

Date: Wednesday, February 13, 2019 12:46:27 PM

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Application
NA_00043818
Janelle Maddox-Regis

1 - General Information

ID: NA_00043818

1. * **Principal Investigator:**
Click **Select** to choose PI:
[Janelle Maddox-Regis](#)

2. * **Will the PI obtain consent for this study ?**
 Yes No

- 2b. * **Is the PI a physician-investigator or mid-level provider who will be consenting participants for this study?**
 Yes No

3. * **Is the PI a JHHS RN?**
 Yes No

4. * **Indicate the PI's primary affiliation:**
(Select "Other (Affiliation Not Listed)" if the PI's primary affiliation is not listed):
[Other - Affiliation Not Listed](#)

5. * **Title of Study:**
Test Study 123456

6. * **Provide a BRIEF statement of your research question and plan:**
This application is for training purposes only.

7. * **Select the type of review requested:**
Expedited

8. * **Will an external IRB act as the IRB of record for this study?**
 Yes No

 Peds CIRB
 Early Phase CIRB
 Late Phase CIRB
 Other

* **Describe Other:**
Vanderbilt University will serve as the Single IRB for this study.

9. **What kind of study is this?**
Multi-site study

* **Will Hopkins/Affiliates serve as the lead/coordinating center for this multicenter study?:**
 Yes No

* **Provide the lead/coordinating center PI's name and contact information:**

11. * **Does this project ONLY involve review of records?**
 Select "Yes" if this project will **ONLY** involve review of charts/medical records.
 Yes No
12. * **Is this a quality improvement project?**
 Yes No
13. **Is there a component of your proposed project that is a public health surveillance activity?**
 Yes No
15. * **Is this a resubmission of an expired, terminated, withdrawn or disapproved application?**
 Yes No
17. * **Is this a conversion of an active study already approved by a Hopkins/Affiliates IRB (including the JHM All Children's Hospital IRB)?**
 Yes No
21. * **Estimated time to complete this study:**
 5years
22. * **Does the institutional policy on physician consent require that a physician-investigator or mid-level provider obtain informed consent for this research?**
 Yes No

23. **Study Team Members:**

Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Consenting Physician-Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
View	Maddox-Regis	Janelle	MHS	SOM Admin Clinical Invest Human Subjects	Other - Affiliation Not Listed	Other Staff	no			
View	Test	Reg User 1			Other - Affiliation Not Listed	Co- Investigator	no		no	yes

2 - Study Team Compliance Training

1. All Study Team Members listed below must complete indicated training requirements

PIs of active IRB Protocols must complete the **REwards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REwards** requirement.

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those

members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REwards Completed	CRBO Required	Date CRBO Completed
Maddox-Regis	Janelle	Yes	11/20/2018	Yes	12/11/2014	Yes	7/9/2015	1/1/2012		

Study Team:

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REwards Completed	CRBO Required	Date CRBO Completed
Maddox-Regis	Janelle	yes	11/20/2018	yes	12/11/2014	yes	7/9/2015	1/1/2012		
Test	Reg User 1	yes	1/1/2018	yes	1/1/2018	yes	1/1/2018	4/7/2014		

2. If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View JHM PI External IRB Training Certificate(0.01)	7/3/2014 11:50 AM	0.01	Submitted

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6 – Protocol Information

2.0 * Clean Protocol:

Click **Add** to upload a new clean document. Click **Update** to upload a clean revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View Sponsor Protocol(1)	2/27/2013 4:24 PM	1	Submitted

9.0 Additional pilot data or relevant publications

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View Additional pilot data or relevant publications(0.01)	5/4/2011 10:12 AM	0.01	Submitted

10.0 * If your study is occurring at JHH or JHBMC, check all of the below that apply:

- There are research activities or drugs administered in this protocol that are intended to induce symptoms in research participants, such as: procedures to provoke an allergic reaction (pulmonary, nasal, or GI), induced sputum, or exercise stress test.
- Research participants will undergo high risk, invasive procedures that are NOT part of prescribed routine clinical care for the participant. Examples include bronchoscopy, cardiac catheterization, use of a glucose clamp, or insertion of an arterial line. (Lumbar puncture is not considered high risk.)
- There are drugs administered as part of the protocol that have a likelihood of causing an allergic reaction, or side effects, which could require the use of rescue medications.

This is the first time you have been listed as PI on a more than minimal risk application.

None of the above

11.0 * Does your study involve organ transplantation from an HIV positive donor (living or deceased) to an HIV positive recipient?

Yes No

13.0 * Does this study involve HIV testing in the State of Maryland?

Yes No

You may use the required State of Maryland consent form for HIV testing in addition to the JHMIRB approved consent form.

14.0 Will any photographic images or recordings (audio or video) of participants be taken solely for research purposes?

Yes No

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7 - Clinical Trials Information

1. * Is this a clinical trial?

Yes No

2. * Indicate the study phase:

I/II

3. * Is the trial funded either in whole, or in part by the National Institutes of Health?

Yes No

Per the [NIH Final Rule](#), if the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award.

5. * Has the trial been registered at register.clinicaltrials.gov?

Per policy [clinicaltrials.gov](https://register.clinicaltrials.gov) is the only site to be used to register clinical trials.

Yes No

7. Describe your plan for registration (e.g., will register after IRB approval):

will register after IRB approval

8. Who is the Responsible Party?

Hopkins Investigator

9. Which trial registry site was this trial registered on?

clinicaltrials.gov

10. * ClinicalTrials.gov identifier (NCT Number):

Please enter only the eight digits of the registration number (without "NCT").

12345678

8 - Conflict of Interest

1. * Does the PI or any study team member (or their spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that

- 1) could be affected by the research, or
- 2) is in an entity that could be affected by the research?

This applies to current interests/relationships and those within the past 12 months.

Yes No

All conflicted individuals must disclose potential conflicts of interest to the Office of Policy Coordination (OPC) before this application can be approved.

5. * To the best of your knowledge, does Johns Hopkins have a financial interest that 1) could be affected by the research or 2) is in an entity whose financial interest could be affected by the research?

Yes No

9 - Support Information

1. * Check all sources of support (pending or awarded):

- Monetary
- Material or Equipment (e.g., drugs or devices)
- None of the above

4. * MONETARY SUPPORT:

Click Add/Update to select monetary support source:

Source	Status	Grant Number
view Phillip Morris Corp	Awarded	678234

7. * Does this research have COMMERCIAL FUNDING?

Yes No

11. Do you have or do you anticipate receiving federal funding for this study?

Yes No

10 - Study Location

- 1.0 Johns Hopkins Primary Sites:

Location	PI Name	PI Email	PI Phone	Notes
View Johns Hopkins Hospital	Janelle Maddox-Regis	jmaddox3@jhmi.edu	410-502-0376	

Johns Hopkins ICTR-CRU Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

Other Johns Hopkins Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

Other Non-Hopkins Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

If using a JHCP location click on the help link for guidance and to complete the JHCP Research Application.

2.0 Is this study using a Johns Hopkins Clinical Research Network site?
 Yes No

3.0 Is this study using a PCORI-Path site?
 Yes No

The following sites were selected under the legacy Study Location page:

Johns Hopkins All Children's Hospital, Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Kennedy Krieger Institute, Howard County General Hospital, Suburban Hospital, Sibley Memorial Hospital, Johns Hopkins Singapore, Cardiovascular Specialists of Central Maryland, Johns Hopkins Applied Physics Laboratory, Other Hopkins Sites (This box has been left blank on purpose. TRAINING PURPOSES ONLY), Johns Hopkins Community Physicians (JHCP), JHH adult inpatient unit (Osler 5), JHH adult outpatient unit (Carnegie 3), Bloomberg Children's Center PCRU, Neurobehavioral research unit (KKI), Other ICTR-CRU sites (Test), Anne Arundel Health Systems Research Institute (AAHRSI), Greater Baltimore Medical Center (GBMC), Inova Health System, Peninsula Regional Medical Center, Reading Health System, King Khaled Eye Specialist Hospital, National Institute on Aging (NIA), National Institute on Drug Abuse (NIDA), Geisinger Health System PCORI PaTH, Penn State PCORI PaTH, Temple PCORI PaTH, UPMC PCORI PaTH, University of Utah PCORI PaTH, Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, National Rehabilitation Hospital, Union Memorial Hospital, Washington Hospital Center, Baltimore City Health Department (BCHD) (This box has been left blank on purpose. TRAINING PURPOSES ONLY)

Multicenter sites where another PI will conduct the research was selected.

The following was entered as the lead/coordinating center PI's name and contact information:
This box has been left blank on purpose. TRAINING PURPOSES ONLY

If separate lead/coordinating center documents were uploaded they can be found on the 'Application Documents' page.

Non-Hopkins/Affiliates sites where the study team will conduct the research was selected.

The following information was entered for the Non-Hopkins sites:

Name and address of site: Mattel
Name of Site Contact: Barbie
Site Contact Phone: 555-4444
Site Contact Email: barbie@mattel.com
Has the site provided permission to conduct research? Yes
Does the site have an IRB? Yes
Has the site's IRB approved the research? Yes
Is this an international site? Yes
Country of Origin: No information entered.
Provide an FWA: 123456

If any approval documents were uploaded they can be found on the 'Application Documents' page.

11 - Sample Size

1. * Will this research involve intervention/interaction with participants?

Yes No

2. * How many participants will be consented (or enrolled with a waiver of consent) at Hopkins/Affiliates?

25

3. * Will the study have a screening evaluation after consent has been obtained?

Yes No

4. * How many participants will be accrued at Hopkins/Affiliates?

1

5. * For multi-center studies, how many participants will be accrued at all sites (including Hopkins/Affiliates)?

1

6. What will you do with the Protected Health Information (PHI) of your screening failures?

Retain PHI

Destroy PHI

7. Justify your reasoning for retaining the PHI of your screening failures:

test

8. * Will you need JHHS nursing staff for any research-related activities (e.g., as participants, blood draws, drug administration, device use, specimen collection, increased monitoring, survey administration)?

This question does not apply to research conducted only on the ICTR-CRU units using ICTR-CRU nursing staff. If you will only be using ICTR-CRU nursing staff question 8.0 should be answered "no."

Yes No

9. * Upload the Approval of Research Involving Nursing or Nursing Resources Form.

Please note: The IRB cannot approve your application until the signed form is uploaded.

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
view JHH Nursing Research Form(0.01)	2/19/2014 1:51 PM	0.01	Submitted

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12 – Participant Information

1.0 * Will you obtain identifiable data, records, specimens, or samples, or have access to codes, links or identifiers?

Yes No

2.0 * Age ranges of participants (e.g., 0-17, 18-100):

8-88

3.0 * Study population - check all that apply:

- Male adults (18+)
- Female Adults (18+)
- Male children (<18) [Who cannot consent for themselves]
- Female children (<18) [Who cannot consent for themselves]
- Males (<18) [Who can consent for themselves as permitted by law]
- Females (<18) [Who can consent for themselves as permitted by law]

4.0 Special Study Populations - check all populations that may be enrolled:

- Adults lacking capacity to consent
- Pregnant Women
- Non-viable neonates/neonates of uncertain viability
- Prisoners
- Non-English speakers
- Children who are in foster care or wards of the state

5.0 * Will you enroll healthy volunteers?

- Yes No

6.0 Hopkins Study Populations - check all populations that you will target for recruitment or record review:

- JHH/JHBMC adult emergency department patients/records
- Employees/records

- JHU School of Medicine residents/interns/records
- JHU School of Medicine students/records
- Other JHU students/records
- Hopkins/Affiliates inpatients
- Hopkins/Affiliates outpatients
- JHH obstetric patients

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13 - Recruitment Information

1. * Check all sources of recruitment for this study:

- No intervention/interaction with participants (e.g., chart record review)
- Individuals who are clinical patients of the PI or co-investigators
- Review of clinical records of individuals who are not clinical patients of the PI or co-investigators prior to their consent
- Referral of individuals specifically for research purposes by treating clinicians not on the study team

- Prior Hopkins/Affiliates study participants
- Individuals who learn about the study through advertisements or peer/network recruiting

2. * Describe the process for recruiting these individuals, including:

- individual(s) responsible for approaching participant(s)
- where and when recruitment will take place
- how privacy issues will be addressed in recruitment process

This box has been left blank on purpose. TRAINING PURPOSES ONLY

5. * Are you submitting recruitment materials and/or telephone screening scripts for review?

- Yes No

6. Check the recruitment materials that you are submitting for review:

- Brochures
- Letters
- Flyers
- Newspaper Advertisements
- Radio Advertisements
- TV Advertisements
- Postcards
- Website postings
- Posters
- Telephone screening scripts
- Other

7. Recruitment materials and/or telephone screening scripts (Leave a 1.5" margin at top of the document for IRB approval stamp)

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
view Flyer(0.01)	10/18/2010 12:41 PM	0.01	Submitted

11. JHM-IRB waiver of privacy authorization (HIPAA Form 4)

Required for:

- Chart/record review of individuals who are not patients or former study participants of the PI or study team
- Receiving PHI from a referring Clinician not on the study team
- Conducting telephone screening prior to obtaining written consent
- DO NOT SUBMIT this form if you are only reviewing the clinical records of your own patients and patients of study team members

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
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Title	Date Modified	Version	Status
View HIPAAForm4.doc(0.01)	3/3/2011 12:07 PM	0.01	Submitted

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14 - Consent and Waivers

[For Adults and Individuals under 18 who can consent for themselves]

1. * Check the type(s) of consent planned for this study:

- Written Consent**
- Waiver of Documentation of Consent (including oral consent)**
- Waiver of Consent**
- Consent was previously obtained which accounts for the activity proposed in this new submission and no new consent is required.**

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15 - Written Consent

[For Adults and Individuals under 18 who can consent for themselves]

3.0 **Adult Consent Form(s):**

Click **Add** to upload a new consent form. Click **Update** to upload a tracked copy of a revised consent form. (Click **History** to see all uploaded versions of an existing consent)

Title	Date Modified	Version	Status
View VUMC Approved Master Consent Form(0.01)	3/3/2011 12:17 PM	0.01	Submitted
View JHM Tailored Consent Form(0.01)	2/13/2019 11:59 AM	0.01	Submitted

6.0 * Will you consent participants on a non-JHM IRB template?

Yes No

7.0 * Explain reason for using non-JHM IRB template:

JHM is relying on an External IRB. A JHM IRB template is not allowable.

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17 – Assent and Parental Permission for Research Involving Children

1.0 * Check the type of assent planned for this study:

- Assent with a signature by the child (either in the parental permission form or a separate assent document)**
- Assent without a signature by the child (including an assent statement in the parental permission form [without child**

signature] and oral assent)

- Waiver of assent
- No assent or waiver required

4.0 * How many different assent forms will be used?

1

4.1 * Assent Form

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View VUMC Assent Form(0.01)	10/18/2010 12:43 PM	0.01	Submitted

8.0 Check the type of parental permission planned for this study:

- Written permission
- Waiver of documentation of parental permission (including oral permission)
- Waiver of parental permission
- Parental permission not required
- Parental permission was previously obtained which accounts for the activity proposed in this new submission and no new parental permission is required

In certain cases, parental permission is not required [e.g. if the child is seeking care for sexual health needs or is considered emancipated].

Please explain why parental permission is not required:

xxx

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20 - Supplemental Study Documents

You are not required to submit standard and recognized questionnaires or tests if they have not been altered for specific use in this study.

1. Upload supplemental study document(s) requiring a JHM IRB approval logo:

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document)

Title	Date Modified	Version	Status
View This document has been left blank on purpose- TRAINING PURPOSES ONLY.doc(0.01)	10/18/2010 12:44 PM	0.01	Deleted
View TEST UPLOAD - Copy (42).zip(0.01)	2/6/2017 11:51 AM	0.01	Deleted

2. Upload supplemental study document(s) not requiring a JHM IRB approval logo:

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document)

Title	Date Modified	Version	Status
View External IRB Submission Checklist Items(0.01)	1/31/2014 2:51 PM	0.01	Submitted

21 - Drugs

1. * Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)?
 Yes No

2. * Are all of the drugs, substances, or biologicals used in this study approved for marketing by the FDA or approved under an IND by the FDA?
 Yes No

3. * Will any of the drugs, substances, or biologicals used in this study be prepared or manipulated after initial product manufacturing?
 Yes No

* List those being prepared or manipulated after initial product manufacturing:
xxx

4. * Select all facilities where the drug is stored, dispensed or manipulated.

- JHH Pharmacy
 JHBMC Pharmacy
 Sibley Memorial Hospital Pharmacy
 Suburban Hospital Pharmacy
 Howard County General Hospital Pharmacy
 Johns Hopkins All Children's Hospital Pharmacy
 Other

5. * Are any of the drugs, substances, or biologicals used in this study classified as Controlled Substances?
 Yes No

6. FDA-approved product used according to the FDA-approved indication (e.g. dosage, route of administration, population, etc.)

Click **Add** to enter new drug information. Click **Update** to modify existing drug information.

Name

[View Drug #1](#)

7. FDA-approved product used for an indication that is not FDA-approved and an IND application WAS NOT submitted to the FDA.
8. FDA-approved product used for an indication that is not FDA-approved and an IND application WAS submitted to the FDA.
9. Non-FDA-approved product and an IND application WAS NOT submitted to the FDA.
10. Non-FDA-approved product and an IND application WAS submitted to the FDA.

22 - Devices

1. * Will any devices be studied in this research (including devices which are FDA-approved for marketing)?

Yes No

2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research?

Yes No

23 - Human Biological Samples

1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research?

Yes No

24 - Institutional Biosafety Committee

1. * Will any of the following be used in this research?

- Recombinant or synthetic nucleic acid molecules
- Potential infectious agents or viral-based vectors
- Biological toxins
- None of the above

26 - Imaging/Radiation

1. * Does this study involve imaging (e.g., MRI, CT, PET, x-rays, ultrasound, fluoroscopy or nuclear medicine)?

Yes No

34 - SKCCC CRO

1. * Is this study cancer related (e.g., cancer prevention, screening, therapeutic, diagnostic, etc.), involving cancer patients, using cancer center facilities/resources?

Yes No

* Does this study involve a drug that will be administered/dispensed in the Weinberg IDS?

Yes No

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36 – Data Confidentiality

1. * I confirm that all the procedures listed below will be used to protect the confidentiality of data and samples collected and stored for research purposes:

Yes No

- Only authorized persons will be granted access
- Only authorized persons may enter and view study data
- Passwords and system IDs will not be shared
- Physical security of the workstations/files will be maintained
- Adequate back-up plan is in effect
- Staff trained on data entry system and importance of security procedures
- Workstations with databases will not be left unattended

3. * Will PHI or other confidential information be stored on laptops or other mobile devices (such as mobile phones, tablets, netbooks, flash drives and other portable storage devices) for this study?

Yes No

4. * Will a Certificate of Confidentiality be obtained for this study?

Yes No

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38 - Approval Documents

1.0 External IRB Initial Approval Letter:

Title	Date Modified	Version	Status
View VUMC Approval Letter(0.01)	2/13/2019 12:46 PM	0.01	Submitted

2.0 Continuing Review Approval Letter:

Title Date Modified Version Status

There are no items to display

3.0 Copy of the External IRB's approved IRB application:

Title Date Modified Category Version Status

There are no items to display

4.0 Other Study Documents:

Title Date Modified Version Needs Stamping Status

There are no items to display

5.0 Legacy Approved Documents:

Title Date Modified Version Status

There are no items to display

Study Team Information

1.0 * Study Team member:

[Janelle Maddox-Regis](#)

2.0 * Study Team role:

Other Staff

3.0 * Primary Affiliation:

Other - Affiliation Not Listed

4.0 * Will this study team member be consenting participants for this study?

Yes No

6.0 Will this person serve as a lead study coordinator?

Yes No

Study Team Information

1.0 * Study Team member:

[Reg User 1 Test](#)

2.0 * Study Team role:

Co-Investigator

3.0 * Primary Affiliation:

Other - Affiliation Not Listed

4.0 * Will this study team member be consenting participants for this study?

Yes No

6.0 Will this person serve as a lead study coordinator?

Yes No

Study Team Conflict of Interest

Study team member:

[Janelle Maddox-Regis](#)

1. Does this study team member have a conflict of interest?

2. Will this study team member server as a non-conflicted designee?

Study Team Conflict of Interest

Study team member:

Reg User 1 Test

1. Does this study team member have a conflict of interest?

Yes

2. Will this study team member server as a non-conflicted designee?

No

Support Source

1. * Select support source:

Phillip Morris Corp

2. Select support source status:

Awarded

3. Enter the grant number (if awarded):

678234

Click OK to display information on the application. Click Save on Support Information page to save information entered on this screen.

Support Source

1. * Select support source:

Trex Medical Corporation

2. Select support source status:

Pending

3. Enter the grant number (if awarded):

1029384576

Click OK to display information on the application. Click Save on Support Information page to save information entered on this screen.

xxx

FDA-approved product used for an indication that is not FDA-approved and an IND application was not submitted to the FDA

1. * Drug / alternative medicine / botanical product name:

Drug #1

2. Name of Manufacturer:

Frito Lay

3. * Did you request an opinion from the FDA on whether an IND application was required for use of the drug listed in 1.0?

4. Provide FDA exemption determination letter:

Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document).

Title	Date Modified	Version	Status
There are no items to display			

5. Explain why you believe your clinical investigation is exempt from the IND application requirements and provide assurance that all of the following elements apply (32 CFR 312.2)

- i. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- ii. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
- iii. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document).

Title	Date Modified	Version	Status
There are no items to display			

xxx

FDA Marketing Clearance and FDA Approved Indication

1. * Device Name:

Device #2

2. * Name of device manufacturer:

Stanley Black and Decker

3. * Is there a separate supply of the device(s) used only for this study?

No

4. Provide available FDA marketing clearance documents (e.g., 510k, PMA).

Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document).

Title	Date Modified	Version	Status
view This document has been left blank on purpose. TRAINING PURPOSES ONLY.doc(0.01)	10/18/2010 12:50 PM	0.01	Submitted

5. * Is the device electrical or battery powered?

Yes

6. * Will the device be used at JHH, JHBMC, KKI or JHACH?

Yes

7. * Has the device been approved for use by Johns Hopkins Clinical Engineering or Johns Hopkins ACH Biomedical Engineering?

Yes

8. * Provide the approval documentation:

Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View This document has been left blank on purpose. TRAINING PURPOSES ONLY.doc(0.01)	10/18/2010 12:51 PM	0.01	Submitted

10. * Does the unit(s) to be used in this research have the identical service tag number(s) as that in the approval documentation?
Yes

xxx

Has Investigational Device Exemption

1. * Device Name:

Device #2

2. * Name of device manufacturer:

Stanley Black and Decker

3. * Is there a separate supply of the device(s) used only for this study?

No

4. * IDE Number:

This box has been left blank on purpose. TRAINING PURPOSES ONLY

5. * IDE Holder:

[Sponsor](#)

6. Provide FDA Documentation of IDE:

Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document).

Title	Date Modified	Version	Status
There are no items to display			

7. * Is the device electrical or battery powered?

Yes

8. * Will the device be used at JHH, JHBMC, KKI or JHACH?

Yes

9. * Has the device been approved for use by Johns Hopkins Clinical Engineering or Johns Hopkins ACH Biomedical Engineering?

Yes

10. * Provide Johns Hopkins Clinical Engineering or Johns Hopkins ACH Biomedical Engineering approval:

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11. * Please indicate a timeline for submission to Johns Hopkins Clinical Engineering Services or Johns Hopkins ACH Biomedical Engineering:

12. * Does the unit(s) to be used in this research have the identical service tag number(s) as that in the approval documentation?

Yes