Come Be INSPIRED as an IRB Member
To Begin

• Go to https://braan.bumc.bu.edu/brainlogin.asp
  or

• www.bumc.bu.edu/inspir and go to Click here to try and login to INSPIR.
INSPIR Web Page

www.bumc.bu.edu/inspir

Integrated Network for Subject Protection in Research

What is INSPIR?
INSPIR stands for the Integrated Network for Subject Protection in Research. It was developed at Baylor College of Medicine and commercialized as BRAAN but has been customized for use here at Boston University and Boston University Medical Center. It is supported by a Human Subjects Research Enhancement Grant from the NIH.

Click here to try and login to INSPIR.

Getting Started with INSPIR
If you have not activated your INSPIR account, submit a request for access.

I need assistance with INSPIR
Whether you are having difficulty setting up your INSPIR account or using a INSPIR module, help is here!
Click the “Login” button
Enter BU User Name and Password
Click on ESP1
Electronic Submission of Protocols to IACUC, IRB

Be Sure To Read
Your Welcome Page

Welcome
SUSAN FISH
Board Member Role

Welcome SUSAN FISH
Board Member Role

• View protocols
• Search
• Reports
• Guide
To Prepare for a Meeting

- Click **View Protocols**
- Select a meeting date, or all meetings
- ***** means *you* have work to do!
- To begin review, click on the protocol # H-xxxxxx
<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
<th>Version</th>
<th>Fdbk</th>
<th>Mtg</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
View a Specific Meeting Date

<table>
<thead>
<tr>
<th>Select a meeting date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/11/04 - Panel Purple - CHAIR: R. FORSE</td>
</tr>
<tr>
<td>05/11/04 - IACUC - CHAIR: R. CORLEY</td>
</tr>
<tr>
<td>05/08/04 - Panel Green - CHAIR: J. WOODSON</td>
</tr>
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</table>

- **EXEMPT REVIEW**

<table>
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<tr>
<th>Protocol</th>
<th>Date</th>
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<tbody>
<tr>
<td>H-2031E</td>
<td>04/25/04 - Panel Blue - CHAIR: L. VACHON</td>
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- **EXPEDITED REVIEW**

<table>
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<tbody>
<tr>
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<td>04/25/04 - Panel Blue - CHAIR: L. VACHON</td>
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- **FULL BOARD REVIEW**

<table>
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<tr>
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<tbody>
<tr>
<td>H-2031E</td>
<td>04/25/04 - Panel Blue - CHAIR: L. VACHON</td>
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</tbody>
</table>

- **Protocols for My Meetings**

<table>
<thead>
<tr>
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<th>Title</th>
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<th>Fdbk</th>
<th>Mtg</th>
</tr>
</thead>
<tbody>
<tr>
<td>H-2031E</td>
<td>XMPT MCL 1 25 04</td>
<td>Amendment</td>
<td>Yes</td>
<td>3/11/04</td>
</tr>
</tbody>
</table>
What Would You Like To Do?

1. Give Feedback
2. Letters/protocol history
   What has happened with the protocol in INSPIR
3. Search adverse events
4. View All Feedback
   Comments from all reviewers for all reviews done
5. View External Attachments
   All documents scanned by IRB office (attached externally)
6. View protocol deviations
7. View protocol exceptions
8. View/edit notepad
   Notes among reviewers, Chairs, and IRB office
9. View/print protocol
   See, review, and/or print the submission
10. Logout
View/Print Protocol
The IRB Application

Institutional Review Board

Status: In Review
Initial Submit Date: 2/26/2004

Section Aa: Title & PI
Protocol Number: H-20310
A1. Protocol Title: XMPT MCL 2 25 04
A2. Principal Investigator
ID: 457730
Name: MICHELLE LEONARD
School: MEDICINE (MED)
Department: PEDIATRICS
Section: PEDIATRICS
CRC Center: None
Location: ndmrbnklnknl
Phone: 555-222-9966
Fax: 555-222-9966
E-mail: MLEONARD@TRANSXIC.COM
Title: MS
A3. PI's Administrative Contact
ID: 111377
Name: DENISE CANALES
Administration Office: 1rd
Phone: 555-222-9966
Fax: 555-222-9966
E-mail: DCANALES@BOM.TMC.EDU

Section Ab: General Information

A3b. Cooperative Agreement
Is this a cooperative agreement protocol? No
COMPARE Button

This compares the submitted version to the previously approved version.
Comparing Versions

Where the difference is

What the difference is

New addition
Institutional Review Board

Status: In Review
Initial Submit Date: 2/25/2004

**Section Aa: Title & PI**

Protocol Number: H-20310

A1. Protocol Title: XMPT MCL 2 25 04

A2. Principal Investigator
ID: 457730
Name: MICHELLE LEONARD
School: MEDICINE (MED)
Department: PEDIATRICS
Section: PEDIATRICS
CRC Center: None
Location: mkmmbnkmld
E-mail: MLEONARD@TRANSDIG.COM
Phone: 555-222-9965
Fax: 555-222-9966

A3. PI's Administrative Contact
ID: 111377
Name: DENISE CANALES
Administration Office: fad
E-mail: D'CANALES@BOM.TMC.EDU
Phone: 555-222-9908
Fax: 555-222-9900

A3b. Cooperative Agreement
Is this a cooperative agreement protocol? No
View the Attachment

<table>
<thead>
<tr>
<th>Attachment</th>
<th>File Name</th>
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<tbody>
<tr>
<td>Section K2 : HIPAA Form(s)</td>
<td><strong>[040225153720PHS Policy on Humane Care and Use of Laboratory Animals.htm]</strong></td>
</tr>
<tr>
<td></td>
<td>File Size Uploaded: <strong>6003</strong> bytes, Date Uploaded: <strong>2/25/2004</strong></td>
</tr>
</tbody>
</table>
Section P. Device Studies

Categorize the device:
- Humanitarian use device

If applicable, provide the IDE number / HDE number. State the name of the device, the manufacturer and who holds the IDE.

Does this study involve the use of an investigational electrical device? Yes

If you believe this study involves an NSIR (non-significant risk) device, please justify this determination.

Section Q. Consent Form(s)

Section R: Recruitment Materials

Mode: Newspaper
Exact language of recruitment material: mmmmmm
Please use this version when reviewing the protocol. To print, click print from your browser toolbar. If you are a PI and need a consent form for subject signature, click here for the printer friendly version.

RESEARCH CONSENT FORM

H-20310 - XMPM MCL 2 25 04

Background

Purpose

What Happens In This Research Study
You will be one of approximately 9 subjects to be asked to participate at this location. A total of 300 subjects at all institutions will be asked to participate in this study.

The research will be conducted at the following location(s): Boston University Medical Campus.

You can see and get a copy of your research related health information. Your research doctor may be able to provide you with part of your information while the study is in progress and the rest of your information at the end of the study.
Software to View ICF and Reports
RESEARCH CONSENT FORM

H-20310- XMPT MCL 2 25 04

Background

Purpose

What Happens In This Research Study
You will be one of approximately 9 subjects to be asked to participate at this location. A total of 300 subjects at all institutions will be asked to participate in this study.

The research will be conducted at the following location(s): Boston University Medical Campus.

Risks and Discomforts

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Potential Benefits

The benefits of participating in this study may be:

However, you may receive no benefit from participation.
Checked for External Attachments
What would you like to do?
Items for the PI’s letter

1. To enlarge your writing space

2. Your review & Comments for discussion

3. Non Templated Modifications
   - What you enter here will go onto the PI’s modification memo, verbatim.

4. Board Comments/Questions
   - What you enter here will be discussed during the board meeting but will not be seen on the PI’s modification memo.

5. Templated Modifications
   - 1. BLOOD TO BE DRAWN: The consent form must include the amount of blood to be drawn at each visit and the total amount to be drawn over the course of the study and must conform to current blood volume guidelines. Blood volumes must be quantified in teaspoons, tablespoons, or cups.
   - 2. CHILD ASSENT: The following is the BCM IRB policy regarding Children’s Assent. Children under the age of 7. Assent will not be obtained. Children between 7 and 12: Assent may be obtained but is not mandatory. If obtained, it can be documented in one of two ways: (1) the pediatric subject would sign on an age-appropriate consent form in addition to the signed consent of the parent on a regular consent form. (2) the following paragraph can appear just before the parent’s signature and the pediatric subject would not sign on any consent form. My signature on this consent form attests to the fact that my child (full name) has seen limits imposed by age, maturity, and psychological state. Given his/her assent (affirmative agreement) to participate in this research project. Children 12-18: Assent must be obtained. It may be documented in the form of an initial sheet. Please fill in the consent form as needed.
Non-Templated Modifications

• Items intended for letter to PI
• Conditions you want the PI to meet
• State clearly, so PI knows what you want him/her to do
• Begin with date, write conditions, end with your initials
Board

Comments/Questions

- Protocol Review
  - Issues to discuss
  - Questions of other reviewers/IRB staff
- Comments that do not go to PI
- Begin with date, write comments, end with your initials
Templated Modifications

- Commonly used conditions
- Automatically inserted into PI’s letter
- Editable by coordinators
IGNORE Recommendations & Renewal Interval
Save Your Comments
“View All Feedback”
<table>
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<tr>
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<th>User</th>
<th>Notes</th>
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<tbody>
<tr>
<td>3/16/2004</td>
<td>LVACHON</td>
<td>I can type notes to the coordinator.</td>
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<tr>
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<tr>
<td>------------------------</td>
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<td>2/25/2004</td>
<td>M. Banks</td>
</tr>
<tr>
<td>Submitted</td>
<td>2/25/2004</td>
<td>M. Leonard</td>
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Search by old study number
To find a study using the "old" IRB number, enter the "old" IRB number in the Title search field and then click on "search".

Protocol Number:  
Protocol Title: 2001-191  
Protocol Personnel:

Status:
Admin Mode Required  
Approved  
Assigned to Committee  
Board Mode Required  
Closed  
Disapproved  
Exempt  
In Review

(Do Not Include AN- or H-)  
(Main Title Search)  
(Last Name, First Name)  
(Personnel includes everyone on the protocol)
Search by Personnel

At least 3 letters
All Protocols for this Person

Search For Protocols - Microsoft Internet Explorer

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>Assigned to Committee Board</td>
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<td>Mods Required</td>
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APPROVED

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<tr>
<th>Number</th>
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<th>Expires</th>
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</table>
Always Log Out
Congratulations!
You’ve Been
INSPIRED