

## Introduction

The TE Hubbell Kidney Cancer Warrior Institute Grants Policy Statement is intended to make available in a single document the general terms and conditions of discretionary grant and cooperative agreement awards. These general terms and conditions apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary.

This document also is designed to be useful to those interested in the TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grants process by providing information about that process and its associated authorities and about responsibilities. The TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE Grants Policy and Procedure is available online at <http://www.kcwi.org>.

## Grant Policies and Procedures

For research and educational grants:

TE Hubbell Kidney Cancer Research Institute  
Grant Programs  
920 Greenbriar Cove Road  
Union Grove, AL 35175  
Phone: 256-508-7544  
Email: [belinda.hubbell@TE Hubbell Kidney Cancer Warrior Institute.org](mailto:belinda.hubbell@TE Hubbell Kidney Cancer Warrior Institute.org)  
Website: [www.TE Hubbell Kidney Cancer Warrior Institute.org](http://www.TE Hubbell Kidney Cancer Warrior Institute.org)  
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## **Introduction**

A Research and / or educational grant is provided to support a research plan as presented in a grant application (including approved modifications, if any) and approved for funding by TE Hubbell Kidney Cancer Warrior Institute. The specific terms and conditions applicable to a Grant awarded by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE are set forth in these policies and procedures and the grant agreement, which incorporates by reference these policies and procedures. The grant agreement must be signed on behalf of the grantee institution (“Grantee Institution”) by an administrative official who has signatory authority and also must be signed by the principal investigator. For purposes of this policy and procedures, the Grantee Institution and Principal Investigator will be referred to as “Grantee”. In case of multiple grantee institutions or multiple investigators involved will refer collectively to all involved.

### **1.0 Requirements of Individual Grant Mechanisms**

Each TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grant mechanism has unique characteristics, such as duration, funding levels, receipt designations, eligibility requirements, project requirements and authorized budget allocations. For grants submitted in response to a Request for Applications, these characteristics and requirements are detailed in the request for that grant and are incorporated by reference into the policy and procedures.

### **2. Online Procedures**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grants are managed through the TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grant program. The principal investigator and associated organization who originally submitted application materials through the TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grant system will submit the request to the TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE grant program. All grant agreements and subsequent amendments will be executed by manual signatures.

### **3. Grant Agreement Execution and Award**

#### **3.1 Applicant Certification**

Prior to initiation of the contracting process, applicants must certify that the signature process will be manually controlled.

#### **3.2 Submission of Required Documents**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE requires submission of process information, applicant information, and regulatory documents (known as “Required Documents”). These include:

- Institutional W-9 form
- Automated Clearing House (ACH) electronic funds transfer information
- Institutional Review Board and / or Institution Animal Care and Use Committee Regulatory documents
- Institutional contracts
- Updated biographical narrative and picture of principal investigator and co-investigator.
- Sources of other financial support

All documents must be sent within sixty (60) days of notification of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's intent to fund. All requested documents must be received and approved prior to release of a final Grant Agreement. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE reserves the right to withdraw a notice of intent to fund should the Required Documents not be received.

### **3.3 Release of Final Grant Agreement**

The final grant agreement must be signed by the Principal Investigator, the Grantee Institution within thirty (30) days of its release. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE reserves the right to withdraw a notice of intent to fund should the final agreement not be returned in a timely manner.

### **3.4 Evaluation for Duplicative Funding**

Applications for research funding require applicants to list all other research support including project title and specific aims. Potential overlap is reviewed prior to awarding a Grant. It is the principal Investigators responsibility to notify TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE of duplicate funding. Investigators may not receive funding that would result in duplication of funding for the same research and / or educational activities being conducted by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.

### **3.5 Grant Effective Date**

The effective date of the Grant Agreement is the date on which TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE signs the Grant Agreement. This date serves as the basis for the anniversary date for the Grant. No work may be charged prior to this effective date.

### **3.6 Delays in Grant Start Date**

The applicant may request a delay of the start date of the Grant of up to 3 months from the date that TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE notifies of intent to fund. An extension form must be completed and resubmitted to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE for approval.

#### **4. Organizational Assurances**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE does not assume any responsibility for the conduct of a Research Plan or for the activities of the Principal Investigator or the Grantee Institution since they are under the scope and direction of the Grantee Institution and subject to its policies. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE does however; require that Grantee disclose at the time of application whether human subjects, human biological/anatomical materials, animals, recombinant DNA, biohazardous materials, or genetically engineered mechanisms will be utilized in the proposed research and to receive assurance that the principal investigator and the Grantee Institution will implement the necessary safeguards in the projects funded by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.

##### **4.1 Research Involving Human Subjects**

Research involving human subjects will be guided by one of the following statements of ethical principles:

- The World Medical Association's Declaration of Helsinki (as amended in 2008).
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical Research; or
- Other appropriate international ethical standards recognized by U.S. Federal Departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

##### **4.2 Research Involving Human Biological / Anatomical Material**

Research involving the use of human biological and / or anatomical materials will be guided by the recommendations set forth in the National Institutes of Health, Office of Human Subjects Research Medical Administrative Series (MAS) #M01-2 entitled "Procurement and Use of Human Biological Materials for Research." Summary information about the recommendations of the Tissue Resource Committee from which policies were developed and the policies and procedures contained in the MAS can be found at <http://ohsr.od.nih.gov/info/sheet 17.html>. Grantees from outside the United States must follow the guidelines established by an international equivalent governing the protection of human research subjects. In addition to the above, applicants must disclose in the grant application if the project involves recombinant DNA, biohazardous materials, genetically engineered mechanism, human fetal tissues, and / or human anatomical substances. Whenever applicable, the research protocol will be reviewed and approved by the Grantee Institution's biohazards committee and conform to the relevant PHS guidelines.

##### **4.3 Research Involving Animals**

Research involving animals will be guided by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals or the International Guiding Principles for Biomedical Research Involving Animals or equivalent guidelines of an international animal welfare board.

#### **4.4 Required Documentation**

The following institutional approvals must be obtained by the Grantee and provided to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE prior to the involvement of human subjects, biological/anatomical material, or animals in TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE funded research.

**Important:** TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may withhold a Grant payment until Grantee submits all required documentation, including but not limited to the above listed documents. Grantee is required to submit a yearly renewal of the above documentation with each of its annual scientific progress reports.

#### **Human Subjects & Biological/Anatomical Material Use Assurances**

- Documentation of review and final approval by the Institutional Review Board or international local ethics board equivalent including the type of review obtained; expedited or full board review.
- Verification of compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) or international equivalent.
- Documentation of Office of Human Research Protection (“OHRP”) assurance or international equivalent.
- Assurance that any research involving human subjects will be guided by one of the following statements of ethical principles: a) The World Medical Association’s Declaration of Helsinki (as amended in 2008), b) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection Biomedical and Behavioral Research; or c) other appropriate international ethical standards recognized by U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.
- Samples of the human subject, patient, and/or biological/anatomical information informed consent documents.

#### **Animal Use Assurances**

- Documentation of the review and final approval of the Institutional Animal Care and Use Committee (“IACUC”) or international animal welfare board equivalent.

#### **Human Subjects & Biological/Anatomical Material Use Assurances Requirements:**

**Documentation must:**

- Describe the same studies proposed in the Research Plan. The Grant project title does not need to be an exact match.
- Stipulate the project's approved beginning and/or renewal and expiration dates.
- Be written on Grantee Institution letterhead.
- Be written in English and signed by Principle Investigator and Grantee Institution authorized agent.

**For Animal Use Assurances Requirements:**

**Documentation must:**

- Describe the same studies proposed in the Research Plan. The Grant project title does not need to be an exact match.
- Stipulate the project's approved beginning and expiration dates.
- Be written on official Grantee Institution letterhead.
- Be written in English and signed by Principle Investigator and Grantee Institution authorized agent.

**4.5 Government Compliance:**

Grantee must comply with all applicable laws in connection with its use of the Grant including but not limited to PHS regulations, Final Rule CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research, as may be amended from time to time. Grantee must cooperate with TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in supplying additional information to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and in complying with any procedures that might be required by any governmental agency in order for TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE to establish that it has observed all requirements of the law with respect to the Grant.

**5.0 Required Grant Reports**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's policies for managing research grants from the time of initial award through completion seek to maximize flexibility while maintaining the highest standard and preserving the integrity of the peer review and funding process. Throughout the term of the Grant, scientific progress will be monitored by Grant Managers assigned to the Grant. Grantee is encouraged to communicate regularly with its Grant Managers. Format and content requirements for Grant progress, financial, and final research reports are reviewed by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE annually. Grantee is responsible for reviewing and complying with all reporting requirements in effect at the time reports are due.

For questions related to submissions, project and/or scientific questions Grantee should contact Grant Manager assigned to the Grant.

**5.1 Quarterly and Annual Scientific Progress Reports**



Grantee is required to submit annual scientific progress reports that detail the research progress, challenges, the remedy, research outcomes, and inventions occurring during the reporting period. Scientific progress reports are due on each anniversary of the Grant date for the duration of the project. Final Research report is described in section 5.4 below.

The required content must be including the following:

- **Hypothesis & Specific Aims**
  - The overall hypothesis of the entire project.
  - Progress on each specific goal in the research plan, including a description of progress, justification for delays or changes, the projected completion date for research addressing the specific goal, and current status. Justification and approval by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will be required prior to implementation of any changes to the research design or specific goals and must be submitted for approval using the Change of Research Plan request form.
- **Research Outcomes**
  - A list of the research accomplishments during the reporting period.
- **Publications, Presentations & Posters**
  - A list of all manuscripts submitted, in press or published, with full publication information.
  - A list of all posters or presentations displayed or presented at scientific meetings.
- **Patents, Products, Copyrights & Intellectual Property**
  - A list of all patents or patent applications filed during the reporting period directly resulting from TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE funding.
  - A list of the specific research products developed during the reporting period. Examples of products include novel therapeutic targets, biomarkers, vectors, novel therapies, risk assessment tools and/or algorithms, new technologies, educational materials, etc..
- **Professional Awards & Promotions**
  - A list of all professional awards and promotions received by any of the key personnel during the reporting period.

### **5.3 Research Publications**

During the Grant term, Grantee is responsible for ensuring TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE is notified immediately upon the acceptance of a manuscript for publication and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE is acknowledged as a funding source on all publications related to the project with the statement “This research was supported by a grant from the TE Hubbell Kidney Cancer Warrior Institute (TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE).

#### **5.4 Final Research Report**

A final research report must be provided within thirty (30) days after the end date or early termination of the Grant term and must include all items specified above.

#### **5.5 Final Financial Report**

A final financial report is due within forty five (45) days after the end date or early termination of the Grant term. All unexpended funds must be remitted immediately to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE upon submission of the final financial report.

#### **5.6 Other Reports and Engagements**

With reasonable prior notice to Grantee, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may require additional reporting from Grantee and may also require Grantee to participate in site visits, telephone conferences, presentations or other speaking engagements. In such cases, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall use good faith efforts to accommodate Grantee's scheduling conflicts.

#### **5.7 Non-Confidential Nature of Reports**

Scientific progress, financial, and final research reports are not considered confidential. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may use third parties who have expertise to review the reports and evaluate the progress of the project. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will share Grant information with donors who have provided financial support for TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE research. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will not be responsible for any damages resulting from the disclosure of the content of the reports to such parties. Therefore TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE recommends that Grantee does not include any information in the reports that public disclosure might result in a waiver of the opportunity to obtain a patent.

#### **5.8 Timely Submission of Reports**

Failure to provide timely and complete reports will constitute an event of default of the Grant Agreement, which at TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's sole discretion may result in, among other things, the early termination of the Grant, reimbursement to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE for expended and unexpended Grant funds, and preclude Principle Investigator and / or Grantee Institution from future TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE funding.

### **6. Funding and Payments**

#### **6.1 Duration**

The project will be supported for the time specified in the Research Plan and reflected in the Grant Agreement.

## **6.2 Consortia and/or Subcontracts**

As part of the initial Grant, a Grantee may subcontract with a third party to assist with a project by establishing a consortium or subcontract agreement whereby a research project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee can elect to contract for performance of a portion of the activities. All consortia and subcontracts are subject to and must comply with the Grant Agreement, which incorporates these policies and procedures entered into by Grantee and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, and it is the responsibility of Grantee to ensure compliance.

## **6.3 Ownership of Research Equipment**

Equipment costs cannot exceed thirty percent (30%) of the total direct costs. Approved equipment purchased during the term of a TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE funded project is intended for the use of the Principle Investigator, their staff, and any collaborators. Title of the equipment shall be vested in the Grantee Institution conducting the project. However, in the event of an approved transfer of a Grant to another Institution, the equipment necessary for the continuation and success of the project may be transferred to the new institution with prior written approval from TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. Upon completion of the project all equipment shall remain at the Grantee Institution.

## **6.4 Payment Schedule**

All Grant funds must be expended in accordance with the project's approved budget. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will disburse the funds thirty days after the effective date of the Grant. All project reports must be submitted prior to additional funds being released.

## **6.5 Payment Form**

Grantee will receive a hard copy check if electronic transfer is not available.

## **6.6 Indirect costs**

Indirect costs are not allowed in the Grant projects.

## **6.7 Expenditures Out-of-Scope of Grant**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will not be responsible for any expenditure made that is out-of-scope of grant.

## **6.8 Personnel Costs**

No personnel on the Grant may have a base salary above \$190,000 per year.

## **6.9 Audits**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE or its designated representative shall have the right to request and receive from the Grantee Institution and Principle Investigator copies of any and all documents and other information related to the Grant at any time during or after the term Grant. This right includes but not limited to the right to review all financial books and records of the Grantee Institution and Principle Investigator related to the Grant and to perform an audit or other accounting procedure of all expenses related directly or indirectly to the Grant.

## **7.0 Changes in Grant Status**

All changes in Grant status are considered amendments to the Grant Agreement and must be submitted as changes to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.

### **7.1 Changes in Research Plan**

Changes in research design and/or specific goals require a change request and obtain approval by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. Minor adjustments do not require written approval, but must be communicated to Grant Manager at TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE encourages communication between the principle investigator and the grant manager and must include: the specific change, the reason for the change, and a revised research plan.

### **7.2 Change of Grantee Institution**

All changes in the Grantee Institution require prior approval from TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.

From The Principle Investigator:

- A final research report defining status at Original Grantee Institution.
- Reason for departure.
- Plans for continuation of the project and confirmation that the transfer will not alter the project's plans.
- Effective date of transfer.
- New Institution name, address, and phone number.
- Signature of Principle Investigator.

**From the Original Grantee Institution:**

- A signed request form from the original Grantee Institution relinquishing the Grant to the new institution signed by an authorized agent.
- Completed Change of Grantee Final Expenditures signed by principle investigator and grantee authorized business agent.

- A check for any unexpended funds sent to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.

**From the New Institution:**

- Signed request document from the new institution stating its willingness to accept the Grant under the terms and conditions of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's Policies and Procedures. This request must be signed by the new principle investigator and the authorized agent at the new institution.
- IRB/HIPAA/IACUC approval from the new institution.
- Budget for the remainder of funds for the Grant term.

Once TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE is in receipt of and has reviewed the above information and documents, and has approved the Grant transfer, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will submit a new Grant Agreement to be signed by the new institution. Upon receipt of a fully executed Grant Agreement from the new Institution TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will notify the original Grantee Institution of the termination of its Grant Agreement and forward the reimbursed funds according to Grant agreement.

**7.3 Change of personnel**

Changes in the Principle Investigator will be made only under extreme circumstances (retirement, incapacity, or death).

Changes in key personnel who dedicated more than 20% time to a Grant must submit a change form. The documentation required for change of key personnel (20% or more time to Grant) include: the reason for personnel change, verification of eligibility of new personnel, verification of qualifications, verification of availability of new personnel, and description of how the change will affect the scope of work, implementation and timeline of the research project.

**7.4 Early termination by Grantee for any Reason (Except Default)**

A Grantee may terminate a Grant early and return all unexpended funds. A final research report, and a final financial report, along with a check for any unexpended funds shall be mailed within sixty (60) days after early termination. All reports must be signed by principle investigator and authorized agent of Grantee Institution.

**8.0 Intellectual Property**

**8.1 Publications and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE Licensed Marks**

TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will release information regarding the Grant, including pictures of the Principle Investigator, as well as the research summaries, scientific progress and final reports, to the general public and news media. Grantee shall ensure that

Grantee has the authority to grant TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE the right to publish the works and photographs related to the project.

Grantees are encouraged to publish the results deriving from their TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE-funded research project. Grantees must release all information regarding the Grant under the following terms and conditions:

- TE Hubbell Kidney Cancer Warrior Institute shall grant to Grantee Institution a limited, non-exclusive license to use the TE Hubbell Kidney Cancer Warrior Institute name and signature logo solely for the purpose of acknowledging TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's funding of the project. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will provide the Grantee Institution with camera-ready artwork of said licensed marks. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall retain all right, title and interest in and to the Licensed Marks, all of which shall remain the exclusive property of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. All use of the Licensed Marks shall be in accordance with, and subject to, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's quality control and standard trademark guidelines. Grantee Institution shall return such artwork to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE upon completion of the project or earlier, at TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's request.
- Grantee Institution must acknowledge TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE as a funding source on all publications and in all presentations related to the project in a clear, unambiguous, and readily-identifiable fashion, using the following acknowledgement: **"This research was supported by a grant from TE Hubbell Kidney Cancer Warrior Institute"**. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE reserves the right to offer grant-naming opportunities to donors and corporate partners, and depending on the Grant awarded, Grantees may be required also to acknowledge such donors or partners.
- Grantee Institution will present to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, prior to printing, distribution, publication, display or use, any and all promotional materials, publications, articles, pictures, press releases and scripts of all statements, oral and written, to be made by the Grantee Institution, the Principle Investigator, their agents or spokespersons, which use or refer to the Licensed Marks. Such materials and statements must reference the Licensed Marks with a registered trademark symbol, and must be of high quality consistent with Grantee Institutions' and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's public image. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall have approval rights with respect to the use of the Licensed Marks in the materials and statements submitted by Grantee Institution. Additionally, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may require, at its sole discretion, the removal of the Licensed Marks from any of the materials and statements at any time during the project.

- Copies of all other news releases, articles, pictures, and any other published material, which may be developed in connection with the project or the grant, shall be furnished by Grantee Institution to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE prior to publication, or as soon thereafter as practical.

## **9.0 TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE Policy on Intellectual Properties and Royalties**

Discoveries, works of authorship, or inventions derived from research performed, supervised or subcontracted by the Principle Investigator and the Grantee Institution during the term of the Grant will be subject to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's Patent, Intellectual Property, and Technology Transfer Policy as set forth:

- The primary purpose of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in funding meritorious research is to advance its mission to find a cure for Kidney Cancer. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE recognizes, however, that Inventions (as defined below) having public health, scientific, business, or commercial application or value may be made in the course of research supported by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. It is the desire of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE that such inventions will be administered in such a manner that they are brought into public use at the earliest possible time. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE recognizes that this may be accomplished through the filing of applications for registration of patents and/or copyrights in such inventions and the commercial licensing of such inventions to third parties.
- All inventions shall be reported to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in writing within three (3) months after their conception or discovery.
- In the event that the Grantee Institution/Inventor desires to file a patent or copyright application or assert any intellectual property right in the invention, such Grantee Institution shall notify TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE immediately in writing and upon TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's request, shall provide TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE with all documentation relating to the filing or assertion of rights. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall agree to maintain the confidentiality of such documentation by executing a confidentiality agreement mutually agreed to by the Grantee Institution/Inventor and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE.
- In the event that the Grantee Institution/Inventor contemplates entering into a license, lease, sale, assignment or revenue-generating agreement relating to the invention (collectively, a "Commercialization Agreement"), any such Commercialization Agreement shall be reviewed by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. To the extent such agreement names TE HUBBELL KIDNEY

CANCER WARRIOR INSTITUTE as a party or otherwise subjects TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE to potential liabilities or responsibilities, such agreement shall be approved by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE prior to execution. If the Grantee Institution has an established and applicable patent, intellectual property, or technology transfer policy, and procedure for administering inventions, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE will defer to that policy with the following restrictions:

- TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall be granted the non-exclusive, royalty –free license to practice the invention for non-commercial research purposes. This license will be subject to any restrictions on use or other limitations set forth in any Commercialization Agreement entered into by Grantee Institution/Inventor. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall participate in the income (net of any direct out-of –pocket patenting or licensing costs) derived from the invention, unless TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE’s sharing of net income shall be directly proportionate to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE’s proportion of support for the research giving rise to the invention, but in no event shall exceed fifty (50%) of the total net income earned. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE waives receipt of any income until the net income from the invention exceeds \$250,000.
- No patent or patent application, copyright or other intellectual property right will be abandoned without prior notification to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and without giving TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE the opportunity to take title to the invention to the extent permitted by law.
- The Grantee Institution/Inventor, when it licenses an invention to another party for commercialization, shall include provisions in the Commercialization Agreement obligating the licensee to commercialize the invention in a diligent manner and include appropriate diligence requirements and milestones, and shall monitor the licensee. Unless otherwise agreed by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in writing, the Grantee Institution shall agree that:
  - If it or its licensee has not taken effective steps within (3) three years (or whatever is a reasonable longer time in the circumstances) after issuance of a patent or a clear determination of commercial value in an invention practical or commercial application through licensing or otherwise on terms that are reasonable in the circumstances; and
  - If it or its licensee cannot show reasonable cause why it or its licensee should retain title to and all rights in the administration of the invention for a further period of time, then unless no other parties have superior rights (as provided under this Policy), TE



HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall have the right to require the institution or its licensee:

- a) To license (on an exclusive basis where possible) said patent or intellectual property right to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE with the right to grant sublicenses;
- b) To cancel any outstanding exclusive licenses;
- c) To grant licenses under said patent or intellectual property right on a non-exclusive, royalty-free basis or on such other terms that are reasonable in the circumstances to third parties; and/or
- d) To compel such other reasonable disposition of the invention rights as may be mutually agreed upon in writing by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and the Institution and/or its licensees.

If the Grantee Institution has not established and applicable patent, intellectual property, or technology transfer policy, and procedure for administering inventions, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall have the sole right to determine the disposition of the invention rights in a manner consistent with this Policy. In such cases, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may, in its sole discretion, elect to do one or more of the following:

- a) Have a patent and/or copyright application filed, and decide to whom it shall be assigned. In such a case, the Institution and the Inventor shall execute all documents necessary to assist in the filings and the assignment;
- b) Decide that patent or copyright should be or not be filed;
- c) Release the invention to the Inventor or Inventor's designee;
- d) Submit the invention to a qualified organization for administration and licensing;
- e) Determine by negotiation the fair share of royalty income to be paid to the Inventor, the Grantee Institution, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, and any other parties who contributed funds that supported the invention; or
- f) License or make other arrangements for the application and use of the invention on an exclusive or non-exclusive, royalty-free basis as seems reasonable in the circumstances.

Notwithstanding any other provisions of this policy, if an invention is derived from research funded by the joint support of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and an agency or department of the United States Government, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall defer to the patent intellectual property, or technology transfer policy of that agency or

department upon written receipt of a written statement by the appropriate agency or department notifying TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE of its policy and procedures and identifying the right and interests of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in the invention.

If any invention is funded by the joint support of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and a health agency or funding organization, other than an agency or department of the United States government, and that other agency or organization has an intellectual property policy that conflicts with TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's policy, the other agency or organization, the Inventor, the Institution, and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE shall negotiate in good faith a mutually satisfactory disposition of the invention rights.

The right of TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE to participate in revenue derived from an invention may only be waived in writing, and no provision of these Policies and Procedures shall constitute such a waiver.

## 10.0 Sample Grant Agreement

### TE Hubbell Kidney Cancer Warrior Institute

#### Grant Agreement for Research and Education Grants

Date Stamp

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Principle Investigator Last Name	First Name	Middle Initial
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Degree	Grant Number
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Grantee Institution	Grant Term
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Project Title	Grant Amount ( US Dollars)
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In consideration of the above referenced Grant from TE Hubbell Kidney Cancer Warrior Institute and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the above referenced Principle Investigator and the Grantee Institution (collectively, the Grantees) and TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE agree to comply with the following terms and conditions. All terms not defined herein shall have the meanings assigned to them in the Policies and Procedures for Research and Education Grants; Revision A, dated May 2012. This Agreement shall be null and void if not executed by all parties on or before \_\_\_\_\_ date.

**1. Policies and Procedures for Research and Education Training Grants:**

The Grantees represent that they have read and understand the attached Policies, which shall be incorporated herein by reference and shall be deemed an integral part of this agreement. In the event of any conflict between the Agreement and the Policies, the terms of the Agreement shall prevail. To the extent that this Agreement, including the attached Policies, does not address a particular issue, the Grantees shall defer to and comply with the policies and procedures of the Grantee Institution.

## **2. Certifications, Representations and Warranties and Covenants:**

- a) The Grantees certify that to the best of their knowledge, the information provided in their grant application (The “Application”) is complete and true. The Grantees agree to promptly notify TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE of any changes to the information provided in the Application.
- b) The Grantees agree to comply with all applicable laws and regulations, including but not limited to the Health Insurance Portability & Accountability Act (HIPAA) of 1996, in connection with this Grant. The Grantees certify that the grant funds awarded hereunder shall be expended in accordance with all applicable anti-terrorist financing and asset control laws, statues, and executive orders, including but not limited to the USA Patriot Act and US Executive Order No. 13224.
- c) The Grantees represent and warrant that any research or activities that might involve human subjects have been approved by an Institutional Review Board, or international local ethics board equivalent; any human subjects research will be performed by institutions or entities with an Office of Human Research Protection (OHRP) assurance or international equivalent; and that any research involving human subjects will be guided by one of the following statements of ethical principles:
  - i. The World Medical Association’s Declaration of Helsinki (as amended in 2008);
  - ii. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or
  - iii. Other appropriate international ethical standards recognized by the U.S. federal governments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.
- d) The Grantees represent and warrant that any research involving the use of human biological and/or anatomical materials will comply with the recommendations set forth in the National Institutes of Health, Office of Human Subjects Research Medical Administrative Series (MAS) #M01-2 entitled “Procurement and Use of Human Biological Materials for Research”. Grantees from outside the United States must follow the guidelines established by an international equivalent governing the protection of human research subjects.
- e) The Grantees represent and warrant that any research involving animals has been approved by an Institutional Animal Care and Use Committee (IACUC) or international animal welfare board equivalent; and will be guided by the current Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals or the international Guiding Principles for Biomedical Research Involving Animals.
- f) The Grantees represent and warrant that wherever applicable, the research protocol will be reviewed and approved by the Grantee Institution’s biohazards committee and conform to the relevant PHS guidelines.
- g) The Grantees represent and warrant that they have not accepted and will not accept duplicate funding for the project which is the subject matter of this Grant.

- h) Each signatory for each entity that is a party to this agreement represents and warrants in his or her capacity and has been duly authorized to execute this agreement on behalf of the entity so indicated and that no additional authorization or approval is required.
- i) Each entity party represents and warrants that it has all the requisite power and authority to execute, deliver, and perform this agreement and consummate the transactions contemplated hereby. The execution, delivery and performance of this agreement and the consummation of the transactions contemplated hereby have been duly authorized and approved by all required action on the part of such party. This agreement has been duly and validly executed and delivered by each party and constitutes the legal, valid, and binding obligation of such party, enforceable against it in accordance with its terms.
- j) None of the execution and delivery of the agreement by the Grantee Institution, the consummation of the transactions contemplated hereby or compliance by the Grantee Institution with any of the provisions hereof conflict with, or result in any violation of or default under (with or without notice, the lapse of time or both) or give rise to a right of termination or cancellation under any provision of: a) the certificate of formation of the Grantee Institution; b) any contract or permit to which the Grantee Institution is a party or c) any applicable law or any order of any governmental body.

**3. Grant term and Remittance of Funds:**

The term of this agreement shall be effective as of the date hereof and shall terminate on the date provided above, unless extended in accordance with the Policies. Notwithstanding the above, this agreement may be earlier terminated a) in accordance with the default provisions below or b) by any of the Grantees for any reason upon written notification to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. The grant funds awarded hereunder may not be obligated or extended prior to the effective date of this agreement or subsequent to the termination of this agreement, except to liquidate authorized obligations in accordance with the Policies. Upon expiration or early termination of this agreement by any of the Grantees for any reason, all unexpended grant funds must be remitted to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE no later than 60 days after the expiration or early termination date.

**4. Default and Early Termination:**

- a) If TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE should fail to perform or be in breach of any warranties, representations, covenants, or obligations contained in the agreement, or anticipatorily breach this agreement, and such default is not curable or such default is curable but remains uncured for 30 days after written notice thereof has been given to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, the Grantees collectively, and at their election, may immediately terminate this agreement with written notice to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE. In the event of a termination due to a breach, the Grantees shall provide TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE with a final research report within 30 days, which shall include all information available as of the termination date, and a final financial report and reimbursement of all expended funds within 60 days after the early termination date.
- b) If any of the Grantees should fail to perform or be in breach of any of the warranties, representations, covenants, or obligations contained in this agreement, or anticipatorily

breach this agreement, and such default is not curable or such default is curable but remains uncured for 30 days after written notice thereof has been given to the Grantees, TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, at its sole election, may immediately terminate this agreement with written notice to the Grantees. In the event of a termination due to a breach, the Grantees shall provide TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE with a final research report within 30 days, which shall include all information available as of the termination date, and a final financial report and reimbursement of all unexpended funds within 60 days after the early termination date.

- c) TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE has the right to terminate a Grant immediately at any time during the project period in the event of the occurrence of any one or more of the following events:
- a. Grant funds cannot reasonably be expended in accordance with the budget;
  - b. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE does not receive a scientific progress report and/or financial report when due and/or such reports do not contain the required information or the information included is not satisfactory as determined by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in its sole discretion;
  - c. The personnel and/or the research project change and any or all of these changes are not previously approved in writing by TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE;
  - d. Grantee Institution loses or changes its Internal Revenue Service tax-exempt status;
  - e. Grantee Institution or Principle Investigator is debarred from the receipt of federal or state funding;
  - f. Principle Investigator is absent from or leaves the Grantee Institution without 60 days prior notification to and receipt of written approval from TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE;
  - g. Principle Investigator transfers to another institution without consensus among TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE, Principle Investigator, and the original and new Grantee Institutions about transfer of project;
  - h. Grantee Institution and Principle Investigator fail to receive and maintain the IRB< HIPAA< and/or IACUC (or clearly designated appropriate bodies of Grantee Institution) approval of the project;
  - i. Grantee Institution or Principle Investigator fails to comply with the obligations under “TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE Policy on Intellectual Property and Royalties” and Required Grant Reports” in the Policies and other material terms and conditions of this agreement; or
  - j. Grantee Institution or Principle Investigator commits a will breach of this agreement or an act of gross negligence or willful misconduct in connections with the project.

In the event of an early termination due to any of the above events, Grantee shall provide TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE within 30 days after the termination date a final research report, which shall include all information available as of the termination date and within 60 days I) a final

financial report 2) reimbursement for the full amount of funds granted that have been expended in connection with and subsequent to any of the above events; and 3) a refund of all unspent funds as of the termination date.

- d) TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE has the right to terminate a Grant immediately at any time during the project period and receive within 30 days after termination a final research report, and within 60 days after termination a final financial report and reimbursement of all funds awarded in the event it has a reasonable good faith basis to believe there has been scientific misconduct, financial or administrative impropriety, or fraud committed by Principle Investigator or the Grantee Institution.

**5. Government Compliance:**

The Grantees shall comply with all applicable laws in connection with their use of the Grants funds awarded under this agreement, including but not limited to PHS regulations, Final Rule, CFR Part 50, Subpart F, and Responsibility of Applicants for Promoting Objectivity in Research, as may be amended from time to time. The Grantees will cooperate with TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE in supplying additional information to TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE and in complying with any procedures that might be required by any governmental agency in order for TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE to establish that it has observed all requirements of the law with respect to the Grant.

**6. Liability and Insurance:**

- a) Grantee Institution shall be responsible for all aspects of the research, investigation, funding and administration of or in connection with the Grant.
- b) To the extent permitted under the international, federal, state, and local laws which govern the Grantee Institution, the Grantee Institution shall indemnify and hold TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE harmless from and against any and all costs, losses, or expenses, including reasonable attorney's fees, that TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may incur by reason of the connection of the Grantee Institution and/or Principle Investigator's negligence or misconduct or any third party claim arising out of or in connection with the project which is the subject of the Grant. If this provision is prohibited under the laws that govern the Grantee Institution, then this provision shall be deemed unenforceable and shall have no force and effect.
- c) In the event of any dispute out of this agreement, the parties shall use good faith efforts to resolve their differences amicably. In the event they are unsuccessful, the parties agree not to commence litigation until attempting to resolve their dispute through mediation. Either TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE on the one hand or the Grantees on the other hand may initiate the mediation process with 30 days written notice to the other party. The dispute shall be submitted to mediation in Huntsville, Alabama. Mediation of the dispute shall be completed within 15 days of commencement, unless the parties extend the time by mutual agreement or unless the mediator declares the parties to be at an impasse. Any dispute arising out of or in connection with this agreement that is not able to be

resolved as stated above shall be filed and heard in the state or federal court of Huntsville, Alabama, and the parties consent to the exclusive jurisdiction of such courts.

- d) Grantee Institution shall be required to maintain adequate liability insurance comparable to coverage by institutions of similar size and nature, covering the Principle Investigator, employees, officers, and agents of Grantee Institution for the duration of the project. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE may request to be provided certificates evidencing the insurance coverage at any time during the term of the project.

**7. Miscellaneous:**

The nature of this arrangement is a funding agreement, and no employment, partnership, joint venture, or agency relationship is created. The Grant is accepted by the Grantees with the understanding that TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE is not obligated to provide any additional financial support, or other support in connection with the Grant or project to which the Grant is applied or for any other reason. TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE reserves the right to modify the terms or conditions of this agreement with 30 days written notice to the Grantees. None of the Grantees may assign any rights or obligations under this agreement without TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE's prior written consent. In the absence of such prior written consent, any such assignment will be void. This finding by any court of competent jurisdiction that any provision of this agreement or part thereof is unenforceable shall not affect enforceability of the remaining provisions of this agreement. This agreement shall be governed by and construed in accordance with the laws of the State of Alabama. If and to the extent any provision of this agreement is found to be prohibited under, contrary to, or ineffective under any existing or future law, this agreement shall be considered amended to the smallest degree necessary to make this agreement conform to such law and be effective there under. The terms of Sections 2,3,4,5,6 and 7 of this agreement and the provisions of "Publications and Licensed Marks" and "TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE Policy on Intellectual Property and Royalties" in the Policies shall survive the termination of this agreement. This agreement may be executed by the parties hereto in counterparts, including by facsimile transmission, each of which when so executed shall be deemed an original and all of which together shall constitute one and the same agreement.



Agreed To and Accepted:

**Grantee Institution:**

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Signing Official Signature:

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Signing Official Printed Name:

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Signing Official Title:

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Date:

**Principle Investigator:**

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Principal Investigator Signature:

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Principle Investigator Printed Name:

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Principle Investigator Title:

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Date:

**TE Hubbell Kidney Cancer Warrior Institute:  
d/b/a TE HUBBELL KIDNEY CANCER WARRIOR INSTITUTE:**

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Signing Official Signature:

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Signing Official Printed Name:

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Signing Official Title:

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Date: