

## 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 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 four 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 will benefit children.
- The research proposed may not have had significant funding from outside sources.
- Proposals should be based on sound science and should “make a difference.”
- 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 who hold a full-time appointment and be able to serve as PI.

#### Instructions for Pre-proposals:

1. On a single sheet of paper, provide the following information regarding the applicant:

Name:

Academic Degrees:

Job Title:

Department Affiliation:

Campus Address:

Contact Phone Numbers (office and mobile):

Email Address:

Citizenship:

2. In 2 pages or less, provide an Abstract, a 250-word Lay Summary, and the Specific Aims for the project.

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

4. If you have a *current* postdoctoral fellow with US citizenship whom you would consider nominating for the Hartwell Postdoctoral Fellowship, please provide their name and academic degrees below the items listed in #1 above. This information is for the purposes of review planning only, and is not a criterion for review of your application. Do not attach postdoctoral fellow nomination materials at this time.

Submit 15 complete paper copies and one electronic copy to Tracy Cabot, 4113 HSLC, by Noon, Thursday, June 12, 2014. Contact Tracy Cabot at 263-6515 or [tlcabot@wisc.edu](mailto:tlcabot@wisc.edu) if you have questions.

# THE HARTWELL FOUNDATION

## INDIVIDUAL BIOMEDICAL RESEARCH AWARD

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### *2014 APPLICATION PROCESS AND ADMINISTRATIVE GUIDELINES*

The Hartwell Foundation seeks to inspire innovation and achievement by offering individual researchers an opportunity to realize their professional goals. We believe that philanthropy is a serious responsibility and that wealth appropriately used is an essential mechanism for improving the state of mankind. Through a unique and selective funding process, we provide financial support to stimulate discovery in early-stage biomedical research that will benefit children of the United States. We want the research to make a difference.

#### I. APPLICATION PROCESS

##### INSTITUTIONAL NOMINATION

Each 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 four nominations to compete in a process that seeks to fund early-stage, innovative, and cutting-edge biomedical research. The Foundation's goal is to fund proposals that have not yet qualified for significant funding from outside sources, and that have the potential to benefit children of the United States. From time-to-time the Foundation also selects institutions for limited participation, which are invited to 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. For *each* funded Nominee, the participating institution will receive a Hartwell Fellowship to fund one postdoctoral candidate of their choice who exemplifies the values of the Foundation. Each Hartwell Fellowship will provide support for two years at \$50,000 direct cost per year.

##### PROGRAM QUALIFICATIONS AND INVESTIGATOR ELIGIBILITY

**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 provide technical support to the investigator, as well as how it fosters 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 open internal competition that includes appropriate areas of basic and applied life sciences, including engineering focused on biomedical applications. All nominations must clearly demonstrate a commitment to research that has the potential to benefit children of the United States.

**Investigator:** Only researchers nominated by a participating institution selected by The Hartwell Foundation are eligible to compete for a Hartwell Individual Biomedical Research Award. All candidates for the Award should hold U.S. citizenship, maintain a full-time appointment in the sponsoring institution and must have institutionally committed office and laboratory space adequate to perform the proposed research.

## **AWARD EVALUATION CRITERIA: INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

In selecting awardees, The Hartwell Foundation takes into account the transformative nature of the innovation, the extent to which a strategic or translational approach might accelerate the clinical application of research results to benefit children, the extent of collaboration in the proposed research, the institutional commitment to provide encouragement and technical support to the investigator, and the extent to which funding the Nominee will make a difference. Nominees must submit a Research Proposal, for which the importance of clarity and attention to the guidance provided in this document should not be underestimated. Based upon the compelling nature of the proposal the Foundation invites a limited number of Nominees for a personal, closed interview at a Foundation designated venue in Charlotte, NC. At the interview each candidate also makes a concise presentation describing their proposed research. Interview expenses are paid by the Foundation: travel is arranged by the selected Nominee and lodging is arranged by the Foundation.

**Proposal – Non-technical:** All Nominees must submit a non-technical summary of the proposed research suitable for a lay audience (5 page max), which specifically addresses why the research is early-stage, innovative, and cutting-edge; and how the research will potentially benefit children of the United States. Nominees must explain the unmet need that is addressed by the proposed innovation and how the pursuit of the proposed research will make a difference. Proposals must not be an incremental extension of existing research being conducted by either the applicant or others. It is expected that proposals will represent research too early to qualify for traditional sources of funding, which if successful, will have the potential to be transformative. The non-technical summary must also identify key collaborations and explain the approach that could be used to translate results to the patient, either currently or in the future.

**Proposal – Technical:** All Nominees are required to submit a detailed technical description of their proposed research (10 page max). Proof of principle is desirable, but not required. Nominees must summarize the state-of-the-art, including differences in the experimental approach or proposed research methodology that distinguishes it from earlier or existing effort by others. Proposals must outline aims and objectives for the research plan. Relevant literature references, including at least one literature review, must be included. A projected time-line with reasonable milestones must indicate how effectively and responsibly the work will be accomplished. The research plan must include a backup strategy for any technical or feasibility limitations, including contingencies related to collaborator dependencies. Evidence for applicant's expertise in any proposed technology is essential and should be noted. Nominees should make every possible attempt to convey the technical aspects of their proposal without excessive use of jargon or acronyms.

**Proposal – Additional Non-Technical Information:** All Nominees must include a detailed budget, current and pending sources of funding, anticipated research outcomes, Nominee vision of project success, plans for technology transfer, and the contemplated approach to seek follow-on funding at the completion of the award period (no page limitations).

**Interview and Presentation:** All Nominees selected for a personal interview are required to be available in Charlotte, NC on an assigned date and time for at least three hours. The actual interview will last approximately one hour and will consist of in part, a slide presentation lasting not more than 30 minutes that summarizes the research proposal. The presentation must identify the proposed innovation; research aims and strategy; expected technical outcomes; timeline and milestones; and the role of collaborators. Nominees are expected to describe the context of the proposed research in terms of state-of-the-art and any ongoing work by others. Nominees must define what will constitute project success and the anticipated benefit to children of the United States must be explicit. Every possible effort should be made to convey the technical aspects of the proposed research without excessive use of jargon or acronyms.

All presentation slides must be legibly numbered in the footer at the bottom right as # of n, where n is the total number of slides. The total number of slides may not exceed 20. Video with

or without audio is acceptable as a means to enhance clarity within the presentation, but may not substitute for slides. Nominees at the completion of their personal interview agree to provide their presentation to The Hartwell Foundation on a USB portable drive.

Nominees who are not interviewed will not be considered further in the competition. All decisions by the Foundation are final.

#### **TIMELINE**

- April 15, 2014: Announcement of Hartwell Top Ten participating Centers of Biomedical Research — invitation will be sent to all 2014 participating institutions to submit nominations for a Hartwell Individual Biomedical Research Award.
- April 15 – September 15, 2014: Participating institutions hold Internal Competitions to select Nominees for a Hartwell Individual Biomedical Research Award.
- September 15, 2014: Due date for receipt of nominations and associated documentation at the Foundation in Memphis.
- October 4, 2014: The Hartwell Foundation will notify Nominees selected for interview and provide the date and time of the interview.
- November 4 - 20, 2014: The Hartwell Foundation will interview Nominees for the Hartwell Individual Biomedical Research Award Tuesday-Thursday, November 4-20, in Charlotte, NC.
- April 1, 2015: Announcement of Hartwell Individual Biomedical Research Awards, with funding complete in April.
- June 30, 2015: Due date for participating institutions who have won a Fellowship award to submit required supporting documentation, with funding complete in July.

#### **REQUIRED DOCUMENTS: ANNUAL COMPETITION**

**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 documents to the Foundation on a USB portable drive, which will have one directory named for each Nominee for the Individual Biomedical Research Award; each directory must include four (4) files:

1. Nominee Research Proposal (*print to PDF – do not scan*)
2. Nominee Current Curriculum Vitae (*print to PDF – do not scan*)
3. Current color photo of the Nominee (head shot, from the shoulder up) in *jpeg format*
4. Cover Letter (may be scanned to PDF) from the chief executive that describes clearly:
  - 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 contact information

The Foundation will notify each institution by email upon receipt of their documentation. Incomplete documentation, inclusion of unrequested materials or failure to provide an appropriate

head shot photo may result in the submission being returned to the institution, jeopardizing the status of the Nominee for further consideration.

**Participating Institution — Fellowship Award:** Participating institutions will receive one Hartwell Fellowship Award for each winning Individual Biomedical Research Award. Following the Awards announcement, the institution will be provided a *Designated Recipient* form, which requires the signature of both the Hartwell Fellow and the chief executive of the institution, acknowledging that they have each 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.

Participating institutions that have qualified for a Hartwell Fellowship will be required to complete and submit the following supporting documentation to the Foundation no later than June 30. Documentation must be provided on a USB portable drive, which will have one directory named for each designated Fellow; each directory will include five (5) files:

1. Completed official Hartwell Fellowship Designated Recipient form
2. Current Color Photo of Fellow (head shot in jpeg format)
3. Recent CV of Fellow that provides contact information at the participating institution
4. Synopsis of intended postdoctoral research training (not to exceed one page)
5. Cover Letter from the chief executive (may be scanned PDF) that describes clearly the identity of the recipient of a Hartwell Fellowship and includes:
  - Departmental affiliation of the Fellow
  - Name of Fellow’s Mentor, including departmental affiliation and contact information
  - Statement in regards to Fellow meeting the Hartwell U.S. citizenship requirement

The Foundation will notify each institution by email upon receipt of their documentation. If all documentation has been received and approved by The Hartwell Foundation, the Fellowship will be funded in July. Fellows must commence their Fellowship training no later than November 1 in the year of the Award.

**Nominee Research Proposal — Format Requirements:** compliance is essential.

**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 pt spacing. The use of bold font must be reserved only for section headers and in highlighting key authorship in the References (see instructions). Unless multiple sections can be completely self-contained on a single page, start each major Section (I-XI) on a new page. Limit the use of italics. Do not underline text.

**Header:** starting with page 1, 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 Section I); and Arabic numerals, as p. # of n, for the body of the proposal (the Non-Technical Summary must begin on page 1); number only the Appendix cover page.

**Proposal Title:** the choice of Title should ideally identify the proposed innovation, be terse but engaging, stimulate interest and not be overly dramatic; referencing children in the Title is unnecessary. The Title must not begin with an adjective — such as *The*, *A*, or *An*. The Title should not include “study” or “investigation” or “analysis” or “examination” or similar terms; and should not include any pronouns or any parentheses. Except for a summary colon, the Title should be free of punctuation. Every effort should be made in the Title to avoid abbreviations, acronyms, technical terms or jargon terms that are unlikely to be understood by 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 (Section I).

Do not cite literature references in the Non-Technical Description of Research (Section II) 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 III), cite references using a parenthetical numerical format (i.e., (1), (2), (3) ...) in a 12 pt font, not as superscript. Each citation in the Technical section must be listed numerically in sequence of appearance in Section XII: 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., <sup>(1, (2, (3, ...)</sup>), placing the numbered note in sequence at the bottom of the same page where the citation occurs.

**Nominee Research Proposal — Structure Requirements:** address explicitly all responses in *first person singular* (avoid the use of the vague "we").

**Title Page** (do not number this page): use only "Title Case" format — however, 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.

**Contents** (must begin on page number i): table of detailed page listings for sections I–XIII, including relevant sub-sections.

I. **Glossary of Terms** (no page limits — begin on page number ii): an informative section that includes, in alphabetical order, explanations of obscure technical terms, unusual abbreviations, acronyms, or jargon that might be critical for a non-technical reader to understand the proposal. Use this section to provide a useful explanation for the lay reader (i.e., not simply dictionary definitions or the words that indicate what each letter in an acronym refers). List sequentially, one item per line and provide extra line spacing between the terms for ease of reading. Use figures, charts or photos to aid with explanations.

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

Note: Omit numbered literature citations to support this section; utilize first person singular.

A) Lay Summary – single paragraph description of proposed research (400 words or less) suitable for a non-technical audience; avoid jargon or acronyms, unless the lay reader is certain to be familiar with them. The Lay Summary must include:

1. Statement of Problem (e.g., magnitude of the problem in the United States)
2. Compelling Interest to the Foundation – identify the unmet need
3. Proposed Innovation(s) – describe the innovation(s) and any advantages or limitations of other known approaches
4. Justification for Funding – describe what will happen if successful; how will the innovation be deployed to benefit children

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

1. Early-Stage – discuss timing of discovery or recognition of the innovation including if 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: To cite a literature reference to support the early stage nature of the proposed innovation, offer the publication and date in parenthesis (e.g., US Patent, 2012; PNAS, 2014).

2. Innovative – describe creative basis of the innovation(s), justifying uniqueness or advantage (e.g., because meets an unmet need, provides an unrecognized benefit, offers significant improvement, overcomes the lack of strategic knowledge, leads to a new perspective, overcomes accepted consensus, provides a valuable intervention, etc.)
  3. 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); describe how the innovation(s) will generate a dynamic tactical advantage or a paradigm-shifting strategic benefit
- C) Likelihood of Success – keeping in mind that The Hartwell Foundation seeks to fund high risk, transformative research
1. Address the possibility of success from the perspective of conceptual and/or technical risk, not by offering assurances that the proposed research will necessarily succeed
  2. Discuss whether in translation of the research there is any potential that unexpected or adverse consequences might exceed the contemplated benefit
- D) Compelling Benefits of the Proposed Research to Children in the United States – to what extent will the innovation ultimately benefit children in the U.S. by addressing an unmet need; if data is available, provide incidence and prevalence, including morbidity and mortality statistics
- E) Laboratory and Productivity Technologies – describe:
1. Lab facilities (sq ft) that will be available to conduct the research and to what extent such facilities are under your control
  2. Technologies you will use or leverage to maximize productivity in the proposed research
  3. Expected necessity for and/or the benefit to be realized from any core facilities provided by the institution to facilitate the research
- F) Key Collaborations – identify all collaborators and succinctly describe their expected contribution, including whether a collaborator will be the sole source of materials or resources necessary for the proposed research.
- Note: Provide name and academic degrees, job title, department affiliation, name of institution and geographic location; only identify individuals other than the principal investigator and key laboratory support personnel.
1. Collaborators Integral to the Success of the Proposed Research (may be reimbursed for services but generally do not take salary)
  2. Collaborators or Mentors Who Provide Guidance in Achieving Success (receive no financial support)
- G) Timeline – describe the anticipated process and milestones necessary to translate the proposed research to benefit children now or in the future
- H) How Funding the Research Will Make a Difference – explain how transformative the impact will be if the proposal is funded and success is achieved; explain why the proposed research will not be pursued if the proposal is not funded; and describe those who will benefit most from the proposal being funded and why
- I) Professional goals of the Nominee – explain how funding from The Hartwell Foundation will advance the professional goals of the Nominee

**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 as (#, Review Article)
- B) Context – competitive analysis of the proposed innovation with appropriate literature references
  - 1. Contrast the proposed research with current academic and industry efforts in the same or similar area — provide reference citations that support your view of the existing competition.
  - 2. Describe presumed advantages of the proposed approach and/or technology compared to limitations of approaches and technologies being pursued by others
- C) Aims – provide the text of each Aim in bold font. Describe each Aim in technical detail:
  - 1. Rationale – be explicit about the hypotheses and assumptions; explain why the approach chosen is compelling and likely to succeed
  - 2. Approach – identify the priorities, objectives and outputs; acknowledge impending technical issues; offer an appreciation of risk vs. gain
- D) Research Strategy – connection between the Aims and methodology should be evident; the research design should be scaled to integrate personnel, technology and disciplines within budget and the funding period, sufficient to produce success; where appropriate, provide detail about statistical evaluation of data
- E) Backup Strategy – offer a strategy for any technical or feasibility limitation that might be potentially encountered in the research, including possible contingencies related to collaborations
- F) Timeline – discuss the timeline to achieve success; provide a single chart (horizontal bar graph) to describe a timeline for achieving the Technical Aims, indicating realistic milestones (Objectives)

**IV. Budget (no page limit): *unjustified line items will not be funded***

Proposed use of funds for each year of funding must be arranged in a Single Table, constructed with four columns, (adjacent example) — any other budget format is unacceptable. The 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
<b>Personnel (including fringes)</b>			
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
<b>Supplies</b>	\$ 4,600	\$ 5,200	\$ 6,500
<b>Animals, cages, etc.</b>	\$ 5,200	\$ 7,500	\$ -
<b>Core facilities</b>	\$ 8,600	\$ 17,700	\$ 21,000
<b>Equipment</b>			
example instrument	\$ 22,630	\$ -	\$ -
<b>Travel</b>	\$ 600	\$ 600	\$ 600
<b>Publication Costs</b>	\$ 900		\$ 1,400
<b>BALANCE</b>	\$ 100,000	\$ 100,000	\$ 100,000

The PI, Key Laboratory Support Personnel and any Collaborators who are Integral to the Success of the proposed research and who are paid for services must be identified by name, academic degrees and job title (job title only, if unnamed at the time of application).

Salary expense must include all fringes: The Hartwell Foundation will only agree to pay for non-discretionary government required tax deductions, social security, workman’s comp, disability insurance, and relevant medical insurance.

A) Budgeted Line Items — Justification:



1. Nominee (PI) – provide name and academic degrees; describe explicitly the contribution of the Nominee in the proposed research and identify the percentage effort

Note: If any salary is taken by the PI, it must be justified why it is necessary to do so and why no other options are available (percentage effort may not be used as a justification). The justification should begin “Salary must be taken because...”

2. Key Laboratory Support Personnel (including fringes) – provide name, academic degrees and job title of *all* participating personnel, 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
3. Specific Line Items – an explanation of how funds will be used is not a justification; 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

Note: Each justification should begin “This line item is necessary because...”

4. 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
5. Student Expense – if the project cannot succeed without student participation, justification must be provided. The student must be identified by name (unidentified students will not be funded), including: received and pending academic degrees, extent to which all class work has been completed and years remaining until graduation. In any case, because The Hartwell Individual Biomedical Research Award is not an educational training grant, funds may not be used to support student tuition

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.

- B) Collaborators – if a Collaborator Integral to the Success of the proposed research requires any financial support other than payment for specific technical services, then the reason why the project cannot succeed without their participation must be explained
- C) Sufficient Funding – state explicitly whether funding provided by The Hartwell Foundation will be sufficient to achieve the proposed Aims

**V. Existing Sources of Research Funding Available to the Nominee (no page limit):**

- A) Funding source (including start-up funds)
- B) Funded project title and identification number (as appropriate):
  1. Identify the PI
  2. Role of Nominee, including committed percentage effort
  3. Expected or actual amount of annual funding received by Nominee, as direct cost/yr (if not constant, then provide amounts for each year of funding)
  4. Funding initiation and expiration dates
  5. Technical Aims for each award
  6. If available, provide a link to the website of the funding agency to confirm all existing and pending research support (e.g., NIH specific project reporter link to the grant)

**VI. Pending Sources of Research Funding Available to the Nominee (no page limit):**

- A) Funding source (including start-up funds)

- B) Funded project title and identification number (as appropriate):
  - 1. Identify the PI
  - 2. Role of Nominee, including committed percentage effort
  - 3. Requested amount of annual funding requested by Nominee, as direct cost/yr (if not constant, then provide amounts for each year of funding)
  - 4. Funding initiation and expiration dates
  - 5. Technical Aims for each proposal
  - 6. If available, provide a link to the website of the funding agency to confirm all pending research support (e.g., NIH specific project reporter link to the grant)

**VII. Intellectual Property** (no page limit):

- A) Intellectual Property Plan – outline a plan to disclose and protect any discovery or proprietary information that may derive from research outcomes
- B) Current Status – describe any existing or contemplated intellectual property disclosures related to the proposed research
- C) Patent(s) Received or Application(s) Filed – provide a description, including reference number(s); do not include the actual patents
- D) 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) 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 the approach that will be used 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., expansion of 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 commercialization of intellectual property

**IX. Key Laboratory Support Personnel** (no page limit): *do not submit CVs*

Identify all technicians, post docs, research associates or students (individuals *other than* the Nominee or project collaborators) who will be integral in supporting the research, even if their financial support is not through the Hartwell Award:

Note: For personnel not yet identified at the time of application submission describe explicitly the *desired* qualifications.

- A) Name and academic degrees, job title, departmental affiliation and expected start
- B) Qualifications and experience relevant to supporting the proposed research
- C) Current and contemplated sources of financial support, as applicable:
  - 1. Funding source if other than Hartwell (including start-up funds)
  - 2. Funded project title for each award and identification number:
    - a. Role of individual, including percentage effort
    - b. Expected or actual amount of source funding, as direct cost/yr
    - c. Details regarding expected salary
    - d. Funding initiation and expiration dates
    - e. Technical Aims for each award
    - f. If available, provide a link to the website of the funding agency to confirm all existing and pending research support

- X. **Collaborators** (no page limit): *do not submit CVs*
- A) Collaborators Integral to the Success of the Proposed Research – may be reimbursed for services and generally do not take salary:
1. Name and academic degrees
  2. Job title
  3. Institution and geographic location
  4. Department affiliation
  5. Contact phone number(s) and email address
  6. Whether or not travel is required to support collaboration
  7. Source(s) of all existing or anticipated funds supporting the collaboration:
    - a. Annual funding, as direct cost/yr
    - b. Funding initiation and expiration dates
    - c. If available, provide a link to the website of the funding agency to confirm all pending research support (e.g., NIH specific project reporter link to the grant)
- B) Collaborators or Mentors Who Provide Guidance in Achieving Success – receive no financial support:
1. Name and academic degrees
  2. Job title
  3. Institution and geographic location
  4. Department affiliation
  5. Contact phone number(s) and email address
  6. Whether or not travel is required to support collaboration
- XI. **Follow-on Funding** (no page limit): describe the contemplated approach that will be taken to attract additional funding at the conclusion of the Hartwell award
- XII. **References** (no page limit):
- A) Order references numerically, in sequence of appearance in Section II of the text.
  - B) List authors, title, publication, volume: page number, and year
  - C) Highlight in bold font within relevant references the name of the Hartwell Nominee, any Key Laboratory Support Personnel or Collaborator(s).
  - D) For publications with three or more authors, it is acceptable to use *et al*, but only in so far as the Nominee, Key Laboratory Support Personnel or any Collaborator(s) have been included in the authorship and properly highlighted in bold font.
  - E) If no references cite the Nominee, named Key Laboratory Support Personnel or Collaborator(s), provide an explanation in a note prior to the first listed reference.
- XIII. **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 photo of Nominee.
- A) The name, academic degree(s), contact phone number and email address of the Chair of the primary department affiliation (and any secondary departmental affiliations) of the Nominee
  - B) Supporting Letters of Collaboration dated, signed and on institutional letterhead (no page limit )
  - C) Other cited documentation, institutional policies, etc. (no page limit)

## **II. 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 requirements:

### **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:

- 2014: September 28 - October 1 in Memphis, TN in conjunction with St. Jude Children's Research Hospital
- 2015: September 27 - 30 in Ann Arbor, MI in conjunction with The University of Michigan
- 2016: September 25-28, 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 1:30 PM on Wednesday. Attendees are expected to be present and actively participate in all sessions, including Foundation-sponsored social functions. Travel is arranged by the Hartwell Investigator and lodging is arranged by the Foundation, with expenses paid by the Foundation.

### **BUDGET**

The recipient of a Hartwell Individual Biomedical Research Award determines the best use of the funds to support the direct cost of the project within Foundation guidelines, 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; funds may not be used to support student tuition. The Award "start" date is April 1. Hartwell Awards "end" when the funds are completely depleted.

Budgets are developed by the investigator on a yearly basis and reviewed by the Foundation 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 may not to be returned to the Foundation. Hartwell Investigators may be asked to budget funds that carryover beyond the three year term of the Award until reasonably consumed.

### **CARRYOVERS AND EXTENSIONS**

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

**Hartwell Fellowship** – Following resignation of the Fellow, unconsumed funds may not be returned to the Foundation; such funds may be deployed by the participating institution to support research in the lab of the mentor. 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.

**Individual Biomedical Research Award** – In the event of unexpended funds, the Investigator must communicate the explanation for the carryover in the Annual Report, or if apparent only after submission of the Annual Report, such explanation must be communicated to the Foundation by email. If the carryover funds at the end of the three year grant cycle are deemed to be excessive by the Foundation, the Investigator may be asked to participate in additional quarterly reviews until the funds are consumed, wherein a final report will be required.

#### **CONTINUATION OF FUNDING IN 2<sup>ND</sup> AND 3<sup>RD</sup> YEARS: INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

The Hartwell Foundation expects each recipient of a Hartwell Individual Biomedical Research Award to demonstrate progress toward projected milestones described in the proposal. Progress is evaluated in quarterly reviews and the annual report. The Foundation reserves the right to withdraw future funding if the Hartwell Investigator does not demonstrate progress or refrains from participating in required Foundation activities. 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 who is not selected for interview or chosen for an award.

#### **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**

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 the Award end date is 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 – INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

Participating institutions agree to utilize an open and effective means to call for proposals from appropriate areas of basic and applied life sciences related to human health that are consistent with the values of The Hartwell Foundation, including engineering focused on biomedical applications. Proposals must reflect relevance in terms of potential benefits to children. The Foundation will only consider proposals in biomedical research. The Foundation will not consider for example, research in public health, epidemiology, social science, psychology, ecology, environmental impacts, anthropology, or botany.

## **FUNDING OF AWARDS – RECEIPT AND DISTRIBUTION OF FUNDS**

Funds are distributed by The Hartwell Foundation by paper check and must be deposited within 45 days. The participating institution agrees that best effort will be made to enable immediate access to funds by each reward recipient. Requests submitted to the Foundation for a replacement check will only be honored if an explanatory request is 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 of their choice who exemplifies the values of the Foundation. Each Hartwell Fellowship will provide support for two years at \$50,000 direct cost for two years. Each Fellowship must be used to fund one postdoctoral candidate of the institution's choice, selected from areas of biomedical science, consistent with Fundable Projects as described for the Individual Award.

It is the intent of The Hartwell Foundation that the Fellowship will support scientists and biomedical engineers who have completed requirements for a doctoral degree and are still in the early stages of career development. The Fellowship must be used to pursue further specialized research training, not to extend or complete clinical training. The Fellowship will be funded in July.

The following rules apply to the Hartwell Fellowship:

- Hartwell Fellows must be citizens of the United States
- Fellows must commence their postdoctoral training no later than November 1, or the Fellowship award to the Institution may be rescinded
- Funds may be used for salary, health insurance, or travel related to a scientific meeting, but not for the purchase of supplies or equipment or other fringe benefits
- 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 a summary of the impact that the award had on their career goals
- If appreciable funds remain following a resignation of the Hartwell Fellow, the sponsoring institution must designate a timely replacement within Foundation guidelines; no adjustment to residual funds will be provided by The Hartwell Foundation

## **HARTWELL 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, 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 developed as a result of funding the Individual Biomedical Research Award and the Hartwell Fellowship. However, recipients must notify the Foundation of all intellectual property resulting from the supported research.

## **INTERVIEW FOR INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

As part of the evaluation process for the Individual Biomedical Research Award, the Foundation will invite selected Nominees for a personal, closed interview at a Foundation designated venue in Charlotte, NC during which each candidate will make a concise presentation describing their proposed research. The actual interview will last approximately one hour and in part, will consist of a slide presentation that should not last more than 30 minutes. The presentation should be engaging and advantageously deploy color. No more than 20 slides may be shown during the presentation. Video with or without audio is acceptable as a means to enhance clarity, but may not substitute for slides. At the completion of the interview, Nominees agree to provide their presentation on a USB drive to The Hartwell Foundation. Nominees who are not interviewed for the Individual award will not be considered further.

## **INTERVIEW SCHEDULE FOR INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

Nominees selected by the Foundation for a personal interview are required to be available in Charlotte, NC on an assigned date for three hours. The actual interview will last approximately one hour. The Foundation will conduct interviews from 9 AM – 5 PM, each day:

- November 4-6
- November 11-13
- November 18-20

Interview travel is arranged by the Nominee and lodging is arranged by the Foundation; travel and lodging expenses are paid by the Foundation.

## **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 FOR INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

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; must not be an incremental extension of existing research being conducted by either the applicant or others; 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 (electronic signatures will not be accepted). 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](http://www.thehartwellfoundation.org), as an additional information source.



## **PROGRESS REPORTS – INDIVIDUAL BIOMEDICAL RESEARCH AWARD**

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 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 Quarterly Review will take place in the first month following the end of each quarter, starting in April. 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. A template will be provided for a summary of research progress toward goals and objectives, which requests:

- A concise non-technical summary of progress versus plan, including any technical advances made in the research versus plan
- 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 RESULTING FROM HARTWELL FUNDING**

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.

## **RECEIPT OF FUNDS**

Funds are distributed by The Hartwell Foundation by paper check and must be deposited within 45 days to enable convenient access by award winners. Requests submitted to the Foundation for a replacement check will only be honored if an explanatory request is submitted on letterhead and signed by the Provost or CEO of the institution.

## **SITE VISITS**

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

## **START-END DATES**

**Hartwell Fellows:** postdoctoral study should commence upon receipt of funds but in no case later than November 1 of the year in which the award announcement was made, or the Fellowship award to the Institution will be rescinded. The active period of the Fellowship is intended to be two years from commencement of training, unless the end date is extended by virtue of carryover

of funds. At the conclusion of funding, the Hartwell Fellow should submit to the Foundation a summary of the impact that the award had on their career goals.

**Hartwell Investigators:** proposed research should commence no later than the date of receipt of funds, which are expected to be available to the sponsoring institution by the end of April, following announcement of the Award. The end date for the Individual Award is intended to be three years from the date of the April 1 announcement and following submission of the Annual Report due April 30, unless the end date is extended by virtue of carryover of funds.

#### **TUITION EXPENSES**

The Hartwell Individual Biomedical Research Award is not an educational training grant and funds may not be used to 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. The Foundation will make available appropriate video conference equipment to each recipient typically within two months of funding their Award.

Participating institutions agree to provide each Hartwell Investigator with necessary Internet bandwidth connections to enable effective video conferencing. The Award recipient and the institution both agree to have video conference installed and operational within one month following receipt of the equipment.

At the conclusion of their funded research, Hartwell Investigators may keep their video conference equipment for the purpose of utilizing the communication network provided by the Foundation for further collaboration.

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