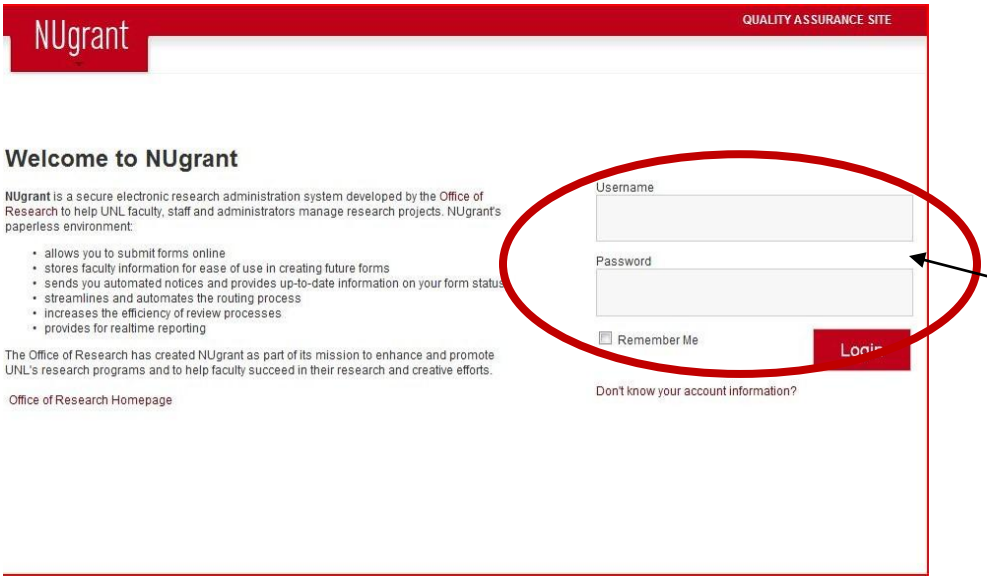
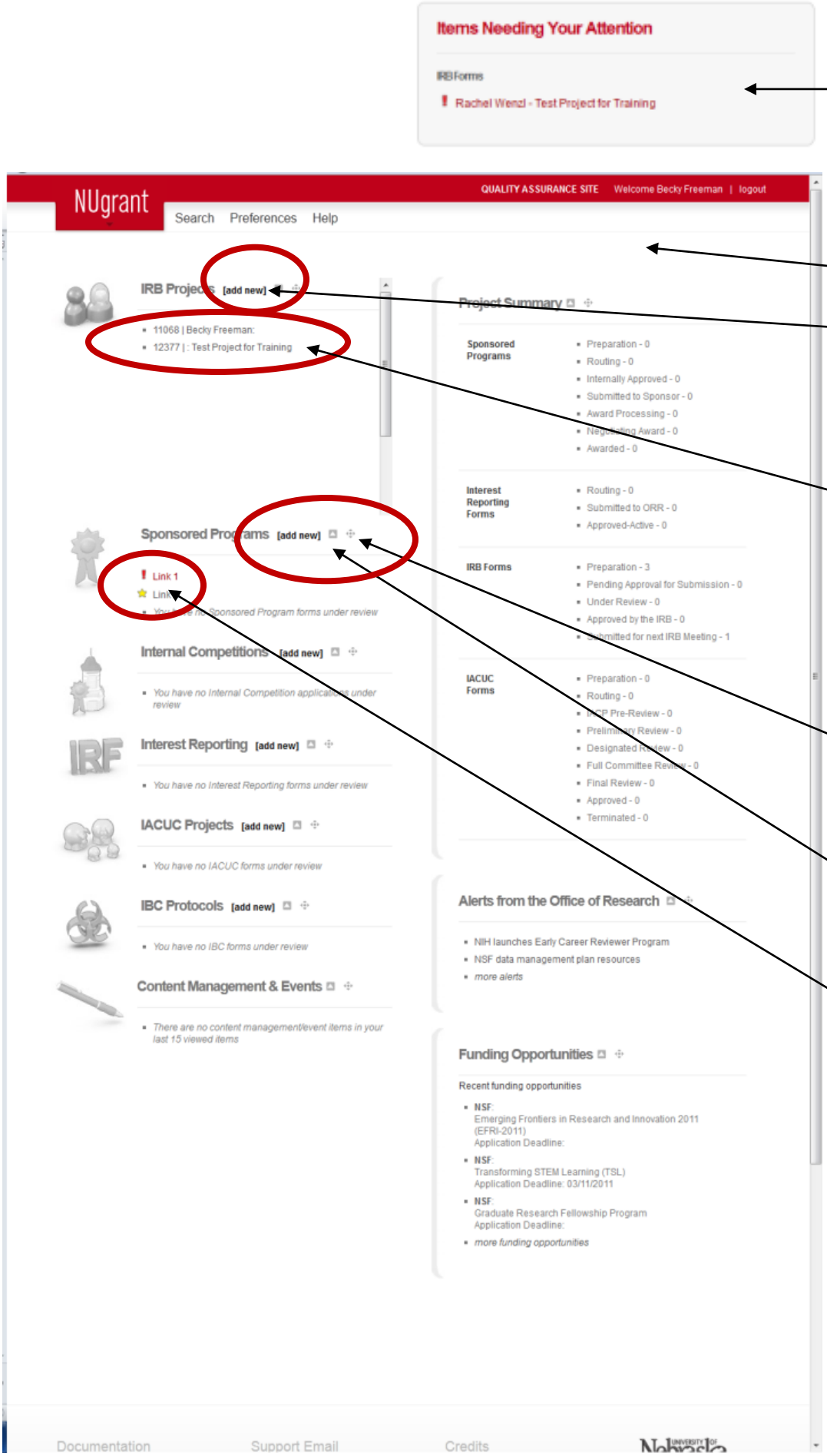
We have recently made enhancements to the NUgrant IRB module. The forms remain unchanged, but the main navigation page has been revised to make using the system easier. This help document will explain how to navigate NUgrant with the new features.



Log into https://nugrant.unl.edu.

The login name and password are the same information you use to access Blackboard.

If you do not know your login information, go to http://my.unl.edu . There are links on the right hand side of the page to help you access your login information.



The Items Needing Your Attention box appears on the Home Page only when there is a form you need to sign or if there is a COI question you need to respond to. The box will appear here.

To start a new project, click on the *Add New* link. The form will open in a new window.

Projects that need action by the PI will be listed under the appropriate module.

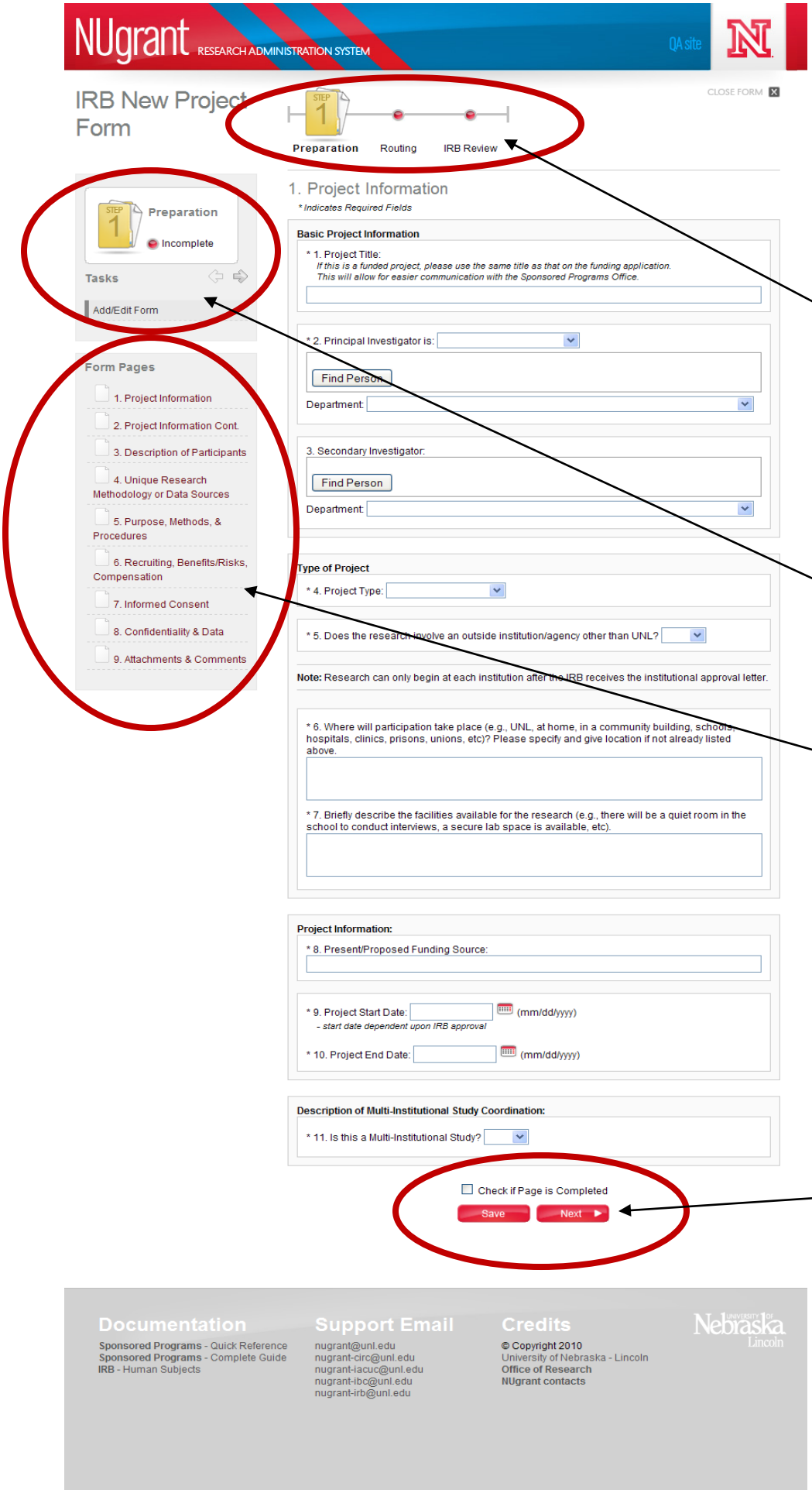
You can customize your homepage by:

* Re-ordering the NUgrant modules (click on the ✥ and drag the module up or down.)

* Collapsing modules you do not use.

If you want to keep track of a project and always have it on your homepage, you can star that project.

HINT: Make sure you do not have the pop-ups blocked. If you do, the form will not open



STEP 1: Preparation

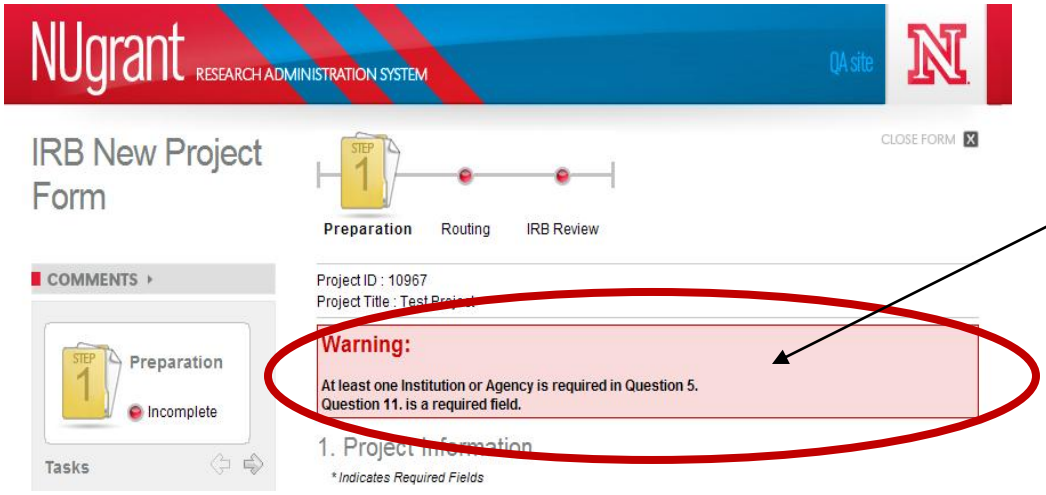
PAGE 1

The steps to protocol preparation are listed across the top. When creating your project, you will be completing *Step 1: Preparation*.

The tasks that need to be completed for each step are listed along the side.

Use the form pages to move through the form.

Once a page is complete, click on the box to indicate the page is complete. If you are not finished with that page, do not check the box. NUgrant will not allow you to move to the next page if required information needs to be entered and the box is checked.

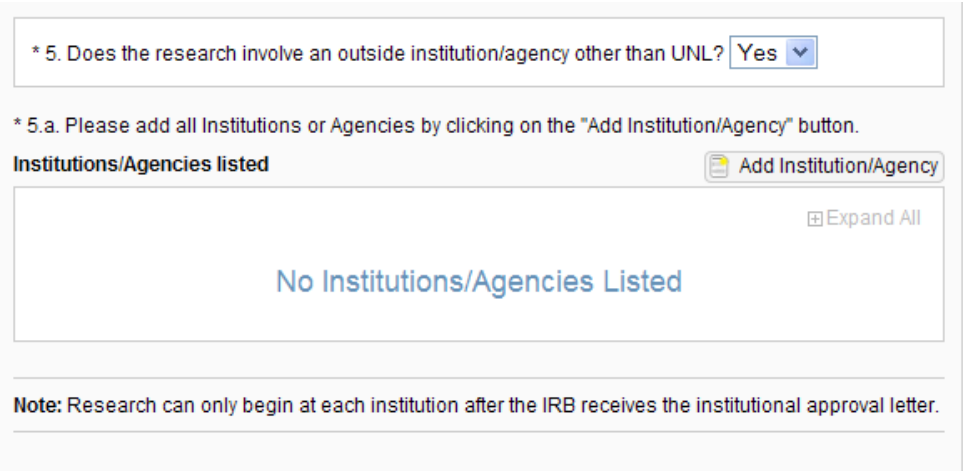


PAGE 1

If you mark the page as complete, NUgrant checks to make sure all required questions are answered. If you missed a question, you will see a warning message. The message will tell you exactly which question needs to be answered.

You can either go back and answer those questions or uncheck the box at the bottom to move on to the next page.

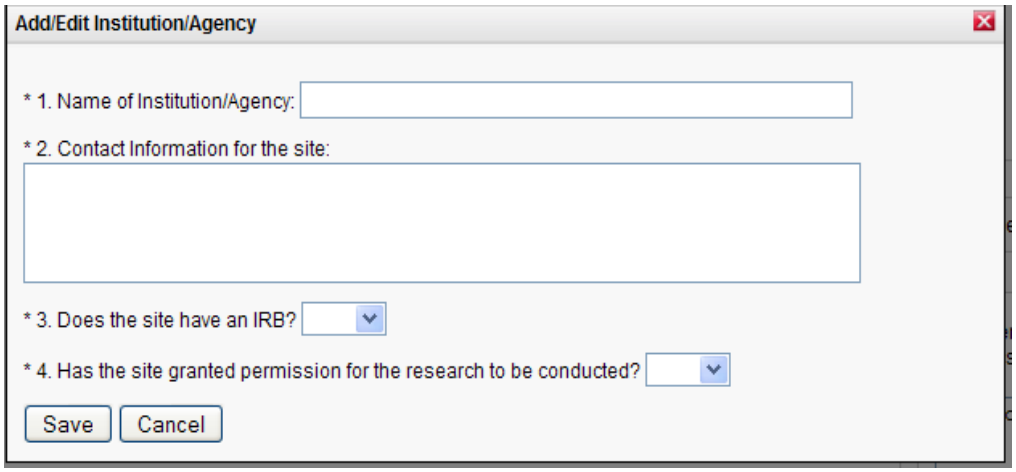
The check box at the bottom of each page will need to be checked before you can submit the project.



The warning message indicates that question 5a needs to be answered. If question 5 would have been answered as No, question 5a wouldn't have appeared.

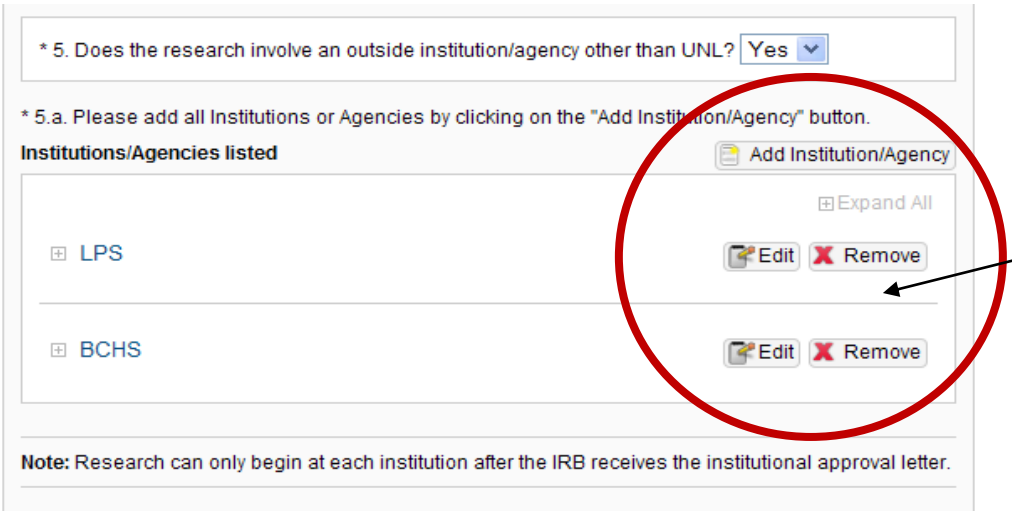
PAGE 1

When you click on *Add Institution/Agency* for question 5a, this screen appears.

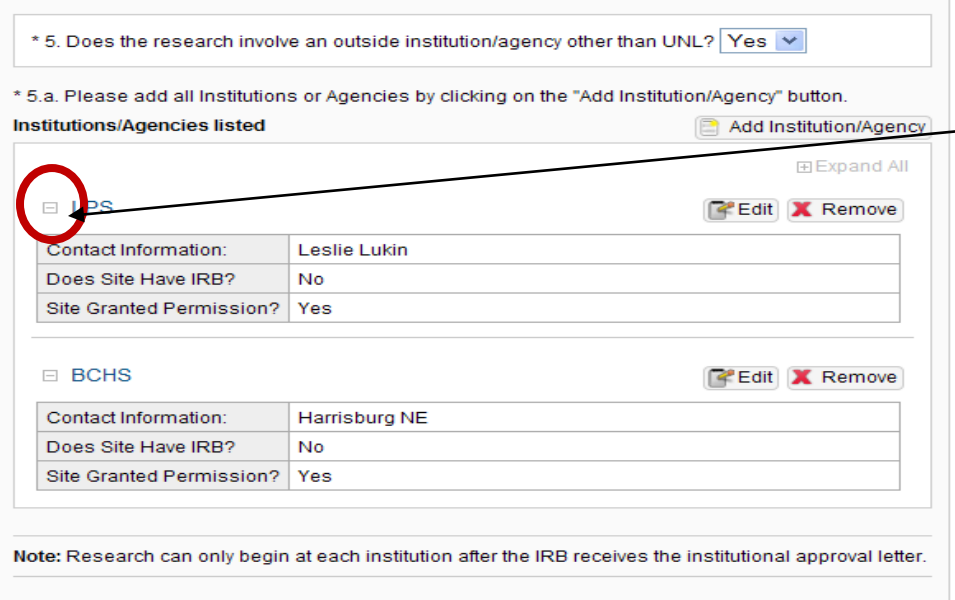


Once you have added institutions, the institutions/agencies are listed.

You can add additional institutions or edit/remove the institutions you have listed.



If you want to see the details about the institutions or to hide the details, click on the +/- side beside the institution. This screen shows the question with the information expanded.



Description of Multi-Institutional Study Coordination:

* 11. Is this a Multi-Institutional Study? Yes

* 11.a. Is the UNL investigator the Lead Investigator? Yes

* 11.a.i. Describe the provisions for the management of information obtained from the different sites that might be relevant to the protection of participants.

If you are not the lead investigator on a Multi-Institutional Study, this project could qualify as a Collaborative Research Study. This would mean that the lead institution's IRB would be the IRB of record and UNL would probably defer to the decision of that institution's IRB regarding human research protections if it has a Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP).

* 11.a.ii. Is this project being reviewed by an IRB at an institution with a FWA? No

PAGE 1

The warning message on page 1 also indicated that question 11 wasn't answered. This screen shows question 11 with all possible questions that could appear.

If question 11 is answered as no, the additional questions won't appear.

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2. Project Information Continued

* Indicates Required Fields

* 1. Does the research involve prisoners? No

* 2. Will the research only be conducted in schools or educational settings? Yes

* 2.a Does the research study involve only normal education practices (such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)? No

* 3. Does the research involve *only* the use of educational tests, survey procedures, interview procedures, or observation of public behavior? Yes

* 3a. Does the research involve children (under 19 years of age)? Yes

* 3a1. Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed? No

* 3a1a. Is the information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects? No

* 3a1b. Could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation? No

* 3b. Are the subjects elected or appointed public officials (e.g. senior officials, such as mayor or school superintendent, rather than police officer or teacher)? No

* 3b1. Does any Federal statute require without exception that the confidentiality of personally identifiable information be maintained thoughout the research and thereafter? No

* 4. Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? Yes

* 4.a. Are these sources publicly available? No

* 4.a.1. Will the information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects? No

* 5. Does the research involve only studying, evaluating or examining public benefit or service programs? Yes

* 5.a. Is the research or demonstration project conducted or approved by the Department or Agency Head? Yes

* 5.a.1. Does the research or demonstration project involve the study, evaluation, or examination of:

* 5.a.1.a. Public benefit or service programs: No

* 5.a.1.b. Procedures for obtaining benefits or services under public benefit or service programs: No

* 5.a.1.c. Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs: No

* 5.a.1.d. Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs: Yes

* 5.a.2. Does the research or demonstration project involve **only** the study, evaluation, or examination of the previous 4 categories? No

* 6. Does the research involve only a taste and food quality evaluation or food consumer acceptance study? Yes

* 6.a. Are wholesome foods without additives consumed? No

* 6.a.1. Is food consumed that contains a food ingredient, agricultural chemical, or environmental containment at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture? No

* 7. Does the research present more than minimal risk to human subjects? No

For each category, please mark if it is a part of the project:

- Clinical studies of drugs and/or medical devices.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

* 7.a. Does the research involve **only procedures included in the previous 8 categories**? No

* 7.b. Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? No

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PAGE 2

Page 1 was successfully completed. A check mark now appears next to the page indicating the page is complete.

The questions on page 2 are used to preliminarily classify the project as exempt, expedited, or full board. Depending on how the questions are answered, more questions may appear. The page shown here displays all possible questions that could appear.

Once you have submitted the project, the review category will be shown on the IRB Projects Details page. This category may change once it has been pre-reviewed by IRB staff.

HINT: Answer the questions to the best of your ability. This will help the project to be more accurately classified and will prevent delays in the review.

You can move page to page using the *Previous* and *Next* buttons. The *Save* button saves the form. Pages will be saved as you move to another page.

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8. Confidentiality & Data
9. Attachments & Comments

PDF Version

Project ID : 10967
Project Title : Test Project

3. Description of Participants

* Indicates Required Fields

* 1. In the chart below, please indicate the estimated number of participants per category.

	Male	Female	Unspecified	Totals
Adults				0
Children				0
Totals:	0	0	0	0

2. Please indicate what special groups will be utilized/recruited for your study. Check all that apply.

- Adults, Non Students
- UNL Students
- Children (under age 19)
- Decisionally Impaired
- Institutionalized Persons
- Students
- Pregnant Women/Fetuses/Neonates
- Persons with Neurological Impairment
- Persons with Limited Civil Freedom
- Language Impaired
- Persons with HIV/AIDS
- Prisoners
- Persons with Psychological Impairment
- Persons with Mental Retardation
- Adults w/ Legal Representatives
- Handicapped
- Employees
- Other

Inclusion Criteria

* 3. Will participants of both sexes/genders be recruited?

* 4. Will participation be limited to certain racial or ethic groups?

* 5. Describe the participant population to be included in this research and how they are selected, including any special characteristics targeted for inclusion.

* 6. Describe your access to the population that will allow recruitment of the necessary number of participants.

* 7. The research plan should have adequate provisions to protect the privacy interests of participants. Explain provisions to protect privacy interests of participants. This refers to how investigators will access private information from or about participants during and after their involvement in the research (e.g., time, place, etc of research procedures).

* 8. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

Exclusion Criteria

* 9. If not already described above, will any groups or categories of participants be excluded from this research?

* 10. Will some or all subjects likely be vulnerable to coercion or undue influence?

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For question 1, you will need to enter a whole number in the field. If you want to recruit 30-40 participants, enter 40 in the box. Also, if you aren't going to recruit a certain number of males vs. females, you can leave those boxes empty and only list the number in the unspecified box. If you want to recruit 15 males and 15 females, then you can list those numbers in the appropriate box and leave the unspecified box empty.

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4. Unique Research Methodology or Data Sources

** Indicates Required Fields*

* 1. Will your project involve audio taping?

* 2. Is this project web-based research?

* 3. Is this study utilizing Protected Health Information (PHI; e.g., information obtained from a hospital, clinic, or treatment facility)?

* 4. Does this project involve genetic data, sampling, or analysis?

* 5. Does this project ask questions about illegal drug use or criminal activity that places the participant at risk for legal action?

* 6. Does this project involve photography?

* 7. Does this project involve videotaping?

* 8. Does this project involve archival or secondary data analysis?

* 9. Does this project involve biological samples?

* 10. Does this project ask participants to perform physical tasks?

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PAGE 4

For each of the questions on this page, when you answer *Yes*, additional questions will appear.

The questions ask about how the data/identities of participants will be protected.

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5. Purpose, Methods, & Procedures

** Indicates Required Fields*

Describe the research purpose of the project

* 1. What is the significance/purpose of the study? (Please provide a brief 1-2 paragraph explanation in lay terms, to include a brief literature justification.)

Description of the Methods and Procedures

* 2. Describe the data collection procedures and what participants will have to do.

* 3. How long will these procedures take the participants to complete? Please describe the duration of the session, the number of sessions, over what period of time, etc.

* 4. Will there be any follow-up or will reminders be sent?

* 5. Differentiate any procedure being done solely for research purposes from procedures being done anyway.

* 6. Describe the time you have available to conduct and complete the research (ex. the time from initiation of the research to completion of data analysis).

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PAGE 5

Once you get to this page, you will start answering questions that provide the main details of your study.

Your responses are not limited by the box that appears. The box will expand as you type.

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6. Recruiting, Benefits/Risks, Compensation

** Indicates Required Fields*

Description of Recruiting Procedures

* 1. How will the names and contact information for participants be obtained?

* 2. How will participants be approached about participating in the study?

Description of Benefits and Risks

* 3. Explain the benefits to participants or to others.

* 4. Explain the risks to participants. What will be done to minimize the risks? If there are no known risks, this should be stated.

* 5. Describe the availability of medical or psychological resources that participants might require as a consequence of the research.

Description of Compensation

* 6. Will compensation (including money, gift certificates, extra credit, etc.) be provided to participants?

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PAGE 6

This page focuses on recruitment, benefits, risks, and compensation.

If you indicate there is compensation (question 6), you will be asked to provide detailed information about the compensation being offered.

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7. Informed Consent

** Indicates Required Fields*

Informed Consent Process

* 1. How will informed consent/assent be obtained?

* 2. Who will conduct the consent interview?

* 3. Who will provide consent or permission?

* 4. What is the waiting period, if any, between informing the prospective participant and obtaining consent?

* 5. What steps will be taken to minimize the possibility of coercion or undue influence?

* 6. What is the spoken language used by those obtaining consent?

* 7. What is the language understood by the prospective participant or the legally authorized representative?

* 8. Will any subjects be decisionally impaired so that they may not have the capacity to give consent? Yes

* 8.a. Please explain the process in detail.

* 9. In certain cases for children over the age of 14, such as UNL students who are 17 or 18, waivers of informed consent can be granted. Would you like to request a waiver of consent? Yes

If you are requesting (a) a waiver of informed consent, or (b) a waiver of the consent procedure requirement to include all or alter some or all of the elements of informed consent [45 CFR 46.116 (d)], you must document your responses to each of the following statements.

Can you answer 'true' to the following questions? If so, the project may be considered for a waiver of Informed Consent. You must justify your responses to each question.

* 9.a. The Research involves minimal risks or less.

* 9.b. By Waiving informed consent, the individual will remain unharmed and retain all rights they would normally be entitled.

* 9.c. It would be unfeasible to conduct the research if informed consent has to be obtained.

* 9.d. Whenever appropriate, subjects will be provided with additional pertinent information before and after their participation

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PAGE 7

This page focuses on the informed consent process.

The questions have been answered so that every possible question will appear. Question 8 and 9 have sub-questions. These questions may not appear depending how you answer the previous question.

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8. Confidentiality & Data

** Indicates Required Fields*

Description of How Confidentiality will be Maintained

* 1. The research plan should make adequate provisions to maintain the confidentiality of the data. How will confidentiality of records be maintained?

* 2. Will individuals be identified during data collection or in the results?

* 3. How long will records be kept?

* 4. Where will records be stored?

* 5. Who has access to the records/data?

* 6. How will data be reported (e.g., in a dissertation or thesis, in scientific journals, at conferences, etc)?

Monitoring of data to ensure safety

* 7. Does this research involve more than minimal risk to participants?

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This page focuses on the confidentiality of the data obtained.

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9. Attachments & Comments

** Indicates Required Fields*

Copies of questionnaires, survey, or testing instruments:

Please list all questionnaires, surveys, and/or assessment instruments/measures used in the project.

Uploaded Attachments:

Please submit copies of the following:

Funding application;
Institutional Approval letters;
Recruitment flyers, ads, phone scripts, emails, etc.;
Informed Consent Forms, emails, and/or letters;
If transcriptions are required, Confidentiality Agreement that transcriptionist will sign;
If this is a study utilizing PHI, Release of Authorization that will be used to obtain permission from the participant for the agency/institution to release protected health information for project purposes or a letter from the agency/institution documenting agreement to provide protected health information for project purposes;
All Instruments/measures used in the project.

Please upload documents as PDFs.

Browse... Upload

Enter general comments here.

Comments can also be viewed below or by clicking the 'Comments' link in the upper left hand column of this page.

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All documents related to the research should be uploaded on this page.

Please list the names of the measures, testing instruments, etc that you will be using in your research.

Upload all documents here. This would include documents such as: recruitment scripts, letters or flyers, informed consent documents, funding applications, interview questions, surveys, or testing measures, institutional approval letters, and confidentiality agreements.

HINT: Upload the documents as PDF files. Please include each document as a separate file rather than one large file. Also, include screen shots of any pages that appear on-line.

If you have comments that you want to make the IRB aware of, you can enter those here. You could include information here that you feel is not appropriate to include in other questions.

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STEP 2

Preparation | Routing | IRB Review

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STEP 2 Routing

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Routing Signatures

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* Indicates Required Field

* Do you or your immediate family have any financial interests related to this research?

As the principal investigator or secondary investigator on this project, you must address the following:

* 1. Are the research procedures the least risky procedures that can be performed consistent with sound research design?

* 2. Is the research likely to achieve its aims?

* 3. Is the proposed research of sufficient scientific importance to justify the risks entailed?

* 4. Are there adequate resources (e.g. facilities, qualified staff, access to population that will allow recruitment of the required number of participants) to complete the study.

Reminders:
a. As a reminder CITI training is a requirement for all investigators and key project personnel before research can be reviewed.

b. New findings developed during the course of the research which may relate to the participant's willingness to continue participation must be provided to the participant

Oversight:
I agree that I have read the protocol application, and that I am fully aware of all the procedures to be followed. I will provide oversight, monitor the research, and ensure that the conduct of the study is in compliance with UNL IRB policies and all applicable state and local regulations. I will notify the IRB of any change or of any unanticipated problem involving risks to the participants or others

Please Note: If you are a faculty advisor, you will be responsible for the conduct of this research.

To sign this document please enter your login name and password below.

* Login Name:

* Password:

* Approval: I Approve this as written / Request Revisions

Comments: *(required on request revisions)*

Submit

Confirmation of Signatures

Principle Investigator:

Name:	Signed:	Date:	Show/Hide Routing Answers
Becky Freeman	—	—	

Secondary Investigator:

Name:	Signed:	Date:
Danny Hoyt	—	—

Documentation
Sponsored Programs - Quick Reference
Sponsored Programs - Complete Guide
IRB - Human Subjects

Support Email
nugrant@unl.edu
nugrant-circ@unl.edu
nugrant-iacuc@unl.edu
nugrant-ibc@unl.edu
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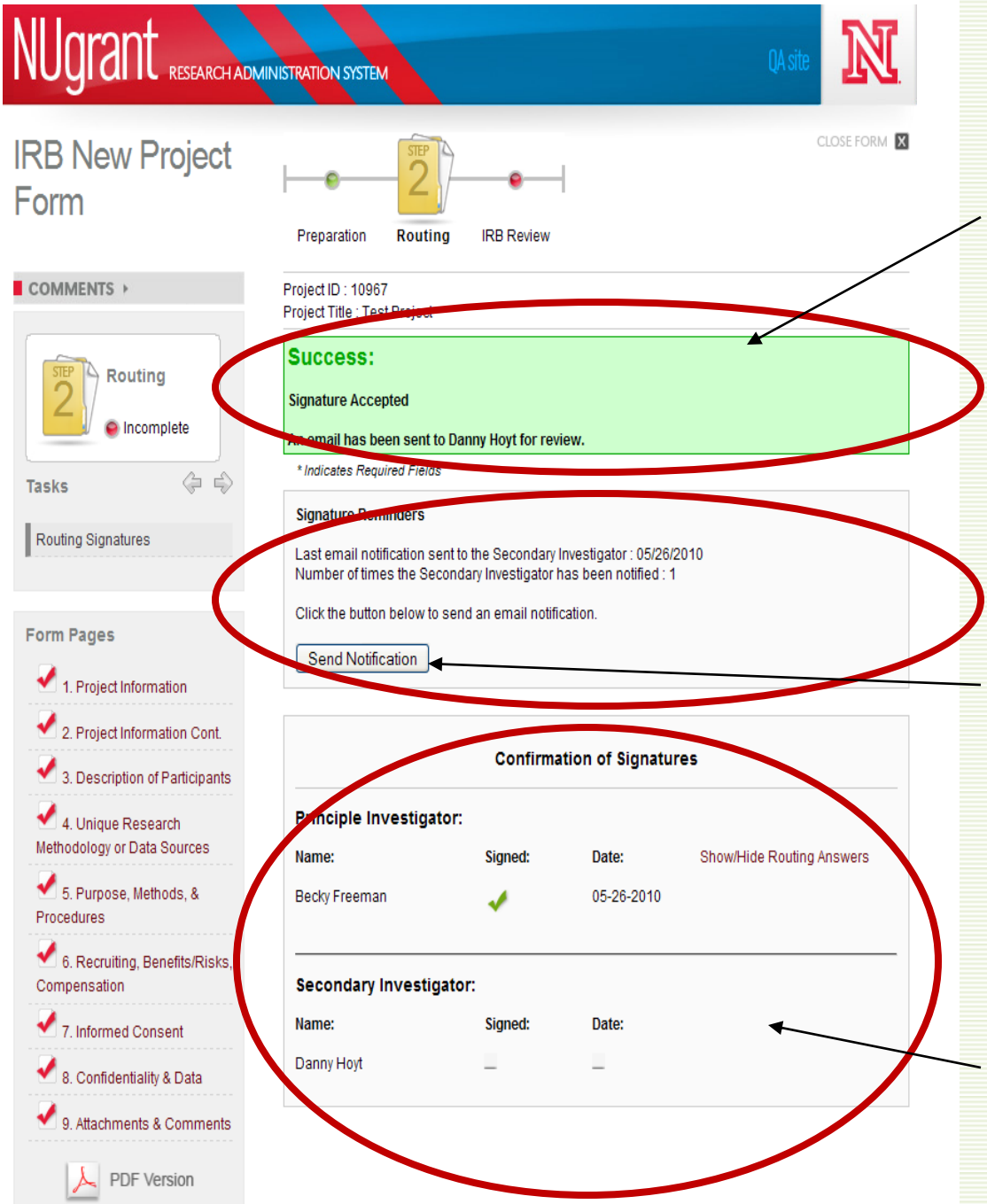
Step 2: Routing

The routing step requires the people listed as PI and Secondary Investigator to approve the research. Once the routing is started, the form cannot be edited. Notice that Preparation now has a green button. Also, the project has changed to Step two.

The approval page asks the PI and Secondary Investigator to indicate if they have any financial interests related to the research. If the answer is yes, the person will be asked to provide more information/elaborate. The PI and Secondary Investigator won't be able to view each other's responses.

If you are not ready to approve the project, you can request revisions be made to the project. To do this, enter your login information and click on the *Request Revisions* button. In the text box, you can include comments. As soon as you click on the submit button, edits can once again be made to the form. If you are satisfied with the project, click on the *I approve as written* button.



Step 2: Routing

Once the PI has signed the form, a Success message will appear. An email will then be sent to the Secondary PI requesting their approval.

The Secondary PI can sign off on the project before the PI. In that case, an email will be sent to the PI requesting approval.

If you are waiting on the other investigator to approve the project, you can send that person a reminder message. NUgrant will record when the last message was sent. Also, the email will come from the person logged into NUgrant.

This section shows individuals who have approved the project and the approval date. You can also view your responses to the questions on the approval page. Remember, you can only see your responses.

Step 3: IRB Review

NUgrant RESEARCH ADMINISTRATION SYSTEM QA site

IRB New Project Form

CLOSE FORM

Preparation Routing IRB Review

COMMENTS

IRB Review
Incomplete

Tasks

IRB Review

Project ID : 10967
Project Title : Test Project

IRB Review

This form is currently being reviewed by the IRB office.

Below is a list of Timestamps for this form.

Action Taken:	Date & Time:
Submit for Review	05/26/2010 13:19:51
Submit to IRB Office	05/26/2010 13:34:46

Form Pages

1. Project Information
2. Project Information Cont.
3. Description of Participants
4. Unique Research Methodology or Data Sources
5. Purpose, Methods, & Procedures
6. Recruiting, Benefits/Risks, Compensation
7. Informed Consent
8. Confidentiality & Data
9. Attachments & Comments

PDF Version

During Step 3: IRB Review, you will be able to see each time an action is taken on this screen.

Printer Friendly Version

Sent By: Becky Freeman
Sent On: 06/04/2010 02:18 pm
Reference: IRBProjectForm - 14245
Subject: IRB New Project Form
Message: You have been assigned as Secondary Investigator on an IRB New Project Form with Becky Freeman. Please logon using the link below to review this form.

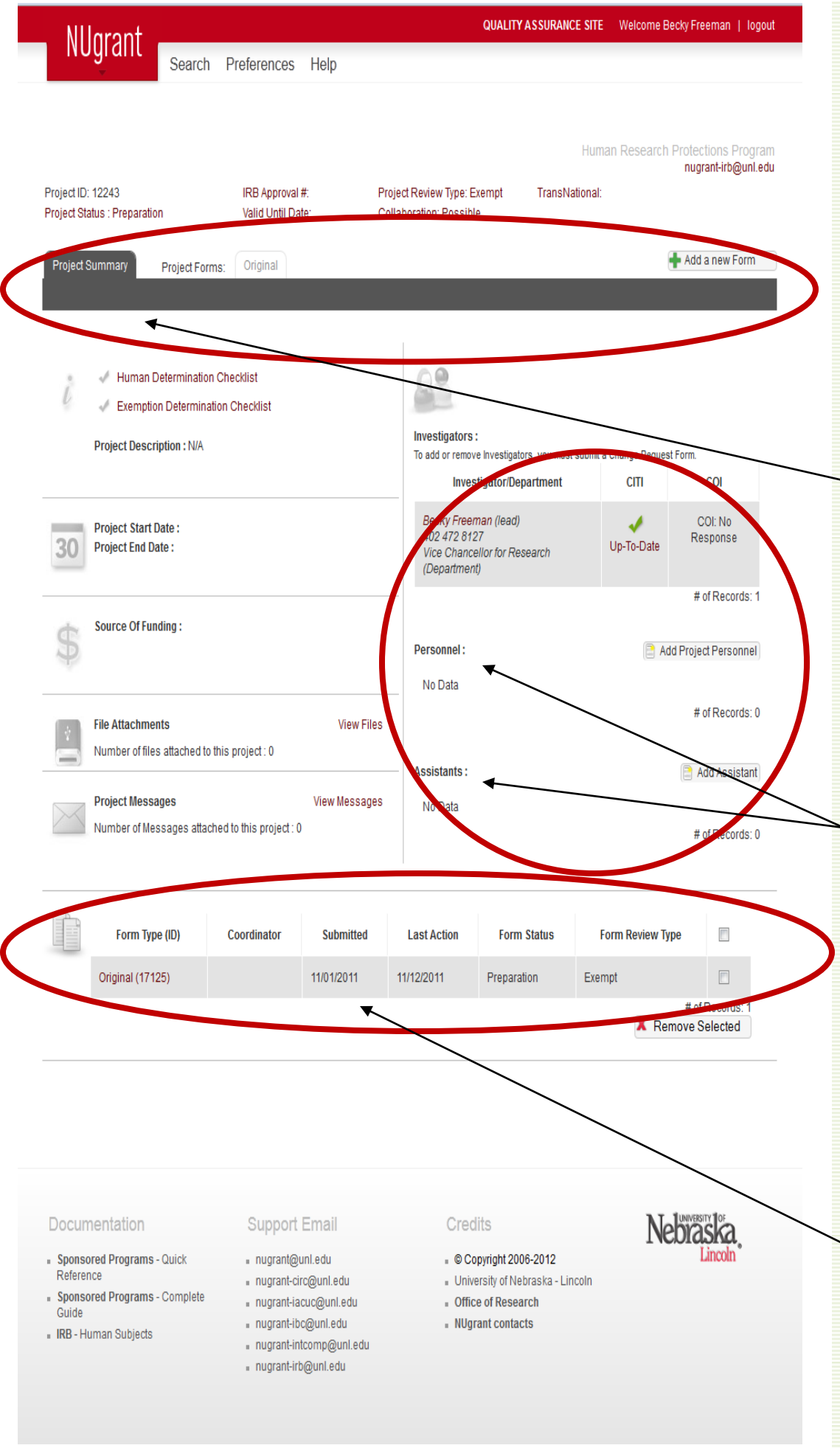
Project ID: 11009

Project Title: Test project

Close

Attachments: No Data

Once the project has been reviewed, you will receive a message similar to this one. If you open the message through your email account, the message will have a link that will take you directly to your project once you login.



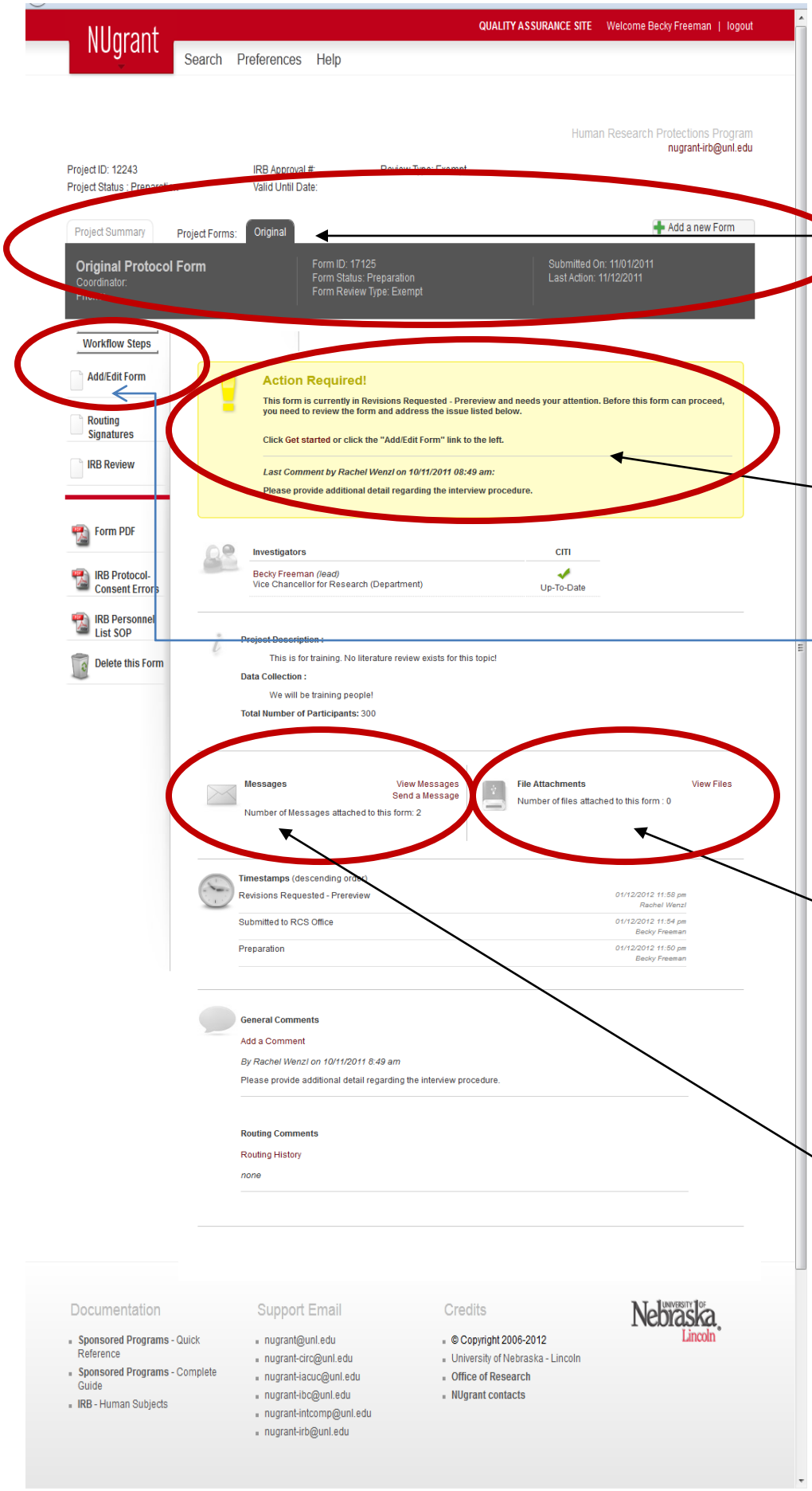
IRB Project Page

Once you have closed your IRB project form, you will be taken to the IRB Project page.

This page is the main summary page. The grey bar will indicates which page you are viewing. Basic project details appear on the summary page. You can also click on the tabs to view a specific form page.

Key personnel and research assistants can be added on this page. Please note: if you list someone as an assistant, they have full access to the project on NUgrant including submitting forms. If the person is only listed as key personnel, they are authorized to work on the research, but they will not have access to the NUgrant protocol.

You can also access the forms from the bottom of the page.



IRB Project Page

This shows the form page. Everything on this page is related to the original protocol. Each change in protocol, continuing review, or final report form will have a separate tab.

Once revisions have been requested, a box will appear under the gray bar. The box will include the revisions requested.

Revisions can also be accessed by clicking on the *Add/Edit Form* button. This opens the form.

Files associated with the form are accessible here. Once the form is approved, the stamped informed consent documents can be found here.

Messages sent related to the form will be accessible here. Once the form is approved, the official approval letter can be found here.

IRB Project Page, cont

Additional Features on this page include:

* Capability to add additional forms - continuing review, change request, and final report.

* Save/Open a PDF copy of the form.

* IRB Help Documents

The *Timestamps* will show how the form is moving through the review process.

You can add comments about the form here. These will be seen by anyone with access to the project.

NUgrant

QUALITY ASSURANCE SITE Welcome Becky Freeman | logout

Search Preferences Help

Human Research Protections Program
nugrant-irb@unl.edu

Project ID: 12243
Project Status : Preparation

IRB Approval #:
Valid Until Date:

Review Type: Exempt

Project Summary | Project Forms: Original | Add a new Form

Original Protocol Form
Coordinator:
Phone:

Form ID: 17125
Form Status: Preparation
Form Review Type: Exempt

Submitted On: 11/01/2011
Last Action: 11/12/2011

Workflow Steps
- Add/Edit Form
- Routing Signatures
- IRB Review
- Form PDF
- IRB Protocol-Consent Errors
- IRB Personnel List SOP
- Delete this Form

Investigators	CITI
Becky Freeman *(lead)* Vice Chancellor for Research (Department)	Up-To-Date

Project Description :

Data Collection :

Total Number of Participants: 0

Messages View Messages
Email this Form
Number of Messages attached to this form: 0

File Attachments View Files
Number of files attached to this form : 0

Timestamps (descending order)

Certification of Exemption	11/12/2011 02:47 pm Shane Kimbrough
Revisions Submitted - Prereview	11/05/2011 06:22 pm Shane Kimbrough
Revisions Requested - Prereview	11/05/2011 02:16 pm Shane Kimbrough
CITI Training/COI Requested	11/01/2011 11:57 pm Shane Kimbrough
Submitted to RCS Office	11/01/2011 04:16 am Shane Kimbrough
Routing	10/30/2011 11:10 am Shane Kimbrough
Preparation	10/26/2011 03:04 [illegible] Shane Kimbrough

General Comments Add a Comment
none

Routing Comments Routing History
none

Documentation
- **Sponsored Programs** - Quick Reference
- **Sponsored Programs** - Complete Guide
- **IRB** - Human Subjects

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- nugrant-intcomp@unl.edu
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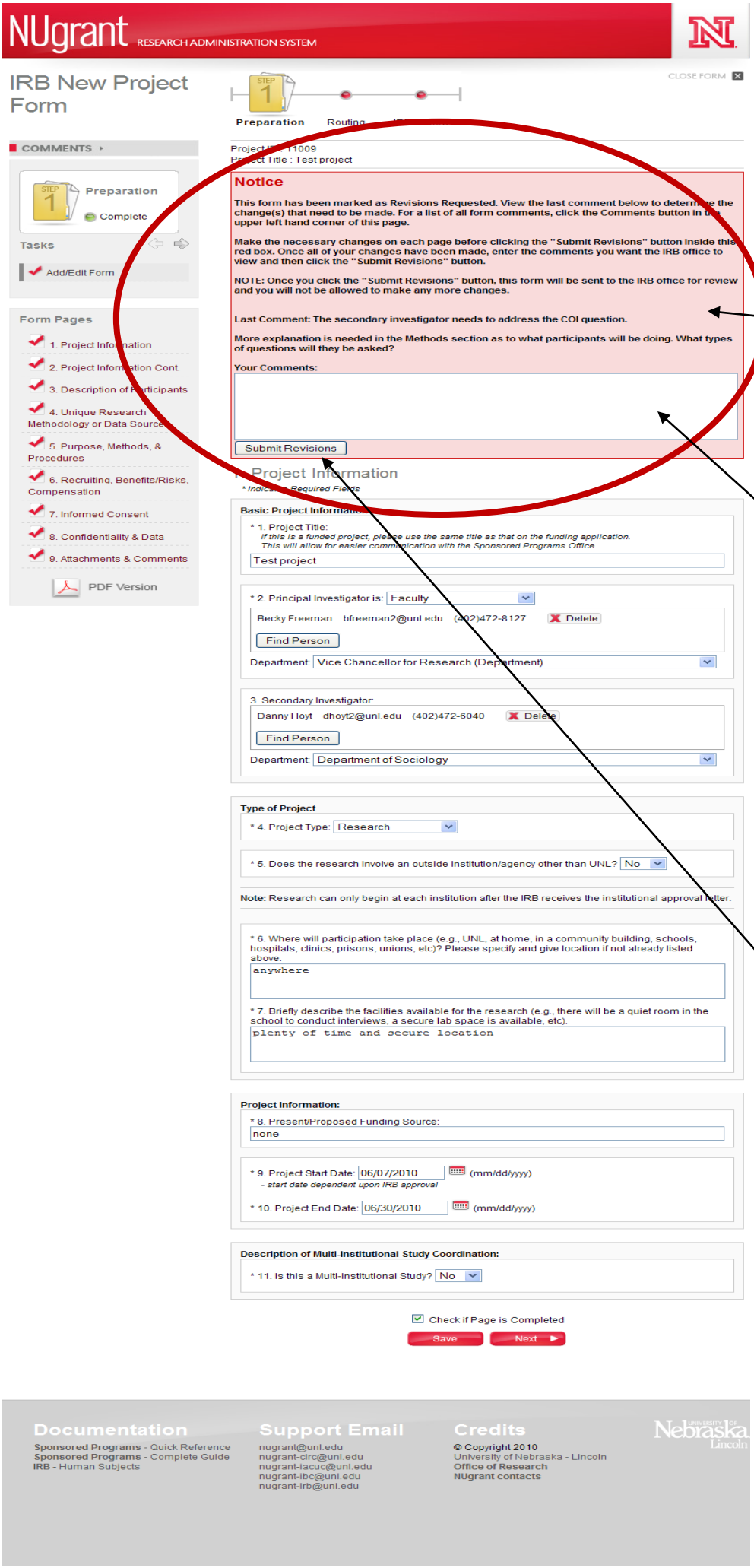


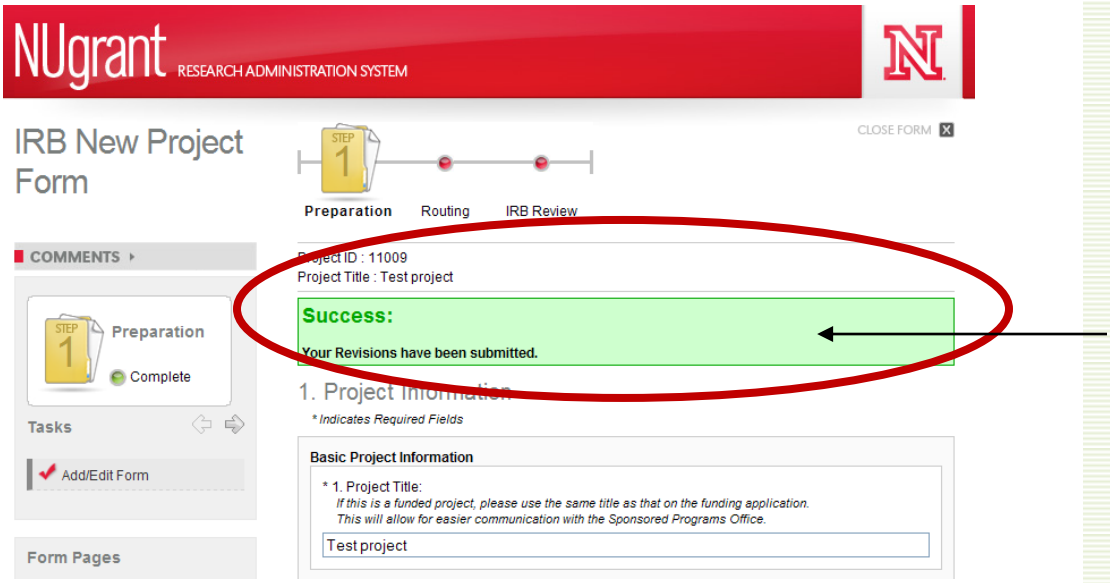
Making the requested revisions.

The information requested in the email and on the form page will appear on each page of the form. You can easily see what revisions need to be made while working in the form.

Once you have made all of the revisions, you can type a message in the box (if you choose).

NOTE: Please type your revisions in ALL CAPS, it will enable the reviewer to quickly find what has been revised in your protocol.

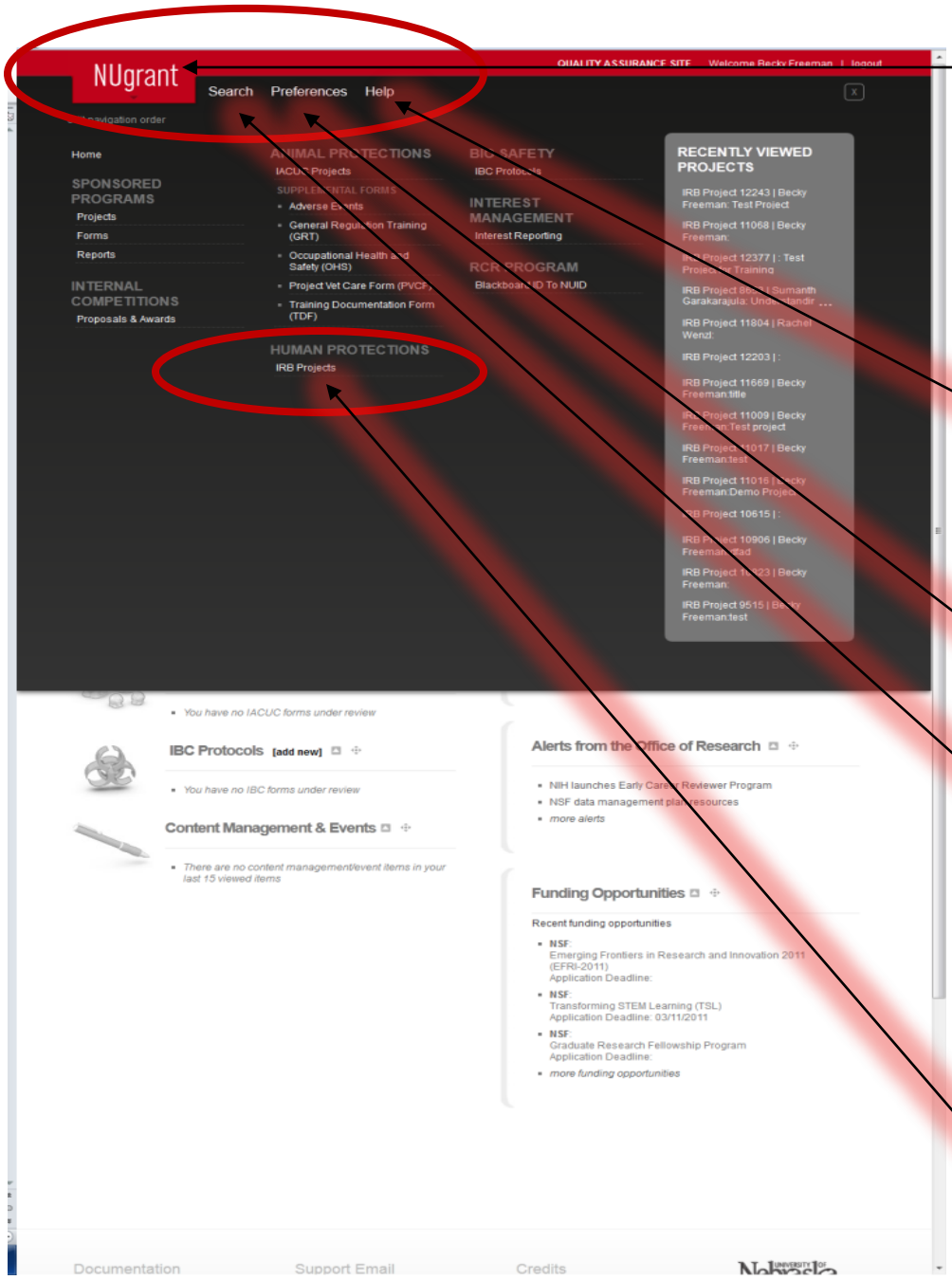
Click the *Submit Revisions* button to submit the revisions to the IRB office. Make sure you don't click on the button until all revisions have been made. Once revisions are submitted, you will be locked out of editing the form.



Step 3: IRB Review: Making the requested revisions.

As soon as you click the *Submit Revisions* button, you will see a green *Success* message at the top of the form. Once the IRB has reviewed the revisions, you will either receive another revisions requested message or an approval message.

Main Navigation



If you click on the arrow under NUgrant, the main navigation menu appears. This will help you move to different NUgrant modules by going to the home page or to the specific module.

The *Help* section provides you with people to contact and resources for using NUgrant.

The *Preferences* section lets you set your NUgrant Preferences.

The *Search* feature will let you search among the projects and areas of NUgrant that you have access to.

The *IRB Projects* link under the *Human Protections* heading will take you to a list of all of your IRB projects including projects in preparation, projects under review, approved projects, and projects which are no longer active.