

Introduce yourself(s), with title & institution.

“We are on the design team for the IRBrely project.”

Share your screen with participant

Guide participant in making their WebEx window full-screen

- Click View tab, then Full-Screen

Study Instructions:

(Read aloud the Introduction.pdf to participant)

## Welcome

Thank you for making time today to participate in this usability evaluation.

A challenge for a multisite study is the necessity to get approval from all the IRBs at sites involved in order to initiate the study. IRBrely seeks to address this problem by allowing a set of institutions to opt to rely on a single reviewing IRB for a given multisite research project, so that the research team files for IRB approval with a single or reduced set of institutions.

Through the usability evaluation, we seek to understand how easy or difficult it is to use the IRBrely system. We will ask you to accomplish a set of tasks using the system to evaluate the usability of a subset of features and tools. We are not testing you. You are helping us test the system. There are no wrong answers.

Today, you will be completing the task in the role of an IRB representative.

In the course of the evaluation you will tell us how you are trying to solve each task, which commands you think are appropriate and why. Thus, you will need to read each task aloud and think aloud - as a running commentary on what you are doing and what you think the system has done in response. You should indicate both positive and negative aspects of the tasks you are performing.

Before we start we will ask about your experience with IRB reliance. After completing the tasks we will ask you some questions about your overall impressions of the system.

The session will last approximately one hour. We will be using standard usability software to capture your interactions with the system. This may include audio or video recording that will be used only for quality improvement and will not be published. We will guide you through a training task so that you can become familiar with the tools.

Do you have any questions?

(after reading instructions)

- Close Introduction.pdf
- share mouse
- click Red Button
- Say "All tasks will be performed in this WebEx windows environment. to user that this is the same text just read, so if they're ready to go ahead and click Start Task"

Study Instructions:

This is the window where your tasks will appear.

When you are ready, click **Start** to begin.

**If participant accidentally clicks END TASK early:**

- Stop the Morae Session
  - Turn OFF screen sharing
  - Save Morae Session
  - Start a new Morae Session
  - Run through steps up to unfinished task
  - Turn ON screen sharing
- 
- Note which task was initially unfinished  
Note break in session in filename of recording

## Interview (Pre-Survey)

Before we begin, we would like to ask you a few questions.

When you are ready, click **Start** to begin.

When you are done, say "I am done" and click **End Task** found in the instruction box.

### Institution members Interview Questions

Facilitator Note: Limit this pre-survey discussion to 5 minutes

1. Tell us a little about your role at <institution name>

2. What system(s) do you currently use for IRB submission, review, and approval?

3. Have you ever, on behalf of <institution name> or another institution, reviewed multisite studies for IRB reliance or agreed to rely on the decisions of another institution's IRB?

3a. (If yes):

1. (If yes) How many times have you done this?
2. (If yes) Briefly describe the process
  - a. what made it successful?
  - b. what were the the pain points?

Task Name: PRACTICE TEST

If the participant hasn't done so already, prompt participant to read entire task aloud.

Prompt participant to **think aloud** if they forget to do so.

Today, you are going to play the role of **George Davis**, the **IRB Director** at **The Jeffersonian Institute**.

Before we begin, we'd like for you to do a practice task to familiarize yourself with the usability tools.

## Task Instructions

Please read the entire task aloud before starting.

1. **Open a Google Chrome web browser in the WebEx environment (not your own computer),**
2. **Go to [nih.gov](https://www.nih.gov).**
3. **Once you have seen the NIH web page, close the browser.**

Ready? If so, click **Start Task** to begin.

When you are done, say "I am done" and click **End Task**.

## Task 1 - Info Website - Institution

If the participant hasn't done so already, prompt participant to read entire task aloud.

Prompt participant to **think aloud** if they forget to do so.

Excellent! You've finished the practice task! Do you have any questions?

Now you are ready to begin the first of nine tasks: find information on the website.

### Task Instructions

Please read the entire task aloud before starting.

1. **Open the Google Chrome browser window in the WebEx environment (not your own computer).**
2. **Then, click on the IRBrelly - Informational Website link**
3. **Determine how a potential Reviewing IRB is initially identified for an IRBrelly Network study.**
4. **Close the browser when you are done.**

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box.**

**Please tell us a bit about your experience performing this task:**

1. **Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**

## Task 2 (join) - Download agreement

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the second of the nine tasks: download the agreement form.

Please read the entire task aloud before starting.

### Task Instructions

For the rest of the tasks, you are going to play the role of George Davis, the IRB Director for the Jeffersonian Institute. You would like to review the IRBrelly agreement because the Jeffersonian Institute is interested in joining the IRBrelly network.

Here is your contact info:

Name: George Davis

Title: IRB Director

Home Institution: Jeffersonian Institute

Email: [gdavis@thejeffersonian.org](mailto:gdavis@thejeffersonian.org)

1. **Open the Google Chrome browser window in the WebEx environment (not your own computer).**
2. **Then, click on the IRBrelly - Informational Website link**
3. **Find where to download the IRBrelly agreement from and download the agreement .pdf document.**

**Mention that they have received an email if they appear stuck.**

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

**Please tell us a bit about your experience filling out the form:**

1. **Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**

## Task 3 (join) - Personal account registration

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the third of the nine tasks: personal account registration.

Please read the entire task aloud before starting.

### Task Instructions

Time has passed, you've reviewed the agreement, and the Jeffersonian Institute has decided to join IRBrelly. From the email you received when you requested to download the agreement, begin your institution's registration by creating a personal account on the website.

1. To find this email, click on the MailCatcher bookmark in the Google Chrome web browser.
2. Create a personal account
  - Feel free to make up some of the information requested.
3. Once you have created an account, stop and end this task.

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

### Supporting Documents to Perform Task

Sample email (direct Participant to MailCatcher app) with link to Personal Account registration.

"Download Joinder Agreement" Email

Date: Tue, 04 Aug 2015 15:15:35 -0400  
From: IRBrelly <info@irbrelly.org>  
To: Curious George <curious@monkey.com>  
Message-ID: <55c10f576072c\_bdd23a92fde2067f@viridis.mail>  
Subject: Download Joinder Agreement

Hi Curious,

Thank you for your interest in IRBrelly. Click the link below to download the IRBrelly agreement and template Joinder to the agreement, which allows an institution to join IRBrelly.

Download IRBrelly Agreement and Joinder  
[https://viridis.dartmouth.edu/irbrelly/download\\_joinder/EuWzq0-BqHdm3Nzxtp6cLA](https://viridis.dartmouth.edu/irbrelly/download_joinder/EuWzq0-BqHdm3Nzxtp6cLA)

Once your institution has reviewed the agreement and decided to join IRBrelly, you must then complete your account registration in order to initiate your institution's joinder process. Click the link below to complete your registration:



Complete Registration

[https://viridis.dartmouth.edu/irbrely/set\\_password/EuWzq0-BqHdm3Nzxt6cLA](https://viridis.dartmouth.edu/irbrely/set_password/EuWzq0-BqHdm3Nzxt6cLA)

Thank you,  
Team IRBrely

**Please tell us a bit about your experience filling out the form:**

- 1. Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**

## Task 4 (join) - Institutional registration

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the fourth of the nine tasks: institutional registration.

Please read the entire task aloud before starting.

### Task Instructions

Your personal account has been created and you are ready to register the Jeffersonian Institute.

1. From the current web page, complete and save the institutional registration form.
  - You do not yet have the downloaded agreement signed.
  - Feel free to make up the information needed to fill out the registration form.

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

### Supporting Documents to Perform Task

Signed Agreement

Please tell us a bit about your experience filling out the form:

1. Overall, this task was... (1 = Very Difficult; 5 = Very Easy)
2. For your own institution, would you be able to provide the information that was requested on this form? Feel free to comment aloud if you have further insights.
3. For your own institution, is there any additional information you would want to provide on this form? Feel free to comment aloud if you have further insights.

Task 5 (join) - Upload institutional agreement & submit

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the fifth of the nine tasks: upload institutional agreement and submit.

Please read the entire task aloud before starting.

## Task Instructions

1. **The Jeffersonian Institute is now registered and the agreement you downloaded has been signed.**
  - **Upload the signed agreement to IRBrelly and then submit.**
  - **A copy of the signed agreement for you to upload is in the SUPPORTING MATERIALS folder on your desktop.**
2. **Log out and close the browser when you are done.**

Ready? If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

## Supporting Documents to Perform Task

Filled out Agreement Form

**Please tell us a bit about your experience performing this task:**

1. **Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**

## Task 6 (cede) Acknowledge willingness to be the Reviewing IRB for a study

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the sixth of the nine tasks: acknowledge willingness to be the reviewing IRB for a study.

Please read the entire task aloud before starting.

### Task Instructions

Your joinder application has been approved. For the past few months, you have been using IRBrelly to indicate the Jeffersonian Institute's willingness to be the reviewing IRB or to rely on another IRB.

#### Here is your log in info:

User ID: [gdavis@thejeffersonian.org](mailto:gdavis@thejeffersonian.org)

Password: password

1. **Open EMAIL1 in the EMAIL-INBOX folder on the desktop in the WebEx environment**
2. **Find out the details of this study and indicate that the Jeffersonian Institute is willing to be the Reviewing IRB.**

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

### Supporting Documents to Perform Task

.pdf of what email would look like:

From: [IRBRELY\\_ADMINISTRATORS@hms.harvard.edu](mailto:IRBRELY_ADMINISTRATORS@hms.harvard.edu)

To: George Davis

Subject: Action Required - New IRBrelly Cede Request Submitted: 3 - The role of natural selection in selective breeding

=====

A researcher at your institution has submitted an IRB Cede Review Request.

ID: 3 - The role of natural selection in selective breeding

Overall Principal Investigator (PI): Charles Darwin

Requested Reviewing IRB: The Jeffersonian Institute

Sites involved: The Jeffersonian Institute, Camden College, Black Mesa Research Facility, Poppleton University School of Medicine

As the Principal Investigator's Home Institution, The Jeffersonian Institute may elect to serve as the Reviewing IRB for the proposed research. To view the details of this request and enter your decision, [log in to IRBrelly](#).

The Points of Contact for the other sites involved in this request have been notified of the request and will be notified again once a proposed Reviewing IRB has been identified, so that each may indicate whether they will elect to cede authority or to review the research that is proposed to be conducted.

Thank you

Questions?

For questions related to the IRBrelly system or process, please contact [IRBRELY\\_ADMINISTRATORS@hms.harvard.edu](mailto:IRBRELY_ADMINISTRATORS@hms.harvard.edu).

**Please tell us a bit about your experience filling out the form:**

- 1. Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**
- 2. For your own institution, would you be able to provide the information that was requested on this form? Feel free to comment aloud if you have further insights.**
- 3. For your own institution, is there any additional information you would want to provide on this form? Feel free to comment aloud if you have further insights.**

# Task 7 (cede) - Check the status of a request and determine where it is in the process

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the seventh of the nine tasks: check the status of a request and determine where it is in the process.

Please read the entire task aloud before starting.

## Task Instructions

Last week, you indicated The Jeffersonian Institute's willingness to be the Reviewing IRB for a study on "The effect of insight meditation on symptoms of Acute Syndrome 1 (AS1)".

1. **Check the status of this request and determine where it is in the process:**
  - which institutions have made a determination regarding reliance?
  - which have not yet made a determination?

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

**Please tell us a bit about your experience performing this task:**

1. **Overall, this task was...** (1 = Very Difficult; 5 = Very Easy)

## **Task 8 (cede) - Find out why a site does not want to rely**

**Prompt participant to think aloud if they forget to do so.**

Now you are ready to begin the eighth of the nine tasks: find out why a site does not want to rely.

Please read the entire task aloud before starting.

### **Task Instructions**

For the study on "**The effect of insight meditation on symptoms of Acute Syndrome 1 (AS1)**", **Springfield General Hospital** has indicated they do not want to rely.

1. **Find out why Springfield General Hospital does not want to rely.**

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box.**

**Please tell us a bit about your experience performing this task:**

1. **Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**

## **Task 9 (cede) - Determine who to contact at a site for more information**

Prompt participant to **think aloud** if they forget to do so.

Now you are ready to begin the ninth and final of the nine tasks: determine who to contact at a site for more information.

Please read the entire task aloud before starting.

### **Task Instructions**

For the same study as the previous task, "**The effect of insight meditation on symptoms of Acute Syndrome 1 (AS1)**":

1. **Determine who to contact at Springfield General Hospital for more information about why this site does not want to rely.**

**Ready?** If so, click **Start Task** to begin. Please remember to tell us how you are trying to solve each task.

If you are unsure what do next, you can click **Show Instructions** and reread the task instructions. Or, if you have a question about the task, you can just ask the team.

When you are done, say "I am done" and click **End Task found in the instruction box**.

**Please tell us a bit about your experience performing this task:**

1. **Overall, this task was... (1 = Very Difficult; 5 = Very Easy)**



## **Task 10 (cede) - Explain that determination letter is out of scope**

Task Instructions:

**This is the end of what we have built in the prototype. In the future, we will add the capability for you to issue a determination letter through this tool.**

Click **Start Task** and then **End Task** to continue.

## Task - Post-Test - Institution

### Post-Survey

*Thank you for participating in this usability session. Please take a few minutes to answer the following questions. Your feedback is valuable and will help improve the IRB process!*

1. Do you know who at your institution would likely play the following roles: - an IRB Point of Contact- an Institutional Official- a Signing Authority on an agreement

- Yes I know who would perform all of these roles
- Yes I know who would perform some of these roles
- No, I don't know

2. Are you comfortable with the applicant, Reviewing IRB and all sites involved being able to view all information about the request and determination (including all decision forms)?

- Yes
- No

Comments:

3. When and how would you like to discuss items of concern with other POCs involved in the study (e.g. local context issues)?

Comments:

4. Thinking about the system as a whole....I thought the system was easy to use.

Strongly Disagree    1    2    3    4    5    Strongly Agree

5. Thinking about the system as a whole....I found the various functions in this system were well organized.

Strongly Disagree    1    2    3    4    5    Strongly Agree

6. Thinking about the system as a whole...I would imagine that most people would learn to use this system very quickly.

Strongly Disagree    1    2    3    4    5    Strongly Agree

7. Thinking about the system as a whole...What did you like about the system?

Comments:

8. Thinking about the system as a whole...What did you dislike about the system?

Comments:

9. Thinking about the system as a whole... Would you use this tool when requesting IRB reliance for your own studies?

Yes

No

Comments:

10. Thinking about the system as a whole...Any other comments?

Comments:

## Comments

1. Please feel free to tell us (say aloud) any additional thoughts you have on the software.

Comments: