### 01. Study Title and Research Personnel

<table>
<thead>
<tr>
<th><strong>Short Title:</strong></th>
<th>EXAMPLE STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Title:</strong></td>
<td>EXAMPLE STUDY</td>
</tr>
</tbody>
</table>

| **Owning Organization:** | TEST DEPT 1 |

<table>
<thead>
<tr>
<th><strong>SBR Selection:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Will any Duke Medicine facility be a performance site?</td>
<td>Yes ☑️ No</td>
</tr>
<tr>
<td>Does this project require SBR oversight for any other reason?</td>
<td>Yes ☑️ No</td>
</tr>
<tr>
<td>Select the SBR to which this project belongs:</td>
<td>None (SBR)</td>
</tr>
</tbody>
</table>

| **Principal Investigator (PI):** | test pi |

<table>
<thead>
<tr>
<th><strong>Primary Regulatory Coordinator:</strong></th>
<th></th>
</tr>
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</table>

<table>
<thead>
<tr>
<th><strong>Primary Study Coordinator Contact:</strong></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Co-Principal Investigators:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td>First Name</td>
</tr>
<tr>
<td>----------</td>
<td>------------</td>
</tr>
<tr>
<td>There are no items to display</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Co-Principal Investigators act in the same capacity as the Principal Investigator, sharing equal responsibility.</strong></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Other Key Personnel:</strong></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Faculty Sponsor:</strong></th>
<th></th>
</tr>
</thead>
</table>

| **Faculty Sponsors are being phased out of the IRB form.** | |

| **Key Personnel are research** | |
personnel who are directly involved in conducting research with human subjects, or who are directly involved with the handling of identifiable private information related to those subjects, including protected health information, in the course of a research project.

02. Study Personnel Outside Duke

For Key Personnel who are outside Duke and not listed in the personnel database: Complete and attach Key Personnel form along with documentation of Human Subjects Certification.

Note: If any non-Duke member of the study team needs to access the eIRB system, they will need to obtain a Duke NetID and be listed on page 01. Study Title and Research Personnel.

[Click here to download the necessary Key Personnel form.]

03. Protocol Application Type

Select the type of protocol you are creating:

- **Regular Study Application**
- **Application for Exemption from IRB review**
- **DCRU Phase I External IRB Application**

"DCRU Phase I External IRB Application" is a special category not commonly used. Do not select this option unless you are sure your protocol falls under this category.

Select Protocol Phase for FDA regulated drugs or biologics (choose only one):

- [ ] I
- [ ] II
- [ ] III
- [ ] IV

04. Sponsor and Funding Source
* Add all funding sources for this study:

<table>
<thead>
<tr>
<th>Name</th>
<th>Acronym</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departmental/Divisional Funds</td>
<td></td>
<td>Duke</td>
</tr>
</tbody>
</table>

If research costs are indirect only, select "None". For departmental or PI funding, select "Department/Divisional/PI".

If you cannot find the funding source on the list, please email eirb@mc.duke.edu to request that it be added to the database.

* Is the Sponsor a different entity than the Funding Source?
  - Yes ☐
  - No ☑

Select the Sponsor:

Departmental/Divisional Funds

Sponsor - Name of the primary entity that will oversee implementation of the study and is responsible for regulatory compliance.

* Will any samples/data be transferred to/from Duke as part of this study?

Yes ☐

No ☑

Enter the SPS (Sponsored Projects System) number, if applicable:

1234

* Is the study funded by a grant from the Federal Government?

Yes ☑

No ☐

If Yes, enter the Grant Number or Other Federal Agency Proposal or Application Number:

TEXT

The Federal Funding Agency ID Number is the Sponsor's grant number assigned to your project and available on your Notice of Award (example: R01HL012345). If unknown, enter the SPS number.

Attach either the entire grant, or an explanation of why a grant is not needed:

Name Date Modified

There are no items to display

05. Multi-site Research

* Is this a multi-site study?

Yes ☑

No ☐

If Yes, complete the following:

Is the PI/Co-PI the lead investigator or primary grant awardee?

Yes ☑

No ☐

Is Duke the central coordinating center for this study?
Is Duke serving as a central statistical center for this study?

- [ ] Yes
- [ ] No

Is Duke serving as a central laboratory, reading center, analysis center or other central resource for this study?

- [ ] Yes
- [ ] No

List all sites at which you will conduct the research or be principal investigator responsible for the conduct of the research:

<table>
<thead>
<tr>
<th>Name/Location</th>
<th>IRB Approval Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display

Duke’s Federal-Wide Assurance (FWA) requires that we provide oversight for all human research protection activities at all sub-sites, when a Duke investigator serves as the primary grant awardee on a multi-site study funded by the U.S. Government. Therefore we must verify that there is an active IRB approval in effect at each sub-site for your study.

### 05.1 Research at Sites External to Duke University Medical Center

Provide a description of the procedures that will be used to inform sites of unanticipated problems involving risks to subjects or others, interim results, protocol modifications and other information that may be relevant to the protection of subjects.

### 05.2 Multi-site Statistical Center

How will you ensure that each collaborating institution holds an applicable OHRP-approved Assurance?

How will you ensure that each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects?

How will you ensure that informed consent is obtained from each subject in compliance with HHS regulations?

How will you ensure that protocol information, including reports of unanticipated problems involving risks to subjects or others, protocol modifications and interim results, is promptly disseminated to all sites?

### 05.3 Multi-site Coordinating Center

How will you ensure that management, data analysis, and data safety and monitoring systems are adequate, given the nature of the research involved?
How will you ensure that sample protocols and informed consent documents are developed and distributed to each collaborating institution?

How will you ensure that each collaborating institution holds an applicable OHRP-approved Assurance?

How will you ensure that each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects?

How will you ensure that any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified?

How will you ensure that informed consent is obtained from each subject in compliance with DHHS regulations?

View: 06. Research Summary

06. Research Summary & Abstract

The Research Summary should include sufficient information for evaluation of the proposed study, independent of any other document, though the PI is expected to include additional information considered important for review by the IRB.

* Attach Research Summary here:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrintSm.pdf</td>
<td>5/15/2009 12:49 PM</td>
</tr>
</tbody>
</table>

Ordinarily the summary should not exceed 4 pages in length or use font size smaller than 12 pt. Consult the Research Summary Template for additional help.

The Research Abstract should summarize the main points of your study in one paragraph. The following guidelines may help you:

1. Purpose and objective (1-2 sentences)
2. Study activities and population group (2-4 sentences)
3. Data analysis and risk/safety issues (1-2 sentences)

Please type your Research Abstract here:

**Please type your Research Abstract here:**

View: 07. Full Protocol

07. Full Protocol

* Indicate the Protocol source below (check only one):

- PI initiated
- Commercial / Industry (for-profit group) initiated

The protocol source is the author of the protocol. If the protocol is a joint authorship between multiple sources, select the primary author.
08. Drugs, Biologics, and Other Substances

Add all drugs, biologics, or other substances being evaluated as a part of this research study for which an IND is provided for the indication used in this study:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>IND #</th>
<th>IND Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add any other drugs, biologics or other substances here that are being used as a part of this research study, for which an IND is not provided:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Complete the following if this study includes Investigational Drugs, biologics or other substances:

Are you using the Investigational Drug Service (IDS) at Duke?
- Yes  
- No

Are you using the Investigational Chemotherapy Service (ICS) at Duke?
- Yes  
- No

Are you using the Infectious Disease Research Pharmacy at Duke?
- Yes  
- No

Who will be responsible for the storage, inventory and control of the drug/biologic or other chemical, metabolite, nutritional substance or other substance to be evaluated in this research?
TEXT

Where will the drug/biologic or other chemical, metabolite, nutritional substance, or other substance to be evaluated in this research be stored?
TEXT

Who will be responsible for giving or administering the drug/biologic or other chemical, metabolite, nutritional substance or other substance to subjects?
09. Devices

Include all devices being evaluated in this study to determine their safety or effectiveness, and include information about a humanitarian use device where requested.

<table>
<thead>
<tr>
<th>Add Devices with an IDE here:</th>
<th>Complete an IDE Billing Notice as applicable. This can be attached with the Brochure.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>IDE #</td>
</tr>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Add devices without an IDE here, including any Humanitarian Use Device that does not require an IDE because it is to be used according to its FDA approved product labeling and its safety or effectiveness is not being evaluated:

- Device Name
- There are no items to display

Who will be responsible for the storage, inventory and control of the device to be evaluated or the Humanitarian Use Device?

Where will the device to be evaluated or the Humanitarian Use Device be stored?

Who will be responsible for giving or administering the device to be evaluated or the Humanitarian Use Device to the research subject?

From where will the device to be evaluated or the Humanitarian Use Device be dispensed?

---

View: 10. Subject Population and Enrollment

10. Subject Population Groups and Enrollment

*Population Groups:*

- Adults (Check all that apply)
- Minors who are Wards of State
- Minors
- Patients

If Minors are included, the study will be routed to the Department of Pediatrics Chair for Pediatric Risk Assessment.
<table>
<thead>
<tr>
<th>Population Groups excluded from participation in this study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant Women</td>
</tr>
</tbody>
</table>

1 Students and Employees over whom Key Personnel have a supervisory role may **not** be enrolled in this study.

2 Healthy Controls must be given a Notice of Privacy Practices.

3 Cooperative sites that are using the Duke IRB must have an IRB agreement.

4 Complete and attach a Decedent Research Notification on page 12.2. Waiver of Consent and HIPAA Authorization.

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**10.1 Subject Procedures and Costs**

**Procedures**

- Genetic Testing
- Gene Transfer
- DNA Banking
- Testing for Reportable Infectious Diseases
- Human Cell Banking

**Will blood be drawn in this study for research purposes?**

- Yes  No

  **If Yes**, maximum amount to be drawn in any 8 week period (ml):

  **Number of blood draws per week:**

  Enter blood volume in ml.
Will the Operating Room be used in this study?
- [ ] Yes  
- [ ] No

If Yes, Anesthesia time in minutes required (for research purposes):
Include only research time, not clinical care time.

Costs and Compensation

* Will there be extra costs to subjects or insurance as a result of the research (e.g. tests, hospitalization)?
- [ ] Yes  
- [ ] No

* Will there be Subject Compensation?
- [ ] Yes  
- [ ] No

If Yes, Compensation for Travel / Lost Income: $ 
Other Subject Compensation:

View: 11. Subject Recruitment Materials

**11. Subject Recruitment Materials**

All materials that will be used to advertise the study in order to recruit subjects must be approved by the IRB. Types of subject recruitment materials include, but are not limited to, the following:

**Direct Advertising**
- Posters
- Billboards
- Flyers
- Brochures

**Media Advertising**
- Newspaper Ads
- Magazine Ads
- Radio Ads
- TV commercials / Video
- Internet website

**Other Types of Advertising**
- Newsletter
- Email
- Postcards / Letters

(Note: Doctor-to-Doctor letters do not require IRB approval)

Attach a copy of each advertisement that you will be using with this study. If any Ad will have multiple wording variations, attach a copy of each version of the Ad.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Category</th>
<th>Previously Approved by IRB</th>
<th>Date Modified</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

There are no items to display

View: 12. Privacy and Confidentiality

**12. Privacy and Confidentiality**

* Explain how you will ensure that the subject's privacy will be protected:

TEXT

Consider privacy interests regarding time and place where subjects provide information, the nature of the information they provide, the type of experience they will be asked to participate in during the research, and who receives and can use the
**Explain how you will ensure that the confidentiality of the subject's data will be protected:**

How will the research records and data be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction? Records and data include, for example, informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheets, screening logs or telephone eligibility sheets, web based information gathering tools, audio/video/photo recordings of subjects, labeled specimens, data about subjects, and subject identifiers such as social security number.

### 13. Protected Health Information (PHI)

* Indicate how you intend to use potential subjects' Protected Health Information (PHI):

- [ ] I will review, but not record, PHI prior to consent.
- [ ] I will record PHI prior to consent.
- [ ] I do not intend to use PHI prior to consent.
- [ ] I will record PHI without consent. (decedent research, database repository, chart review)

### 14. Consent Process

Attach draft consent forms. To attach a revised version of an existing document, click the [Edit] link.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Date Created</th>
<th>Last Modified</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Consent forms must be MS Word documents and follow the specific format outlined by the IRB. Click here to download a copy of the eIRB consent form template.

**Note:** Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

Who will conduct the consent process with prospective participants? Give the
Who will provide consent or permission? (Select all that apply)

- Consent Provider (checked)
- Participant (checked)
- Parent(s) or Legal Guardian(s)
- Legally Authorized Representative (LAR)

How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate? If you are not giving the person overnight to consider whether or not to participate, please justify.

Where will the consent process occur?

What steps will be taken in that location to protect the privacy of the prospective participant?

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?

What arrangements will be in place for answering participant questions before and after the consent is signed?

Describe the steps taken to minimize the possibility of coercion or undue influence.

What provisions will be in place to obtain consent from participants or their legally authorized representative who do not read, are blind or who do not read/understand English?

View: 15. Specialty Committee Reviews

15. Specialty Committee Reviews

Select all committees which will be required to review this protocol:

There are no items to display

The protocol will be made available to the selected Specialty Committees for review. Important Note: To avoid delays in the review of this protocol, please be sure to determine and meet the specific requirements of each Specialty Committee.

*For Durham Regional and Duke Raleigh Hospital approvals, send site specific forms to DRH and/or DRAH.

*For VA Hospital, submit your study separately to the VA IRB. You must obtain VA IRB approval.
**View: 16. Departmental Review**

### 16. Departmental Review

To route the study to your department's administrator for assignment of the Departmental IRB Reviewer, select the administrator:

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

There are no items to display

If you are unsure whether to choose a Department Administrator or a Departmental IRB Reviewer, you should always pick an Administrator.

**Note:** When both a Department Administrator and Departmental IRB Reviewer are selected, it will be sent to the Administrator by default.

Before selecting a Departmental IRB Reviewer, please read important information in the box to the right:

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Member</td>
<td>TEMP</td>
<td>TEST IRB</td>
</tr>
<tr>
<td>Committee Member 1</td>
<td>TEST</td>
<td>TEST DEPT 1</td>
</tr>
</tbody>
</table>

**Important** - The list to the left does not guarantee availability. Please make sure to contact the Departmental IRB Reviewer before selecting them and submitting this protocol, to avoid delays in the event the reviewer is not available. **To avoid delays in the review of this protocol, users in the following Departments must always choose the Administrator:**

- Anesthesiology
- Medicine
- Ophthalmology
- Pediatrics
- Surgery

*Please Note: Upon completion of this form, the study will be located in the "Presubmission" area on your study staff workspace, and available for further editing. When the study is ready for review, it must be submitted using the "Submit Study" activity button.*

**View: 17. Clinical Trials Memo**

**Required registration of studies in ClinicalTrials.gov**

On September 27, 2007 Congress enacted U.S. Public Law 110-85 (also known as H.R. 3580, or Food and Drug Administration Amendments Act of 2007). This act mandates the expansion of ClinicalTrials.gov, expands the required submission elements and establishes penalties for not listing a trial. Investigators and sponsors must ensure that applicable drug, biologic and device trials are registered within 21 days of enrollment of the first subject and preferable before first subject enrollment.

**Which studies must be registered?**

Registration is required for any research study that:

- Uses a drug, biologic, or device as the intervention or control/comparison AND
- Prospectively assigns human subjects to intervention and at least one concurrent control or comparison
groups AND

- Studies the safety, efficacy or cause-and-effect relationship between an intervention and a health outcome

The registration requirement does not apply to:

- The use of FDA approved, marketed products used in the course of medical practice
- Phase I clinical investigations of drugs or biologics
- Small clinical trials to determine the feasibility of a device or clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
- FDA required pediatric postmarketing surveillance of devices

Investigators and sponsors are encouraged to register all studies to ensure they meet the publication requirements of the International Committee of Medical Journal Editors (ICMJE) and to promote transparency in clinical research.

Who is responsible for registering the study?

- For investigator-initiated trials, the lead principal investigator responsible for conducting and coordinating the overall clinical trail should take responsibility for registration
- For Sponsor-initiated trials the sponsor should take responsibility for registration
- Trials sponsored by the federal government (e.g. NIH) should be registered by the grantee
- Trials associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the U.S. FDA should be register by the IND/IDE holder
- If the individual or sponsor who should register the trial is unwilling or unable to register the trial it should be registered by a participating investigator

How do I register a study at Duke?

Contact Rebeka Branagan by email (rebeka.branagan@duke.edu) or phone (668-2579) to establish a user account to register a study with the ClinicalTrials.gov Protocol Registration System

Who do I contact for more information?

Contact either Rebeka Branagan (rebeka.branagan@duke.edu) or Wesley Byerly (wesley.byerly@duke.edu) for questions or for additional information