

THE HARTWELL FOUNDATION

INDIVIDUAL BIOMEDICAL RESEARCH AWARD 2017 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.

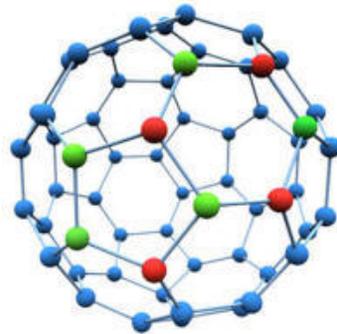


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LIMITED SUBMISSION PROCEDURE

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.

Hartwell Top Ten Centers of Biomedical Research must submit at least one Nominee each year that holds an MD degree to retain their special distinction.

Nominee: Only researchers nominated by a participating institution selected by The Hartwell Foundation are eligible to compete for the Individual Biomedical Research Award. All candidates 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 institutionally committed laboratory and office space adequate to perform 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 should address either a specific unmet need in translational medicine or a strategic problem in applied science. 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. The Foundation will not consider research in public health, epidemiology, social science, psychology, ecology, environmental impacts, anthropology, or botany.

Based upon the compelling nature of the proposed research the Foundation invites a limited number of Nominees for a closed personal interview. In selecting Nominees for consideration, The Hartwell Foundation takes into account the extent that funding the proposed research will make a difference and the likelihood that translation of research success will benefit children of the United States. The Foundation also takes into account the extent and nature of collaboration by the Nominee and how it will facilitate success; evidence that the Nominee has appropriate expertise and research facilities to conduct the proposed research; and the extent to which funding the Nominee will make a difference in the trajectory of their professional career.

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 extramural funding or that will receive 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 Contemplated 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, 2017: announcement of participating Centers of Biomedical Research that invites selected institutions to submit nominations for a Hartwell Individual Biomedical Research Award.

April 15 – September 15, 2017: participating institutions hold Internal Competitions to select Nominees for a Hartwell Individual Biomedical Research Award.

September 15, 2017: Nominations for the Individual Biomedical Research Award are due at the Foundation office in Memphis, TN.

October 6, 2017: The Hartwell Foundation will notify Nominees selected to interview for a Hartwell Individual Biomedical Research Award and provide the date and time of the interview.

October 31 – November 16, 2017: The Hartwell Foundation will interview Nominees for the Hartwell Individual Biomedical Research Award in Charlotte, NC.

April 1, 2018: the Foundation will announce Hartwell Individual Biomedical Research Awards, with funding complete in April.

REQUIRED SUBMISSION DOCUMENTS

Participating Institution — Nomination: 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 sign the nomination, acknowledging that they have 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 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 named specifically for each Nominee for the Individual Biomedical Research Award.

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

FORMAT REQUIREMENTS

Text: 1-inch margins, single-column text, and only black, 12-point Times Roman font; use single line spacing. Do not indent paragraphs. Separate paragraphs from each other and from headers by 6-point spacing. The use of bold font must be reserved only for section headers and in highlighting key authorship in the References (see instructions). Start each major Section (I–XI) on a new page. Limit the use of italics. Do not underline text. Do not paginate the Title page.

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.

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

Proposal Title: the choice of Title should ideally identify the proposed innovation, be terse but engaging, stimulate interest and not be overly dramatic. The Title must not begin with an adjective — such as *The*, *A*, or *An*. The Title should 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 should not include any reference to *children*, *childhood*, *pediatric*, or *related terms*. The Title must also not include any pronouns, any parentheses, or exclamation or question marks and except for a summary colon, must be free of punctuation. Avoid abbreviations, acronyms, technical terms or jargon terms in the Title that are unlikely to be familiar to a lay reader.

In-Text Abbreviations, Comments, References, and Citations: within the text of the proposal define the first use of any unusual abbreviation, acronym or jargon followed by its preferred identification in parenthesis; include a detailed explanation in the Glossary of Terms.

Do not cite any literature references in the Nontechnical Description of Research (Section I) except to support the early stage nature of the proposed innovation: provide *only* 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 a 12-point font, not as superscript. Number each citation in the Technical section numerically, in sequence of appearance in Section X: References.

Comments, explanations, or additional information relating to specific passages in the text must be cited by footnoting using a numerical format in superscript font (i.e., ⁽¹⁾, ⁽²⁾, ⁽³⁾, etc.), placing the numbered note in sequence at the bottom of the same page where the citation occurs.

Title Page: do not number this page. Use only <Title Case> format and do not capitalize adjectives, conjunctions, and most prepositions. Center all text. Spaced about an inch below the Title provide the name of Nominee and academic degrees, job title(s); on separate lines provide the primary or principal department affiliation, 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.

Table of Contents: begin on page number *i* — provide detailed page listings for Glossary and Sections I–XI, including relevant sub-sections labeled A,B,C, etc..

Glossary: begin on page number *ii* — arrange terms alphabetically, in bold font

ORGANIZATION AND CONTENT REQUIREMENTS

* Address explicitly all responses in *first-person singular tense* (avoid the use of the vague "we"). *

I. **Glossary of Terms** (no page limit): an opportunity to communicate

- Enable the reviewer to quickly find and understand an unfamiliar term while reading the proposal without creating significant interruption; consider deploying figures and photos to *communicate effectively* with your reader
- Include unusual terms, technical terms, obscure or unusual abbreviations, acronyms, or jargon that might be critical for a reviewer unfamiliar with the proposed research
- Provide useful non-obvious explanations for the lay reader, not simply dictionary definitions, or the words that indicate what each letter in an acronym refers; do not provide useless terms that clutter and distract from the intended purpose
- Figures, charts or photos will aid with explanations
- Undefined terms may not be used to define a Glossary term

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

Note: Do not provide numbered literature citations within this section. If necessary to cite a literature reference or patent in support, list the publication and date in parenthesis (e.g., Nature, 2014; US Patent 2015). Publications or patents listed here must appear in the list of references.

- A) Lay Summary** – single paragraph description of proposed research (450 words or less) suitable for a nontechnical audience; avoid jargon or acronyms, unless the lay reader is certain to be familiar with them:
- **Statement of Problem** – magnitude of the problem in the United States in terms of 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
 - **Innovation(s)** – describe the innovation(s) and compare to any advantage(s) or limitation(s) of other known approaches
 - **Justification for Funding** – describe what will happen if proposed research is successful (e.g. diagnosis, therapeutic intervention, prevention, etc.) and how it 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 jargon that are unlikely to be understood by a lay reader, explain explicitly in three separate paragraphs how the research is:
- **Early-Stage** – discuss timing of discovery or recognition of the innovation including as appropriate, the date of acquisition of any preliminary data and the date of first disclosure of intellectual property; justify why the research is pioneering and not an extension of previous research or simply an incremental advancement

Note: Preliminary data is not a prerequisite for funding consideration

Note: To cite a literature reference to support the early stage nature of innovation, offer only the date and if possible, publication in parenthesis (e.g., US Patent, 2012; PNAS, 2014)

- **Innovative** – identify the innovation(s) and contrast advantages versus any limitations of other known approaches, such as the state-of-the-art; describe how the innovation(s) may generate a dynamic tactical advantage or create paradigm-shifting strategic value; explain how the innovation(s) meet an unmet need, provide an unrecognized benefit, offer significant improvement, overcome the lack of strategic

knowledge or technology, lead to a new perspective, overcome accepted consensus, provide a valuable intervention, etc.

- **Cutting-Edge** – describe how the proposed research will utilize the most up-to-date technology, resulting in advantageous development or deployment of the innovation(s)
- C) **Impediments to Success** – offer a critical evaluation of risk. In two paragraphs describe:
- **Technical and/or Conceptual Risk**
 - **Potential Adverse Consequences** – any likelihood that in translation of the research to benefit children there could be consequences that might exceed the contemplated benefits
- D) **Compelling Benefits of the Proposed Research to Children in the U. S.** – describe how the proposed research if successful may ultimately benefit children in the U.S., either strategically or in translation to the bedside; if available, cite relevant incidence and prevalence, including morbidity and mortality statistics
- E) **Laboratory and Productivity Technologies** – describe:
- **Lab and Office Facilities (sq. ft):** space that will be available to conduct the research and to what extent such facilities are under your control
 - **Technologies:** what technologies will be used or leveraged to maximize productivity
 - **Core Facilities:** expected necessity for and/or the benefit to be realized from any specialized/core facilities or competencies provided by the institution
- F) **Key Collaborations** – identify all collaborators and 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 and may be reimbursed for services, but generally do not take salary
 - **Collaborators or Mentors Who Provide Guidance in Achieving Success** – receive no financial support
- Note: Provide name and academic degrees, job title, name of institution and as appropriate, geographic location.
- G) **How Funding the Research Will Make a Difference** – explain who will benefit from the proposal being funded and if the proposed research is successful, how the research results benefit children of the U.S.; describe whether or not the proposed research will be pursued if the proposal is not funded by the Foundation
- H) **Anticipated Pathway for Translation** – describe the anticipated pathway leading to any potential strategic or direct biomedical applications (e.g., enabling technology, published knowledgebase, product development, clinical trial strategy, clinical intervention, etc.) that would ultimately benefit children of the U.S.
- I) **Professional Goals** – explain your passion for the proposed research and how funding from The Hartwell Foundation will advance your professional goals (e.g. academic promotion, future funding, recognition for your discoveries, etc.); maintain first-person singular tense

III. 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 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, including those approaches being pursued by others
 - **Anecdotal Supporting Evidence** – describe any observations or indications that support your innovation
- C) Aims** – provide for each Aim in bold font:
- **Rationale** – describe in technical detail the hypotheses and assumptions
 - **Approach** – identify the priorities, objectives and outputs; acknowledge potential technical issues; describe the risk vs. gain of the selected approach; explain why the approach is compelling and likely to succeed
- D) Research Strategy** – by Aim
- **Research Design** – connection between the Aims and methodology should be evident; describe anticipated outcomes; integrate personnel and technology sufficient to produce success within available budget and the funding period
 - **Statistical Approach** – identify contemplated methodology
- 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 collaborations
- F) Timeline**
- **Milestones** – identify the milestones required for achieving each Aim, including any potential barriers to success
 - **Horizontal Bar Graph** – in a single chart depict the timeline for step-wise accomplishment of each Aim, by milestone achievement (objective)

IV. Budget : no page limit

- A) Single Table** – arrange the proposed use of funds for each year of funding as depicted in the accompanying example — any other budget format is unacceptable; columns in the table should consist of category line item description and expenses; the total expense for each year must be provided and be equal to \$100,000

Category	Year 1	Year 2	Year 3
Personnel (including fringes)			
PI name, MD, Ph.D.	\$ -	\$ -	\$ -
example name, Ph.D., post doc	\$ 47,045	\$ 48,500	\$ 50,000
example name, Res Asst II	\$ 10,425	\$ 20,500	\$ 20,500
Supplies	\$ 4,600	\$ 5,200	\$ 6,500
Animals, cages, etc.	\$ 5,200	\$ 7,500	\$ -
Core facilities	\$ 8,600	\$ 17,700	\$ 21,000
Equipment			
example instrument	\$ 22,630	\$ -	\$ -
Travel	\$ 600	\$ 600	\$ 600
Publication Costs	\$ 900		\$ 1,400
BALANCE	\$ 100,000	\$ 100,000	\$ 100,000

- **Personnel** – identify in the Budget table the PI, Key Laboratory Support Personnel and any Collaborators Integral to Success, even if not taking salary: 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
 - **Other Category Line Items** – other acceptable line items in the Budget table include supplies; animals, cages and related expenses; core facilities; equipment; travel; and publication costs
- B) Justification of Expenses** – explain why funding of each line item in the Budget table is essential and why each is necessary to achieve the Aims; unjustified items will not be funded
- **Nominee (PI)** – provide name and graduate academic degree(s); describe explicitly in first person singular tense the expected benefits derived from the contribution of the Nominee in the proposed research; and identify the *actual* contemplated percentage effort to manage the research
- Note: 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** – provide name, graduate academic degrees and job title of all funded lab personnel; 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
 - **Funded Collaborators Integral to Success** – provide name, graduate academic degrees and job title of all relevant collaborators, including the expected benefits from their contribution and their percentage effort to the research; where 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 would make a particular 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
- C) Student Expense** – the Individual Biomedical Research Award is not an educational training grant and Hartwell funds should not be used to support student tuition. However, if student participation is required, then identify each student by name, including received and pending academic degrees, extent of completion of class work and the years remaining until graduation. Justify why the project cannot succeed without student involvement by providing their estimated percentage effort and the expected benefit derived from their participation in the research. In addition, describe explicitly any fringe benefits.
- Note: If citing institutional requirements that dictate the amount for student expenses, then provide verbatim the institution policy statement, not rate tables, in section XIII of the Appendix.
- 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 of collaboration, access to core or service facilities, costs that you are assuming covered from other sources and similar considerations.

- V. Existing Research Funding Available to the Nominee** (no page limit)
- 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**
 - **Link to Website of Funding Agency** – to confirm existing and pending research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>
 - **Describe any Overlap Between the Aims or Objectives with the Hartwell proposal**
- VI. Submitted or Contemplated Future Research Funding Involving the Nominee** (no page limit)
- A) Funding Source**
 - C) 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**
 - **Link to Website of Funding Agency** – to confirm existing and pending research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>
 - **Describe any Overlap Between the Aims and Objectives with the Hartwell proposal**
- VII. Intellectual Property:** no page limit
- A) Current 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:** provide a non-confidential description, including reference number(s); do not include the actual patents
- Note:* 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
- VIII. Research Outcomes and Vision of Project Success:** no page limit
- A) Definition of Project Success:** define succinctly what will constitute project success and explain how clinical translation of research results 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 timing for translation of research results to potential biomedical applications (e.g., published knowledgebase, product development, clinical trial strategy, and/or clinical intervention)
 - D) **Technology Transfer:** outline a general plan for technology transfer that will enable licensure and/or and commercialization of intellectual property
- IX. Collaborators Contact Information (do not submit CVs):** no page limit
- A) Name and Academic Degrees
 - B) Job Title, Departmental Affiliation, Institution and Geographic Location
 - C) Contact Phone Number(s) and Email Address
- X. Follow-on Funding** (no page limit) – describe the contemplated approach that will be taken to attract additional funding during and at the conclusion of the Hartwell award
- XI. References** (no page limit):
- A) **Order References Numerically** – must follow sequence of appearance in the Technical Section
 - B) **Listing** – authors, title, publication, volume, page number, and year
 - C) **Hartwell Nominee or Support Personnel or Collaborator(s)** – highlight in bold font within relevant references
 - D) **Multiple Authors** – for publications with three or more authors, it is acceptable to use et al, but only if the Nominee, Key Laboratory Support Personnel or any Collaborator(s) have been properly highlighted in the listing of the first three (3) authors
- Note: If no literature references cite either the Nominee, named Support Personnel or Collaborator(s), then provide an explanation in a note at the beginning of this section prior to the first listed reference
- XII. Appendix:** as the last numbered page in the proposal, the Appendix cover page must provide a list of contents
- Note: Do not include entire publications, entire patents, or CVs; do not include a photo of Nominee.
- 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:** dated, signed and on institutional letterhead (no page limit)
 - **Chair of Primary Department** (required)
 - **Collaborator Identified as a Practicing Physician** (required)
 - Other Supporting Letters of Collaboration
 - D) **Other Documentation:** material cited in the proposal, institutional policies, etc. (no page limit)

NOMINEE PERSONAL INTERVIEW

The Hartwell Foundation will invite a limited number of Nominees for a closed personal interview followed by presentation that summarizes their proposed research. Interviews will be at a designated venue in Charlotte, NC. The Foundation will conduct interviews from 9 AM – 5 PM on Tue-Wed-Thu each week during the first three weeks in November. Nominees selected for an interview are required to be available on their assigned date for three hours. The Foundation will reimburse interview expenses: the Nominee is responsible for travel arrangements and the Foundation is responsible for food and lodging.

The interview of each selected Nominee 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.

The presentation summarizing details of the research proposal should ideally last not more than 30 minutes and may not exceed 15 slides. Nominees must number each slide legibly as (say) # of 15, in the footer at the bottom right. 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 follow the Lay Summary outline offered in the Nontechnical Description of Research, while avoiding excessive use of jargon and acronyms. It should begin with the statement of the problem, placing the proposed research in context of unmet need, while emphasizing compelling interest to the Foundation. The proposed innovation(s) must be identified, contrasting advantages versus any limitations of other known approaches or the state-of-the-art; including an outline of the research aims, technical strategy, expected outcomes, and contemplated timeline. The presentation should conclude with what will constitute project success and the anticipated strategic or translational benefit to children of the United States.

Failure to follow guidance for the slide presentation may result in Nominee disqualification.

Nominees agree to provide their presentation to The Hartwell Foundation on a USB portable drive at the completion of their 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.

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:

2017: September 24-27, Durham, NC in conjunction with Duke University

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

2019: September 22-25: 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

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.

The investigator develops a Budget on a yearly basis, which the Foundation reviews semi-annually. Expenditures should be consistent with the budget submitted in the funded award proposal. Unspent funds remain the property of the funded investigator and the sponsoring institution may not return such funds to the Foundation.

The Individual Award “start” date is April 1 and the “end” of the Award occurs when only nominal funds remain (see Carryovers and Extensions).

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 the explanation for the carryover in the Annual Report. If unexpended funds are apparent only after submission of the Annual Report, the Investigator must notify the Foundation as soon as possible. If at the end of the three-year grant cycle the carryover funds are excessive, the Investigator must continue to budget such funds and participate in additional quarterly reviews until remaining funds are nominal, when a final report will be required. The Individual Award “start” date is April 1 and the “end” of the Award occurs when only nominal funds remain.

Hartwell Fellowship – Following a resignation of the Fellow, the Institution may not return unconsumed funds to the Foundation. If granted permission from the Foundation such 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. The Fellow and Mentor mutually determine an acceptable “start” and “end” date (see Rules under Hartwell Fellowship).

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 participating in the Hartwell competition is not open to application; institutions are chosen at the discretion of the board. Hartwell announces the list of 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, up to and including 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 in the application proposal. The Hartwell Foundation will not deploy future year 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 financial reports to the Foundation as part of the Annual Report. Such reports must detail expenditures by category and compare expenses to plan; official reports are due April 30 each year, unless extended by virtue of carryover of funds.

FINANCIAL BENEFIT

The Hartwell Foundation provides financial support for biomedical research that will benefit children. 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 Hartwell 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 in any intellectual property.

FRINGE BENEFITS

Funding from The Hartwell Foundation covers only mandated non-discretionary fringe benefits and medical insurance. Examples of discretionary fringe benefits that are not covered 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 by their relevance in terms of 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.

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 reward 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. The following process and rules apply:

Selection of Fellows – The Fellowship may only 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 awardees that are most likely to make best use of funding.

Designation of Recipient – The Foundation will provide the sponsoring participating institution a Designated Recipient form, which requires the signature of both the Hartwell Fellow and the chief executive of the

institution. By signing the form, each acknowledging that they each have read the current 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 Fellowship, participating institutions are required to complete and submit to the Foundation the following supporting documentation on a USB portable drive by June 30.

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 setting
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 in regards to the Fellow meeting The Hartwell Foundation requirement for U.S. citizenship

Fellowship Rules

- Hartwell Fellows must hold a PhD or equivalent doctorate and be citizens of the United States.
- The Fellowship mentor may not be a Hartwell Investigator currently funded as a recipient of an Individual Biomedical Research Award.
- Fellowship funds will be available in July of the year of the Award announcement and Fellows must commence their postdoctoral training no later than November 1 in the same year, or risk that the Foundation may rescind the Fellowship to the Institution.
- Fellows may generally use funds for salary, health insurance, or travel related to a scientific meeting; but not 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
- At the conclusion of funding, the Hartwell Fellow should submit on their departmental stationery a letter summarizing the impact that the Fellowship had on their career goals.
- The sponsoring institution may not return unconsumed Fellowship funds. If granted permission from the Foundation, residual funds may generally support research in the lab of the mentor. However, if appreciable funds remain following a resignation of the Hartwell Fellow, the sponsoring institution must designate a timely replacement in accordance with Foundation guidelines, keeping in mind that the Foundation will make no upward adjustment to funding.

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.

To retain their special distinction, Hartwell Top Ten Centers of Biomedical Research must each year submit at least one Nominee for the Individual Biomedical Research Award that has an MD degree (e.g., MD, MD-Ph.D., MD-DDS, etc.).

INDIVIDUAL BIOMEDICAL RESEARCH AWARD

Only investigators nominated by the chief executive of an invited research institution are eligible for consideration for the Hartwell Individual Biomedical Research Award. Each Award is for three years at \$100,000 direct cost per year. The funding cycle is from April 1 to March 31.

The following rules apply to the Individual Biomedical Research 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 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 recipient agrees to Quarterly Reviews with the Foundation regarding progress toward goals and objectives, as well as the submission of a written Annual Report that summarizes the research and expenses to budget
- The recipient agrees to cite “The Hartwell Foundation” as a funding source for published articles on the funded research, including research manuscripts, and to provide a PDF version of the publication to the Foundation

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.

With the exception of 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 – 5 PM on Tue-Wed-Thu 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 interview will last approximately one hour and will consist of a personal discussion followed by a concise slide presentation of the scientific research proposal not to exceed 15 slides (see Application

Process for detailed requirements). 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. Nominees who do not complete the Interview will not receive further consideration in the competition. All decisions by the Foundation are final.

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 the Nominee and the Chief Executive from each sponsoring institution must sign The Hartwell Foundation *Official Nomination* form (the Foundation cannot accept electronic signatures). Each signee acknowledges they have read The Hartwell Foundation 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.

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 to 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 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 should address either an unmet need in translational medicine or a strategic problem in applied science.

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

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 Investigators: proposed research should commence no later than the date of receipt of funds, which should be available to the sponsoring institution by the end of April, following announcement of the Award. The end date for the Individual Award is three years from the date of the April 1 announcement and following submission of an 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 Fellows: postdoctoral study should commence upon receipt of funds but in no case later than November 1 of the same year of the award announcement, or risk that the Foundation may rescind the

Fellowship to the Institution. The active period of the Fellowship is two years from commencement of training, unless there is an extension by virtue of carryover of funds, in which case the Fellow may determine the end date. For further information, see the Fellowship rules.

STRATEGIC BIOMEDICAL RESEARCH

Biomedical research that 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.

TRANSLATIONAL BIOMEDICAL RESEARCH

Biomedical research that targets unmet medical need by exploiting insight, discovery or innovation derived from applied research and clinical observations as a guide for diagnosis, intervention, or prevention, including clinical trials. Translational research success often has the potential to impact directly healthcare outcomes.

TUITION EXPENSES

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

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.

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