no page limit) – describe the contemplated approach that will be taken to attract additional funding during and / or at the conclusion of the Hartwell award.
- X. References** (no page limit): if no citations are made to either the Nominee or any Support Personnel or any Collaborator(s), an explanation is required at the beginning of this section, prior to the first listed reference.
- **Order References Numerically** – must follow sequence of appearance in the Technical Section.
 - **Content** – authors, title, publication name, volume, page number, and year are required.
 - **Highlight Key Authors** – Nominee, Support Personnel and any Collaborator(s) must be highlighted in bold font.
 - **Multiple Authors** – for publications with more than two authors it is acceptable to use *et al.*, but only if the Nominee, Key Laboratory Support Personnel and any Collaborator(s) have been properly highlighted in the listing prior to the use of *et al.*
- XI. Appendix:** as the last numbered page in the proposal, the Appendix cover page must provide a list of contents
- A) Chair of Nominee Primary Department:** name, academic degree(s), contact phone number and email address.
- B) Collaborator Identified as a Practicing Physician:** name, academic degree(s), contact phone number and email address.
- C) Letters of Support** (no page limit) must be dated, signed, and on institutional letterhead.
- **Chair of Primary Department** (required)
 - **Collaborator Identified as a Practicing Physician** (required)
 - **Other Supporting Letters of Collaboration:** if the proposed research represents a continuation of postdoctoral research, it may be beneficial to include a letter of support from the mentor.
- D) Other Documentation** (no page limit): include only material that has been cited in the proposal, including institutional policies, etc.
Do not include any CVs, publications, patents, or any photos.

NOMINEE PERSONAL INTERVIEW

The Hartwell Foundation will invite a limited number of Nominees for a closed personal interview that includes a presentation that summarizes their proposed research. Interviews will be at a designated venue in Charlotte, NC. The Foundation will conduct interviews from 9 AM – 6 PM each week during the first three weeks in November. The Nominee arranges travel and the Foundation arranges lodging; travel expenses, including food and lodging are paid by the Foundation.

The interview will last approximately one hour and will consist of a personal discussion, followed by a concise slide presentation that summarizes the details of the research proposal. Nominees selected for an interview are required to be available on their assigned date and time for three hours. The date and time of scheduled interviews is not negotiable. Nominees who do not complete an Interview will not receive further consideration in the competition.

The slide presentation should summarize the relevant technical details of the research proposal; may not exceed 15 slides and should ideally, not last more than 30 minutes. Nominees must number each slide legibly in the footer at the bottom right, as # of 15. Video with or without audio is acceptable as a means to enhance clarity within the presentation, but may not substitute entirely for slides. It is unnecessary to disclose confidential information.

The presentation should be delivered from a first-person point of view and avoid the vague use of “we” or “our”. It is expected that the presentation will in principle, follow the Lay Summary outline offered in the Nontechnical Description of Research, while avoiding excessive use of jargon and acronyms.

The presentation should begin with the statement of the problem, placing the proposed research in context of an unmet need, while emphasizing its compelling interest to the Foundation. The proposed innovation(s) must be identified and described clearly, including relevant experiments and technology that will be used to construct or test hypotheses. Effort should be made to contrast the proposed research with the state-of-the-art, describing any advantages or limitations compared to known approaches. The research aims must be presented with their rationale, including technical strategy, expected outcomes, and a contemplated timeline for their completion. The presentation should conclude with what will constitute project success and the anticipated strategic or translational benefit to children of the United States.

At the completion of the interview, Nominees agree to provide their presentation to the Foundation on a USB portable drive.

Failure to follow all presentation guidelines may result in termination of the interview and disqualification of the Nominee.

All decisions by the Foundation are final.

ADMINISTRATIVE GUIDELINES

The Hartwell Foundation expects that research institutions selected to participate in the Hartwell Individual Biomedical Research Award competition will adhere to the following guidelines:

ACCOUNTABILITY

The Foundation requires accountability from the participating institution regarding both the nomination process and the use of award funds provided to individual investigators. All qualified investigators at selected institutions should have the opportunity to apply for a Hartwell Individual Biomedical Research Award. Individuals who receive a Hartwell Individual Biomedical Research Award must demonstrate that they utilize award funds efficiently and responsibly. Participating research institutions are responsible for maintaining adequate records and receipts of expenditures that demonstrate they properly administer Award funds.

ANNUAL MEETING BIOMEDICAL RESEARCH

All recipients of a Hartwell Individual Biomedical Research Award agree to attend an annual meeting each year in lieu of a formal second Quarterly Review, where Investigators will make a presentation summarizing research progress toward goals and objectives:

2018: September 23-26, Baltimore, MD in conjunction with The Johns Hopkins University

2019: September 22-25: Dallas, TX in conjunction with UT Southwestern Medical Center

2020: October 04-07: Location to be determined

Attendance at the Annual Meeting is mandatory for all Hartwell funded Investigators. The meeting begins at 6 PM Sunday evening and ends approximately 2:00 PM on Wednesday. Attendees must be present and actively participate in all sessions, including Foundation-sponsored social functions. The Hartwell Investigator arranges travel and the Foundation arranges lodging, with expenses paid by the Foundation.

BUDGET

The investigator develops a Budget on a yearly basis, which the Foundation reviews semi-annually with the Investigator. Within Foundation guidelines, the recipient of a Hartwell Individual Biomedical Research Award determines the best use of the funds to support the direct cost of the project, including but not limited to salaries, supplies, equipment, personnel, animal experimentation, human clinical trials, collaboration, publication costs, or travel related to the conduct of research. The Hartwell Individual Biomedical Research Award is not an educational training grant and therefore funds may not support student tuition. Yearly expenditures should be consistent with the budget submitted in the funded award proposal.

CARRYOVERS AND EXTENSIONS

Requests for carryovers or extensions are unnecessary. Unexpended funds from any award year may carry forward to the next year without permission of the Foundation. The following guidelines are applicable:

Individual Biomedical Research Award – In the event of unexpended funds, the Investigator must communicate an explanation for the carryover in the Annual Report. If at the end of the three-year grant cycle

the carryover funds are excessive, the Investigator must continue to budget such funds to support research on their Hartwell project and participate in additional quarterly reviews until remaining funds are nominal, when a final report will be required.

Hartwell Fellowship – If at the end of two years from commencement of postdoctoral training there are unconsumed funds, the Fellow and Mentor may carryover such funds to extend their research, as desirable. Otherwise, any funds remaining after two years may, without permission from the Foundation, continue to support research in the lab of the Fellow’s mentor, preferably to support another postdoctoral researcher.

In the event a Fellow resigns for any reason before completing two years of training, the Institution may not return unconsumed funds to the Foundation. If granted permission from the Foundation, such residual funds may support research in the lab of the Fellow’s mentor, preferably to support another postdoctoral researcher. However, if at least one year of Hartwell Fellowship funding remains, the sponsoring institution must designate a replacement within Hartwell guidelines with no adjustment to the funding provided by the Foundation.

COLLABORATION

All Nominees for the Hartwell Individual Biomedical Research Award must demonstrate they are collaborative. Each Nominee must identify at least one participating collaborator that is a practicing physician, preferably in pediatric medicine.

CONTINUATION OF FUNDING

The Hartwell Foundation expects each recipient of a Hartwell Individual Biomedical Research Award to demonstrate progress toward milestones described in the proposal. Evaluation of progress will occur in quarterly reviews and the annual report. The Foundation reserves the right to delay or withdraw future funding if the Hartwell Investigator does not demonstrate progress or refrains from participating in required Foundation activities. Delay or withdrawal of funding will not occur without advance notice to the investigator and the participating institution.

CRITIQUE OF NOMINEE DOCUMENTATION

The Hartwell Foundation is not obligated to provide written or verbal feedback regarding any documentation submitted by a Nominee for a Hartwell Individual Biomedical Research Award.

ELIGIBILITY PARTICIPATING INSTITUTION

The selection process for participation in the Hartwell competition is not open to application; institutions are chosen at the discretion of the Foundation. Hartwell announces eligible participating institutions in mid-April each year.

ETHICS

The Hartwell Foundation expects all awardees to adhere to the highest standards of research ethics. Concerns regarding violations in ethical conduct of research may lead to notification of institutional officers and possible revocation of funding by the Foundation.

FINANCE REPORTS

It is the intent of The Hartwell Foundation that the Individual Biomedical Research Award shall be only for the direct support of research described by the Nominee in the application proposal. The Hartwell Foundation will not provide additional funds to cover over-expenditures in any budget year. The participating institution and the recipient of a Hartwell Individual Biomedical Research Award agree to submit official annual financial reports to the Foundation as part of the Annual Progress

Report. Such reports must detail expenditures by category and compare expenses to plan; official reports are due April 30 each year.

FINANCIAL BENEFIT

The Hartwell Foundation provides financial support for biomedical research that will benefit children of the United States. It is not the intent of the Foundation to enrich itself by the funding of such research. However, if the participating institution receives financial benefit as a result of a Hartwell Individual Biomedical Research Award, the Foundation expects to receive 5% of the share due the institution as a contribution in further support of the Foundation's mission. The Foundation waives any ownership rights to any intellectual property.

FRINGE BENEFITS

Fringe benefits are additional compensation provided to an employee that does not affect basic wage rates. Funding from The Hartwell Foundation may be used to cover only medical insurance and non-discretionary benefits mandated by the supporting institution. Examples of discretionary non-wage compensation benefits that the Foundation will not cover include life insurance, retirement plans, childcare, tuition, parking, etc.

FUNDABLE PROJECTS

Participating institutions agree to utilize an open and effective process to call for proposals from areas of natural and applied science related to children's health, including biomedical engineering. Proposals must be consistent with the values of The Hartwell Foundation and potential benefits to children of the United States. The Foundation will not consider research in public health, epidemiology, social science, psychology, ecology, environmental impacts, anthropology, or botany. The Foundation will not consider research in areas of medicine generally associated with adult health unless there is a particularly compelling benefit to children of the United States.

FUNDING OF AWARDS

The Hartwell Foundation will fund all awards by paper check, which deposit must occur within 45 days. The participating institution agrees that they will make best effort to enable immediate access to funds by each award recipient. Requests submitted to the Foundation for a replacement check require an explanation submitted on letterhead and signed by the CEO, or Provost.

HARTWELL FELLOWSHIP

For each Nominee selected for the Individual Biomedical Research Award, the sponsoring participating institution will receive a Hartwell Fellowship to fund one postdoctoral candidate selected from areas of biomedical science who exemplifies the values of the Foundation. Each Fellowship will provide support for two years at \$50,000 direct cost per year and will be funded yearly in July.

Institution Selection of Fellows – Participating Institutions may determine their own internal selection process for the Fellowship but in any case, must follow Fellowship Requirements (see below). The Fellowship may only be used to support scientists and biomedical engineers who have completed a Ph.D. or equivalent doctorate and are still in the early stages of career development. Fellowship funds may not be used to extend or complete clinical training. Institutions should select recipients that are the most likely to benefit from the financial support.

Official Designation of Fellowship – The Foundation will provide the sponsoring participating institution an official Designated Recipient form that requires the signature of both the Hartwell Fellow and the chief

executive of the institution, acknowledging that they have each read the Application Process and Administrative Guidelines promulgated by The Hartwell Foundation for the current competition and agree to such terms and conditions as set forth in the documents.

Fellowship Activation – To activate the Hartwell Fellowship, participating institutions are required to complete and submit to the Foundation by June 30 in the same year of the Official Announcement of the award the following supporting documentation on a USB portable drive. The drive will have one directory named for each designated Fellow and each directory will include five (5) files:

1. Completed Official Hartwell Fellowship Designated Recipient form
2. Completed Fellowship Contact and Background Information form (provided by the Hartwell Foundation) that includes a summary of intended research training
3. Recent Color Photo of Fellow and Primary Mentor together, in a laboratory/technology setting suitable for announcement of the Award on The Hartwell Foundation web site (thehartwellfoundation.org)
4. Fellow Current Curriculum Vitae (print to PDF – do not scan)
5. Cover Letter from the chief executive (may be scanned PDF) that describes clearly the identity of each recipient of a Hartwell Fellowship, including:
 - Primary Departmental affiliation of the Fellow
 - Identity of Fellow’s Primary Mentor, including departmental affiliation
 - Statement with regard to the Fellow meeting The Hartwell Foundation requirement for U.S. citizenship

Fellowship Start-End Dates – The Fellow and Mentor mutually determine an acceptable “start” and “end” date for postdoctoral research training within the Fellowship Rules. Fellowship funds will be made available to the institution each year, in July.

Fellowship Requirements:

- Hartwell Fellows must hold a Ph.D. or equivalent doctorate and be citizens of the United States.
- The Fellowship mentor may not be a Hartwell Investigator currently funded by the Foundation.
- Fellows must commence their postdoctoral training no later than November 1 in the same year of the Official Announcement of the award, or risk that the Foundation may rescind the Fellowship to the Institution.
- Fellowship funds are intended to cover salary, health insurance, and travel related to a scientific meeting; and may not be used for the purchase of supplies or equipment or other fringe benefits without permission from the Foundation.
- No part of the Fellowship may cover institutional overhead or other indirect costs, nor should the recipient or the sponsoring research laboratory be obligated or penalized to pay by substitution such indirect costs by any other means.
- The active period of the Fellowship is two years from commencement of employment, unless there is an allowable extension by virtue of carryover funds.
- At the conclusion of the Fellowship, the Hartwell Fellow should submit on their departmental stationery a letter that summarizes the impact that the Fellowship had on their career goals.
- In the event a Fellow resigns for any reason before completing two years of training, the Institution may not return unconsumed funds to the Foundation. If granted permission from the Foundation, such residual funds may support research in the lab of the Fellow’s mentor, preferably to support another postdoctoral researcher. However, if at least one year of Hartwell Fellowship funding remains, the sponsoring institution must designate a replacement within Hartwell guidelines with no adjustment to the funding provided by the Foundation.

HARTWELL TOP TEN INSTITUTION

Every year The Hartwell Foundation announces its Top Ten Centers of Biomedical Research in the United States, inviting each center to nominate individuals for a Hartwell Individual Biomedical Research Award. Selected institutions may submit up to three nominations to compete in a process that seeks to fund early-stage, innovative, and cutting-edge biomedical research. Each year Hartwell Top Ten Centers of Biomedical Research must submit at least one Nominee for the Individual Biomedical Research Award that holds a Doctor of Medicine degree (e.g., MD, MD-Ph.D., MD-DDS, etc.).

INDIVIDUAL BIOMEDICAL RESEARCH AWARD

Only researchers nominated by the chief executive of a Hartwell Participating Institution are eligible for consideration for an Individual Biomedical Research Award. Each Award is for three years at \$100,000 direct cost per year and funded yearly in April. The funding cycle is from April 1 to March 31. The following rules apply to the Award:

- The recipient should be a citizen of the United States or hold permanent residence, must hold a full-time appointment in the sponsoring institution, and must be eligible to serve as a principal investigator in biomedical research.
- Within Foundation guidelines, the Award recipient may determine best use of the funds to support the direct cost of the project.
- No part of the Award may cover institutional overhead or other indirect costs, nor should the recipient be obligated or penalized to pay by substitution such indirect costs by any other means.
- The Award recipient agrees to participate in Quarterly Reviews by video conference regarding updates to progress toward goals and objectives.
- The Award recipient agrees to attend and participate each year in the full agenda of the Hartwell Annual Meeting Biomedical Research.
- The Award recipient agrees to submission of a written Annual Report that summarizes the progress of the proposed research and Budget expenses.
- The Award recipient agrees to cite “The Hartwell Foundation” as a funding source for published articles regarding the funded research and to provide a PDF version of all such publications to the Foundation.
- The sponsoring Institution and the Award recipient agree they will provide a recent color photo of the Award recipient in a laboratory/technology setting that is suitable for announcement of the Award on The Hartwell Foundation web site (thehartwellfoundation.org).

INSTITUTIONAL OVERHEAD AND INDIRECT COSTS

By accepting The Hartwell Individual Biomedical Research Award or a Hartwell Fellowship, the participating institution agrees not to use any part of the funding for institutional overhead or other indirect costs and will not obligate or penalize the recipient of an award or a sponsoring research laboratory to pay by substitution such indirect costs by any other means.

Except for health insurance, no portion of an award may be subject to deductions for discretionary fringe benefits by the Sponsoring Institution.

INTELLECTUAL PROPERTY

The Hartwell Foundation waives any ownership rights in any intellectual property that occurs because of funding either the Individual Biomedical Research Award or the Hartwell Fellowship. However, recipients must notify the Foundation of any patent applications filed or received resulting from the supported research.

INTERVIEW PROCESS

As part of the evaluation process for the Individual Biomedical Research Award, the Foundation will invite selected Nominees at Hartwell expense, for a personal closed interview at a Foundation designated venue in Charlotte, NC. The Foundation will conduct interviews from 9 AM – 6 PM each week during the first three weeks in November. Nominees selected for an interview are required to be available on an assigned date for three hours. The date and time of scheduled interviews is not negotiable. Nominees who do not complete the Interview will not receive further consideration in the competition. All decisions by the Foundation are final.

The interview will last approximately one hour and will consist of a personal discussion followed by a concise slide presentation on the proposed research, not to exceed 15 slides (for detailed guidance see Application Process: Nominee Personal Interview). The presentation should not last more than 30 minutes. Nominees agree to provide their presentation on a USB drive to The Hartwell Foundation at the end of the interview.

MATERIAL CHANGE OF CIRCUMSTANCES

The Foundation recognizes the possibility that unexpected technical or feasibility limitations, including those involving collaboration, may occur in the course of research, which may necessitate the modification of original aims, timeline and corresponding budget. However, in the event of any material change of circumstances regarding the status of an individual Hartwell Investigator or a participating research institution, the Foundation at its sole discretion reserves the right and final authority to determine the disposition of any remaining funds and equipment purchased or made available with Hartwell support.

NOMINATION PROCESS

Research institutions selected by The Hartwell Foundation agree to nominate research proposals from their faculty and research staff in an open and competitive application process of their own design. Nominated research must be innovative, early-stage and cutting-edge; and must have the potential to benefit children of the United States. Nominees should not yet have qualified for significant funding from outside sources. Eligible institutions may not nominate the same individual in two consecutive annual competitions.

OFFICIAL NOMINATION FORM

At the time of Nomination for the Individual Biomedical Research Award both the Nominee and the Chief Executive from each sponsoring institution must sign The Hartwell Foundation *Official Nomination* form acknowledging they have read the current *Application Process and Administrative Guidelines* for the Individual Biomedical Research Award provided by The Hartwell Foundation and agree to such terms and conditions as set forth. **The Foundation will not accept electronic signatures.** An improperly completed Nomination form will be returned to the sponsoring institution for correction, with the risk that the Nominee may not receive further consideration in the competition. All decisions by the Foundation are final.

PRESS RELEASES AND MEDIA COMMUNICATIONS

The Hartwell Foundation expects that all recipients of Hartwell funding will properly receive timely recognition from their supporting participating institution. Prior to a press release or media publication that refers to The Hartwell Foundation, participating institutions should offer the Foundation an opportunity to review the desired text for accuracy. Following such public communications,

participating institutions should provide the Foundation with a copy of the released information and a reference to the medium where it appeared. Published disclosures should cite the Foundation web site, www.thehartwellfoundation.org, as an additional information source.

PROGRESS REPORTS

The Foundation reserves the right to withdraw funding if the recipient of an Individual Biomedical Research Award does not demonstrate progress toward identified milestones, as evidenced in Quarterly Reviews, Annual Reports, or site visits:

Quarterly Reviews – Hartwell Investigators agree to submit quarterly a concise summary of research progress toward goals and objectives (template provided) to supplement their videoconference quarterly review with the Foundation. The Quarterly Review will take place in the first month following the end of each quarter, starting in April. The report is due 1 week prior to the scheduled review. Reported progress should follow realistic milestones as suggested in the original Research Proposal, modified as necessary to account for any encountered limitations. From time-to-time, the Foundation may request the investigator to provide the review during a site visit. The Hartwell Annual Meeting supplants the third quarter review of progress.

Annual Report – By April 30 of each year, all Hartwell Investigators agree to submit an annual progress report. The Foundation will provide a template adequate for a summary of research progress toward goals and objectives that requests:

- A concise nontechnical summary of progress versus original timeline
- Steps taken to reach original project goals, including any divergence from the research plan or consideration of contemplated alternatives
- An analysis of expenditures versus the budget, noting any significant category changes, additions, deletions, carryovers, or extensions
- Manuscripts submitted for publication and/or published
- Description of any discovery or IP, including announcement of any patent(s) filed

PUBLICATIONS

The Hartwell Foundation encourages publication of research results and retains no rights. Publications resulting from Hartwell funding must cite “**The Hartwell Foundation**” as a funding source. Award recipients must notify the Foundation of all publications that result from the supported research and should when available, provide a PDF of the publication to the Foundation.

RESEARCH PROPOSAL

All Nominees for the Individual Biomedical Research Award must submit a written research proposal that addresses the Foundation mission to fund innovative, early-stage, cutting-edge applied biomedical research that has the potential to benefit children of the United States. Proposals must address an unmet need, either in children’s healthcare as translational biomedical research, or by targeting a strategic problem in biomedical research with the potential to reshape and broaden the systematic examination of an uncharted area that will enable or advance translational research. Nominees must follow the specific guidance provided in the Application Process document offered by the Foundation.

The Foundation will not fund basic research motivated by curiosity and a desire to extend fundamental knowledge with long-delayed or unpredictable benefits; or consider funding research in public health, epidemiology, social science, psychology, ecology, environmental impacts, anthropology, or botany.

The Foundation will not consider research in areas of medicine generally associated with adult health unless there is a particularly compelling benefit to children of the United States.

SABBATICAL

Recipients of a Hartwell Individual Biomedical Research Award agree not to take a sabbatical during the three-year period of funding.

SITE VISITS

Recipients of a Hartwell Individual Biomedical Research Award agree to participate in occasional site reviews, as mutually convenient.

START-END DATES

Hartwell Investigator: announcement of all Individual Biomedical Research Awards is made to the sponsoring participating institution on April 1. Proposed research should commence no later than the date of receipt of funds, which will be disbursed by the Foundation to the sponsoring institution by the end of April. The end date for the Individual Biomedical Research Award is three years from the date of the April 1 announcement (March 31) or following submission of a final Annual Report due April 30, unless extended by the Foundation by virtue of significant carryover of funds. For further information, see the Individual Biomedical Research Award rules.

Hartwell Fellow: announcement of postdoctoral Fellowships is made to participating institutions that win an Individual Biomedical Research Award on April 1. Fellowship funds are made available yearly to the institution in July. The Fellow and Mentor mutually determine an acceptable “start” and “end” date for postdoctoral research training, where postdoctoral study should commence upon receipt of funds, but in no case later than November 1 of the same year of the award announcement. The active period of the Fellowship is two years from commencement of training, unless there is an extension by virtue of carryover funds. For further information, see the Hartwell Fellowship Rules.

Hartwell Institution: announcement of Institutions selected for participation in the Hartwell process is made April 15. Participating institutions hold their internal competition to select Nominees for the Individual Biomedical Research Award until nominations are due on September 15 at the Foundation office in Memphis, TN.

Disbursement of funds for the Individual Biomedical Research Award and the postdoctoral Fellowships will be made yearly to participating institutions. To enable effective commencement of research the Foundation expects that participating institutions will make award funds readily accessible, without delay.

STRATEGIC BIOMEDICAL RESEARCH

Strategic biomedical research addresses an unmet need in medicine or technology by targeting an enabling approach, which if successful will lead to essential advances and benefits that make it possible for others to broaden the systematic examination of an uncharted area of applied science or facilitate focused development of innovation. Strategic research success has the potential to reshape a complex technical problem that may also accelerate clinical and translational research.

STUDENT TUITION EXPENSE

The Hartwell Individual Biomedical Research Award is not an educational training grant and therefore funds may not support student tuition.

TRANSLATIONAL BIOMEDICAL RESEARCH

Translational biomedical research targets unmet medical need by exploiting discovery, new knowledge, insight, innovation and clinical observations as a guide for diagnosis, intervention, or prevention, including clinical trials. Translational research success has the potential to impact directly the delivery of healthcare outcomes.

VIDEO CONFERENCE

Recipients of a Hartwell Individual Biomedical Research Award agree to use videoconference methodology for periodic communications with the Foundation and other recipients. Participating institutions agree to provide each Hartwell Investigator with necessary Internet bandwidth connections to enable effective video conferencing.