

**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

BUMC: INSPIR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <http://www.bumc.bu.edu/Departments/HomeMain.asp?DepartmentID=448> Go Links

www.bumc.bu.edu NEWS EVENTS PEOPLE PLACES FEEDBACK HELP SEARCH INDEX

Integrated Network for Subject Protection In Research

INSPIR

Index

- ▶ [What is INSPIR](#)
- ▶ [Getting Started](#)
- ▶ [Assistance](#)
- ▶ [Email Forwarding](#)
- ▶ [IRB INSPIR Training Registration Form](#)

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!

Contact

Mailing Address:
715 Albany Street,
Boston, MA 02118

© Copyright Trustees of Boston University FEEDBACK SEARCH INDEX

Start 3 Inter... Inbox - M... Education Microsoft... Microsoft... 2:57 PM

Click the "Login" button

The screenshot shows a Microsoft Internet Explorer browser window with the title "LOGIN - Microsoft Internet Explorer". The address bar displays the URL "https://braan.bumc.bu.edu/brainlogin.asp". The left sidebar shows a list of favorites, with "INSPIR login" circled in red. The main content area features the INSPIR logo and a "Login" button labeled "Login >>>". A red arrow points to this button.

Address: <https://braan.bumc.bu.edu/brainlogin.asp>

INSPIR
Integrated Network for
Subject Protection in Research

Help Information

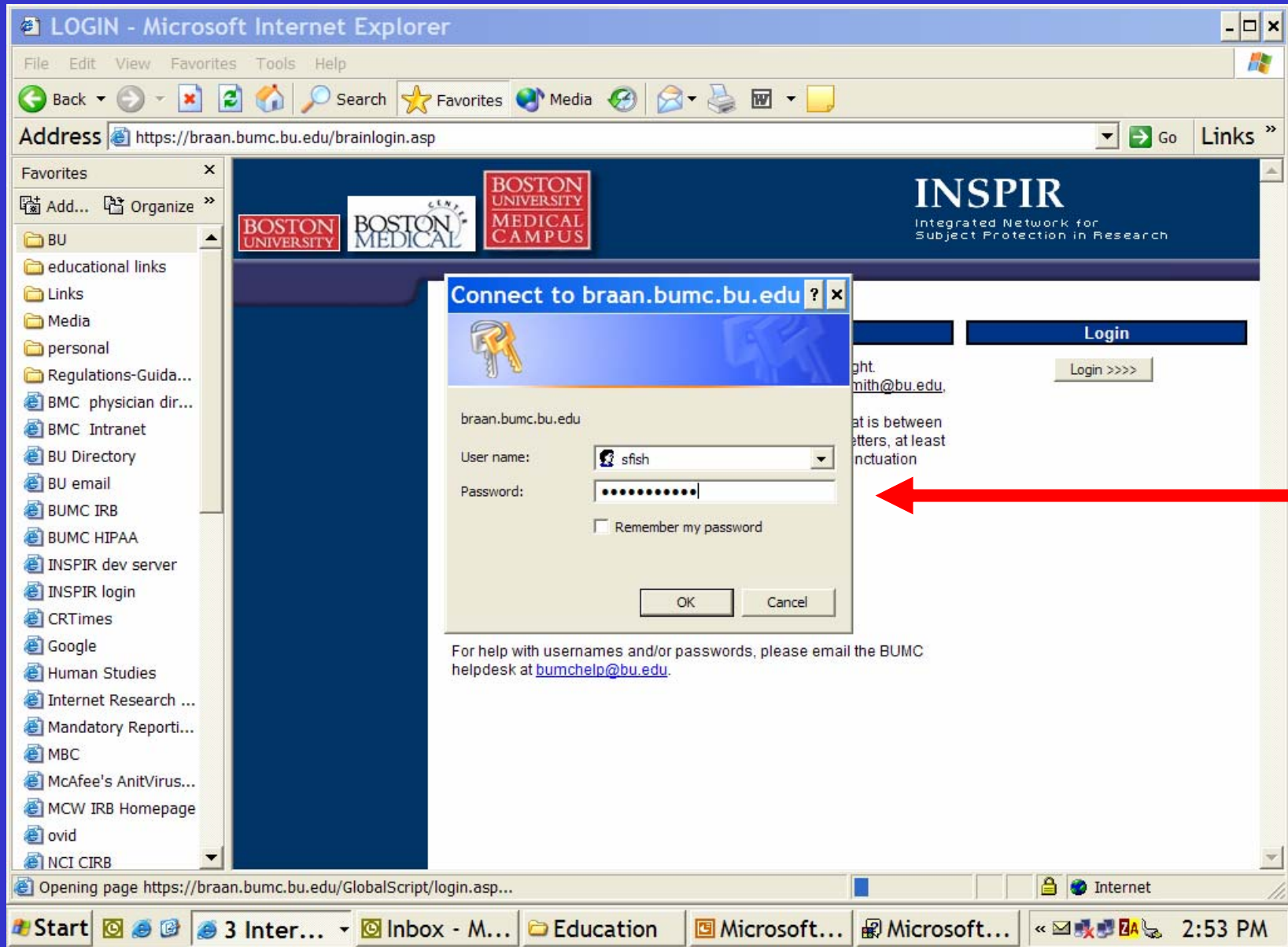
- To access INSPIR, click on the **Login** button to the right.
- In the login window enter your BU login name: for jsmith@bu.edu, enter "jsmith" (8 characters or less).
- Enter your Kerberos password (this is a password that is between 10 and 14 characters long, at least two uppercase letters, at least two lowercase letters and at least one number or punctuation mark).

[Click here for information on INSPIR](#)
[Click here for assistance with INSPIR related problems](#)
[Click here to request access to INSPIR](#)

For help with usernames and/or passwords, please email the BUMC helpdesk at bumchelp@bu.edu.

Login
Login >>>

Enter BU User Name and Password



Click on ESP1

Electronic Submission of Protocols to IACUC, IRB

The screenshot shows a Microsoft Internet Explorer browser window displaying the INSPIR website. The address bar shows the URL: <https://braan.bumc.bu.edu/globalScript/BrainMain.asp>. The website header includes logos for Boston University, Boston Medical Center, and INSPIR (Integrated Network for Subject Protection in Research). The main content area features a navigation bar with a 'Home' button and two links: 'ESP1 - Electronic Submission of Protocols to IACUC, IRB' and 'ESP2 - We are currently upgrading ESP2. Please check back later.' A red arrow points to the 'ESP1' link. Below the navigation bar is a 'General Notices' section, which is highlighted with a red box. The 'General Notices' section contains two notices, both dated 3/15/2004 and marked as 'New!'. The first notice states: 'We are currently experiencing some difficulties with the IRB Consent Form. Please do NOT enter information into Section Q (Consent Section) until we can make the appropriate modifications. We will post an announcement here when the system is corrected. Thank you for your understanding. We apologize for any inconvenience this causes.' The second notice states: 'Welcome to INSPIR BUMC investigators. As of 3/15/04 you may create new IRB protocols within INSPIR. If your IRB protocols have been migrated you may create a Conversion to INSPIR amendment. If you don't find one or more of your protocols listed in the View Protocol screen there are pending issues still being resolved. As soon as those issues are resolved those studies will be migrated to INSPIR.'

INSPIR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/globalScript/BrainMain.asp> Go Links

BOSTON UNIVERSITY BOSTON MEDICAL CENTER BOSTON UNIVERSITY MEDICAL CAMPUS

INSPIR
Integrated Network for
Subject Protection in Research

Home

ESP1 - [Electronic Submission of Protocols to IACUC, IRB](#)

ESP2 - We are currently upgrading ESP2. Please check back later.

General Notices

Notice Posting Date

We are currently experiencing some difficulties with the IRB Consent Form. Please do NOT enter information into Section Q (Consent Section) until we can make the appropriate modifications. We will post an announcement here when the system is corrected. Thank you for your understanding. We apologize for any inconvenience this causes. 3/15/2004 New!

Welcome to INSPIR BUMC investigators. As of 3/15/04 you may create new IRB protocols within INSPIR. If your IRB protocols have been migrated you may create a Conversion to INSPIR amendment. If you don't find one or more of your protocols listed in the View Protocol screen there are pending issues still being resolved. As soon as those issues are resolved those studies will be migrated to INSPIR. 3/15/2004 New!

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Start Inbox - ... Notes 3... INSPIR Microsoft... INSPIR - ... 5:16 PM

Your Welcome Page

Electronic Submission of Protocols System - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/esp1/interface/main.asp> Go Links »

BOSTON UNIVERSITY **BOSTON MEDICAL CENTER** **BOSTON UNIVERSITY MEDICAL CAMPUS**

INSPIR
Integrated Network for
Subject Protection in Research

esp1 **PROTOCOLS**

- ▶ BOARD CHAIR
- ▶ IACUC/IRB
- ▶ BOARD MEMBER
- ▶ INVESTIGATOR
- Email-Help
- Home
- Logout

Welcome
SUSAN FISH

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Start Internet

Notes 3.... INSPIR Microsoft... Electron... Inbox - M... 6:58 PM

Board Member Role

Electronic Submission of Protocols System - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/esp1/interface/main.asp> Go Links »

BOSTON UNIVERSITY BOSTON MEDICAL CENTER BOSTON UNIVERSITY MEDICAL CAMPUS

INSPIR
Integrated Network for
Subject Protection in Research

esp1 PROTOCOLS

- ▶ BOARD CHAIR
- ▶ IACUC/IRB
- ▶ **BOARD MEMBER**
- View Protocols
- Search
- Reports
- Guide
- ▶ INVESTIGATOR
- Email-Help
- Home
- Logout

Welcome
SUSAN FISH

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Internet

Start Inbox - ... Notes 3.... INSPIR Microsoft... Electron... 5:18 PM

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

View Protocols - BOARD MEMBER - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/esp1/interface/Listsmain.asp?parent=BOARD%20MEMBER&setting=VIEW> Go Links

esp1 **PROTOCOLS**

- BOARD CHAIR
- IACUC/IRB
- BOARD MEMBER**
 - View Protocols**
 - Search
 - Reports
 - Guide
- INVESTIGATOR
 - Email-Help
 - Home
 - Logout

Select a meeting date: All Meetings

EXEMPT REVIEW

***** You are designated to review and have NOT finished giving feedback

Number	Title	Version	Fdbk	Mtg
<i>Protocols for My Meetings</i>				

EXPEDITED REVIEW

***** You are designated to review and have NOT finished giving feedback

Number	Title	Version	Fdbk	Mtg
<i>Protocols for My Meetings</i>				
H-20310	XMPT MCL 2 25 04	Amendment	Yes	3/11/2004

FULL BOARD REVIEW

***** You are designated to review and have NOT finished giving feedback

Number	Title	Version	Fdbk	Mtg
<i>Protocols for My Meetings</i>				

APPROVED

Done Internet

Start Inbox - M... Notes 3.1... INSPIR Microsoft... View Pro... 5:24 PM

View a Specific Meeting Date

View Protocols - BOARD MEMBER - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media

Address <https://braan.bumc.bu.edu/esp1/interface/Listsmain.asp?parent=BOARD%20MEMBER&setting=VIEW> Go Links

BOSTON UNIVERSITY BOSTON MEDICAL CAMPUS

INSPIR
Integrated Network for
Subject Protection in Research

esp1 PROTOCOLS

- BOARD CHAIR
- IACUC/IRB
- BOARD MEMBER**
 - View Protocols**
 - Search
 - Reports
 - Guide
- INVESTIGATOR
 - Email-Help
 - Home
 - Logout

Select a meeting date:

- 03/11/04 - Panel Purple - CHAIR: R. FORSE
- 05/11/04 - IACUC - CHAIR: R. CORLEY
- 05/06/04 - Panel Green - CHAIR: J. WOODSON
- 04/22/04 - Panel Blue - CHAIR: L. VACHON**
- 04/20/04 - IACUC - CHAIR: R. CORLEY
- 04/15/04 - Panel Green - CHAIR: J. WOODSON
- 04/08/04 - Panel Blue - CHAIR: L. VACHON
- 04/01/04 - Panel Green - CHAIR: J. WOODSON
- 03/30/04 - IACUC - CHAIR: R. CORLEY
- 03/25/04 - Panel Blue - CHAIR: L. VACHON
- 03/25/04 - Panel Purple - CHAIR: R. FORSE
- 03/18/04 - Panel Green - CHAIR: J. WOODSON

EXEMPT REVIEW

***** You are designated to

Number	Title	Version	Fdbk	Mtg
<i>Protocols for My Meetings</i>				
H-20310	XMPT MCL 2 25 04	Amendment	Yes	3/11/2004

EXPEDITED REVIEW

***** You are designated to review and have NOT finished giving feedback

FULL BOARD REVIEW

***** You are designated to review and have NOT finished giving feedback

Done Internet

Start Notes 3.1... INSPIR Microsoft ... View Pro... Inbox - Mi... 6:37 PM

What would you like to do?

Electronic Submission of Protocols - H-23995 - Microsoft Internet Explorer provided by Verizon Online

File Edit View Favorites Tools Help

Address <https://braan.bumc.bu.edu/esp1/interface/action.asp?setting=PEN&protocol=714321&protocolType=0&title=A+DOUBLE+BLIND%2C+PL> Go Links

Favorites

- BU
- educational li...
- Links
- Media
- personal
- Regulations-G...
- BMC physicia...
- BMC Intranet
- BU Directory
- BU email
- BUMC IRB
- BUMC HIPAA
- INSPIR dev se...
- INSPIR login
- CRTimes
- Google
- Human Studies
- Internet Rese...
- Mandatory Re...
- MBC
- McAfee's Anit...
- MCW IRB Ho...
- ovid
- NCI CIRB

R. Cruz
J. Feldman
L. Gilmartin
P. Green
H. Hong
E. Jamieson
D. Kaufman
J. Kopp
C. Leone
C. Marchant
C. Merrill
I. Montoya
R. Moura
J. Otis
S. Pelton
J. Saukkonen
L. Strunin
L. Vachon
D. Weiner
B. Winrich
H. Xie

L. Diousse
☒ S. Fish
L. Glantz
S. Hess pino
J. Internicola
K. Jordan
K. Khattar
E. Larson
L. Liou
L. McNair
M. Montano
T. Moore
M. Munoz
M. Paasche-orlow
L. Saubermann
C. Streeter
L. Tassinari
J. Weinberg
S. Williams
J. Woodson

Feedback Complete

What would you like to do?

- Give Feedback
- Letters/Protocol History
- Search Adverse Events
- View All Feedback
- View External Attachments
- View Protocol Deviation(s)
- View Protocol Exception(s)
- View/Edit Notepad
- View/Print Protocol
- Logout

Go

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Start 3 Microso... INSPIR Microsoft ... 2 Interne... Microsoft ... 3:37 PM

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

Electronic Submission of Protocols - H-23995 - Microsoft Internet Explorer provided by Verizon Online

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address <https://braan.bumc.bu.edu/esp1/interface/action.asp?setting=PEN&protocol=714321&protocolType=0&title=A+DOUBLE+BLIND%2C+PL> Go Links

Favorites

- Add...
- Org:
- BU
- educational li...
- Links
- Media
- personal
- Regulations-G...
- BMC physicia...
- BMC Intranet
- BU Directory
- BU email
- BUMC IRB
- BUMC HIPAA
- INSPIR dev se...
- INSPIR login
- CRTimes
- Google
- Human Studies
- Internet Rese...
- Mandatory Re...
- MBC
- McAfee's Anit...
- MCW IRB Ho...
- ovid
- NCI CIRB

R. Cruz
J. Feldman
L. Gilmartin
P. Green
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E. Jamieson
D. Kaufman
J. Kopp
C. Leone
C. Marchant
C. Merrill
I. Montoya
R. Moura
J. Otis
S. Pelton
J. Saukkonen
L. Strunin
L. Vachon
D. Weiner
B. Winrich
H. Xie

L. Djousse
S. Fish
L. Glantz
S. Hess pino
J. Internicola
K. Jordan
K. Khattar
E. Larson
L. Liou
L. McNair
M. Montano
T. Moore
M. Munoz
M. Paasche-orlow
L. Saubermann
C. Streeter
L. Tassinari
J. Weinberg
S. Williams
J. Woodson

Feedback Complete

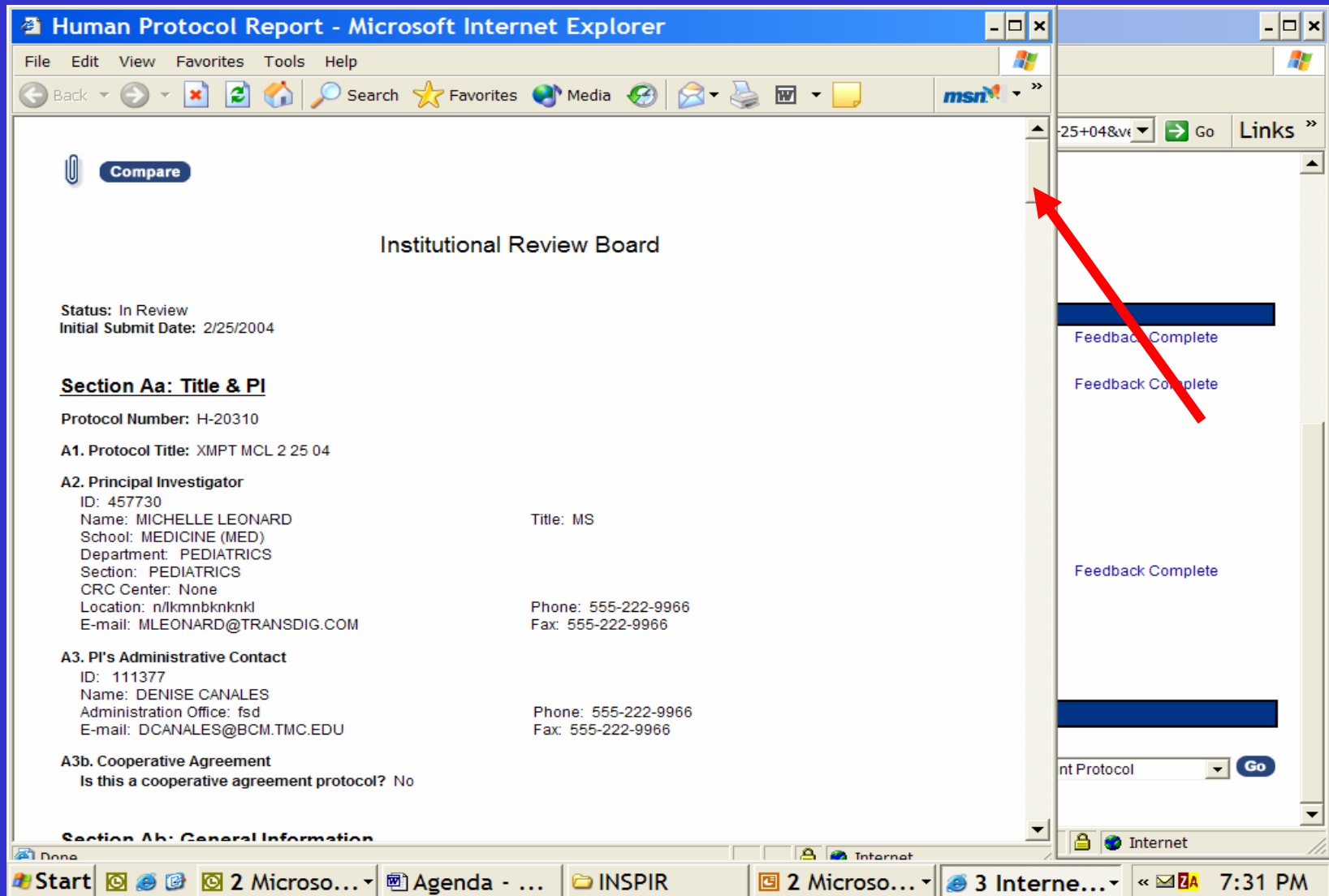
What would you like to do?

- Give Feedback
- Letters/Protocol History
- Search Adverse Events
- View All Feedback
- View External Attachments
- View Protocol Deviation(s)
- View Protocol Exception(s)
- View/Edit Notepad
- View/Print Protocol
- Logout

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Start 3 Microso... INSPIR Microsoft ... 2 Interne... Microsoft ... 3:51 PM

The IRB Application



Human Protocol Report - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print View Source msn

Compare

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	Title: MS
Name: MICHELLE LEONARD	
School: MEDICINE (MED)	
Department: PEDIATRICS	
Section: PEDIATRICS	
CRC Center: None	
Location: n/lkmbnknknkl	Phone: 555-222-9966
E-mail: MLEONARD@TRANSDIG.COM	Fax: 555-222-9966

A3. PI's Administrative Contact

ID: 111377	Phone: 555-222-9966
Name: DENISE CANALES	Fax: 555-222-9966
Administration Office: fsd	
E-mail: DCANALES@BCM.TMC.EDU	

A3b. Cooperative Agreement

Is this a cooperative agreement protocol? No

Section Ab: General Information

Feedback Complete

Feedback Complete

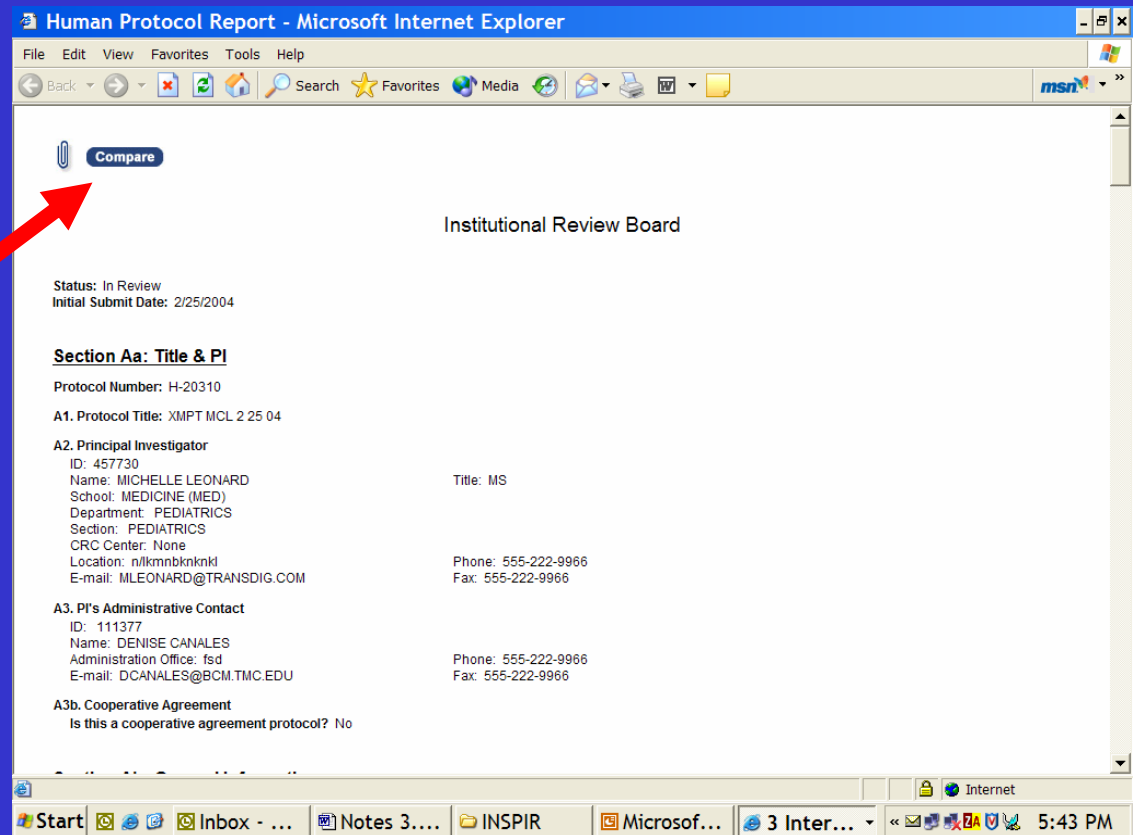
Feedback Complete

nt Protocol

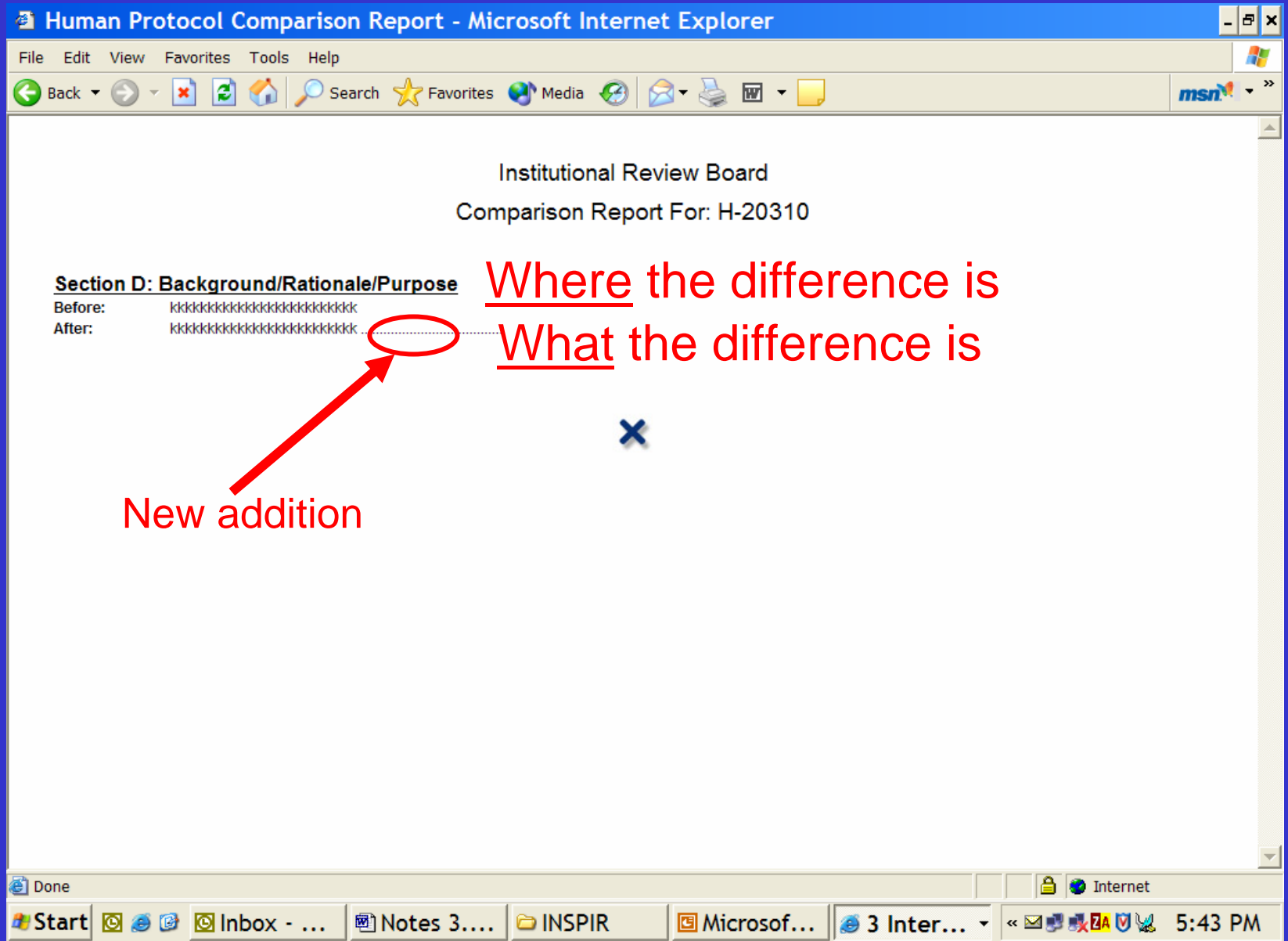
Start 2 Microso... Agenda - ... INSPIR 2 Microso... 3 Interne... 7:31 PM

COMPARE Button

This compares the submitted version to the previously approved version.



Comparing Versions




Attachments- Section S

Human Protocol Report - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail Word

msn

 **Compare**

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	Title: MS
Name: MICHELLE LEONARD	
School: MEDICINE (MED)	
Department: PEDIATRICS	
Section: PEDIATRICS	
CRC Center: None	
Location: n/lkmbnbnknkl	Phone: 555-222-9966
E-mail: MLEONARD@TRANSDIG.COM	Fax: 555-222-9966

A3. PI's Administrative Contact

ID: 111377	Phone: 555-222-9966
Name: DENISE CANALES	Fax: 555-222-9966
Administration Office: fsd	
E-mail: DCANALES@BCM.TMC.EDU	

A3b. Cooperative Agreement

Is this a cooperative agreement protocol? No

Start    Inbox - ...  Notes 3...  INSPIR  Microsof...  3 Inter... 5:43 PM

View the Attachment

View Attachments - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Mail Word

BOSTON UNIVERSITY View Attachments

Attachment	File Name	File Size	Uploaded
Section K2 : HIPAA Form(s)	040225153720PHS Policy on Humane Care and Use of Laboratory Animals.htm	60031	2/25/2004

X

Done Internet

Start Inbox - ... Notes 3.... INSPIR Microsof... 3 Inter... 5:55 PM

To View Consent Form

Human Protocol Report - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media RSS Print Mail

Responsible for storage and documentation of drugs / biological agents:
Investigational Drug Service at BUMC

In the text box below state the name of the drug / biological agent, the name of the manufacturer and who is holding the IND.
kj

Does this research involve a NEW use of an approved drug? If yes, the drug/biological agent name, the name of the manufacturer, and who is holding the IND.
;

FDA approved drugs being used in accordance with FDA labeling which will be administered as part of this research study:
k

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.
j

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

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

Section Q. Consent Form(s)
l

Section R: Recruitment Materials

Mode: Newspaper

Exact language of recruitment material:
mmmmmm

Feedback Complete

Feedback Complete

Feedback Complete

nt Protocol Go

Start 2 Micr... Agenda... INSPIR 2 Micr... Electro... Human ... 7:20 PM

Consent Form Text

Research Consent Form - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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msn

Please use this version when reviewing the protocol. To print, click print from you 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 - XMPT MCL 2 25 04

Background
m

Purpose
x

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.

Z

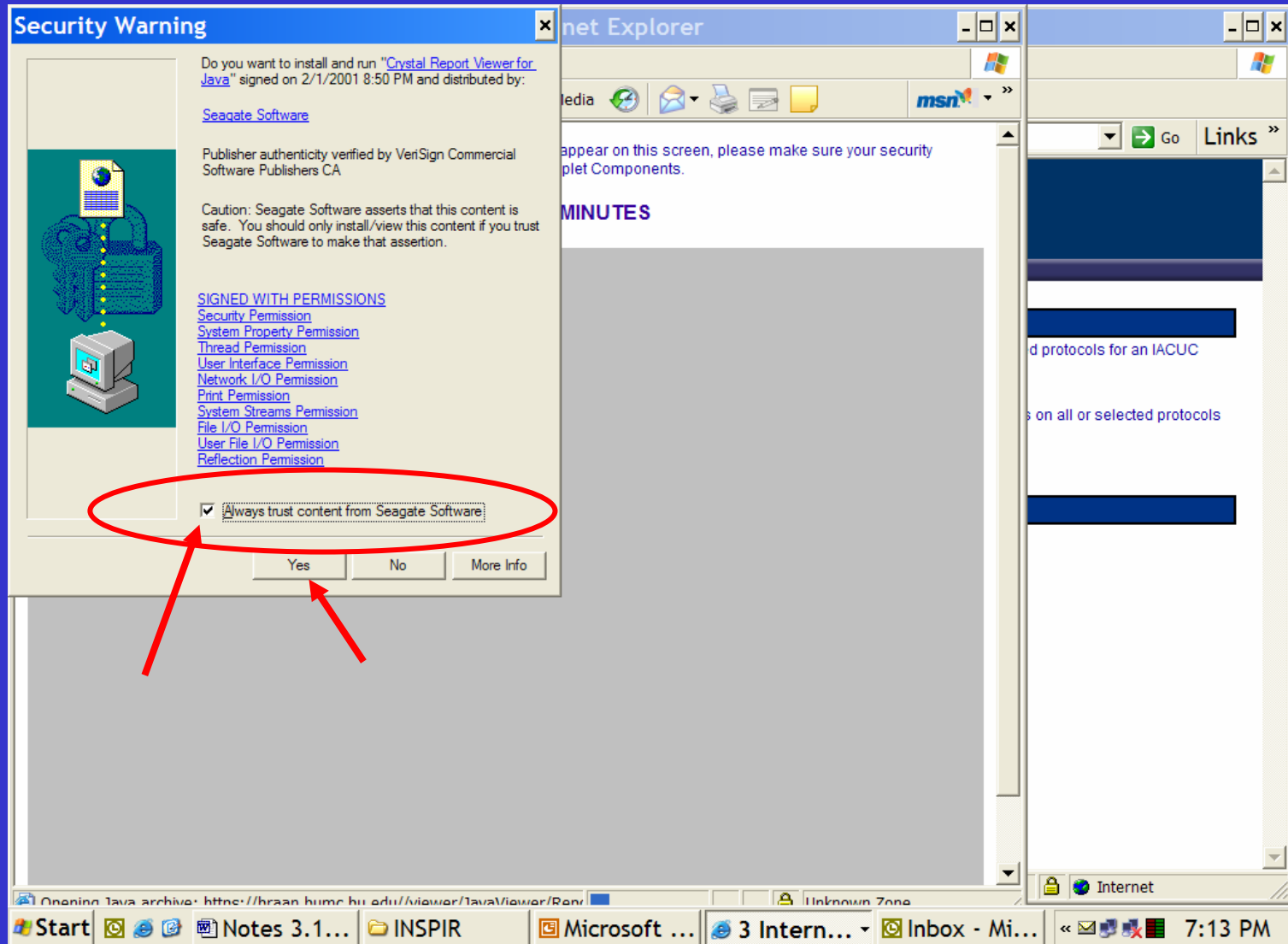
You can see and get a copy of your research related health information. Your research doctor may be able to provide you with part of your information while the study is in progress and the rest of your information at the end of the study.

Risks and Discomforts

Done Internet

Start 2 Microso... Agenda - ... INSPIR 2 Microso... 4 Interne... 7:24 PM

Software to View ICF and Reports



Formatted Consent Form

BUMC CONSENT FORMS - Microsoft Internet Explorer

BUMC CONSENT FORMS

100% 1 of 6

Preview

BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH, DENTAL MEDICINE AND
THE BOSTON MEDICAL CENTER

BOSTON MEDICAL
UNIVERSITY
MEDICAL
CAMPUS

RESEARCH CONSENT FORM

HIPAA Compliant

H-20310- XMPT MCL 2 25 04

Background
m

Purpose
x

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.
z

Risks and Discomforts
z

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.

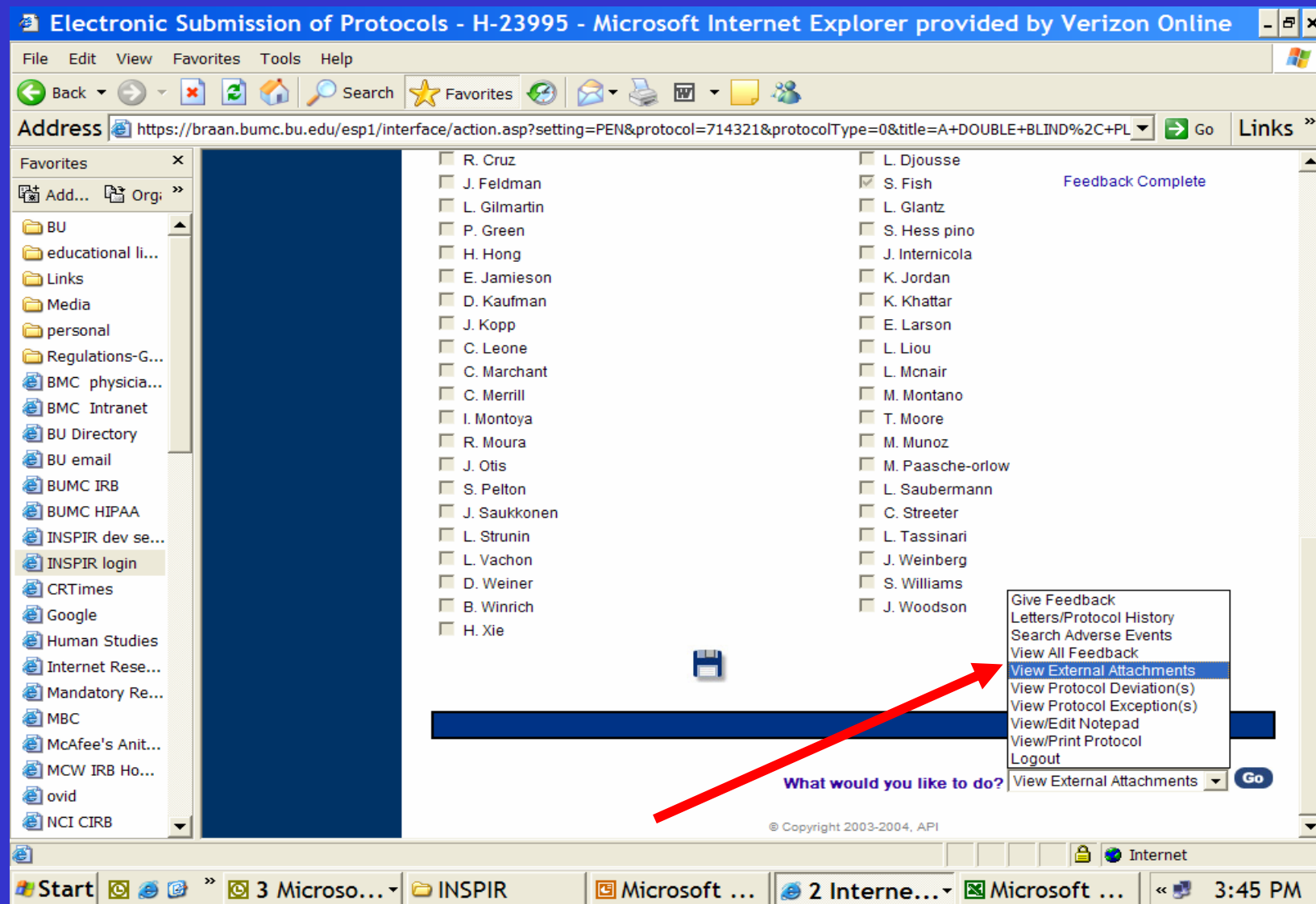
Potential Benefits
The benefits of participating in this study may be: gb. However, you may receive no benefit from

NOT CURRENTLY APPROVED

Done Internet

Start 2 Microso... Agenda - ... INSPIR 2 Microso... 4 Interne... 7:21 PM

Checked for External Attachments



What would you like to do?

Electronic Submission of Protocols - H-20310 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://braan.bumc.bu.edu/esp1/interface/action.asp?setting=PEN&protocol=705051&protocolType=0&title=XMPT+MCL+2+25+04&v> Go Links »

Logout

Nbr Serious Adverse Events: 0
Nbr Exceptions: 0
Nbr Deviations: 0
Meeting Date: 03/11/04 - Panel Purple - CHAIR: R. FORSE
No Vote Letter: ☐ Check if Applicable.

Committee Members

<input type="checkbox"/> S. Auerbach	<input checked="" type="checkbox"/> M. Banks	Feedback Complete
<input type="checkbox"/> W. Bicknell md mph	<input type="checkbox"/> T. Colton	
<input type="checkbox"/> J. Feldman	<input type="checkbox"/> S. Fish	
<input type="checkbox"/> R. Forse	<input type="checkbox"/> L. Glantz	
<input type="checkbox"/> D. Kaufman	<input type="checkbox"/> J. Kopp	
<input type="checkbox"/> C. Leone	<input type="checkbox"/> C. Marchant	
<input type="checkbox"/> D. Mccauley	<input type="checkbox"/> C. Merrill	
<input type="checkbox"/> M. Montano	<input type="checkbox"/> J. Otis	
<input type="checkbox"/> S. Pelton	<input type="checkbox"/> L. Saubermann	
<input type="checkbox"/> J. Saukkonen	<input type="checkbox"/> C. Streeter	
<input type="checkbox"/> L. Strunin	<input type="checkbox"/> L. Vachon	
<input type="checkbox"/> R. Vezina	<input type="checkbox"/> J. Weinberg	
<input type="checkbox"/> J. Woodson		

What would you like to do? **Go**

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Done Internet

Start Inbox - M... Notes 3.1... INSPIR Microsoft... Electron... 5:28 PM

Feedback Complete
Full Protocol/Grant/Brochure
Give Feedback
Letters/Protocol History
Search Adverse Events
View All Feedback
View Protocol Deviation(s)
View Protocol Exception(s)
View/Edit Notepad
View/Print Protocol
Logout

Go

Reviewer Form= Give Feedback

Human Protocol - Give FeedBack - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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BOSTON UNIVERSITY Give Feedback For H-20310

Non Templated Modifications

What you enter here will go onto the PI's modification memo, verbatim.

1 Items for the PI's letter

To enlarge your writing space

2 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.

Your review & Comments for discussion

3 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 parents 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, within the 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 either of the ways indicated above. Please modify the consent appropriately.

Done Internet

Start Inbox - M... Notes 3.1... INSPIR Microsoft... 2 Intern... 5:30 PM

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

Human Protocol - Give FeedBack - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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19. WAIVER OF CONSENT - Please justify waiver of consent by addressing the following questions: a) Define the degree of risk to the research in question. b) Describe the potential harm to subject's rights and welfare if a waiver of consent is granted. c) Describe the practical ability to conduct the study if a waiver is not granted. d) Provide a plan to disseminate new information to subjects after study is complete if applicable

20. Please explain how this device study meets the 812 criteria

21. Please explain how this drug study meets the 312.2 criteria.

Recommendation

☐ ABSTAIN

☐ RECUSE

☐ APPROVE

☐ CONDITIONALLY APPROVE

☐ DEFER

☐ DISAPPROVE

Renewal Interval

☐ Annually

☐ 1 month

☐ By Subject (enter number of subjects)

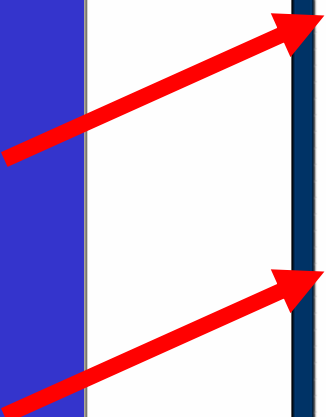
☐ 6 months

☐ 3 months

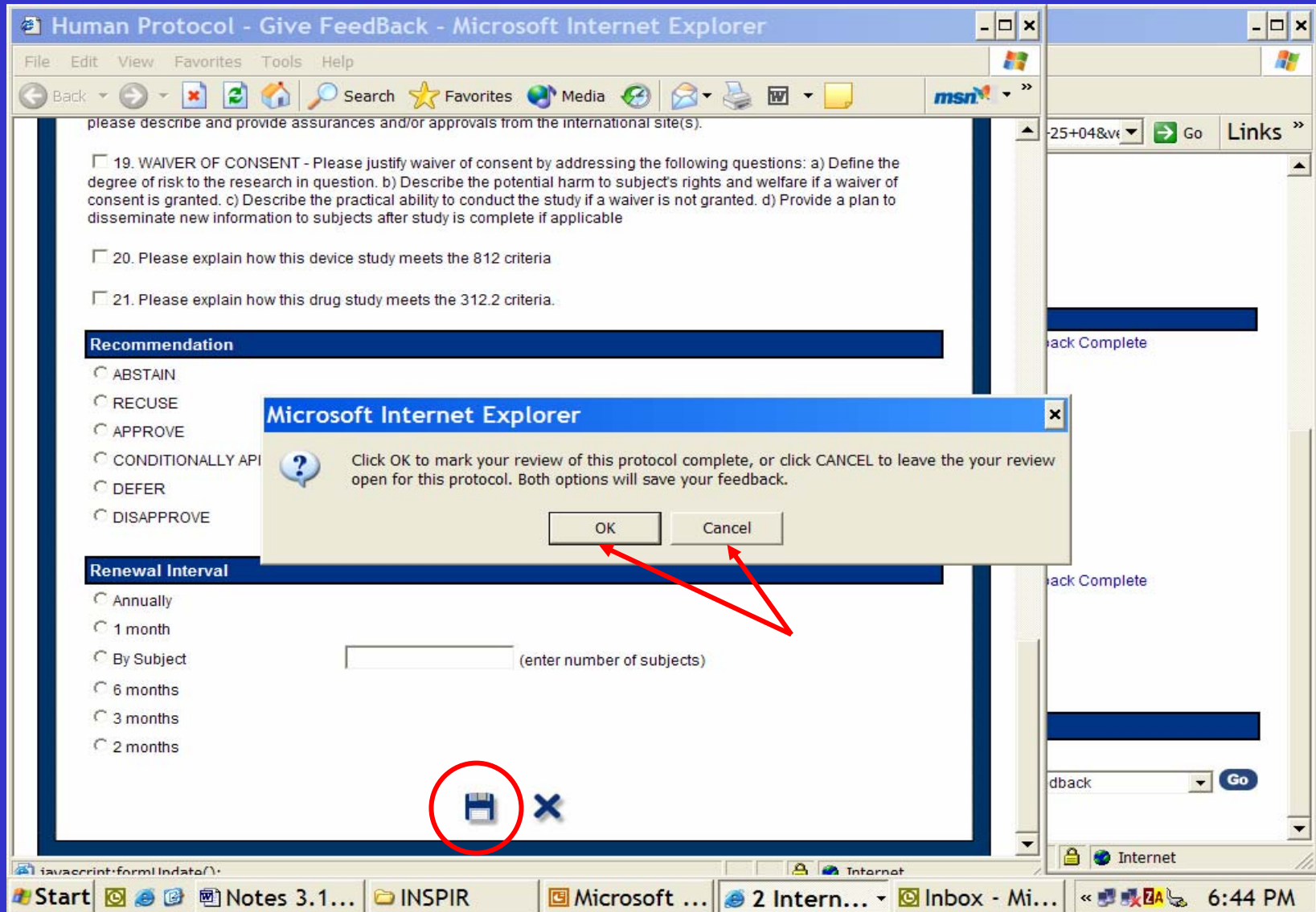
☐ 2 months

Done

Start | Inbox - M... | Notes 3.1... | INSPIR | Microsoft... | 2 Intern... | 5:31 PM



Save Your Comments



The screenshot shows a Microsoft Internet Explorer browser window titled "Human Protocol - Reviewer Feedback - Microsoft Internet Explorer". The address bar is empty. The menu bar includes File, Edit, View, Favorites, Tools, and Help. The toolbar contains Back, Forward, Stop, Reload, Home, Search, Favorites, Media, Print, and a dropdown menu.

The main content area displays a feedback form for a protocol review. The form is divided into sections for comments, recommendations, and designated reviewer information. The first section is titled "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 parents 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, within the 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 either of the ways indicated above. Please modify the consent appropriately."

The second section is titled "Non-Templated Modifications:" and contains a long string of "m"s. The third section is titled "Comments And Questions:" and contains the text "Great Protocol". The fourth section is titled "Recommendation:" and is empty. The fifth section is titled "Designated Reviewer: No" and contains the text "Feedback Date: 3/16/2004" and "Interval Type:". The sixth section is titled "Templated Modifications:" and is empty. The seventh section is titled "Non-Templated Modifications:" and is empty. The eighth section is titled "Comments And Questions:" and contains the text "I propose that this project be deferred". The ninth section is titled "Recommendation:" and is empty.

The status bar at the bottom shows "Done", "Internet", and a taskbar with icons for Start, Notes 3.1..., INSPIR, Microsoft ..., 2 Intern..., Inbox - Mi..., and a clock showing 6:47 PM.

Notepad

The screenshot shows a Microsoft Internet Explorer browser window with the title bar 'Protocol Notepad - Microsoft Internet Explorer'. The address bar contains 'PROTOCOL+2+25+04' and a 'Go' button. The main content area displays a web application titled 'Notepad For H-20311' with a Boston University logo. It features a table with the following data:

Date	User	Notes
3/16/2004	L VACHON	I can type notes to the coordinator.

Below the table is a large blue 'X' icon. On the right side of the browser window, there is a 'Links' section with a dropdown menu showing 'View/Edit Notepad' and a 'Go' button. The taskbar at the bottom shows the Start button and several open applications: 'Notes 3.1...', 'INSPIR', 'Microsoft ...', '2 Intern...', and 'Inbox - Mi...'. The system clock in the bottom right corner indicates the time is 6:50 PM.

Letters/Protocol History

Protocol Letters and History - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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BOSTON UNIVERSITY History Of H-20311

Status History	Date	User	Letters
Draft	2/25/2004 7:37:59 PM	M. Leonard	Progress Report
Approved	2/25/2004 7:36:55 PM	M. Banks	Progress Report
In Review	2/25/2004 7:34:51 PM	M. Banks	Approval Letter
Submitted	2/25/2004 7:33:38 PM	M. Leonard	
Draft	2/25/2004 7:32:04 PM	M. Leonard	
Archived	2/25/2004 7:36:55 PM	M. Banks	Amendment Information
Approved	2/25/2004 7:30:59 PM	M. Banks	Amendment Approval
In Review	2/25/2004 7:28:49 PM	M. Banks	
Submitted	2/25/2004 7:27:33 PM	M. Leonard	
Draft	2/25/2004 7:26:16 PM	M. Leonard	
Archived	2/25/2004 7:30:59 PM	M. Banks	Approval Letter
Approved	2/25/2004 7:25:08 PM	M. Banks	Pending Letter
In Review	2/25/2004 7:22:19 PM	M. Banks	
Assigned to Committee	2/25/2004 1:44:13 PM	M. Banks	
Submitted	2/25/2004 1:41:38 PM	M. Leonard	
Admin Mods Required	2/25/2004 1:28:25 PM	M. Banks	
Submitted	2/25/2004 12:58:38 PM	S. Pelton	
Awaiting Signatures	2/25/2004 12:55:30 PM	M. Leonard	
Draft	2/25/2004 12:54:12 PM	M. Leonard	

Start [Icons] Inbox - ... Notes 3... INSPIR Microsoft... 2 Inter... 5:41 PM

Search

Search For Protocols - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/esp1/interface/FindProtocols.asp?parent=BOARD%20MEMBER&setting=FIND> Go Links »

BOSTON UNIVERSITY **BOSTON MEDICAL CAMPUS** **INSPIR**
Integrated Network for Subject Protection in Research

esp1 **PROTOCOLS**

- BOARD CHAIR
- IACUC/IRB
- BOARD MEMBER**
 - View Protocols
 - Search**
 - Reports
 - Guide
- INVESTIGATOR
 - Email-Help
 - Home
 - Logout

Search For Protocols

Protocol Number: (Do Not Include AN- or H-)

Protocol Title: ? (Main Title Search)

Protocol Personnel: (Last Name, First Name)
(Personnel includes everyone on the protocol)

Status:

- Admin Mods Required
- Approved
- Assigned to Committee
- Board Mods Required
- Closed
- Disapproved
- Exempt
- In Review

Go

Search by old study number

Start | Inbox - Mi... | Notes 3.1... | INSPIR | Microsoft ... | Search Fo... | 6:02 PM

Help ?

The screenshot shows a web browser window titled "INSPIR Help - Microsoft Internet Explorer". A help window is open, displaying instructions: "To find a study using the 'old' IRB number, enter the 'old' IRB number in the Title search field and then click on 'search'." Below the instructions is a "Close" link. The main page is the "INSPIR Integrated Network for Subject Protection in Research" search interface. A red arrow points from the help window to a question mark icon in the "Protocol Title" search field. The interface includes a left sidebar with navigation links: BOARD CHAIR, IACUC/IRB, BOARD MEMBER (selected), View Protocols, Search, Reports, Guide, INVESTIGATOR, Email-Help, Home, and Logout. The search area has fields for Protocol Number, Protocol Title (containing "2001-191"), and Protocol Personnel. A dropdown menu for Status is open, showing options like Admin Mods Required, Approved, Assigned to Committee, Board Mods Required, Closed, Disapproved, Exempt, and In Review. A "Go" button is at the bottom of the search area. The status bar at the bottom shows the URL "javascript:openPopUpHelpWindow('http://www.bu.edu/crtimes/INSPIRpop-ups/2.htm', 'Help');" and the system clock "6:04 PM".

INSPIR Help - Microsoft Internet Explorer

To find a study using the "old" IRB number, enter the "old" IRB number in the Title search field and then click on "search".

[Close](#)

INSPIR
Integrated Network for
Subject Protection in Research

Search For Protocols

Protocol Number:

Protocol Title: ?

Protocol Personnel:

Status:

(Do Not Include AN- or H-)

(Main Title Search)

(Last Name, First Name)

(Personnel includes everyone on the protocol)

Go

javascript:openPopUpHelpWindow('http://www.bu.edu/crtimes/INSPIRpop-ups/2.htm', 'Help');

Start | Inbox - Mi... | Notes 3.1... | INSPIR | Microsoft ... | 2 Intern... | 6:04 PM

Search by Personnel

Search For Protocols - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address <https://braan.bumc.bu.edu/esp1/interface/FindProtocols.asp?parent=BOARD%20MEMBER&setting=FIND> Go Links »

BOSTON UNIVERSITY **BOSTON MEDICAL CENTER** **BOSTON UNIVERSITY MEDICAL CAMPUS**

INSPIR
Integrated Network for
Subject Protection in Research


esp1 **PROTOCOLS**

BOARD CHAIR
IACUC/IRB
BOARD MEMBER
View Protocols
Search
Reports
Guide
INVESTIGATOR
Email-Help
Home
Logout

Search For Protocols

Protocol Number:

Protocol Title: ?

Protocol Personnel: 

(Do Not Include AN- or H-)

(Main Title Search)

(Last Name, First Name)
(Personnel includes everyone on the protocol)

At least 3 letters

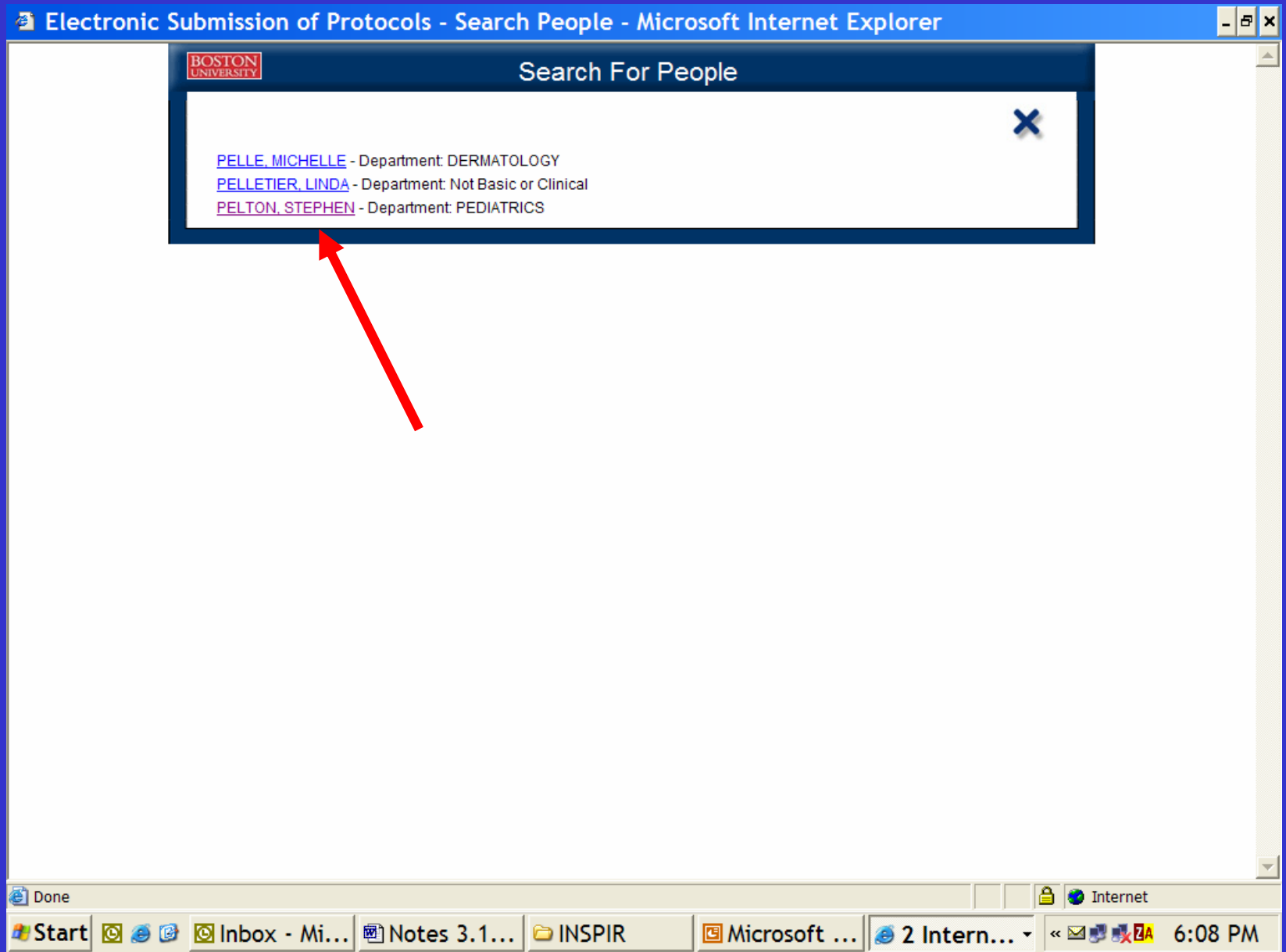
Status:
Admin Mods Required
Approved
Assigned to Committee
Board Mods Required
Closed
Disapproved
Exempt
In Review

Go

Done Internet

Start Inbox - Mi... Notes 3.1... INSPIR Microsoft ... Search F... 6:06 PM

Binoculars



All Protocols for this Person

Search For Protocols - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media RSS Print Mail

Address <https://braan.bumc.bu.edu/esp1/interface/findprotocols.asp#beginresults> Go Links »

Guide

- ▶ **INVESTIGATOR**
- Email-Help
- Home
- Logout

Status:

Admin Mods Required
Approved
Assigned to Committee
Board Mods Required
Closed
Disapproved
Exempt
In Review

Go

APPROVED

Number	Title	Approved	Expires
H-22735 [2001-326G]	ASSESSMENT OF FUNTIONAL ANTIBODY IN HIV	6/25/2003	6/24/2004
H-22736 [2003-360B]	RETROSPECTIVE SEROSURVEY OF ANTIBODY TO	10/27/2003	10/26/2004
H-22737 [89-39B]	HIV SURVEILLANCE IN CHILDREN 89-39B	9/12/2003	9/11/2004
H-22738 [97-64B]	EARLY INTENSIVE ANTIRETROVIRAL	8/27/2003	8/26/2004
H-22739 [2000-418B]	EVALUATION OF THE IMMUNOGENICITY OF	11/8/2003	11/7/2004
H-22740 [2001-343B]	EVALUATION OF CHILDREN WITH INVASIVE	8/27/2003	8/26/2004
H-22741 [2000-248G]	EPIDEMIOLOGY OF HEPATITIS C VIRUS INFECTION	7/2/2003	7/1/2004
H-22742 [2000-315B]	DURABILITY OF ANTIBODY RESPONSE TO	9/4/2003	9/3/2004
H-22743 [2002-212G]	CYTOTOXIC T CELL ACTIVATION AND EARLY	7/3/2003	7/2/2004
H-22744 [2002-086G]	CYTOTOXIC T CELL ACTIVATON IN CHILDREN WITH	4/3/2003	4/2/2004
H-22745 [2002-229B]	HIV-SPECIFIC IMMUNE RESPONSES AND	9/11/2003	9/10/2004

Done Internet

Start [Icons] Inbox - Mi... Notes 3.1... INSPIR Microsoft ... Search F... 6:09 PM

Always Log Out

Electronic Submission of Protocols - H-20311 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Mail Print W Go Links »

Address <https://braan.bumc.bu.edu/esp1/interface/action.asp?setting=APP&protocol=705059&protocolType=0&title=FB+PROTOCOL+2+25+04>

BOSTON UNIVERSITY **BOSTON MEDICAL CAMPUS** **INSPIR**
Integrated Network for Subject Protection in Research

PROTOCOLS

Protocol - Approved

Protocol: H-20311
Title: FB PROTOCOL 2 25 04
Principal Investigator: MICHELLE LEONARD
Review Type: Expedited
Device Risk: Not Applicable
Protocol Risk: 45 CFR 46.406 - Category 3
Protocol, Grant, Brochure: No
Nbr Serious Adverse Events: 0
Nbr Exceptions: 0
Nbr Deviations: 0
Initial Submit Date: 2/25/2004
Approval Date: 2/25/2004
Expiration Date: 3/26/2004

What would you like to do?

- View/Edit Notepad
- Search Adverse Event(s)
- View Protocol Deviations
- View Protocol/Grant/Brochure
- View/Edit Notepad
- View/Print Protocol
- Logout

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Start Notes 3.1... INSPIR Microsoft ... Electroni... Index - Mi... 6:55 PM

Congratulations!
You've Been
INSPIRed