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| INSTRUCTIONS | | | | | | | | | | | |
| * **The investigational site must answer each of the following questions.**   + **Sections 1-5, and 7 for all research**   + **Sections 6 only for human gene transfer research** * **If a question is not applicable, please indicate so.** * **This research is subject to periodic review and renewal.** * **THIS FORM MUST BE TYPED.** | | | | | | | | | | | |
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| SECTION 1: ABOUT THE PRINCIPAL INVESTIGATOR | | | | | | | | | | | |
| PI Name: | | |  | | | | | | | | |
| Mailing Address: | | |  | | | | | | | | |
| Email: | | |  | | | | | Phone: | | |  |
| Study Coordinator: | | |  | | | | | | | | |
| Mailing Address: | | |  | | | | | | | | |
| Email: | | |  | | | | | Phone: | | |  |
|  | | | | | | | | | | | |
| SECTION 2: ABOUT THE FACILITY WHERE THE RESEARCH WILL TAKE PLACE | | | | | | | | | | | |
| Facility/Institution Name: | | | |  | | | | | | | |
| Address: | | | |  | | | | | | | |
| BIOSAFETY LIAISON (OR BIOSAFETY OFFICER FOR PROJECTS INVOLVING BIOSAFETY LEVEL 3 OR ABOVE): | | | | | | | | | | | |
| Name: | |  | | | | | | Attach CV | | | |
| Mailing Address: | |  | | | | | | | | | |
| Email: | |  | | | | | | Phone: | | |  |
|  | | | | | | | | | | | |
| SECTION 3: ABOUT THE RESEARCH PROTOCOL | | | | | | | | | | | |
| Protocol Title: |  | | | | | | | | | | |
| Sponsor Name: |  | | | | | Sponsor Protocol Number: | | | |  | |
| PROTOCOL CONTACT: | | | | | | | | | | | |
| Name: | |  | | | | | | | | | |
| Is Protocol Contact from Sponsor, CRO, or other? | | | | | Sponsor | | CRO | | Other: | | |
| Mailing Address: | |  | | | | | | | | | |
| Email: | |  | | | | | | Phone: | | |  |

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| SECTION 4: STUDY STATUS | | | | | | | | |
| Has this study been registered with the NIH? | | | | | | | | |
|  | **Yes**. Attach the following: | | | | | | | |
|  | | 1. RAC review determination, or | | | | | | |
|  | | 1. If no RAC review, copy of NIH documentation indicating that the initial protocol registration process is complete (from 1st site) | | | | | | |
|  | **No**. Answer the following: | | | | | | | |
|  | | 1. Does this protocol use a new vector, genetic material, or delivery methodology that represents a first-inhuman experience, thus presenting an unknown risk?  Yes No | | | | | | |
|  | | 1. Does the protocol rely on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value?  Yes No | | | | | | |
|  | | 1. Is the proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously?  Yes No | | | | | | |
|  | | | | | | | | |
| SECTION 5: LOCATIONS FOR USE & STORAGE OF ETIOLOGIC AGENTS & rDNA | | | | | | | | |
| List the locations(s) where work will be conducted and where materials will be stored. Include building and room numbers as applicable. | | | | | | | | |
| **Location Name** | | | | **Location Address** | | | **Storage location?** | **Site for conduct of research?** |
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| Optional – Provide additional detail here: | | | | | |  | | |
|  | | | | | | | | |
| SECTION 6: LEVELS OF PHYSICAL AND BIOLOGICAL CONTAINMENT | | | | | | | | |
| Please indicate the biosafety level required for the study agent. Refer to Appendix G of the *NIH Guidelines*): | | | | | | | | |
|  | Exempt |  | BSL-3 | | *Optional – Provide additional detail here:* | | | |
|  | BSL-1 |  | BSL4 | |  | | | |
|  | BSL-2 |  | | |

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| SECTION 7: DECONTAMINATION PROCEDURES | | | | | | |
| Read the decontamination procedures for personnel, equipment, and laboratory areas as defined for your BSL level in Appendix G of the *NIH Guidelines*.  **Do you agree to abide by these guidelines and also work in accordance with your Institution’s BRANY IBC determinations with respect to decontamination procedures?**  Yes  No | | | | | | |
| SECTION 8: DISPOSAL OF CONTAMINATED MATERIALS | | | | | | |
| Do you agree to dispose of all contaminated materials according to your Institution’s BRANY IBC determinations (e.g. decontamination first via autoclave; bleach, etc. as appropriate; sharps into sharps containers; etc.)?  Yes  No | | | | | | |
| SECTION 9: TRAINING OF PERSONNEL | | | | | | |
| Complete the table that follows while considering the following:   * Provide CVs for each key professional person *(i.e. Principal Investigator, Sub-Investigator(s), Research Coordinator(s), Pharmacy or other non-Pharmacy personnel)* * What professional personnel (medical and non-medical) will be involved in the proposed study and what is their relevant expertise? * If an individual will handle the study agent, he/she must provide evidence of infection control training. | | | | | | |
| **Name** | **Role** | **Will handle study agent?** | | **Infection Control Training Attached?** | | **CV** |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
|  |  | ***Yes*** | ***No*** | ***Yes*** | ***No*** |  |
| SECTION 10: ACCIDENTAL EXPOSURE | | | | | | |
| Describe the emergency plans for handling accidental exposure, spills and personnel contamination. | | | | | | |
| Do you agree to **contact NIH and your Institution’s BRANY IBC immediately** in the event an employee, staff, or coworker becomes ill and/or exhibits symptoms and signs consistent with an infection by an organism used in this research?  Yes  No | | | | | | |

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| SECTION 11: RESEARCH INVOLVING GENE TRANSFER |
| *Check here if not applicable and proceed to next section.* |
| 1. **Public Health Considerations - Describe any potential benefits and hazards of the proposed therapy to persons other than the patients being treated. Specifically:** |
| * + 1. On what basis are potential public health benefits or hazards postulated? |
| * + 1. Is there a significant possibility that the added DNA will spread from the patient to other persons or to the environment? |
| * + 1. What precautions will be taken against such spread (e.g. patients sharing a room, health care workers, or family members)? |
| * + 1. What measures will be undertaken to mitigate the risks, if any, to public health? |
| * + 1. In light of possible risks to offspring, including vertical transmission, will birth control measures be recommended to patients? Are such concerns applicable to health care personnel? |
| * 1. **Selection of the Patients** |
| * + 1. How many patients do you plan to involve in the proposed study? |
| * + 1. How many eligible patients do you anticipat***e being abl***eto id***e***ntify each year? |
| * + 1. How will patients be selected if it is not possible to include all who desire to participate? |
| * 1. **Patient-related Procedures** |
| * + 1. Will patients occupy regular hospital beds or clinical research center beds? |
| * + 1. Where will patients reside during the follow-up period? |
| * + 1. What special arrangements will be made for the comfort and consideration of the patients? |
| * 1. **Will the research institution designate an ombudsman, patient care representative, or other individual to help protect the rights and welfare of the patient?**   Yes  No  **Explain either answer**: |
| * 1. **Specific Requirements of Gene Transfer Research**   **To obtain vital information about the safety and efficacy of gene transfer, subjects should be informed that at the time of death, no matter what the cause, permission for an autopsy will be requested of their families. Subjects should be asked to advise their families of the request and of its scientific and medical importance.** |
| * + 1. What steps will be taken to ensure that accurate and appropriate information is made available to the public with respect to public concerns as may arise from the proposed study? |
| * + 1. Do you or your funding sources intend to protect under patent or trade secret laws either the products or the procedures developed in the proposed study? If so, what steps will be taken to permit as full communication as possible among investigators and clinicians concerning research methods and results? |
|  |
| SECTION 12: SUBMISSION REQUIREMENTS CHECKLIST |
| Site-Specific BRANY IBC Application  Principal Investigator’s current professional license, showing expiration date  Principal Investigator’s current curriculum vitae (CV), signed and dated  Evidence of training in appropriate infection control/biosafety procedures (**if applicable**)  CV of all research staff, that will have any contact with the study agent, (Sub-Investigators, Pharmacist(s), Coordinator, etc).  The proposed protocol (and amendments, if applicable) (**\*see note below**)  The Investigator’s Brochure (\***see note below**)  IRB-approved Consent form(s) for the site (\***see note below**)  Responses to NIH guidelines appendix M (**if applicable**)  RAC review letter pertaining to this gene transfer product and clinical trial (**if applicable**)  FDA form 1572, if applicable (\***see note below**)  ***\**NOTE*:* IF PROJECT WAS SUBMITTED FOR BRANY IRB REVIEW AND THE IRB-APPROVED CONSENT FORM(S), PROTOCOL, IDB, AND 1572 ARE ON FILE, DO NOT INCLUDE FOR IBC SUBMISSION.** |

SECTION 13: INVESTIGATORS STATEMENT OF COMPLIANCE

The proposed investigation involves the use of recombinant or synthetic nucleic acids. I am submitting this application with a description of my project, prepared in accordance with BRANY IBC Services’ requirements. I understand the Biomedical Research Alliance of New York's policy concerning such research and I agree to:

1. Comply with the *NIH Guidelines* *for Research Involving Recombinant or Synthetic Nucleic Acid Molecules;*
2. Obtain IBC approval before initiating or modifying research;
3. Report any significant problems, violations of the *NIH Guidelines*, or any significant research related accidents and illnesses to the Biological Safety Liaison/Officer, IBC, NIH OSP and other applicable authorities (if applicable) immediately.;
4. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination;
5. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules;
6. Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
7. Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC;
8. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Liaison/Officer, IBC, NIH OSP, and other appropriate authorities when applicable;
9. Correct work errors and conditions that may result in release of recombinant or synthetic nucleic acid molecules;
10. Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment;
11. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
12. Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
13. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection);
14. If applicable, inform research subjects that at the time of death, no matter what the cause, permission for an autopsy will be requested of their families. Subjects should be asked to advise their families of the request and of its scientific and medical importance;
15. Communicate regularly with the IBC during the approval period regarding continuing review of this project, study termination, and before amending or altering the scope of the project or implementing changes; and
16. Comply with IBC requirements.

**IMPORTANT!** IN ADDITION TO IBC REVIEW, YOU ARE REQUIRED TO APPLY FOR AND OBTAIN OTHER REQUIRED APPROVALS (e.g., IRB, Radiation Safety, IACUC, etc.) BEFORE COMMENCING YOUR RESEARCH.

**I FURTHER UNDERSTAND THAT:**

1. Failure to comply with any of the above, with the IBC’s requirements, or with any applicable regulations may result in immediate termination of IBC approval for this study, and is reportable to my institution, the sponsor, and NIH OSP.

2. This research project will be subject to routine audits by the BRANY Quality Assurance Division, and at the discretion of BRANY’s Institutional Official. The results of such audits may be shared with the appropriate Department Chairpersons and/or the Institutional Official at your facility.

NOTE: Investigators are referred to the IBC’s standard operating procedures for a complete statement of policy and procedures regarding *Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

Principal Investigator (PRINT) Principal Investigator (Signature) Date