LifeSource supports research and provides every family we work with the opportunity to help others through research. Our process for accepting research protocols includes the researcher agreeing to including LifeSource and donor family acknowledgement in any publications related to the research project. We also require that researchers agree that they will maintain confidentiality of the donors information and it will only be used for the research project approved.

Please complete the following information to process the application:

**Contact Information for Requester/Investigators**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator(s): (*include curriculum vitae)* | First: | Middle: | Last: |
| Investigator’s Address: | City: | State:  | Zip: |
| Telephone: | Email: | Fax: |

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator(s): (*include curriculum vitae)* | First: | Middle: | Last: |
| Investigator’s Address: | City: | State:  | Zip: |
| Telephone: | Email: | Fax: |

|  |  |  |  |
| --- | --- | --- | --- |
| Organizational Affiliation(s): |  |  |  |
| Project Title: |  |
| Does this research require IRB approval? | [ ]  Yes – include a copy of the proposal and the letter of approval by the IRB. | [ ]  No – provide explanation of IRB exemption:  |

|  |  |  |  |
| --- | --- | --- | --- |
| The research proposal involves: | [ ]  Research Only | [ ]  Research and Clinical application | [ ]  Clinical Application Only |

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsor's Name: | First: | Middle: | Last: |
| Sponsors Address: | City: | State:  | Zip: |
| Telephone: | Email: | Fax: |
| [ ]  Faculty/Staff Research | [ ]  Faculty Sponsor Sponsor Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Have you submitted a proposal to another agency for this same project? [ ]  N/A [ ]  Yes, Attached

**Project Details**

|  |  |
| --- | --- |
| Project Start Date: |  |
|  |  |
| What type of Organ/Eye/Tissue to be procured:🞏 If requesting Data only, please check here |  |
| Number of organ/eye/tissue specimens required: |  |
|  |  |

|  |  |  |
| --- | --- | --- |
| If there is a Funding Agency, please provide name and amount. | Name: | Amount: |
|  |  |  |  |
| Does this research involve the use of investigational drugs or agents with regard to the above donor population? | [ ]  Yes  [ ]  No |

**Abstract (limit 500 words)**

|  |  |
| --- | --- |
| **Clearly state the hypothesis or research question.** |  |
| **Summarize the objectives of the study in which the donor organ/eye/tissue will be used** |  |
| **Outline the protocol that will be implemented for the research involving the specified organ/eye/tissue.** |  |
| **Include a statement as to the ultimate disposition of used and/or unused research material.** |  |

**Operational Requirements**

Organ, eye and tissue donors occur 24/7. Your availability 24/7 will help ensure your research needs are met. List the following for the researcher notification process:

|  |  |  |  |
| --- | --- | --- | --- |
| Contact Name(s): |  |  |  |
|  |  |  |  |
| Contact phone number(s): |  |  |  |
|  |  |  |  |
| Will they be available 24/7 to take research offers? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  |  |  |  |
| Will they be able to receive the research organ/eye/tissue 24/7? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

**Donor Screening Criteria:** Listing your criteria will help us determine the ability to meet your requirments.

|  |  |
| --- | --- |
| Donor age; *please include measure, i.e. Years, Months, etc.* | Minimum:Maximum: |
|  |  |
| Donor Gender | Male: Y/NFemale: Y/N |
|  |  |
| What is your maximum time for warm ischemia?(The time from asystole or agonal phase until cooling via flush begins) |  |
| What is your maximum time for cold ischemia?(The time from the initiation of cold flush until it reaches the researcher) |  |
|  |  |
| Will you accept donors that have increased risk as defined by the CDC? <https://optn.transplant.hrsa.gov/media/1163/2013_phs_guideline.pdf> | Yes / No |
|  |  |  |
| HIV positive | HbsAg positive | Hep C positive | RPR/STS positive |
| [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  |  |  |  |
| Other criteria, please be as specific as possible. |  |

**Check the boxes of the information needed at the time of the offer.**

|  |  |  |
| --- | --- | --- |
| Indicate clinical information needed at the time researcher notification. Information will be shared verbally and is the responsibility of the researcher to document. No other written information will be provided with the organ and/or tissue. |  | Organ Specific Requirements |

**Recovery/Packaging:**

|  |  |
| --- | --- |
| Who will recover the organ/eye/tissue? |  |
|  |  |
| For solid organs, will the organ need to be flushed of blood? | [ ]  No | [ ]  Yes | Name of flush solution |  |
|  |  |  |
| Does the organ/eye/tissue need to be packaged in solution? | [ ]  No | [ ]  Yes | Name of storage solution |  |

Note: Organs recovered with the intent of transplant are flushed and stored in UW solution. For organs recovered with the intent of research, LifeSource will provide saline gratis. All other requested solutions will be charged accordingly or may be required to be provided by the researcher.

Describe the packaging requirements. List all supplies needed. Be as specific as possible. (e.g. Typical packaging includes one rigid container and two additional sterile barriers)

|  |
| --- |
|  |

List any additional requirements such as blood samples, forms etc

|  |
| --- |
|  |

The tissue provided to the Researcher will be used only for laboratory research or clinical human research protocols as approved by all appropriate research protocols, Institutional Review Board rules and procedures and all applicable state and federal laws, and the Researcher hereby agrees that LifeSource may rely on the Researcher's representations concerning the purpose for the research, the use of the donated tissue and Researcher's compliance with applicable laws, rules and regulations, including any institutional rules and regulations.

LifeSource is primarily engaged in providing organ, eye and tissue procurement and disposition services. LifeSource does not and cannot guarantee the quality of any tissue removed and donated for research purposes and specifically disclaims any and all warranties, guarantees and liabilities.

LifeSource reserves the right to discontinue providing tissue to Researcher at any time in its sole discretion for any reason and as LifeSource may see fit.

Researcher agrees that neither Researcher nor any institution or organization or group of researchers with which Researcher is affiliated shall sell, assign or otherwise transfer the tissue provided by LifeSource or any product derived therefrom to another without the prior written consent of LifeSource.

Researcher acknowledges that in the event Researcher is the physician of donor, Researcher has disclosed any research or economic interest in donor's tissue or any product derived therefrom and Researcher has obtained informed consent from the donor/next of kin. Further, Researcher hereby agrees to indemnify, defend and hold LifeSource harmless from any liability to donor/next of kin or any other person to which LifeSource may be subjected arising from Researcher's breach of any portion of this Agreement or breach of any fiduciary duty, failure to obtain informed consent, conversion of tissue or failure to comply with any state or federal law, rule, regulation or any other applicable restriction on the Researcher.

The Principal Requestor/Investigator and if applicable, other requestor(s)/investigator(s) must initial each statement in the box provided.

|  |  |
| --- | --- |
| **Principal Requestor / Investigator** | **I certify and understand the following:** |
|  | The information furnished regarding the research proposal is correct. I will seek and obtain prior approval for any modification in the application. |
|  | Absolute confidentiality of the data related to the donor population will be maintained.The LifeSource Authorization for Donation, Designation of Gift, and medical and social history forms contain confidential information and will not be provided to me. All donor information will be relayed verbally at the time of organ/tissue offer to researcher. |
|  | Organs, eyes or tissues provided to the researcher by LifeSource are available to us only for the approved project, and not to be redistributed to other unapproved investigators. |
|  | LifeSource reserves the right to terminate participation in the above stated research proposal at their discretion. |

|  |  |  |
| --- | --- | --- |
| Principal Investigator’s Signature: |  | Date: |
|  |  |  |
| Signature of Faculty Advisor *(if applicable)*: |  | Date: |

**Upon completion, please submit to:**

**LifeSource Research Committee**

**Attn: Research Coordinator**

2225 West River Road North

Minneapolis, MN 55411

(612) 800-6100 Phone

**+++++++++++++++++++++++++This Section is for LifeSource Use Only+++++++++++++++++++++++++**

|  |  |
| --- | --- |
| **Project Number:***(assigned by Research Committee designee)* |  |
| **Date Application Received by LS** |  |
| **Research Operations Team** | [ ]  Approved [ ]  Declined | Date: |
| **Research Committee** | [ ]  Approved [ ]  Declined | Date: |

**Comments:**

|  |
| --- |
|  |
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|  |