

THE HARTWELL FOUNDATION

APPLICATION PROCESS AND ADMINISTRATIVE GUIDELINES

INDIVIDUAL BIOMEDICAL RESEARCH AWARD 2023 COMPETITION

The Hartwell Foundation seeks to inspire innovation and achievement by offering individual researchers an opportunity to realize their hopes and dreams. 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 in the United States. Our approach is to be unique, selective, thorough, and accountable. We want the research to make a difference.

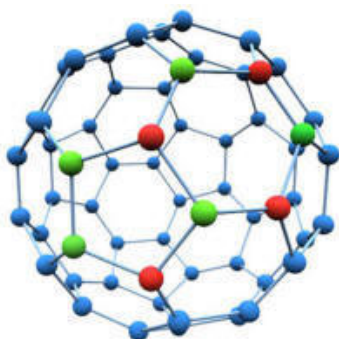


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LIMITED SUBMISSION PROCEDURE

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 that has the potential to benefit children in the United States (the “Competition”). From time-to-time, the Foundation may select an institution for limited participation, with 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 Sponsoring 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

Institution: The Hartwell Foundation selects research institutions for participation in a qualification process that considers 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 considers the institutional commitment to translational approaches that promote rapid clinical application of research results, including technology transfer. Selection of an institution for participation in any given year does not guarantee selection in a subsequent year.

Participating Institutions agree to identify eligible Nominees by holding an internal, open competition of their design from areas of discovery and applied science related to human health, including biomedical engineering. Participating Institutions agree to submit *at least one* Nominee that holds a Doctor of Medicine or equivalent professional degree or who have been admitted and passed coursework in the fields of medicine and/or surgery from an accredited medical school (e.g., MD, DO, DMD, DDS, MBBS, etc.). Failure to follow this requirement may result in the loss of an active nomination and jeopardize the participation of the institution in the subsequent year.

Nominee: Only researchers nominated by a Participating Institution selected by The Hartwell Foundation are eligible to compete for the Individual Biomedical Research Award. All Nominees for the Award must hold U.S. citizenship; must maintain a full-time appointment within the Participating Institution; must have adequate committed laboratory and office space to conduct the proposed research; and agree to the terms and conditions set forth in the Application Process and Administrative Guidelines promulgated by the Foundation, and as updated from time to time.

AWARD EVALUATION CRITERIA

All Nominees must submit a detailed research proposal that is consistent with the Primary Mission of the Foundation, which is to fund early-stage, innovative and cutting-edge applied biomedical research that has the potential to benefit children in the United States. The Foundation seeks to fund research that addresses a specific and compelling unmet need to improve health outcomes for children, either by clinical translation of theory or application, or the strategic solution of a complex technical problem with the potential to advance translational biomedical research. The Foundation does not fund basic research (scientific inquiry motivated by a desire to extend fundamental

knowledge with long delayed and unpredictable benefits); or provide financial support to those in pursuit of commercial ventures.

Translational biomedical research targets unmet medical need by exploiting insight, discovery, or innovation derived from applied research and clinical observations. Translational approaches may explore diagnosis, intervention, or prevention; and often have the potential to directly impact healthcare outcomes. By contrast, strategic research addresses an unmet need in medicine or technology by targeting an enabling approach that can lead to essential advances and benefits that will 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 has the potential to reshape a complex technical problem that may accelerate clinical discovery and translational research.

The Hartwell Foundation does not fund research in public health epidemiology, social science, ecology, environmental impacts, botany, or anthropology. The Foundation will not fund “studies”, surveys, health services research or stand-alone clinical trials; and will not consider biomedical research in areas generally associated with adult health unless there is a readily apparent and particularly convincing benefit to children in the United States.

In large measure, the selection process considers the extent to which funding will make a difference: the likelihood that success of the proposed research will benefit children in the United States and the extent to which funding will have a positive effect on the trajectory of the Nominee’s professional career. The selection process also considers whether the Nominee has appropriate expertise and research facilities to conduct the proposed research, as well as the extent and nature of collaboration by the Nominee and how such collaboration will facilitate success (If Nominee is not a Doctor of Medicine, at least one collaborator must be identified as *actively engaged in practicing medicine*, preferably in pediatrics).

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 mature or well-funded laboratories.

Research Proposal: The Hartwell Foundation seeks to fund early-stage research that is strategic or translational in nature. *Preliminary data are not required.* 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 technology may be 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; proposals that accept uncertainty and leverage technology, not study it. Proposals that already receive or will receive significant extramural funding (e.g., NIH, NSF, DOD, commercial entities, other foundations, etc.) are ineligible for consideration.

Proposals are structured as follows:

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

Nominee Personal Interview: Based upon the compelling nature of the proposed research, the Foundation will invite a limited number of Nominees for a closed professional interview, which includes a technical presentation by the Nominee that summarizes their proposed research. Nominees for the Individual Biomedical Research Award who do not follow Foundation presentation guidelines or who do not complete the Interview will not receive further consideration in the competition. All decisions by the Foundation are final.

TIMELINE

April 15, 2023: invitation extended to select institutions to submit nominations for a Hartwell Individual Biomedical Research Award

April 15 – September 14, 2023: Participating Institutions hold their internal competition to select Nominees

September 15, 2023: electronic submission of nominations for the Individual Biomedical Research Award due

October 7, 2023: invitations extended to Nominees selected for a scheduled Personal Interview

October 14, 2023: deadline for invited Nominees to accept their scheduled Interview with the Foundation

November 1 – November 17, 2023: interviews with selected Nominees

April 1, 2024: announcement of 2023 Hartwell Individual Biomedical Research Awards, with funding to Sponsoring Institutions complete in May

NOMINATION: REQUIRED SUBMISSION DOCUMENTS

The Foundation provides an *Official Nomination* form that the Participating Institution must complete for each candidate. The Nominee and the Chief Executive of the Participating Institution must both sign the nomination (electronic signatures are unacceptable), acknowledging that they each have read the Application Process and Administrative Guidelines provided by the Foundation for the current Competition and agree to such terms and conditions as set forth in the documents.

Participating Institutions must submit all required nomination documents to The Hartwell Foundation using a designated electronic file sharing platform (instructions will be provided prior to due date). The documentation must contain a single file with the Cover Letter from the Chief Executive, as well as one directory identified as < last name >, specific for each Nominee.

The Cover Letter from the Chief Executive (scan to PDF) should describe:

- The names and academic titles of each Nominee
- The internal selection process used by the Participating 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 Foundation following announcement of an award
- The individual responsible for official contact by the Foundation, including phone and email

The directory for each 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* high-quality color photo head shot of the Nominee in *jpeg* format (from the shoulder up — *smiling*)

The Foundation will notify each Participating 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 returning the submission to the Participating Institution, jeopardizing the status of the Nominee for further consideration.

NOMINEE RESEARCH PROPOSAL

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

FORMAT REQUIREMENTS

Text: black Times Roman 12-point font. Use 1-inch margins, single-column text, single line spacing, one space between sentences. Do not indent paragraphs; separate paragraphs from each other by 6-point spacing. Use bold font only to distinguish section and sub-section headings or as required, below. Avoid italics. Do not underline text. Do not hyperlink to any text; URL references must be in black font. Start each major Section (I-X) on a new page.

Title Page: Center all information on the Title page. Use <Title Case> format and follow title capitalization rules: capitalize the first word of the title, the last word of the title, and all nouns, verbs, adverbs, and adjectives; prepositions may only be capitalized if they are used adjectivally or adverbially (Chicago Manual of Style and AP style). Spaced at least 3 inches below the Title provide the name of the Nominee (including discerning initials) and only the highest earned academic degrees (e.g., MD, Ph.D., DVM, DDS — do not list any master's or honorary degrees or include honorary Fellow designations). On separate lines, provide Nominee job title(s); primary or principal academic department affiliation(s); name of Participating Institution, mailing address, contact phone numbers (office and mobile), email address and well-spaced below, include the submission date. Except for designating office or mobile phone numbers, do not include descriptors on the Title page (e.g., Title: ___, Name: ___, Degrees: ___, etc.).

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 on one line the name of the Nominee, including highest earned academic degrees (the header must be identical to the Nominee name as it appears on the Title page).

Footer - Pagination: do not paginate the Title page; center paginate the Contents and Glossary of Terms that appear prefatory to the body of the proposal in lowercase 8-point Roman numerals; center paginate all other pages of the Proposal in Arabic numerals in the footer, as p. # of *n* using 8-point font; and paginate only the Appendix cover page but not its contents.

References: citations may not be used in the Lay Summary (Section I.A). Citations deemed to be critical may be used to support other areas of the Nontechnical Description of Research, where only the publication name and date may appear in parenthesis (e.g., US Patent, 2018; PNAS, 2019). However, Nominees are cautioned that they will be penalized for excessive use of citations in the Nontechnical section.

In the Technical Description of Research (Section II), cite references using a parenthetical numerical format (i.e., (1), (2), (3) ...) in 12-point font, not as superscript. Number each citation in the Technical section in sequence of appearance within the text.

In References (Section IX), bold font must be used to indicate <Review Article>, and to highlight the names of specific key authors: Nominee, Support Personnel, and any Collaborator(s).

In-Text Abbreviations, Definitions, and Comments: uncommon abbreviations or acronyms should be defined parenthetically in the text at the point of first use. Comments, explanations, or additional information relating to specific text passages may be cited as footnotes, using a numerical format in superscript font (i.e., ⁽¹⁾, ⁽²⁾, ⁽³⁾, etc.). Place sequentially numbered-by-appearance notations at the bottom of the same page where the citation occurs.

TEXT RESPONSES

Respond explicitly to all requests for information; do not use “n/a” or “not applicable”.

PROPOSAL ORGANIZATION AND CONTENT REQUIREMENTS

Selection of Proposal Title: The choice of Title should ideally identify the proposed innovation; be succinct but engaging, stimulate interest and avoid being overly dramatic. The use of abbreviations, jargon, or technical terms in the Title that are unlikely to be familiar to a lay reader must be avoided. Acronyms may not appear in the Title.

The Title must not include any pronouns and must not begin with an article — such as *The*, *A*, or *An*. The Title must not include the use of *study*, *investigation*, *analysis*, or *examination*, *discovery*, or similar terms. All proposals must address potential benefits to children and therefore, the Title must not include any reference to *children*, *childhood*, *pediatric*, or similarly related terms, whereas specific terminology such as preterm, neonatal, adolescent, etc., are acceptable. Do not use *new*, *novel*, *innovative*, *unique*, or similar terms in the Title to characterize your research proposal. The Title must not include any parentheses, or exclamation or question marks and except for a summary colon, must be free of punctuation.

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

Glossary of Terms (no page limit): the purpose of the Glossary is to inform the reader by explaining necessary but *unfamiliar* technical terms and concepts, including specialized jargon that may be essential to understanding the proposed research or the innovation. It is not a location to present simple or obvious acronyms for the sake of having a Glossary.

The Glossary should enable the reviewer to quickly find and understand the meaning of unfamiliar terminology without creating significant interruption while reading the proposal. It is an opportunity to offer explanation and simplification of technical terms to a nontechnical reader (even though such terms may not be simple). Use figures or photos for emphasis or to illustrate an unfamiliar technology.

- Arrange entries alphabetically, terms in bold font, with explanations in regular font.
- Include only important terms that you consider useful or indispensable for understanding your proposal, including jargon, obscure or unusual abbreviations or acronyms; *communicate effectively*, emphasizing why the entry is important to understand in view of your proposed research.
- Do not offer explanations that include undefined terms otherwise appropriate for inclusion separately in the Glossary.
- Avoid the gratuitous inclusion of terms that may distract from the intended purpose of the Glossary; do not include simple dictionary definitions or provide only the words that indicate what each letter in an acronym refers.
- Avoid the inclusion of obvious terms that a reviewer is certain to be familiar with (e.g., FDA, NIH, etc.), which will only clutter and distract from the intended purpose.
- Include useful figures, charts or photos if they are important in explaining terms
- Do not use any references to describe a Glossary entry, as descriptive explanations must be self-contained.
- Do not use any hyperlinked text in describing a Glossary entry.

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

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

A) Lay Summary – provide in a *single paragraph* a description of the proposed research (450 words or less) suitable for a nontechnical audience; do not demarcate sentences with descriptors; avoid jargon or acronyms, unless the lay reader is certain to be familiar with them; no citations are allowed:

- **Statement of Problem** – description and magnitude of the problem in the United States; emphasize what makes the problem translationally important (e.g., prevalence, incidence, morbidity, and mortality rates) or strategic (focused development of innovation). Ignore economic considerations.
- **Compelling Interest** – identify what constitutes an unmet need and how addressing it successfully will benefit or improve health outcomes for children in the United States.
- **Innovation** – identify the novel idea(s), discovery, or creative insight, including relevant model test systems, important experiments or a novel technologic approach that will be used to construct or test hypotheses, which may offer a unique translational benefit, inspire a distinctive shift in perspective, or provide a strategic advantage that may accelerate clinical discovery and translational research.
- **Justification for Funding** – describe what will happen if the proposed research is successful (e.g., diagnosis, therapeutic intervention, prevention, clinical trials, etc.) and how successful outcomes will be deployed either translationally or strategically to benefit children.

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

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

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

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

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

Characterize how your proposed research is fundamentally new and original or represents a different approach that overcomes limitations compared to known competing approaches; and how if you are successful the outcome will generate a dynamic tactical advantage or create paradigm-shifting strategic value. Describe how your innovation(s) when clinically translated will provide a benefit that addresses an unmet need or will lead to a heretofore unrecognized benefit.

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

Describe how the proposed research will utilize state-of-the-art technology and/or a ground-breaking approach that will promote success of the proposed research (e.g., how the questions being posed reflect a particular importance and how they will have the greatest possibility of advancement using the specified technology).

C) Impediments to Success – describe:

- **Technical Risk** – identify and discuss any real or potential weakness, methodologic limitation, or unpredictability in generating expected outcomes.
- **Conceptual Risk** – discuss vulnerabilities in the working hypothesis, model test system or technology platform, etc.; contrast the magnitude of structural uncertainty with likelihood of success.
- **Collaboration Risk** – discuss the risk of losing your collaboration partners and how it might destabilize progress and jeopardize research outcomes
- **Potential Adverse Consequences** – discuss the potential for any unintended consequences that might diminish the contemplated benefit of a successful outcome or the translation of the research to benefit children.

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

E) Laboratory and Productivity Technologies – describe all resources under your control:

- **Staffing:** identify the total number of *existing* lab technicians, postdocs, and students under your supervision, irrespective of the proposed research. Disclose any potential conflict of interest or other circumstance that might raise a question about impartiality in the conduct of the research, including whether you currently collaborate, rely upon, or directly employ a relative or member of your household, or whether for the purposes of the proposed research you plan to do so.
- **Office Space (sq. ft.):** describe the space that will be available to you to administrate the research and to what extent such facilities will be under your control.
- **Lab Space (sq. ft.):** describe the office space that will be available to you to conduct the research and to what extent such facilities will be under your control.
- **Technologies and Core Facilities:** identify the location and describe to what extent you will have ready access to core facilities, necessary equipment, or specialized competencies provided by the Sponsoring Institution or as the result of collaboration.

F) Key Collaborations – purposeful collaboration is a fundamental attribute of The Hartwell Foundation, and all Nominees are expected to demonstrate they embrace the strategy. In bold font identify each collaborator by their first and last name and highest earned academic degree(s). In addition, provide the job title and institution or geographic location of each collaborator, and describe succinctly their expected contribution. Identify the technical expertise that will make the collaboration valuable, not just shared scientific interest.

- **Collaborator Who Is Practicing Physician** – if Nominee holds a Doctor of Medicine degree or equivalent (e.g., MD, DDS, DMD, DO, MBBS, etc.), and identifies as a Practicing Physician, indicate place of work, clinical job title, responsibilities, and board certifications.

If the Nominee does not hold a Doctor of Medicine degree or equivalent, at least one collaborator must be identified as a practicing physician, preferably in pediatric medicine.

- **Collaborators Essential to the Success of the Proposed Research** – may be the sole source of materials, resources, or technology necessary for the proposed research; may be reimbursed for services, but generally do not take salary.
- **Collaborators or Mentors Who Provide Guidance in Achieving Success** – receive no financial support.

G) How Funding the Proposed Research *Will Make a Difference*:

- **Benefit of Conducting the Research** – explain how expected outcomes or achievements will independently contribute to make pursuit of the proposed research significant; how conducting the research will do more than just further existing ideas.
- **Benefit to Nominee** – explain how as an independent researcher you will benefit professionally from your proposal being funded.
- **Consequence of Non-Funding** – explain whether the proposed research will be pursued by you or others if it is not funded by the Foundation.

H) Anticipated Pathway for Clinical Translation – describe the necessary stepwise actions leading from technical or strategic impacts that transcend academic peer-reviewed publications or presentations, which will be required to achieve biomedical advances to benefit children in the U.S. (e.g., development of enabling technology, published knowledgebase, product development, clinical trial strategy, clinical intervention, demonstration of safety and efficacy, etc.).

I) Professional Goals – maintaining a first-person point of view, explain your inspiration and motivation to pursue the proposed research; describe how funding from The Hartwell Foundation will advance your long-term professional goals beyond peer-reviewed publications (e.g., academic promotion, future funding, recognition for your discoveries, etc.); elaborate on your passion to benefit children, including any personal experience or storyline that reveals your authenticity and empathy.

II. Technical Description of Research: 10-page limit

A) Introduction – concise, technical overview of the proposed research; identify the unmet need that is addressed by the proposed innovation; include one or more reference citations to a *current* state-of-the-art review, identifying each within the text as (#, Review Article).

B) Context – contrast the proposed innovation with the state-of-the-art — provide reference citations that support your view:

- **Current Academic and Industry Efforts** – contrast the proposed research with any current academic and/or industry efforts in the same or similar area.
- **Competitive Analysis** – describe presumed advantages of the proposed approach and/or technology compared to limitations of existing approaches/technologies.
- **Supporting Evidence** – recognizing that preliminary data is not a prerequisite for funding consideration, describe any available observations or indications by you or others that support your proposed research.

C) Aims – in one introductory paragraph describe the main goal of the project and the nature of the Aims that will be pursued.

Provide separately, for *each* individual, numerically listed Aim:

- **Statement of Aim in Bold Font** – describe the specific issue or problem that you intend to address: the scope, depth, and direction of what you hope to achieve.
- **Rationale** – the first sentence must begin “**The rationale for Aim # is...**”; explain the reasoning behind pursuing the Aim, describing in technical detail any hypotheses or assumptions.
- **Approach** – identify the priorities, objectives, technologies, and desired outcomes; acknowledge potential technical issues; describe the risk vs. gain of the selected approach; why the approach is compelling and likely to succeed; and how achieving the Aim moves the proposed research closer to benefiting children.
- **Research Strategy** – the connection between the Aim, methodology and outcomes should be evident; integrate personnel and technology requirements sufficient to produce success within available budget and the funding period.

- **Statistical Methods** – discuss value uncertainty and if appropriate, statistical methodology: if optimization is proposed for a process governed by multiple factors, you must describe the systematic method or software that will be used to design experiments and determine cause-and-effect relationships.
- D) **Backup Strategy** – offer a strategy for any technical or feasibility limitation that might potentially be encountered in the research, including possible contingencies related to personnel requirements, essential collaborations. or any impediments to success.

E) Timeline

- **Milestones** – identify the detailed objectives required for achieving each Aim, including any potential barriers to success and any interdependence between Aims
- **Horizontal Bar Graph** – in a single chart, depict the timeline for stepwise accomplishment of each Aim by milestone achievement (objective).

III. Budget: no page limit

A) Budget Table:

Template – arrange the proposed use of funds for each year as depicted in the accompanying example; other budget formats are unacceptable. Some expense categories in the example Budget Table may, depending upon the nature of the proposed research, require text adjustments.

Columns in the Budget Table must provide category line-item descriptions, expenses and % Effort. For each year, Expenses must total to \$100,000. To be eligible for Award consideration, the Nominee % Effort should be at least 15%. Each year the Total % Effort for all personnel must exceed 100%.

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

Personnel Expense Category Line Items – regardless of whether funds are being requested, identify within the Budget Table the name of the Nominee (PI), all Key Laboratory Support Personnel, and Collaborators Integral to Success: provide name; highest graduate academic degree(s); and job title, as appropriate (for unnamed personnel at the time of submission it is acceptable to provide job title only)

- **Salary and Fringe Benefits** – budgeted salary must include fringe benefits, 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. Fringes may not exceed limitations as described in the Foundation Administrative Guidelines.

- **% Effort** – all listed personnel in the Budget Table must have an entry for % effort each year. For any year, Nominee Effort may not be less than 15%; and Total committed research effort for all personnel may not be less than 100%.
 - **Additional Budget Expense Category Line Items** – acceptable line items in the Budget Table may include, but are not necessarily limited to supplies; animals, cages, etc., including related husbandry expenses; core facilities; equipment; travel; and publication costs.
- B) Detailed Justification of Budget Line Items** – for each category line item listed in the Budget Table, explain the budget by year, how the cost was derived, and why funding the item is essential to achieve the Aims (unjustified items will not be funded).
- **Nominee (PI)** – regardless of whether funds are requested to support the Nominee, describe explicitly in first person singular tense the expected benefits derived from the contribution of the Nominee. in the proposed research (Nominee % effort may not be less than 15%). It is the preference of the Foundation not to fund any salary of the Nominee. However, if taking salary is contemplated by the PI, an explanation is required of why it is necessary to do so and why no other options are available (percentage effort may not be used as rationale): begin the justification “Salary must be taken because...”. Describe explicitly the breakdown of fringe benefits; fringes may not exceed limitations as described in the Foundation Administrative Guidelines.
 - **Key Laboratory Support Personnel** – regardless of whether funds are requested to support Key Lab Personnel, provide name, earned graduate academic degrees and job title of all lab personnel that will be involved in supporting the research; include the expected benefits from their contribution and their percent effort in the research. Percentage effort may not be used as a justification for taking salary. NOTE: Job requirements must be defined for all individuals that will be recruited for open positions. Describe explicitly the breakdown of fringe benefits; fringes may not exceed limitations as described in the Foundation Administrative Guidelines.
 - **Collaborators Integral to Research Success** – regardless of whether funds are requested, provide name, earned graduate academic degrees and job title of all relevant collaborators listed in the Budget table; describe the expected benefits from their contribution and their percent effort to support the research. Percentage effort may not be used as a justification for taking salary. If salary is taken, describe explicitly the breakdown of fringe benefits; fringes, which may not exceed limitations as described in the Foundation Administrative Guidelines.
 - **Other Line Items Exceeding \$10,000 per year** – for line items that total \$10,000 or more the methodology for estimating the cost build is required. Outline each expense by year and describe the rationale for each item in detail, how each item will make a difference in facilitating the proposed research, and why no other options are available. An explanation of how funds will be used is not a justification.
 - **Travel** – only travel by the Nominee may be covered by the Hartwell Budget. Provide the rationale for contemplated travel in each plan year (a desire to attend a meeting of peers may not be used as a justification for travel). Explain why other sources of funding are unavailable to cover travel expenses. Travel in the first year is not an allowable expense.

NOTE: do not budget for travel to the Hartwell Annual Meeting of Biomedical Research, as expenses are paid by the Foundation.
 - **Publication Costs** – describe rationale for contemplated publication expense by plan year, including why other sources of funding will not be available to cover publication costs. Publication costs in the first year are not an allowable expense.

Student Expense – the Individual Biomedical Research Award is not an educational training grant and Foundation funds cannot be used to support student tuition. If students will be used to support the proposed research, provide the expected benefit derived from their participation in the project and explain why the project cannot succeed without their participation.

Identify each student who will participate in supporting the research by name and earned academic degrees and whether they will take financial support; if an academic degree is pending, provide the extent to which each student has completed class work and the years remaining until graduation; describe the estimated percentage effort of each student in the proposed research. Describe the source of any other student financial support and describe explicitly any contemplated Fringe Benefits, which may not exceed limitations as described in the Foundation Administrative Guidelines.

NOTE: If citing institutional requirements that dictate the amount for student expenses, then provide verbatim the Participating Institution policy statement, not rate tables, in the Appendix (Section X).

- C) Statement Regarding Sufficient Funding** – state explicitly whether funding provided by the Foundation will be adequate to achieve the proposed Aims. Identify any assumptions you are making regarding access to institutional core or service facilities, costs that you are assuming will be covered from other sources, or other relevant considerations such as the extent and benefit of collaboration.

IV. Existing Sources of Research Funding (no page limit): identify all current sources, including institutional Start-Up Funds that will be available to the Nominee. Describe all sources of funding available to the Nominee, whether or not used exclusively to support the proposed research.

Format each individual named source of funding according to the following descriptive outline and repeat the descriptive outline for each source (do not aggregate responses). Begin by describing first, any available (remaining) Institutional Start-Up Funds, followed by any awards made directly to the Nominee as a PI, followed by those awards made available to the Nominee as a Co-PI:

- A) Existing Source of Funding** – provide name (e.g., Start-Up Funds, NIH, NSF, DOD, SBIR, etc.); and where applicable, include Program Identification (R01, R21, U01, Phase #, etc.)

B) Funded Proposal Description

- **Funding Initiation and Expiration Dates**
- **Identify the PI**
- **Role of Nominee** (if not the PI)
- **Nominee Committed Percentage Effort**
- **Total Amount of Remaining Funds Available to Nominee** – direct cost
- **Technical Aims** – discuss any overlap with the Hartwell proposal
- **Link to Website of Funding Agency:** provide a useful link for confirming existing research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>

V. Submitted or Pending Sources of Research Funding (no page limit): identify any possible new institutional Start-Up Funds and in the order of potential for initiation of funding, identify all grant requests submitted and now pending consideration, regardless of whether or not the funds will be used exclusively to support the proposed research.

Format each individual named source of funding according to the following descriptive outline (do not aggregate responses). Begin by describing any new sources of Institutional Start-Up Funds, followed by award requests that will derive from the Nominee as PI, followed by shared award requests that will derive from the Nominee as a Co-PI:

- A) **Pending Source of Funding** – provide name (e.g., Start-Up Funds, NIH, NSF, DOD, SBIR, etc.); and where applicable, include Program Identification (R01, R21, U01, Phase #, etc.)
- B) **Pending Proposal Description**
 - **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 Requested Funds Available to Nominee** – direct cost
 - **Technical Aims** – discuss any overlap with the Hartwell proposal
 - **Link to Website of Funding Agency:** provide a useful link for confirming existing research support status (e.g., NIH specific project reporter link) — see Research Portfolio Online Reporting Tools (RePORT) at <https://report.nih.gov/>

VI. Intellectual Property: no page limit; responses must be explicit.

- A) **Disclosures:** 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 file number(s); do not include the actual patents; provide filing status. Provide a direct link to the U.S. PTO or WTO website specific to patent or patent pending applications, not simply a link to the main webpage.

VII. Research Outcomes and Vision of Project Success: no page limit

- A) **Definition of Project Success:**
 - **Define Succinctly What Will Constitute Project Success:** successful completion of Aims is not a definition of success.
 - **Explain How Outcomes Will Benefit Children in the U.S.**
- B) **Sharing Research Results** – describe your approach to sharing research results with others (specific meetings, publications, or other forms of disclosure).
- C) **Translation of Results** – describe contemplated approach and timing for translation of research success to biomedical applications (e.g., published knowledgebase, product development, clinical trial strategy, and/or clinical intervention) that will benefit children in the U.S.
- D) **Technology Transfer** – outline a general plan for technology transfer to enable licensure and/or commercialization of intellectual property.

VIII. Follow-on Funding Strategy (no page limit): describe the contemplated approach that will be taken to attract additional funding during or at the conclusion of the Hartwell Award.

IX. References (no page limit): if no citations are made to either the Nominee, any Support Personnel, or any Collaborator(s), an explanation is required at the beginning of the list. Patents assigned to Nominee that are related to the proposed research must be disclosed in the

list of References. All citations deployed in the Nontechnical section must also appear in the list of References.

Adhere to the following guidance, as improperly prepared References may result in disqualification of the Nominee:

- A) **Order References Numerically** – citation # must follow sequence of appearance in the Technical Section text
- B) **Content** – author(s), title, publication name, volume, page number and all references must identify the year of publication; do not use hyperlinked text
- C) **Required Review Article(s)** – identify in bold font as #, < **Review Article** >
- D) **Highlight Key Authors** – use bold font to highlight the name of the Nominee, Support Personnel, and any Collaborator(s)
- E) **Multiple Authors** – it is only acceptable to use “et al.” for publications with more than two authors, providing however, that in the listing of authors the Nominee, Support Personnel and any Collaborator(s) have been properly captured and highlighted with bold font

X. **Appendix (no page limit):** the last numbered page in the proposal, the Appendix cover page must provide a complete list of contents, as described below:

- A) **Chair of Nominee Primary Department** – first and last name, highest earned academic degree(s), contact phone number and email address
- B) **Contact Information for Collaborator Identified as a Practicing Physician (if Nominee is not a practicing physician)** – provide first and last name, highest earned academic degree(s), job title, departmental affiliation, Institution (name and geographic location), contact phone number and email address
- C) **Contact Information for Collaborators Essential to the Success of the Proposed Research** – for each Collaborator provide first and last name, highest earned academic degree(s), job title, departmental affiliation, Institution (name and geographic location), contact phone number and email address
- D) **Contact Information for Collaborators or Mentors Who Provide Guidance in Achieving Success** – for each Collaborator provide first and last name, highest earned academic degree(s), job title, departmental affiliation, Institution (name and geographic location), contact phone number and email address
- E) **Letters of Recommendation and/or Support of Direct Collaboration** – all letters should be addressed to *The Hartwell Foundation IBRA Selection Committee*. To be admissible, letters must be dated, signed, and on institutional letterhead.

The preference is for strong, meaningful letters that endorse favorably the significance of the proposed research, describe the benefit of Hartwell funding in the career development of the Nominee, express evidence for the collaborative nature of the Nominee, and rationalize how if the Nominee is successful the proposed research will benefit children in the United States. Avoid submitting gratuitous letters that simply confirm collaboration.

- **Chair of Primary Department** – required
- **Collaborator Identified as a Practicing Physician** – required, if Nominee does not hold a Doctor of Medicine degree or equivalent professional degree (e.g., MD, DO, DMD, MD-DDS, MBBS, etc.). Otherwise, at least one collaborator must be identified as a practicing physician, preferably in pediatric medicine.
- **Collaborator(s) Essential to Success of Proposed Research** – required
NOTE: if the same individual represents more than one category of collaboration, the reason should be detailed.
- **Other Collaborators** – as desired or appropriate

- Collaborator(s) Who Provide Guidance in Achieving Success: include Postdoctoral mentor if the proposed research represents a continuation of postdoctoral research
 - Individuals that provide essential support within Institution core facilities
 - **List of all Signatories in attached letters of recommendation**
- F) Other Documentation (no page limit):** include relevant material(s) cited in other sections of the proposal, including institutional policies, etc. Do not include any CVs, publications, patents, or any photos

NOMINEE PERSONAL INTERVIEW

The Hartwell Foundation will invite a limited number of Nominees for a closed personal interview that includes a technical presentation by the Nominee that summarizes their proposed research. Interviews will take place at a designated venue. Any travel expenses, including food and lodging are paid by the Foundation; the Nominee arranges travel, and the Foundation arranges lodging.

The Foundation conducts interviews during the first three weeks of November. The interview will last approximately 90 minutes and will consist of a personal discussion, followed by a concise slide presentation that summarizes the details of the research proposal. To allow for unanticipated changes in scheduling, Nominees selected for an interview are required to be available on their assigned date for a minimum of three hours before and after their scheduled interview start time. Nominees are encouraged to prepare for a professional interview and to dress appropriately.

The date and time of scheduled interviews are not negotiable and appeals for a change are accepted only in unusual circumstances, with no guarantee that a scheduled interview will be altered. Nominees are advised, therefore, to plan accordingly their availability for a potential interview, including rearrangement of contemplated travel, federal study section participation, clinical service commitments or teaching requirements, as necessary. Nominees who do not complete an Interview will not receive further consideration in the competition.

The slide presentation should summarize the relevant technical details of the research proposal; may not exceed ten (10) slides (excluding the Title slide) and should ideally, not last more than 30 minutes. Each slide must be numbered legibly as # of 10 on a single line in the footer at the bottom right, which during the presentation must be visible on each slide.

Nominees should not attempt to construct complicated slide content to meet presentation limitations. Stick to simple designs. Use text sparingly, color for accent and except for the Title slide, animate content for impact. Ensure tables and figures are labeled and readable. Select photos that enhance understanding. Avoid citations and references. Be prepared for an interactive presentation. Video with or without audio is acceptable to enhance clarity within the presentation but may not substitute entirely for slides. Avoid excessive use of jargon and acronyms. Follow required pagination.

The presentation should be delivered from a first-person point of view and avoid the vague use of third person references such as “we”, “our”, etc. It is expected that the presentation will in principle follow the guidance for the Lay Summary outline, as offered in the Nontechnical Description of Research.

The presentation should begin with a statement of the problem, placing the proposed research in context of an unmet need, while emphasizing a compelling interest to the Foundation. The early-stage, innovative aspect of the proposed research must be identified and contrasted with the state-of-the-art, emphasizing any advantages or limitations compared to known approaches. The research Aims must be presented, emphasizing the rationale for relevant experiments and the technology that will be used to construct or test hypotheses, the expected outcomes, and a contemplated timeline for completion. The presentation should conclude with what will constitute project success and the anticipated strategic or translational benefit to children in the United States. While details offered in the presentation are considered proprietary and a clear description of the innovation is desirable, it is unnecessary to disclose confidential information. At the completion of the interview, all Nominees agree to provide their presentation to the Foundation on a USB portable drive or a designated electronic file sharing platform.

Failure to follow all presentation guidelines may result in termination of the interview and disqualification of the Nominee. All decisions by the Foundation are final.

ADMINISTRATIVE GUIDELINES

The Hartwell Foundation expects that research institutions selected to participate in the Hartwell Individual Biomedical Research Award Competition, including their designated Nominees, Hartwell Investigators and Hartwell Fellows, will adhere to the following guidelines, which supersede all previously released guidelines:

ACCOUNTABILITY

The Foundation requires accountability from each Participating Institution regarding the nomination process and the use of funds awarded to individual researchers. All qualified individuals at Participating Institutions should have the opportunity to seek nomination for a Hartwell Individual Biomedical Research Award. Nominees who receive a Hartwell Individual Biomedical Research Award must demonstrate that they utilize award funds efficiently and responsibly. Sponsoring Institutions are expected to maintain adequate records and receipts of expenditures, which demonstrate they properly administer Award funds, including those that support Hartwell postdoctoral fellows.

ANNUAL MEETING BIOMEDICAL RESEARCH

All recipients of a Hartwell Individual Biomedical Research Award agree in lieu of a second quarter Progress Report to attend the Foundation Annual Meeting and make a presentation summarizing their research:

- 2023: Oct 1-4
- 2024: Sep 22-25
- 2025: Oct 1-4
- 2026: Sep 27-30

The Annual Meeting may take place by video conference or at a designated venue. Any travel expenses incurred, including transportation, food, and lodging are paid by the Foundation; the Nominee arranges travel, and the Foundation arranges lodging.

Attendance at the Annual Meeting is restricted to funded Hartwell Investigators.

Attendees are expected to be present and actively participate in all sessions, including Foundation-sponsored social functions. Hartwell Investigators who do not fulfill the requirement to participate fully at the Annual Meeting do so at the risk of losing their funding.

Because attendance at the Annual Meeting is mandatory for all Hartwell funded Investigators, Nominees for a Hartwell Individual Award should consider the potential impact of this requirement, including any necessity to reduce travel conflicts, federal study section participation, clinical service commitments, teaching requirements, etc., as relevant.

BUDGET

The Individual Biomedical Research Award is limited to the direct support of research; the Award is not an educational training grant and therefore funds may not be used to support student tuition. Individual Award funds are managed by the recipient within their annual Budget plan. The recipient may determine

the best use of available funds to support the direct cost of the research 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.

Recipients of an Individual Biomedical Research Award are responsible for staying within their Budget plan, which the Foundation reviews quarterly with each Hartwell Investigator. Expenditures are expected to be reasonably consistent with the Budget and the yearly Official Financial report submitted to the Foundation by the Sponsoring Institution.

If the Hartwell Investigator or their Sponsoring Institution does not demonstrate an acceptable level of responsibility in the management of award funds the Foundation reserves the right to delay or withdraw future funding, which will not occur without advance notice to the Investigator and the Sponsoring Institution.

CARRYOVERS AND NO-COST EXTENSIONS

Requests for carryovers or no-cost extensions of unused funds are unnecessary. Unexpended funds from any award year may carry forward to the next year without seeking permission of the Foundation, as long as such funds are in direct support of research by the funded Hartwell Investigator (see Budget, guidance and limitations) or Fellow (including Fellow's mentor) and are consistent with the following:

Individual Biomedical Research Award – if at the end of the three-year grant cycle carryover funds are deemed excessive by the Foundation, the Hartwell Investigator may, until such funds are reasonably consumed, be required to submit a quarterly Progress Report that outlines the supported research effort, including the management of intellectual property and administration of remaining funds.

Until all carryover funds are consumed, the Sponsoring Institution must continue to submit an Official Annual Financial Report to the Foundation by April 30 that details all expenditures by category.

Hartwell Fellowship – the Fellowship provides support for two (2) years but may conclude whenever it is advantageous for the Fellow. If at the end of two (2) years from commencement of postdoctoral training there are unconsumed funds, the Fellow's mentor may agree to continue the training and deploy any carryover of funds to extend their research, as desirable. Alternatively, remaining Award funds may, without permission from the Foundation, be used to continue the support of research in the lab of the Fellow's mentor, preferably to support another postdoctoral researcher.

In the event a Fellow resigns for any reason before completing two (2) years of training, the Sponsoring Institution may not return unconsumed funds to the Foundation. If granted permission from the Foundation, such residual funds may support research in the lab of the Fellow's mentor, preferably to support another postdoctoral researcher. However, if at least one year of Hartwell Fellowship funding remains, the Sponsoring Institution must designate a replacement within Hartwell guidelines with no adjustment to the funding provided by the Foundation.

COLLABORATION

All Nominees for the Hartwell Individual Biomedical Research Award must demonstrate they are collaborative. Nominees that do not hold an MD degree must identify at least one participating collaborator that is a practicing physician, preferably in pediatric medicine.

CONDITIONS FOR PERMISSIBLE PARTICIPATION IN FUNDED RESEARCH

To avoid conflict of interest or other circumstances that might raise a question about impartiality, a Hartwell Investigator who intends to utilize or employ for the purposes of the proposed research a relative or member of their household with whom the researcher has a personal relationship, must

disclose such intent to the Foundation in writing prior to the active participation of the individual, whether or not any Hartwell funds will be deployed to support such individual. The Foundation at its sole discretion reserves the right and final authority to determine whether such a personnel plan is acceptable or represents a material change of circumstances and refuse approval.

CONTINUATION OF FUNDING

The Foundation expects each recipient of a Hartwell Individual Biomedical Research Award to demonstrate progress toward agreed Milestones, including responsible management of Award funds (e.g., avoiding negligent gross underexpenditure of award funds). The evaluation of progress will occur in quarterly reviews and the Foundation reserves the right to delay or withdraw future funding if the Hartwell Investigator does not or is unable to demonstrate progress, refrains from participating in required Foundation activities related to quarterly progress reviews and the Annual Meeting or ceases to be affiliated with their original Sponsoring Institution. Delay or withdrawal of funding will not occur without advance notice to the Hartwell Investigator and the Sponsoring Institution.

CRITIQUE OF NOMINEE DOCUMENTATION OR INTERVIEW

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

ELIGIBILITY FOR PARTICIPATING INSTITUTIONS

The selection of an institution for participation in the Hartwell Competition is not open to application. Institutions are selected at the discretion of the Foundation, which announces eligible Participating Institutions in mid-April each year.

ETHICS

The Foundation expects all Award recipients to adhere to the highest standards of research ethics. Concerns regarding violations in ethical conduct of research may lead to notification of institutional officers and possible revocation of funding by the Foundation. If the Foundation becomes aware of information that a recipient or Sponsoring Institution is accused of fraudulent or illegal conduct, or conduct that violates the Sponsoring Organization's ethical guidelines and policies that in the Foundation's sole, reasonable and good faith determination reflects negatively upon the Foundation, its reputation, or its programs in a manner that would materially harm the Foundation, then the Foundation may terminate Award funding with no further obligation to the recipient or the Sponsoring Institution.

FINANCE REPORTS

The recipient of a Hartwell Individual Biomedical Research Award and the Sponsoring Institution agree to submit a yearly Official Financial Report to the Foundation that details all expenditures by category and compares expenses to plan; the Official Financial Report is due April 30 each year.

FINANCIAL BENEFIT

The Primary Mission of The Hartwell Foundation is to fund early-stage, innovative and cutting-edge applied biomedical research that has the potential to benefit children in the United States. It is not the intent of the Foundation to enrich itself by the funding of such research, but rather to enable continuation of its Primary Mission. However, if a Sponsoring Institution receives financial benefit related to the research funded by a Hartwell Individual Biomedical Research Award, the Foundation expects to receive five percent (5%) of the Sponsoring Institution's share of the financial benefit, which shall be used by

the Foundation to further support the Foundation's mission. The Foundation waives any ownership rights to any intellectual property.

FRINGE BENEFIT

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

FUNDABLE PROJECTS

Participating Institutions agree to utilize an open and effective process to call for proposals from areas of natural and applied science related to children's health, including biomedical engineering. Proposals must be consistent with the values of The Hartwell Foundation and focused on the potential benefits to children in the United States. The Foundation will not consider research in public health epidemiology, social science, ecology, toxicology or environmental impacts, anthropology, or botany. The Foundation will not fund "studies", surveys, health services research or stand-alone clinical trials; and will not consider biomedical research in areas generally associated with adult health unless there is a readily apparent and particularly compelling benefit to children in the United States.

FUNDING OF AWARDS

The Foundation will fund all awards by paper check made out to the Sponsoring Institution, which deposit must occur within 45 days. Each Sponsoring Institution agrees that they will make their best effort to enable immediate access to funds by each Award recipient. Requests submitted to the Foundation for a replacement check require an explanation submitted on letterhead and signed by the chief executive officer or Provost of the Sponsoring Institution.

HARTWELL FELLOW

An individual selected for a Hartwell funded postdoctoral Fellowship by a Sponsoring Institution is designated by the Foundation as a *Hartwell Fellow*.

HARTWELL FELLOWSHIP

For each Nominee selected for the Individual Biomedical Research Award, the Sponsoring Institution will receive a Hartwell Fellowship to fund one postdoctoral candidate selected from areas of biomedical science who exemplifies the values of the Foundation, namely benefits to children in the United States. Each Fellowship will provide support for two years at \$50,000 direct cost per year and will be funded yearly in July. Sponsoring Institutions that are eligible for the Fellowship agree to designate a recipient, according to the following guidelines:

Institution Selection of Fellows – Sponsoring Institutions may determine their own internal selection process for the postdoctoral Fellowship but in any case, must follow Requirements (see below). The Fellowship may only be used to support individuals who have completed a Ph.D. or equivalent doctorate and are still in the initial stages of research career development. Fellowship funds may not be used to extend or complete clinical training. Sponsoring Institutions should select recipients that are the most likely to benefit from the financial support and who agree to complete the two-year term of training. Individuals may only hold a Hartwell Fellowship once and are ineligible for reappointment by a Sponsoring Institution.

Official Designation of Fellowship – The Foundation will provide the Sponsoring Institution an official Designated Recipient form that requires the signature of both the Hartwell Fellow and the Chief Executive of the Sponsoring Institution, acknowledging that they have each read the *Application Process and Administrative Guidelines* promulgated by The Hartwell Foundation for the current Competition and agree to such terms and conditions as set forth in the documents.

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

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

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

Fellowship Requirements:

- Candidates for a Hartwell Fellowship must hold a Ph.D. or equivalent doctorate and be citizens of the United States.
- The Fellow's primary mentor may not be a Hartwell Investigator currently funded by the Foundation.
- Fellowship research training must be in an area of science or engineering related to biomedical science.
- Fellows must commence their postdoctoral training no later than November 1 in the same year of the Official Announcement of the Award, or risk that the Foundation may rescind the Fellowship to the Sponsoring Institution.
- Fellowship funds are intended to cover salary, health insurance, and travel related to a scientific meeting; and may not be used for the purchase of supplies or equipment or other Fringe Benefits without permission from the Foundation.
- No part of the Fellowship may cover institutional overhead or other indirect costs, nor should the recipient or the sponsoring research laboratory be obligated or penalized to pay by substitution such indirect costs by any other means.
- The active period of the Fellowship is two (2) years from commencement of employment unless there is an allowable extension by virtue of carryover funds.
- At the **Conclusion of the Fellowship** the Hartwell Fellow should submit a letter on their departmental stationery directed to the President of the Foundation that identifies the time period of active funding, summarizes the impact that the Fellowship had on the career goals of the Fellow, and describes next steps in career development.

Fellowship Resignation – in the event a Fellow unexpectedly resigns or is terminated for any reason before completing two (2) years of training, the Sponsoring Institution may not return unconsumed funds to the Foundation.

- If at least one year of Hartwell Fellowship funding remains, the Sponsoring Institution must within Hartwell guidelines submit supporting documentation to designate a replacement Fellow (see Activation, above), with no adjustment to the funding provided by the Foundation.
- If less than a full year of funding remains on the original Fellowship, the Sponsoring Institution may request permission from the Foundation to use any residual funds to support research in the lab of the Fellow's mentor, preferably to support another postdoctoral researcher.
- No part of unconsumed Fellowship funds may cover institutional overhead or other indirect costs, nor should the mentor or the sponsoring research laboratory be obligated or penalized to pay by substitution such indirect costs by any other means.
- If possible, the departing Hartwell Fellow should submit a letter on their departmental stationery directed to the President of the Foundation that identifies the time period of active funding, summarizes the impact that the Fellowship had on the career goals of the Fellow, and describes the reason for early termination and next steps in career development.

HARTWELL INVESTIGATOR

An individual selected for a Hartwell Individual Biomedical Research Award is designated by the Foundation as a *Hartwell Investigator*.

HARTWELL TOP TEN INSTITUTION

Every year the Foundation announces its Top Ten Centers of Biomedical Research in the United States, inviting each center to become a Participating Institution and nominate individuals for a Hartwell Individual Biomedical Research Award. Participating Top Ten institutions may submit up to three nominations to compete in a process that seeks to fund early-stage, innovative, and cutting-edge biomedical research. Each year Hartwell Top Ten Centers of Biomedical Research must submit at least one Nominee for the Individual Biomedical Research Award that holds a Doctor of Medicine degree or equivalent professional degree or who have been admitted and passed coursework in the fields of medicine and/or surgery from an accredited medical school (e.g., MD, DDS, DMD, DO, MBBS, etc.).

INDIVIDUAL BIOMEDICAL RESEARCH AWARD (IBRA)

Only researchers nominated by the Chief Executive of a Participating Institution are eligible for consideration for an Individual Biomedical Research Award. Each restricted IBRA is made to the individual for three (3) years support of proposed research at \$100,000 direct cost per year and funded yearly in April. The funding cycle is from April 1 to March 31. The following rules apply to the Award:

- Nominees for the Individual Award must be a citizen of the United States, must be eligible to serve as a principal investigator in biomedical research, must have adequate institutionally committed office and laboratory space adequate to perform the proposed research, and must hold a full-time appointment in the Participating Institution at the time of Nomination
- Participating Institutions may not nominate the same individual in two consecutive annual competitions for an IBRA.
- At the time of Nomination for the IBRA both the Nominee and the Chief Executive from each Participating Institution must sign the Foundation *Official Nomination* form acknowledging they have read the current *Application Process and Administrative Guidelines* for the Individual Biomedical Research Award provided by the Foundation and agree to such terms and conditions as set forth.

- IBRA recipients and the Sponsoring Institution agree to provide a recent, high resolution color photo of the Award recipient in a laboratory/technology setting that is suitable for announcement of the Award on the Foundation's web site (thehartwellfoundation.org).
- Within Foundation guidelines, IBRA recipients may determine the best use of the funds to support the direct cost of the project.
- No part of the IBRA may cover institutional overhead or other indirect costs, nor should any Award recipient be obligated or penalized to pay by substitution such indirect costs by any other means.
- IBRA recipients agree to participate in Quarterly Reviews by video conference regarding updates to progress toward goals and objectives.
- IBRA recipients agree to attend and participate each year in the full agenda of the Hartwell Annual Meeting Biomedical Research.
- IBRA recipients agree to cite "The Hartwell Foundation" as a funding source for published articles regarding the funded research and to provide in a timely manner a PDF version of all such publications to the Foundation.
- IBRA recipients may not compete for a second Individual Biomedical Research Award.
- **Change of Institution:** should a Hartwell Investigator move from their original participating institution, research funding may transfer only if the new institution is already a Hartwell designated participating institution. It shall be the obligation of the Awardee to make necessary arrangements to transfer their existing research funds. If the new institution is not a Hartwell participating institution, then all unused/uncommitted research funds must promptly be transferred back to the Foundation.
- **Resignation of IBRA:** upon resignation of the Individual Biomedical Research Award the existing participating institution must promptly return all unused/uncommitted research funds back to The Hartwell Foundation.

INSTITUTIONAL OVERHEAD AND INDIRECT COSTS

By accepting a Hartwell Individual Biomedical Research Award or a Hartwell Fellowship, the Sponsoring Institution agrees not to use any part of the funding for institutional overhead or other indirect costs and will not obligate or penalize the Award recipient or Fellow or a sponsoring research laboratory to pay by substitution such indirect costs by any other means. Except for health insurance, no portion of an award may be subject to deductions for discretionary Fringe Benefits by the Sponsoring Institution.

INTELLECTUAL PROPERTY

The Foundation waives any ownership rights in any intellectual property that may arise from work supported by either the Individual Biomedical Research Award or the Hartwell Fellowship. However, Award recipients, Fellows, and/or Sponsoring Institutions must notify the Foundation if, at any time, any patent applications are filed or received resulting from the supported research within ninety (90) days of any such filing or receipt.

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. The Foundation will conduct interviews during the first three weeks in November. Any travel expenses, including food and lodging are paid by the Foundation; the Nominee arranges travel, and the Foundation arranges lodging.

The interview will last approximately 90 minutes and will consist of a personal discussion, followed by a concise slide presentation that summarizes the details of the research proposal. To allow for

unanticipated changes in scheduling, Nominees selected for an interview are required to be available on their assigned date for a minimum of three hours before and after their scheduled interview start time. Nominees are encouraged to prepare for a professional interview and to dress appropriately.

The date and time of scheduled interviews are not negotiable and appeals for a change are accepted only in unusual circumstances, with no guarantee that a scheduled interview will be altered. Therefore, Nominees are advised to plan accordingly their availability for a potential interview, including any necessity to rearrange contemplated travel, federal study section participation, clinical service commitments or teaching requirements, as necessary. Nominees who do not complete the Interview will not receive further consideration in the Competition. All decisions by the Foundation are final.

For additional guidance, see the Hartwell Application Process: Nominee Personal Interview section of these *Application Process and Administrative Guidelines*.

MATERIAL CHANGE OF CIRCUMSTANCES

The Foundation recognizes the possibility that unexpected technical or feasibility limitations, including but not limited to those involving collaboration, conflicts involving conditions for permissible participation in funded research, or departures of supported research staff, may occur in the course of research that could necessitate the modification of original Aims, timeline and corresponding budget. However, should a material change of circumstances affect the status of an individual Hartwell Investigator or a Sponsoring Institution, the Foundation at its sole discretion reserves the right and final authority to determine the disposition of any remaining funds, including any funds that have not been disbursed pursuant to an Award, as well as any equipment purchased or made available with Hartwell support.

MILESTONES

The Foundation requires all researchers to identify detailed milestone achievements (objectives) required for achieving each Aim described in their research Proposal, including potential barriers to success and any interdependence between Aims. The Milestones, once they are agreed upon, will be reviewed in quarterly Progress Reports and may, from time-to-time, be modified appropriately to reflect research progress or a change in circumstances.

NOMINATION PROCESS

Participating Institutions selected by the 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 in the United States. Nominees should not yet have qualified for significant funding from outside sources. Participating Institutions may not nominate the same individual in two consecutive annual competitions for an Individual Biomedical Research Award.

OFFICIAL NOMINATION FORM

At the time of Nomination for the Individual Biomedical Research Award both the Nominee and the Chief Executive from each Participating Institution must sign The Hartwell Foundation *Official Nomination* form, acknowledging they have read the current *Application Process and Administrative Guidelines* for the Individual Biomedical Research Award provided by the Foundation and agree to such terms and conditions as set forth. **The Foundation will not accept electronic signatures.**

An improperly completed Nomination form will be returned to the Sponsoring Institution for correction, with the risk that the Nominee may not receive further consideration in the competition. All decisions by the Foundation are final.

OVER-EXPENDITURES

The Foundation will not provide additional funds to cover over-expenditures in any budget year.

PARTICIPATING INSTITUTION

Each year the Foundation identifies and invites a select number of institutions to participate in the Competition for Individual Biomedical Research Awards. Only invited institutions may participate in nominating candidates for the Awards. Each year a Participating Institution must submit *at least one* (1) Nominee that holds a Doctor of Medicine degree or equivalent (e.g., MD, DDS, DMD, DO, MBBS, etc.). Failure of a Participating Institution to meet this requirement may result in the loss of its status as a Participating Institution and the right to select Nominees for the Competition in the future.

PARTICIPATION RIGHTS

If the recipient of an Individual Biomedical Research Award or Fellowship, the Sponsoring Institution, and/or a separate legal entity or licensee that owns, holds, or licenses the intellectual property developed with the assistance of the recipient intends to contact or is contacted by a third party concerning possible investment (i.e. offering equity securities or membership interests in exchange for capital, etc.), then it is expected that the Foundation will be notified at least ten (10) business days prior to or offering the opportunity, including the price and terms. The Foundation shall have a right of first offer to participate in such opportunities on the same terms and for the same price as all the other investors but shall not be obligated to exercise such participation rights, and in its sole and absolute discretion may determine whether or not to invest. These participation rights are subject to compliance with applicable federal and state securities laws.

PRESS RELEASES AND MEDIA COMMUNICATIONS

The Foundation expects that all recipients of Hartwell funding will properly receive timely recognition from their Sponsoring Institution. However, prior to a press release or media publication concerning an Award, the Sponsoring Institution agrees to offer the Foundation an opportunity to review and approve the desired text for accuracy. Following such public communications, Sponsoring 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 as an additional information source: www.thehartwellfoundation.org.

PROGRESS REPORTS

Recipients of an Individual Biomedical Research Award agree to participate in reporting progress of their research, including the management of intellectual property and administration of their budget. The Foundation reserves the right to withdraw funding if the recipient does not demonstrate progress toward identified Milestones, as evidenced during Quarterly Reviews.

Quarterly Reviews – the Foundation expects all recipients of an Individual Biomedical Research Award to demonstrate progress toward identified Milestones as evidenced during Quarterly Reviews, beginning Q1: July; Q2: Hartwell Annual Meeting of Biomedical Research in late September – early October; Q3: January; and Q4: April. All Quarterly Reviews are conducted by videoconference. The Foundation schedules a mutually convenient

date and time for Quarterly Reviews with each Hartwell Investigator and requires submission of a written Research Summary prepared by the Hartwell Investigator. Quarterly Reviews must be completed within the designated month and no exceptions are made.

Research Summary – during quarterly videoconference reviews, the Foundation seeks to provide formative feedback to support and guide the individual effort of each Hartwell Investigator. It does so by guided discussion of progress using a formatted Research Summary (template provided by the Foundation) that is prepared by each Hartwell Investigator and submitted at least 24 hours prior to their scheduled review (Quarterly Reviews may not proceed in the absence of an updated Research Summary). The Research Summary describes progress toward meeting goals and objectives (including Budget), which the Hartwell Investigator may be encouraged to modify from time-to-time to account for any limitations or opportunities. The Research Summary is updated and extended quarterly in order to facilitate a longitudinal record of progress.

Scoring Performance – the Foundation may score individual Hartwell Investigator performance as a means to identify the extent and focus of required guidance that will enable the Hartwell Investigator to connect research objectives with practiced behavior in achieving desired Milestones and successful outcomes. Performance is evaluated in Quarterly Reviews against Hartwell expectations that each Hartwell Investigator will be candid, thorough, and accountable in reporting the progress of their research, including the management of intellectual property, administration of their budget, and their participation at the Annual Meeting. It is also expected that Hartwell Investigators will acknowledge and confront new challenges, including the need for any course correction to reflect research progress or a change in circumstances; and that they will collaborate with the Foundation to leverage all available resources to advance their proposed research plan.

Annual Financial Report – each year, as part of the 4th quarter review of progress, the Hartwell Investigator will provide a Budget Expense Summary (template provided). In addition, the Sponsoring Institution is required to provide to the Foundation an Official Annual Financial Report for each Hartwell Investigator by April 30.

PUBLICATIONS

The Foundation encourages publication of research results and retains no intellectual property rights in any such publication. Research publications that result from Foundation funding must provide a citation for “**The Hartwell Foundation**” as a funding source. Award recipients must notify the Foundation of all publications that result from the supported research within ninety (90) days of appearing in press and should when available, provide a PDF of the publication to the Foundation.

RESEARCH PROPOSAL

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

RESEARCH SUPPORT PERSONNEL

There are no citizenship restrictions on Key Laboratory Support Personnel involved in research funded by an Individual Biomedical Research Award.

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 by the Foundation, as mutually convenient.

SPONSORING INSTITUTION

Nominees submitted for Individual Biomedical Research Awards, Hartwell funded Investigators, and designated Hartwell Fellows are sponsored by Participating Institutions where their research or postdoctoral training is expected to take place.

START-END DATES

The official Start and End dates for all Hartwell Awards are determined by the Foundation, considering that exceptional circumstances may determine actual dates:

Hartwell Investigator – announcement of all Individual Biomedical Research Awards is made to the Participating Institution on April 1. Proposed research should commence no later than the date of receipt of funds, which are expected to be disbursed by the Foundation to the Sponsoring Institution by the end of May. To enable effective commencement of research the Foundation expects that each Sponsoring Institution will make award funds readily accessible, without delay. The end date for the Individual Biomedical Research Award is three (3) years from the date of the April 1 announcement (March 31) or following submission of a final Annual Report due April 30. However, the actual end date may be extended by the Foundation by virtue of significant carryover of funds by the Hartwell Investigator. For further information, see the Individual Biomedical Research Award rules in these *Administrative Guidelines*.

Hartwell Fellow – announcement of postdoctoral Fellowships is made to Participating Institutions that win an Individual Biomedical Research Award on April 1. Fellowship funds are made available yearly to the institution in July. To enable effective commencement of training the Foundation expects that each institution will make award funds readily accessible, without delay. In this regard, the Fellow and Mentor mutually determine an acceptable “start” and “end” date for postdoctoral research training, where postdoctoral study should commence upon receipt of funds, but in no case later than November 1 of the same year of the award announcement. The active period of the Fellowship is two years from commencement of training unless there is a desired extension by virtue of carryover funds. For further information, see the Hartwell Fellowship Rules.

Participating Institution – announcement of research institutions selected for participation in the Hartwell Competition is made each year on April 15. Participating Institutions hold their internal competition to select Nominees for the Individual Biomedical Research Award until nominations are submitted on September 15.

STRATEGIC BIOMEDICAL RESEARCH

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

STUDENT TUITION EXPENSE

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

TRANSLATIONAL BIOMEDICAL RESEARCH

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

VIDEO CONFERENCE REVIEW

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

WEB SITE PHOTO

Hartwell Investigator – Award recipient and the Sponsoring Institution agree to provide a recent high resolution color photo of the Award recipient in a laboratory/technology setting that is suitable for announcement of the Award on the Foundation's web site (www.thehartwellfoundation.org).

Hartwell Fellow and Mentor – the Fellowship recipient and the Sponsoring Institution agree to provide a recent high resolution color photo of the Fellow and the Fellow's primary mentor, taken together, in a laboratory/technology setting that is suitable for announcement of the Award on the Foundation web site (www.thehartwellfoundation.org).

Submit only high-resolution photos (e.g., 1 MB) in jpeg format. The intention should be to convey the enthusiasm of the participant(s) and in that regard, seeking a natural smile is most desirable. It is suggested that photos be composed in a laboratory setting, with an interesting background that reflects, if possible, the technology of the Award recipient. While laboratory photos often require lab coats or other appropriate gear required to meet health and safety regulations, the purpose of the photo is to show the smiling face of the recipient (i.e., no face masks or safety glasses). Multiple photos may be submitted for consideration by the Foundation.

For the Hartwell Fellowship, effort should be made to adjust the composition of the photo to keep the Mentor positioned close to the Fellow (e.g., standing slightly behind the Fellow), which will enable a close-up after cropping the image to achieve desired size.