CTSI

NYU Langone Health

CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

New York University | NYU Langone Health | NYC Health + Hospitals

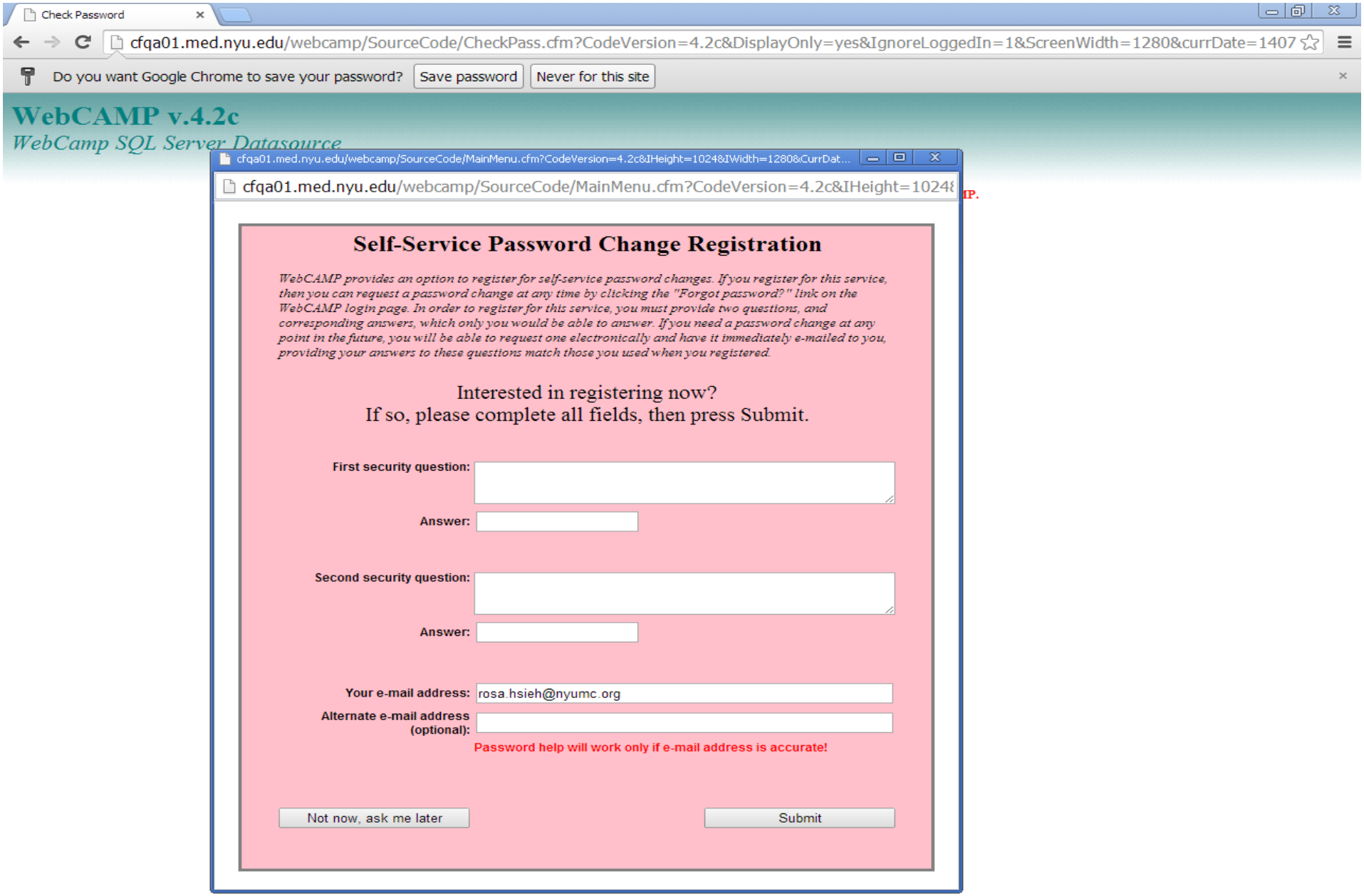
Submitting a **New Application** in WebCAMP

(NOTE: This is after you have submitted an initial application.)

1. Click on the following link: https://webcamp.nyumc.org
   IMPORTANT: **For proper functioning of WebCAMP, please utilize only Google Chrome, Mozilla Firefox or Internet Explorer (i.e., not Safari).**

2. Login using your Last name, First name and the Password you have created for yourself. Click *Continue*.

3. If prompted, complete the **Self-Service Password Change Registration**, which allows you to recover your password if forgotten. Click *Submit*.



4. If prompted, set the **Session time out** minutes, and click *Continue*.

The "time out" limit for your session is currently set to 20 minutes. This means that WebCAMP will become disabled when there have been no new pages displayed for 20 minutes. In the event that you have unsaved data when WebCAMP closes, that data will be lost.

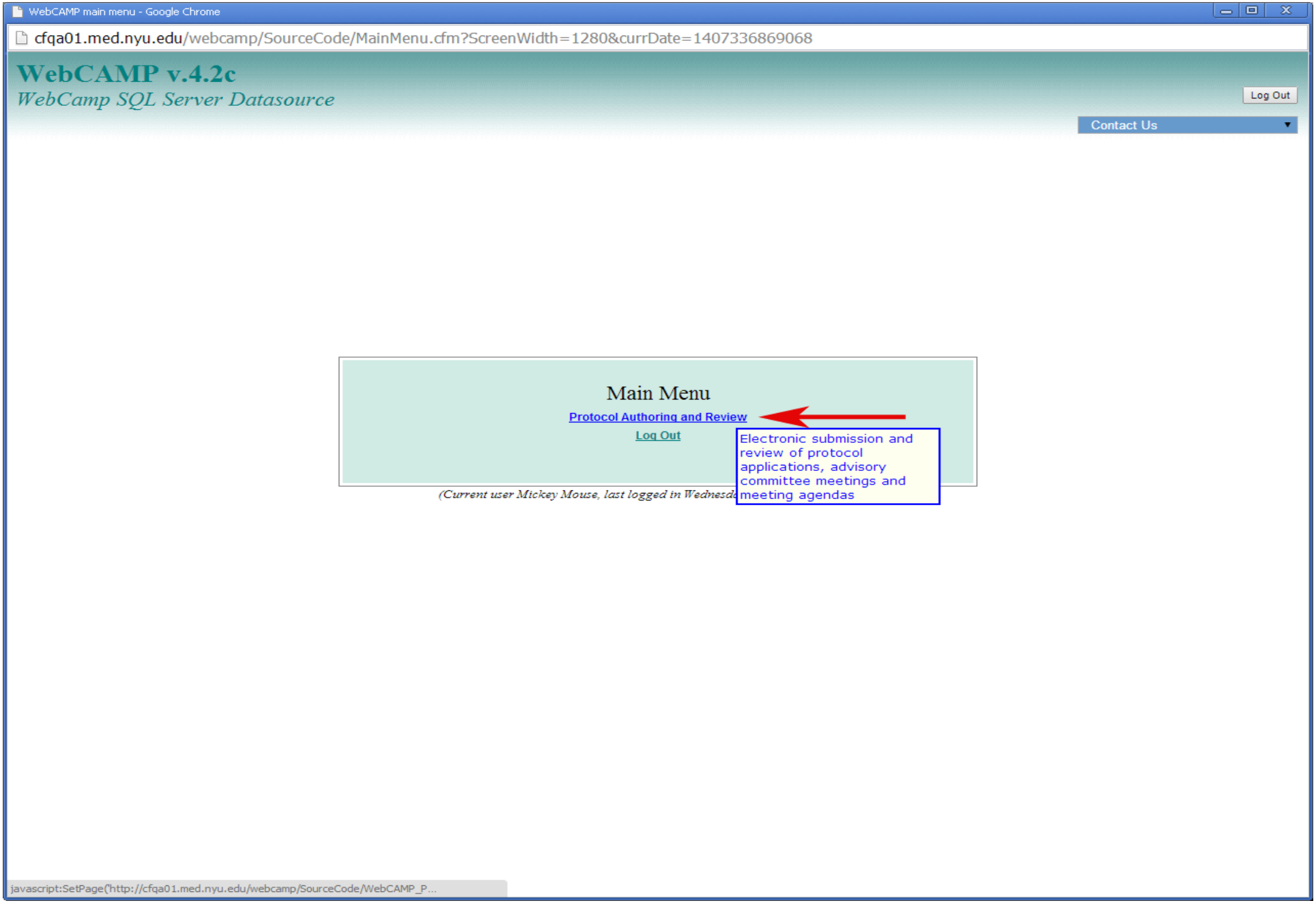
The purpose of the "time out" setting is to protect against unauthorized access to the WebCAMP. If a PC is in a public location and you have logged in and then left the PC unattended, anyone with access to the PC could potentially modify data. The default "time out" setting is therefore set low as a security measure. However, if your PC is in a physically secure location, you may wish to raise the value significantly.

If you would like to set your session's time out to a larger value, please modify the value in the field below. When the value is set as you would like it, press the "Continue" button.

Session time out: 60 *minutes*

Continue

5. Click on **Protocol Authoring and Review**.



6. At the Protocol Submissions screen, click the **View/Edit** link for the study you would like to complete an application for.

   Note that on this screen you may also initiate a new application for another study by clicking ***Begin a new submission.***

Protocol Applications - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/ProtocolApplications.cfm?FirstTime=yes&ScreenWidth=1280&currDate=1407336888496

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

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Protocol Submissions

☑ *Show only latest version of each application*

☐ *Limit to open projects (i.e., those that have been approved AND are not closed, completed, or terminated)*

Begin a new submission

Return to menu

No.	Principal Investigator/Applicant	Primary Contact	Application Type	Internal Project ID	Abbreviated Title	Application Status	Current Project/Program Status (if approved)	Versions (Amendments)	First Accessed*	Last Accessed*
1	Mouse, Mickey rosa.hsieh@nyumc.org	(not specified)	CTSI: Full Support		Mickey's Test Study [View/Edit] [Print] [Cancel] [Download]	In development	N/A	(none)	(never or unknown)	(never or unknown)

*NOTE: "Accessed" columns include only access by study team. Access by NYU CTSI administration and/or review committee members is not shown.

javascript:AddProt();

The application has several sections that must be completed. Note that depending on the Application Type, different content will be required.

7. **PROTOCOL SUMMARY PAGE –** Begin by clicking on the **Protocol Summary Page**, if it is not already selected, and complete the basic study information requested. *Note that the fields for **BLA, NDA,** and **ANDA** fields are not required if they are not applicable.*

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407854170713

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

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[Run Completeness Check]

User Access Rights
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Print selected section
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CTSI: Full Support:
"Mickey's Test Study"
Current status: In development as amendment
New application Amendment

Last modified by Mickey Mouse on 8/12/14 at 10:36AM.

INTERNAL PROJECT ID: (to be entered by administration)
INITIATOR OF PROTOCOL: Mickey Mouse, Professor
PRIMARY CONTACT PERSON: Mickey Mouse [change]

PROTOCOL FLAGS
Check all that apply.
- Study enrollment has ended
- Study is ancillary or substudy
- Study is NIH-Funded
- Study requires Bellevue labs
- This is a renewal submission

CLASSIFICATION OF STUDY ON TRANSLATIONAL CONTINUUM
Which classification is MOST applicable to the current project?
- Basic science More info
- Clinical or patient-related More info
- Post-clinical More info

OTHER DATA WE MAY BE REQUIRED TO REPORT

Informatics-only protocol?	No	Yes
Multicenter study?	No	Yes
Clinical trial?	No	Yes
AIDS-related?	No	Yes
Pediatrics? More info	No	Yes

Does this study involve recombinant DNA? No Yes

FDA license(s)? [view/edit details]

IND:	No	Yes
IDE:	No	Yes
BLA:	No	Yes
NDA:	No	Yes
ANDA:	No	Yes

REGULATORY INFORMATION
Grantee: More info
Mouse, Mickey menu
Human subjects? No Yes
IRB institution:
NYU School of Medicine
PI for IRB: More Info
Mouse, Mickey menu
IRB number (if known):
123456
IRB status:
Approved
Approval date: 1/1/2014
Expiration date: 1/1/2015
Animal subjects? No Yes

BRIEF NAME: Mickey's Test Study
FULL TITLE: Test

Scroll down the page to continue completing the **Protocol Summary Page** information. When you are done, scroll back to the top and click *Save Changes*.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407417395734

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ABSTRACT:

INVESTIGATORS

Action	Role	Name	Degree(s)	Institution	Department	Division	Title	Area of Expertise For This Project	Basic/Clinical	E-Mail/Phone	eRA Commons Username More Info	Status at Study Initiation
[edit] [del]	Lead PI	Mouse, Mickey		NYU School of Medicine	CTSI		Professor			rosa.hsieh@nyumc.org 555-555-5555		

[change lead PI]
[add other PI]
[add co-investigator]

OTHER CONTRIBUTORS/STAFF

None specified [add other contributor/staff]

ANTICIPATED SUBJECT ACCRUAL

Expected START date for subject accrual:
Expected END date for subject accrual:

SOURCES OF SUPPORT FOR THIS STUDY ***(check all that apply)***

Federal: none writing application submitted pending existing
Foundation: none writing application submitted pending existing
Industry: none writing application submitted pending existing
If Industry-supported, is this study: Investigator-initiated / Industry-initiated
Other: none writing application submitted pending existing
Specify:

Do any study investigators have other NIH funding unrelated to this study? Yes No

CTSI Funding Year: Current Protocol Version or Date: NYU Account Chartfield Number:

APPROVAL DATES

Bellevue Approval: (mm/dd/yyyy) Bellevue Expiration: (mm/dd/yyyy) Main Consent Approval: (mm/dd/yyyy) Main Consent Expiration: (mm/dd/yyyy)

8. **ADDITIONAL INFORMATION Page** – Click on the **Additional Information** page and answer all questions listed. Where available, click on the '*More info*' link for a more detailed explanation of the question. Click *Save Changes*.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407854170713

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ADDITIONAL INFORMATION

01. If you have HHC collaborators, specify. (Select all that apply.) More info
01a. Bellevue
01b. Kings County
01c. Lincoln
01d. Gouverneur
01e. Woodhull
01f. Metropolitan
01g. Coney Island
01h. Coler-Goldwater

02. If you have CTSA collaborators, specify. More info
Word count limit: 0 Current word count:

03. Are you a New Investigator? (See 'More Info') Yes No More info

04. Are you an Early Stage Investigator? (See 'More Info') More info

05. Do you have a Research Mentor? Yes No

05a. If yes, complete Mentor Approval Form in Supporting Documents. More info

06. If this study is ancillary, explain relationship to larger study. More info
Word count limit: 0 Current word count:

07. If study has translational/clinical science component, explain. More info
Word count limit: 0 Current word count:

08. If study has comm. engagement or pop. health component, explain. More info
Word count limit: 0 Current word count:

09. Characterize immediate impact of research on health of NYC. More info

9. **LABS AND PHARMACY REQUESTS Page** – Click on the **Labs and Pharmacy Requests** page and answer all questions listed, as they are applicable to your project. Where available, click on the '*More info*' link for a more detailed explanation of the question. Click *Save Changes*.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407857784259

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

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LABS AND PHARMACY REQUESTS

01. Will study require patient labs to be processed by the CTSI CRC? Yes No More info

02. If yes, where will the labs be performed? (Select all that apply.)

02a. Bellevue Hospital (Contact: Eleanor DeCandia)

02b. Tisch Faculty Practice (Contact: Peggy Ross)

02c. Translational Research Core Laboratory (Contact: Rachel Brody)

02d. If Other, specify the facility.

03. Indicate contact person for labs.

04. List patient labs required to be processed by the CTSI CRC. More info

Word count limit: 0 Current word count:

05. Will this study require pharmacy use? Yes No

06. If yes, where is the pharmacy located? (Select all that apply.)

06a. CTSI Pharmacy

06b. Tisch Faculty Practice

06c. Bellevue Hospital (chemo only)

Last modified by Mickey Mouse on 8/12/14 at 11:36AM.

[Run Completeness Check]

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Cancel current application
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10. **RENEWAL PROGRESS REPORT Page** – Since this is a new application, this section is not required.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407854170713

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Print selected section
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RENEWAL PROGRESS REPORT

01. If protocol has changed since last submission, describe changes.

Word count limit: 0 Current word count:

02. Provide a clinical/scientific progress report for the past year.

Word count limit: 0 Current word count:

03. List all publications that have resulted from this study thus far.

Word count limit: 0 Current word count:

04. List all grants that resulted from this study thus far.

Word count limit: 0 Current word count:

05. Describe any unexpected safety concerns and their resolutions.

Word count limit: 0 Current word count:

06. If work for this study is intellectual property, explain.

Word count limit: 0 Current word count:

07. If work for this study is patentable, explain.

Word count limit: 0 Current word count:

08. Number of participants enrolled on the CTSI over the past year.

09. If there has been been no accrual this past year, explain why.

11. **STUDY FUNDING SOURCES Page –** Click on the **Study Funding Sources** page and answer all questions listed. Where available, click on the '*More info*' link for a more detailed explanation of the question. Click *Save Changes*.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407854170713

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STUDY FUNDING SOURCES

01. Who is the OCT contact for this study? More info

02. Who is the study's financial contact person?

03. Funding Agency Name More info

04. Study or Grant Number

05. Funding Period

06. Describe why you are seeking CTSI support. More info

Word count limit: 0 Current word count:

07. Explain how study will lead to extramural funding or further goal. More info

Word count limit: 0 Current word count:

Last modified by Mickey Mouse on 8/12/14 at 10:36AM.

[Run Completeness Check]

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Print selected section
Cancel current application
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javascript:SetPage('UserDefinedContent.cfm?Table=SACAPP_PROTOCOL&Group=Study Funding Sources',top.ContentFrame)

12. **RESOURCES REQUESTED Page** – Click on the **Resources Requested** page and then check the box(es) in the **Requested?** column to indicate which core(s) you would like to request resources or services from. Once the box is checked, click on the **Details of Request** link to specify the details of your request.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407417395734

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Resources Requested

Core	Requested?	Request finalized?	Request approved by core?	Request details
CTSI Biorepository	☐			
CTSI Center for Health Informatics and Bioinformatics	☐			
CTSI Clinical Research Center	☑ Details of Request	No	(request not finalized)	
CTSI Community Engagement and Population Health	☐			
CTSI Core Laboratory	☐			
CTSI Research Subject Safety Office	☐			
CTSI Study Design, Biostatistics and Ethics	☐			
Non-CTSI Resources	☐			
Participant Compensation	☐			

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
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13. For use of the Clinical Research Center (CRC), click **add/delete** to display the list of services available. *Continue to the next page of this manual.*
For use of any other core, specify your request in the **Description/justification of need** text box (be as detailed as possible!).

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407417395734

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

Log Out

Resources Requested: Request Detail - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/ResourcesRequestedDetail.cfm?WhichRec=809&CurrDate=140742341

Detail of Service Request: CTSI Clinical Research Center

THIS REQUEST HAS NOT YET BEEN FINALIZED BUT NOT YET REVIEWED BY THE CORE OR SERVICE PROVIDER.
WHEN YOU HAVE COMPLETED ALL INFORMATION BELOW, PLEASE CLICK THE 'FINALIZE' CHECKBOX.
THIS WILL LAUNCH AN E-MAIL MESSAGE TO THE CORE TO REVIEW YOUR REQUEST.

[add/delete]

Resource	Start Date	End Date	Quantity Requested
(none selected)			

Description/justification of need:

If you have discussed this project's needs with a representative of "CTSI Clinical Research Center", please select from the list below the person with whom you have consulted.

This request is finalized. More info

Last modified by Mickey Mouse on 8/6/14 at 10:46AM.

Close

Request details

Application Stat
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Resources Req
Other Support
Supporting Doc

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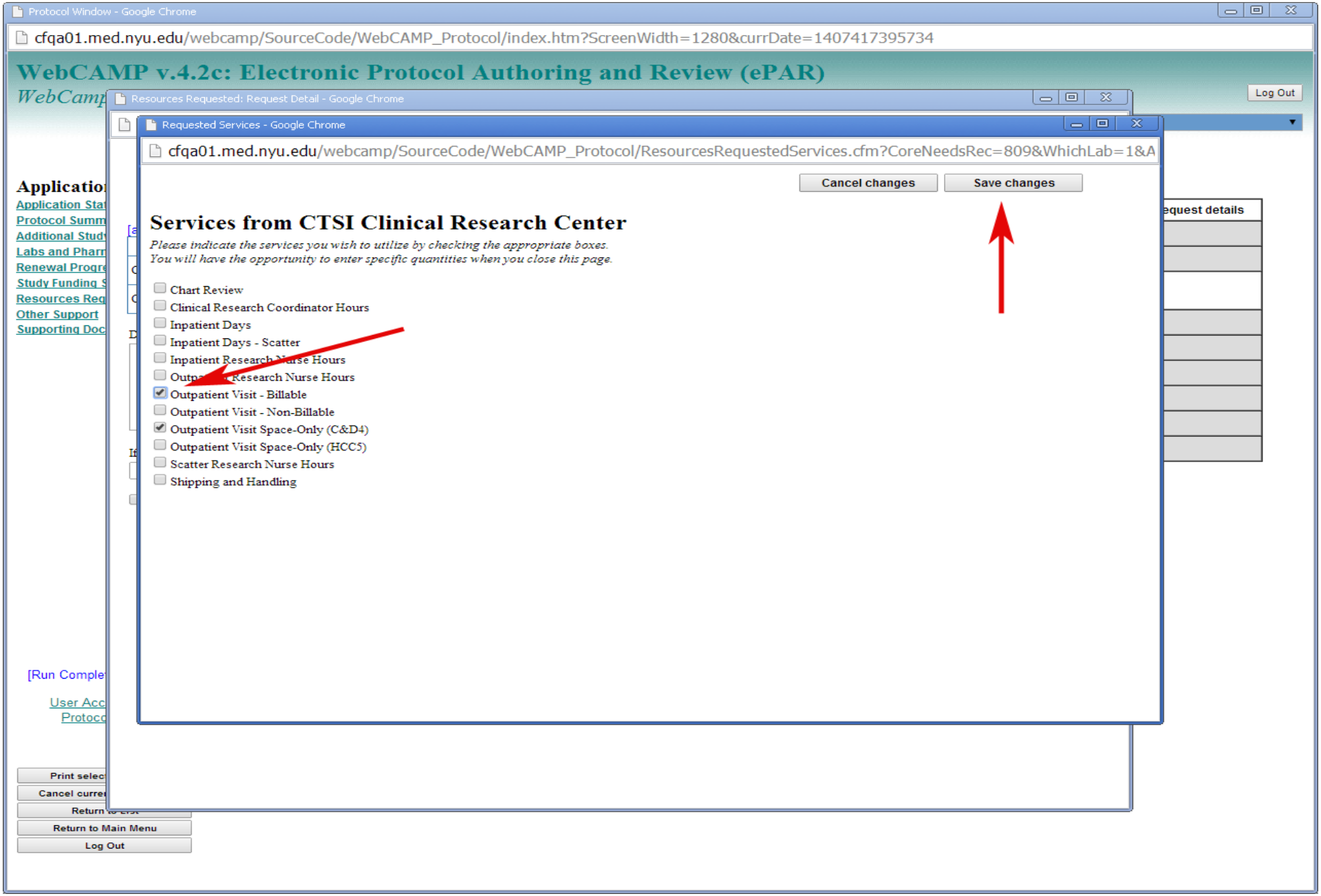
For use of the CRC, check the box next to the resource/service that you are requesting. Select all that apply. Click *Save Changes*. *Note that the list of CRC resources/services available will vary depending on the application type of your project.*



14. For all core-specific requests, you must check off the "**This request is finalized"** box**.** Click *Save Changes*.

IMPORTANT: For the ***Use of Space Only*** application type, please specify the days/times of the week that the space will be used. Include these details in the **Description/justification of need** field.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

Resources Requested: Request Detail - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/ResourcesRequestedDetail.cfm?WhichRec=809&CurrDate=140742659

Detail of Service Request: CTSI Clinical Research Center

THIS REQUEST HAS NOT YET BEEN FINALIZED BUT NOT YET REVIEWED BY THE CORE OR SERVICE PROVIDER.
WHEN YOU HAVE COMPLETED ALL INFORMATION BELOW, PLEASE CLICK THE 'FINALIZE' CHECKBOX.
THIS WILL LAUNCH AN E-MAIL MESSAGE TO THE CORE TO REVIEW YOUR REQUEST.

[add/delete]

Resource	Start Date	End Date	Quantity Requested
Outpatient Visit - Billable			Quantity: 1
Outpatient Visit Space-Only (C&D4)			Hours: 0

Description/justification of need:

If you have discussed this project's needs with a representative of "CTSI Clinical Research Center", please select from the list below the person with whom you have consulted.

☑ This request is finalized. More info

Last modified by Mickey Mouse on 8/7/14 at 10:58AM.

Cancel changes | Save changes

15. Click *Close* to go back to the Resources Requested page and view the list of resources/services you have requested. For each core that you have "finalized" your request, the row will turn yellow to indicate this.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

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Resources Requested

Core	Requested?	Request finalized?	Request approved by core?	Request details
CTSI Biorepository	☐			
CTSI Center for Health Informatics and Bioinformatics	☐			
CTSI Clinical Research Center	☑ Details of Request	Yes	(not yet reviewed)	Specific services requested: 1.Outpatient Visit - Billable 2.Outpatient Visit Space-Only (C&D4) (0)
CTSI Community Engagement and Population Health	☐			
CTSI Core Laboratory	☐			
CTSI Research Subject Safety Office	☐			
CTSI Study Design, Biostatistics and Ethics	☐			
Non-CTSI Resources	☐			
Participant Compensation	☐			

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
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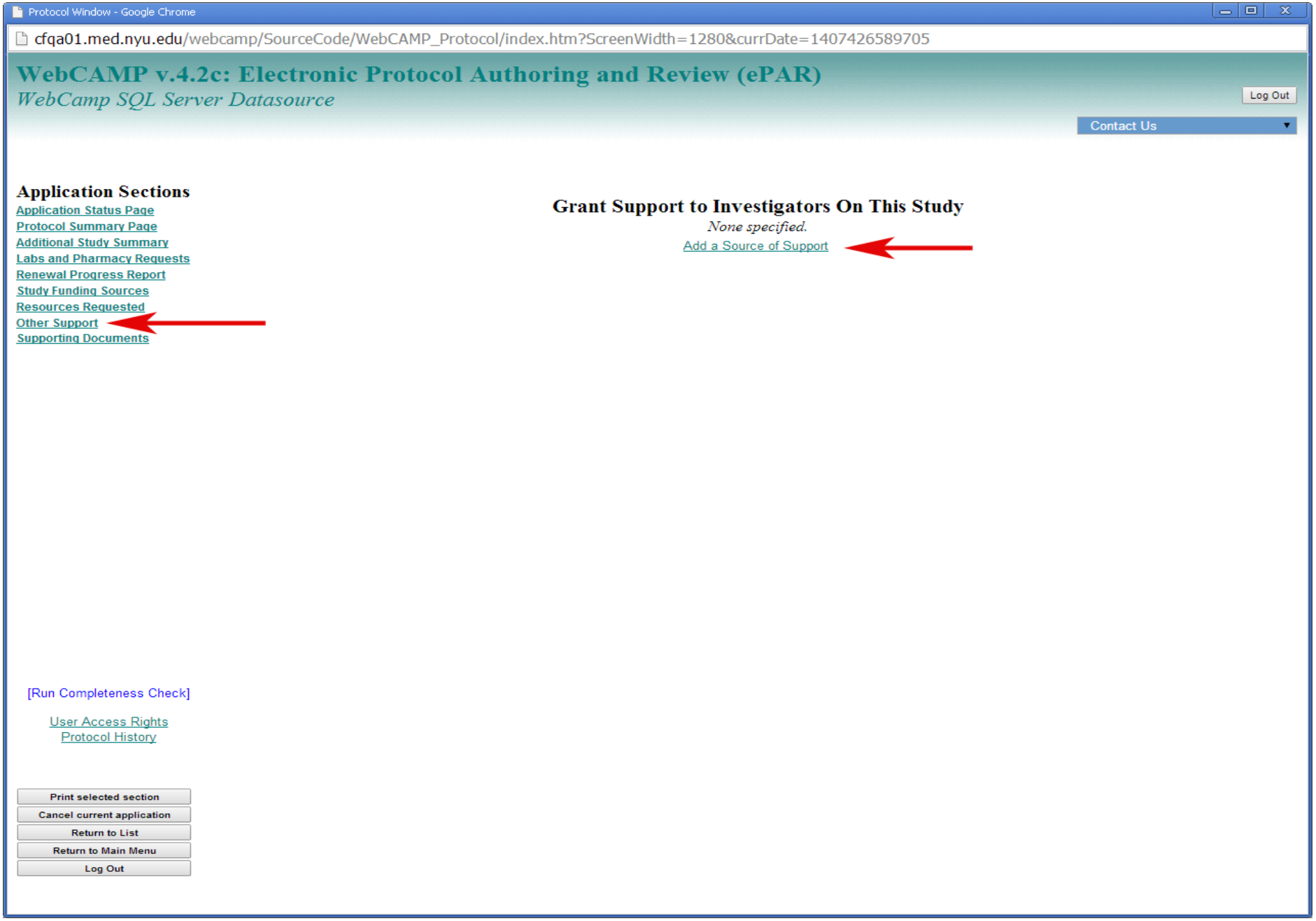
16. **OTHER SUPPORT Page** – Click on the **Other Support** page and then click on the **Add a Source of Support** link to add details regarding grant support for the PI or co-PI(s) of the project. *Note that all grants, regardless of whether they are related to this project, should be listed.*



Select the supported investigator from the drop down menu (usually the PI).

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

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Grant Support to Investigators On This Study

None specified.

(select supported investigator)
(select supported investigator)
Mouse, Mickey

[Run Completeness Check]

User Access Rights
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Print selected section
Cancel current application
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Complete the entire form and then click *Save new record*.

Protocol Window - Google Chrome

Other Support - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/OtherSupport.cfm?WhichRec=New&ThisInv=522&ThisIr

New record.

Cancel new record | Save new record

Log Out

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Status:

Kind of grant:

Date work began on application:

Application submission date:

Principal investigator: menu

Mouse, Mickey's role on grant: Co-PI Co-investigator Other key personnel

Overall grant title: More Info

Subtitle or supplement title: More Info

Does this grant directly support research described in the current application? Yes No

American Recovery and Reinvestment Act (ARRA) grant

Brief description (overall goals of project):

Additional Comments

Print selected section

Cancel current application

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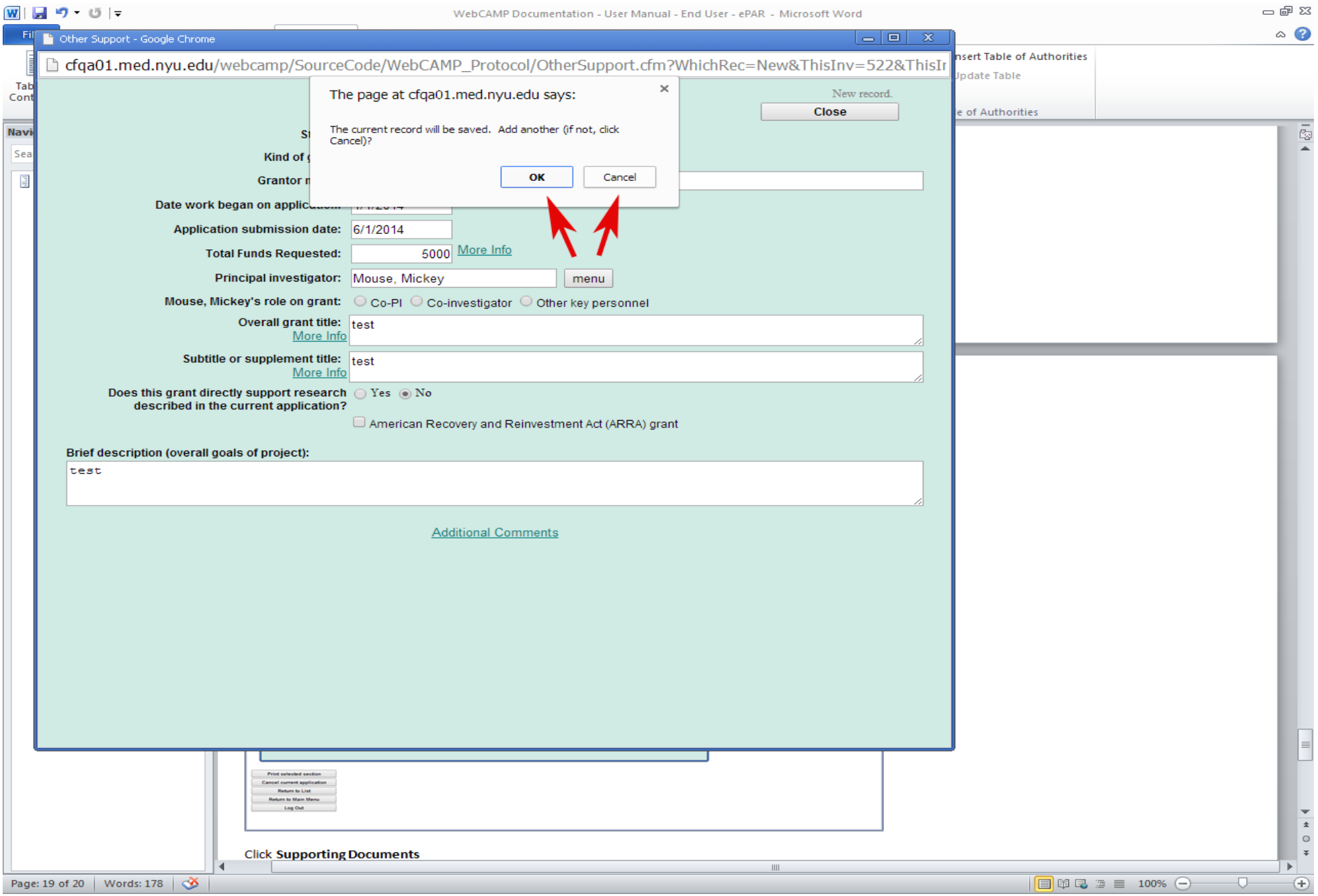
Click *OK* to continue adding other sources. Otherwise, click *Cancel* to save your entry.

IMPORTANT: If you do not need to add another source of support, do not click OK, as your previous entry will not be saved unless you add another source.



17. **SUPPORTING DOCUMENTS Page** – Click on the **Supporting Documents** page to add documents relevant to your study (e.g., protocol, consent(s), IRB approval letter, etc.) *Note that the documents required will vary depending on your project and its application type.* If there are multiple consent/assent(s), make sure to upload all of them.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407417395734

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[Run Completeness Check]

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Supporting Documents

"Mickey's Test Study"

Required Before Submission

Each of the following documents must be submitted with your application. Most documents can be uploaded; some documents are required in hardcopy and are marked as such. If you do not see an "[Upload]" link with a document and the document is NOT marked as REQUIRED IN HARDCOPY, then the document is not currently due. Uploadable documents that you are unable to upload can be submitted in hardcopy; in this case, administrative staff of the NYU CTSI must mark the document as "Received in hardcopy" before you will be permitted to submit your application. In special cases, specific requirements may be waived for a protocol. In this case, NYU CTSI administrative staff must mark the document as "exempt" before you will be permitted to submit your application. For more information, please see application instructions or contact us at:

rick.church@nyumc.org

X **Consent Form(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Data Safety Monitoring Report(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **IRB Application for Initial/New Review** More info [Upload]	Not yet received
X **Relevant Budget(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Research Methodology Summary** [Downloadable Form or Instructions] [Upload]	Not yet received
X **Study Protocol(s)** More info *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received

Other Supporting Documents

You may include below any documents you consider relevant to the current application.

[Add a document]

Last modified by Mickey Mouse on 8/7/14 at 09:16AM.

For fields with a **Downloadable Form or Instructions**, click on the link to download the document. Follow the instructions or fill out the form, as appropriate, and then upload the corresponding document.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407435608227

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Log Out

Required Before Submission

Each of the following documents must be submitted with your application. Most documents can be uploaded; some documents are required in hardcopy and are marked as such. If you do not see an "[Upload]" link with a document and the document is NOT marked as REQUIRED IN HARDCOPY, then the document is not currently due. Uploadable documents that you are unable to upload can be submitted in hardcopy; in this case, administrative staff of the NYU CTSI must mark the document as "Received in hardcopy" before you will be permitted to submit your application. In special cases, specific requirements may be waived for a protocol. In this case, NYU CTSI administrative staff must mark the document as "exempt" before you will be permitted to submit your application. For more information, please see application instructions or contact us at:

rick.church@nyumc.org

X **Consent Form(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Data Management and Security Form** [Downloadable Form or Instructions] [Upload]	Not yet received
X **Data Safety Monitoring Report(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **IRB Application for Initial/New Review** More info [Upload]	Not yet received
X **Relevant Budget(s)** More info *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Study Protocol(s)** More info *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received

Other Supporting Documents

You may include below any documents you consider relevant to the current application.

[Add a document]

Last modified by Mickey Mouse on 8/7/14 at 02:20PM.

For fields where multiple documents can/need to be uploaded, click on **Add a document**, enter a name and click *OK*; then, upload the document(s). For fields where only one document is accepted, simply click **Upload** to add the required document.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol
WebCamp SQL Server Datasource

Log Out

Contact Us

The page at cfqa01.med.nyu.edu says:

Please type a descriptive name for the new document:

OK Cancel

Application Sections

Application Status Page
Protocol Summary Page
Additional Study Summary
Labs and Pharmacy Requests
Renewal Progress Report
Study Funding Sources
Resources Requested
Other Support
Supporting Documents

[Run Completeness Check]

User Access Rights
Protocol History

Cancel current application
Return to List
Return to Main Menu
Log Out

"Mickey's Test Study"

Required Before Submission

Each of the following documents must be submitted with your application. Most documents can be uploaded; some documents are required in hardcopy and are marked as such. If you do not see an "[Upload]" link with a document and the document is NOT marked as REQUIRED IN HARDCOPY, then the document is not currently due. Uploadable documents that you are unable to upload can be submitted in hardcopy; in this case, administrative staff of the NYU CTSI must mark the document as "Received in hardcopy" before you will be permitted to submit your application. In special cases, specific requirements may be waived for a protocol. In this case, NYU CTSI administrative staff must mark the document as "exempt" before you will be permitted to submit your application. For more information, please see application instructions or contact us at:

rick.church@nyumc.org

X **Consent Form(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Data Safety Monitoring Report(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **IRB Application for Initial/New Review** More info [Upload]	Not yet received
X **Relevant Budget(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Research Methodology Summary** [Downloadable Form or Instructions] [Upload]	Not yet received
X **Study Protocol(s)** More info *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received

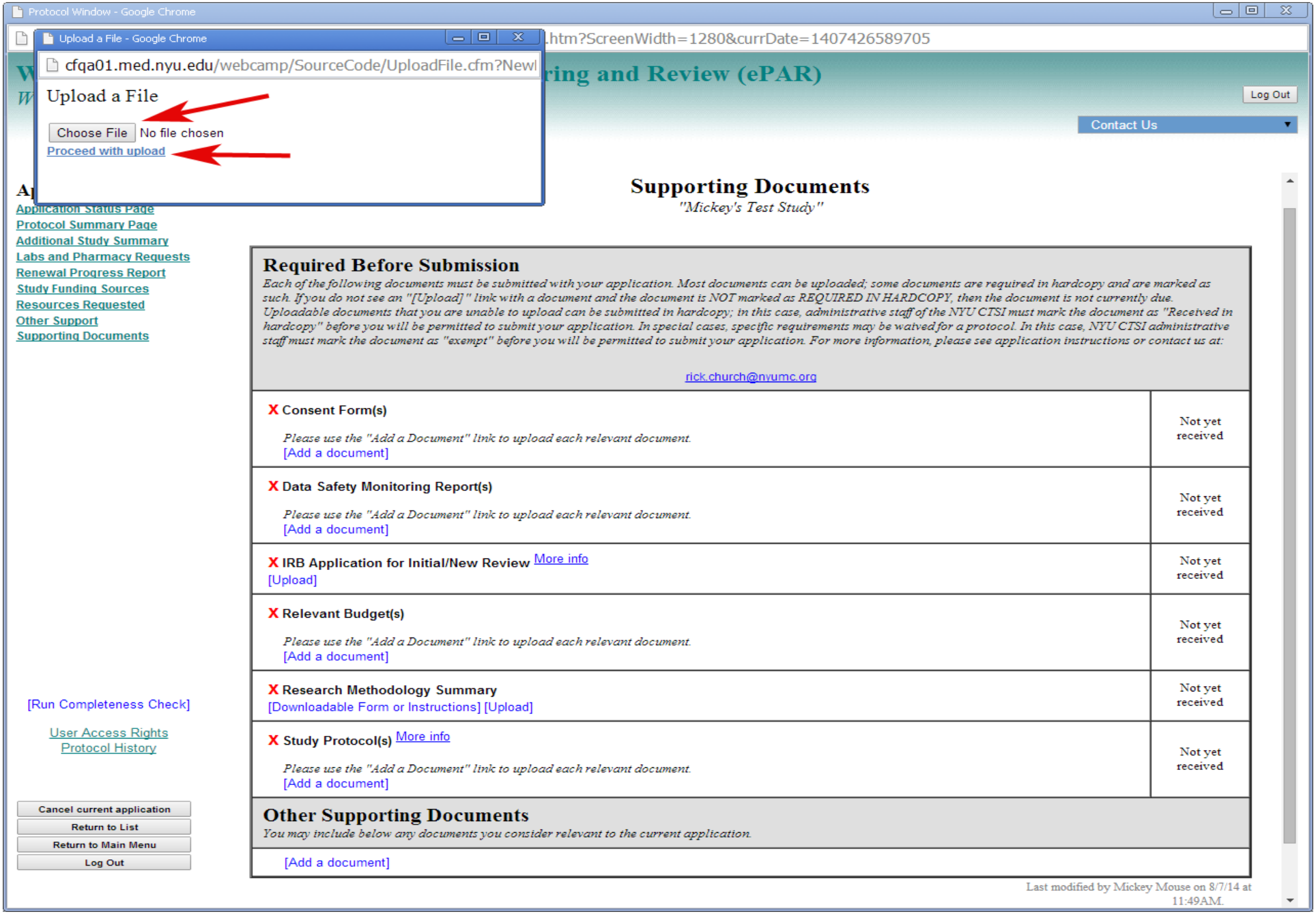
Other Supporting Documents

You may include below any documents you consider relevant to the current application.

[Add a document]

Last modified by Mickey Mouse on 8/7/14 at 11:49AM.

To upload a document, when prompted, click on **Choose File** to attach the file and then click on the *Proceed with upload* link.



Your document should be uploaded and appear in the corresponding section.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407431019186

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

Log Out

Contact Us

Query Database

Application Sections

Application Status Page
Protocol Summary Page
Additional Study Summary
Labs and Pharmacy Requests
Renewal Progress Report
Study Funding Sources
Resources Requested
Other Support
Supporting Documents
Review (8/7/2014)
Administrative Notes
Review Summary Page
Post-Approval Followup

[Run Completeness Check]

User Access Rights
Protocol History
Transfer to Census

Open review window
Amend current protocol
Return to List
Return to Main Menu
Log Out

?

☑ Override editing controls for this session only

Help

Supporting Documents

"Mickey's Test Study"

Required Before Submission

Each of the following documents must be submitted with your application. Most documents can be uploaded; some documents are required in hardcopy and are marked as such. If you do not see an "[Upload]" link with a document and the document is NOT marked as REQUIRED IN HARDCOPY, then the document is not currently due. Uploadable documents that you are unable to upload can be submitted in hardcopy; in this case, administrative staff of the NYU CTSI must mark the document as "Received in hardcopy" before you will be permitted to submit your application. In special cases, specific requirements may be waived for a protocol. In this case, NYU CTSI administrative staff must mark the document as "exempt" before you will be permitted to submit your application. For more information, please see application instructions or contact us at:

rick.church@nyumc.org

√ **Consent Form(s)** 1. test.pdf [View] [Remove] *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Uploaded
X **Data Management and Security Form** [Downloadable Form or Instructions] [Upload]	Not yet received
X **Data Safety Monitoring Report(s)** *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **IRB Application for Initial/New Review** More info [Upload]	Not yet received
X **Relevant Budget(s)** More info *Please use the "Add a Document" link to upload each relevant document.* [Add a document]	Not yet received
X **Research Methodology Summary** [Downloadable Form or Instructions] [Upload]	Not yet received
X **Study Protocol(s)** More info *Please use the "Add a Document" link to upload each relevant document.*	Not yet received

18. **APPLICATION STATUS PAGE** – Click on the **Application Status Page** to view the current status of your application.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

Log Out

Contact Us

Application Sections

- Application Status Page
- Protocol Summary Page
- Additional Study Summary
- Labs and Pharmacy Requests
- Renewal Progress Report
- Study Funding Sources
- Resources Requested
- Other Support
- Supporting Documents

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

Full Title of Application
Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
In development

Some required data are missing from your application.
You can view details of missing data by clicking the "Run Detailed Completeness Check" link below.
When all required fields have been completed, you will see a "Submit for Review" button on this page.
If there are extenuating circumstances that prevent you from providing all required data,
please contact NYU CTSI administration for assistance.

Section	Status
General Protocol Information (Summary Page)	INCOMPLETE
Applicant Demographics	INCOMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

Click on the **Run Detailed Completeness Check** link and you will be provided with a list of possible missing information and warnings.

Protocol Window - Google Chrome

Check Protocol Application Information - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/CheckProt.cfm?CurrDate=1407427

Help

Check Current Application

Mouse: Mickey's Test Study

Close

[Re-Check] [Print]

This page will list obvious omissions or inconsistencies in the information entered for the current application. Information that is absolutely REQUIRED in order for you to submit your application for review is highlighted in yellow. Missing data not highlighted will not prevent you from submitting your application, but you should check these items and address as appropriate. If you submit an application with incomplete or inconsistent data, it may be returned to you for corrections before it can be reviewed. Please speak with the Protocol Review Coordinator if you have questions about missing information.

General Protocol Information (Summary Page)

- The "01. If protocol has changed since the last submission, describe here." field has not been completed. [click to edit]
- The "08. Number of participants enrolled on the CTSI over the past year." field has not been completed. [click to edit]
- The "06. If work for this study is intellectual property, describe here." field has not been completed. [click to edit]
- The "02. Provide a clinical/scientific progress report for the past year." field has not been completed. [click to edit]
- The "05. Describe any unexpected safety concerns and their resolutions." field has not been completed. [click to edit]
- The "04. List all grants that resulted from this study thus far." field has not been completed. [click to edit]
- The "03. List all publications that have resulted from this study thus far." field has not been completed. [click to edit]
- The "07. If work for this study is patentable, describe here." field has not been completed. [click to edit]
- The "09. If there has been been no accrual this past year, explain here." field has not been completed. [click to edit]
- The "10. Total number of participants enrolled since initiation of study." field has not been completed. [click to edit]
- The "11. Number of participants you plan to enroll this coming year." field has not been completed. [click to edit]
- A primary contact has not been specified. [click to edit]
- You have not specified current IRB status. [click to edit]

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Log Out

Contact Us

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rom your application.
Detailed Completeness Check" link below.
a "Submit for Review" button on this page.
you from providing all required data,
tration for assistance.

Section	Status
General Protocol Information (Summary Page)	INCOMPLETE
Applicant Demographics	INCOMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

You may click on the **click to edit** link to navigate to the appropriate sections where information is missing.

Check Protocol Application Information - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/CheckProt.cfm?CurrDate=1407428006436

Help

Check Current Application

Mouse: Mickey's Test Study

Close

[Re-Check] [Print]

This page will list obvious omissions or inconsistencies in the information entered for the current application. Information that is absolutely REQUIRED in order for you to submit your application for review is highlighted in yellow. Missing data not highlighted will not prevent you from submitting your application, but you should check these items and address as appropriate. If you submit an application with incomplete or inconsistent data, it may be returned to you for corrections before it can be reviewed. Please speak with the Protocol Review Coordinator if you have questions about missing information.

General Protocol Information (Summary Page)

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- The "08. Number of participants enrolled on the CTSI over the past year." field has not been completed. [click to edit]
- The "06. If work for this study is intellectual property, describe here." field has not been completed. [click to edit]
- The "02. Provide a clinical/scientific progress report for the past year." field has not been completed. [click to edit]
- The "05. Describe any unexpected safety concerns and their resolutions." field has not been completed. [click to edit]
- The "04. List all grants that resulted from this study thus far." field has not been completed. [click to edit]
- The "03. List all publications that have resulted from this study thus far." field has not been completed. [click to edit]
- The "07. If work for this study is patentable, describe here." field has not been completed. [click to edit]
- The "09. If there has been been no accrual this past year, explain here." field has not been completed. [click to edit]
- The "10. Total number of participants enrolled since initiation of study." field has not been completed. [click to edit]
- The "11. Number of participants you plan to enroll this coming year." field has not been completed. [click to edit]

Applicant Information

All information appears to be complete.

Resources Requested Page

- Description of need for CTSI Clinical Research Center has not been entered on Resources Requested page.
- "Person consulted in core" for CTSI Clinical Research Center has not been entered on Resources Requested page.
- Quantity has not been specified for at least one service requested from CTSI Clinical Research Center on Resources Requested page. Use "[add/modify]" link to specify services.

Supporting Documents

- The required document 'IRB Application for Initial/New Review' has not been provided. [click to edit]
- The required document 'Relevant Budget(s)' has not been provided. [click to edit]
- The required document 'Consent Form(s)' has not been provided. [click to edit]
- The required document 'Study Protocol(s)' has not been provided. [click to edit]
- The required document 'Data Safety Monitoring Report(s)' has not been provided. [click to edit]
- The required document 'Research Methodology Summary' has not been provided. [click to edit]
- The required document 'Data Management and Security Form' has not been provided. [click to edit]

19. Once you have completed all the required missing information and each section has a **COMPLETE** status on the Application Status Page, the ***Submit Application for Review*** button should be available. Click on this button to finalize and submit your application.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

Log Out

Contact Us

Application Sections

Application Status Page
Protocol Summary Page
Additional Study Summary
Labs and Pharmacy Requests
Renewal Progress Report
Study Funding Sources
Resources Requested
Other Support
Supporting Documents

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

Full Title of Application
Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
In development

Your application has passed the completeness check!
Please click below when you are ready to submit it for review.

Submit Application for Review

Section	Status
General Protocol Information (Summary Page)	COMPLETE
Applicant Demographics	COMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

Click *OK* to confirm your submission.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol

WebCamp SQL Server Datasource

Log Out

Contact Us

The page at cfqa01.med.nyu.edu says:

You have selected to submit the current application for review. An application should be submitted only after all sections have been completed, OR you have received an exemption from the Protocol Review Coordinator for certain sections. If you proceed, the application will be locked and submitted to the NYU CTSI for review. You will be prevented from making further changes until after the review process is complete. Do you wish to continue?

OK Cancel

Application Sections

- Application Status Page
- Protocol Summary Page
- Additional Study Summary
- Labs and Pharmacy Requests
- Renewal Progress Report
- Study Funding Sources
- Resources Requested
- Other Support
- Supporting Documents

Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
In development

Your application has passed the completeness check!
Please click below when you are ready to submit it for review.

Submit Application for Review

Section	Status
General Protocol Information (Summary Page)	COMPLETE
Applicant Demographics	COMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

You will be prompted when WebCAMP runs a check for completeness, click *OK.*

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol

WebCamp SQL Server Datasource

Log Out

Contact Us

The page at cfqa01.med.nyu.edu says:

Your application will now be checked for completeness. Please click 'OK' to proceed.

Prevent this page from creating additional dialogs.

OK Cancel

Application Sections

Application Status Page
Protocol Summary Page
Additional Study Summary
Labs and Pharmacy Requests
Renewal Progress Report
Study Funding Sources
Resources Requested
Other Support
Supporting Documents

Full Title of Application
Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
In development

Your application has passed the completeness check!
Please click below when you are ready to submit it for review.

Submit Application for Review

Section	Status
General Protocol Information (Summary Page)	COMPLETE
Applicant Demographics	COMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

You will be prompted to click *OK* again to proceed.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol
WebCamp SQL Server Datasource

Log Out

Contact Us

The page at cfqa01.med.nyu.edu says:

All required fields have been completed. Please click 'OK' to proceed with application submission.

Prevent this page from creating additional dialogs.

OK Cancel

Application Sections

- Application Status Page
- Protocol Summary Page
- Additional Study Summary
- Labs and Pharmacy Requests
- Renewal Progress Report
- Study Funding Sources
- Resources Requested
- Other Support
- Supporting Documents

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

Full Title of Application
Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
In development

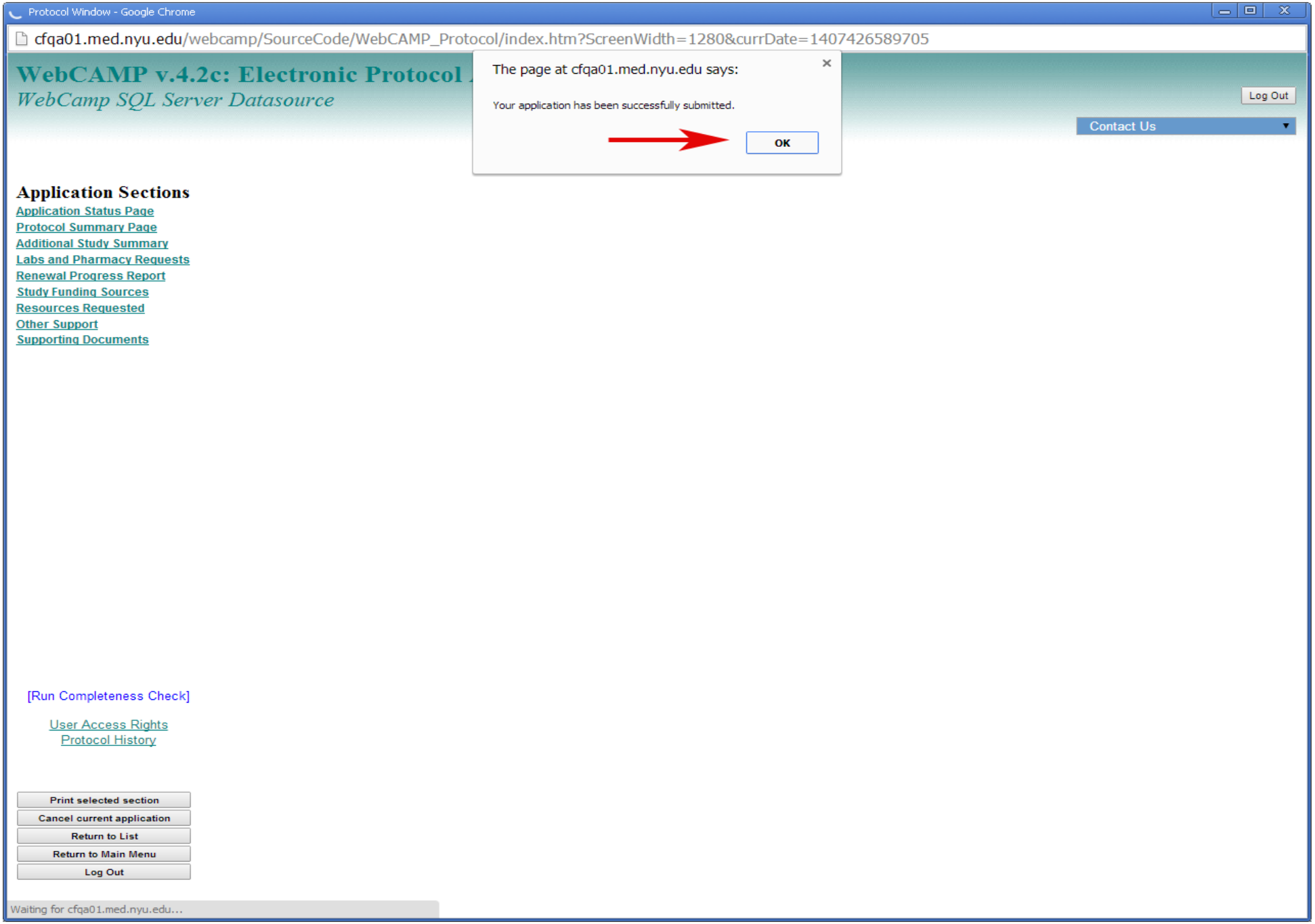
Your application has passed the completeness check!
Please click below when you are ready to submit it for review.

Submit Application for Review

Section	Status
General Protocol Information (Summary Page)	COMPLETE
Applicant Demographics	COMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[Run Detailed Completeness Check]

Once your completed application has been submitted, you can click *OK* one last time.



20. Your application will now have a ***Submitted for initial review*** status, and you will not be able to edit the application any further.

Protocol Window - Google Chrome

cfqa01.med.nyu.edu/webcamp/SourceCode/WebCAMP_Protocol/index.htm?ScreenWidth=1280&currDate=1407426589705

WebCAMP v.4.2c: Electronic Protocol Authoring and Review (ePAR)

WebCamp SQL Server Datasource

Log Out

Contact Us

Application Sections

Application Status Page
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Renewal Progress Report
Study Funding Sources
Resources Requested
Other Support
Supporting Documents

Full Title of Application
Test

Application Type
CTSI: Full Support

Principal Investigator(s) or Primary Applicant
Mickey Mouse

Current Status
Submitted for initial review

Section	Status
General Protocol Information (Summary Page)	COMPLETE
Applicant Demographics	COMPLETE
Resources Requested Page	COMPLETE
Supporting Documents	COMPLETE

[View Details of Completeness Check]

[Run Completeness Check]

User Access Rights
Protocol History

Print selected section
Cancel current application
Return to List
Return to Main Menu
Log Out

21. Your application will be reviewed by the CTSI on the *third Thursday of the month*. Once a decision has been made, you will be notified by email.

Inbox - Steven.Sotero@nyumc.org - Microsoft Outlook

From	Subject	Received	Size
Date: Today			
rick.church@nyumc.org	Review of 'Mickey's Test Study'	Thu 8/7/2014 12:33 PM	22 KB
rick.church@nyumc.org	Application submitted for review	Thu 8/7/2014 12:15 PM	7 KB

Review of 'Mickey's Test Study'

rick.church@nyumc.org

Sent: Thu 8/7/2014 12:33 PM

To: Sotero, Steven; Hsieh, Rosa

Dear Dr. Mouse:

Your application has been reviewed. Please see review below. To respond to any issues noted, you can log in to your protocol by opening your browser and copying the following URL into the address field:

http://cfqa01.med.nyu.edu/webcamp/SourceCode/Login.cfm

Review Details

Proposal Title: *Mickey's Test Study*

Principal Investigator: *Mickey Mouse*

Date(s) of Review:

Outcome of Review: *Approved*

Specific Resource Requests

Resource Provider	Description of Need	Approval By Resource Provider	Quantitative Request (if any)				
			Service or Resource	Quantity Requested	Quantity Approved Free of Charge ("credit")	Rate For Resources Exceeding Credit[1]	Maximum Quantity Available[2]
CTSI Clinical Research Center		Not required	Outpatient Visit - Billable	1	0		