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NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Web Site Usability Evaluation: DAIDS Clinical Research Policies and Standard Procedures Documents with Staff and Researchers

Final Report

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490 VIRGINIA ROAD | CONCORD, MA 01742 | TEL. 978 371 8300 | FAX 978 371 8301 | WEB SITE WWW.USABILITYAIR.ORG

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Introduction

Between July 21, 2011, and October 10, 2011, AIR conducted a total of 10 Web usability tests focusing on the National Institute of Allergy and Infectious Diseases (NIAID) Division of Acquired Immunodeficiency Syndrome (DAIDS) Clinical Research Policies and Standard Procedures Documents Web portal (Documents portal).

Participants included both NIAID DAIDS staff members and extramural researchers. The DAIDS staff members interviewed were referred by a DAIDS health specialist and screened at the beginning of the interview. The screening document is included as appendix A. Extramural researchers who expressed interest in participating in future research during intercept interviews conducted at three conferences between October and November 2009 were contacted and invited to participate in this usability study. In addition, DAIDS staff members who were interviewed were asked for referrals of extramural researchers who may be interested in participating. The screening document for extramural researchers is included as appendix B.

In the usability testing interviews, all participants were asked to perform a series of nine tasks to identify their understanding and navigation of the DAIDS portal. Copies of the usability testing protocols are included as appendixes (appendixes C–D). The tasks included in the interview were:

Task 1: NIAID Home Page
Task 2: DAIDS Portal
Task 3: Find DAIDS Clinical Research Policies and Standard Procedures Documents portal
Task 4: About the Clinical Research Policies and Standard Procedures Documents
Task 5: Finding Specific Information: Enrolling Children in Clinical Research
Task 6: Finding Specific Information: Requirements for Protocol Registration
Task 7: Finding Specific Information: FAQs
Task 8: Finding Specific Information: Contacting DAIDS for help
Task 9: Card Sort for Categories and Labeling of Topics and Links

Due to time limitations, two of the participants (DAIDS staff) did not complete a card sort. Initially, the intent was to divide the links in the Documents portal so that half of the participants would sort half of the items. Given the small sample size, all participants completed the same card sort using some of the links within the following categories: Protocol and Informed Consent, Clinical Site, Regulatory, Pharmacy and Data Management and Statistics. The findings are summarized below.

Findings

Participant Characteristics

A total of 10 participants were interviewed, 7 were members of the DAIDS staff, and 3 were extramural researchers. Table 1 summarizes the demographic characteristics of the participants. Overall, seven participants were female and three were male. Half of the participants had a master's degree and the majority was Caucasian/White. Most of the participants had been in their current position (as either DAIDS staff or extramural researcher) between 1 and 5 years. Of the three extramural researchers, two were affiliated with a university, and one was affiliated with a hospital.

Participants were also asked how often they had visited the NIAID Web site in the past month, and as seen in table 2, four had visited the site once or twice in the past month, three had visited three times or more in the past month and three had not visited the site in the past month.

Table 1. Demographic Characteristics of Web Usability Testing Participants

CHARACTERISTICS	DAIDS STAFF (n=7)	EXTRAMURAL RESEARCHERS (n=3)	TOTAL (N=10)
Gender			
Male	2 (29%)	1 (33%)	3 (30%)
Female	5 (71%)	2 (67%)	7 (70%)
Education			
Master's degree	3 (44%)	2 (67%)	5 (50%)
Ph.D.	1 (14%)	1 (33%)	2 (20%)
PharmD	1 (14%)	0 (0%)	1 (10%)
Some college	1 (14%)	0 (0%)	1 (10%)
Some professional school	1 (14%)	0 (0%)	1 (10%)
Race/Ethnicity			
Caucasian/White	4 (57%)	2 (67%)	6 (60%)
African American	2 (29%)	0 (0%)	2 (20%)
Latino/Hispanic	0 (0%)	1 (33%)	1 (10%)
Declined	1 (14%)	0 (0%)	1 (10%)
Affiliation			
NIAID	7 (100%)	0 (0%)	7 (70%)
Hospital or clinic	0 (0%)	1 (33%)	1 (10%)
University/medical school	0 (0%)	2 (67%)	2 (20%)
Field of Work			
Clinical research	N/A	1 (33%)	1 (10%)
Basic research	N/A	2 (67%)	2 (20%)
Length of time (current position/researcher)			
1–5 years	6 (86%)	2 (67%)	8 (80%)
6–10 years	1 (14%)	1 (33%)	2 (20%)
11–15 years	0 (0%)	0 (0%)	0 (0%)
More than 15 years	0 (0%)	0 (0%)	0 (0%)

Table 2. Frequency of NIAID Web Site Use in the Past Month by Participants

FREQUENCY	DAIDS STAFF (n=7)	EXTRAMURAL RESEARCHERS (n=3)	TOTAL (N=10)
Never	2 (29%)	1 (33%)	3 (30%)
1–2 times	2 (29%)	2 (67%)	4 (40%)
3–5 times	1 (14%)	0 (0%)	1 (10%)
6–9 times	0 (0%)	0 (0%)	0 (0%)
10–14 times	1 (14%)	0 (0%)	1 (10%)
More than 15 times	1(14%)	0 (0%)	1 (10%)

Findings and Recommendations by Task

The findings are presented by task. First, there is a description of each task that participants were asked to complete, a screenshot of the Web page(s) associated with each task and a summary of the findings and recommendations. The interview protocols (appendixes C and D) provide a more detailed view of the questions that were asked as participants completed the tasks.

Task 1. NIAID Home Page

This is the homepage for NIAID (figure 1 below). Please take a moment to look at it, and then I'll ask you a few questions about it. Let's say you want to find the Division of AIDS. How would you find that from this page?

Figure 1. NIAID Homepage http://www.niaid.nih.gov/Pages/default.aspx.

Findings

Two participants (DAIDS staff) were asked to find the Clinical Research Policies and Standard Procedures Documents portal (Documents portal) from the NIAID homepage. Neither of the two participants was able to navigate from the homepage to the Documents portal. That task proved to be very frustrating and as a result was modified so that the remaining participants (8 of 10) were asked to find the DAIDS portal from the NIAID homepage.

Overall, reaction to the homepage (figure 1) was positive. While participants felt it provided good information, most felt it had *too much* information. Participants who used the site the most (DAIDS staff) mentioned it was *not easy to find* information throughout the site. Almost all participants (9 of 10) would only go to the specific information they needed and would not spend time looking around the information and links available. One extramural researcher noted that he would spend time looking through the site since he found it interesting and had never visited the site before.

From the NIAID homepage, there are two navigational paths to the DAIDS portal. One path is through the *Resources for Researchers* link beneath *Labs and Scientific Resources.* Another path to the DAIDS portal is through the link *Organization* beneath *About NIAID* (see figure 2 below with the correct links circled in red). Only one participant was able to find the DAIDS portal from the NIAID homepage through the *Organization* link. Participants did not expect to find the DAIDS portal in the *Resources for Researchers* link. When asked directly about the link *Resources for Researchers,* most participants (8 of 10) were not able to describe the type of information it might contain.

Figure 2. NIAID Homepage http://www.niaid.nih.gov/Pages/default.aspx.

Almost all participants (9 of 10) looked at the homepage and expected to see a link that would direct them to the different divisions within NIAID. Looking at the links on the homepage, most participants did not expect to find the DAIDS portal through any of the existing links. Two participants (DAIDS staff) thought the link *HIV/AIDS* on the left side of the page under *Health & Research A to Z* might lead them to the DAIDS portal. They were surprised there was no link to the DAIDS portal on the HIV/AIDs health topics page, particularly since most of the page was information about HIV/AIDS research. If asked to try again, some of the DAIDS staff and extramural researchers (3 of 8) also thought the *Find NIAID researchers* and the *About NIAID* links may direct them to the DAIDS portal. Most participants (7 of 8)—both DAIDS staff and extramural researchers—noted they would use the search function and type in DAIDS.

Recommendations

We recommend changing the labels of the links leading to the DAIDS portal since the current labels were not clear to the Web usability testing participants.

- The link leading to the Documents portal and the DAIDS portal is labeled *Resources for Researchers,* but it was not clear to participants what information would be found by clicking on that link. Although alternate titles were not tested, possible labels may include *Information for Researchers, Information for Grantees* and *Meeting Grantee Requirements,* to name a few.
- The most direct link leading to the DAIDS portal is labeled *Organization,* but participants did not think it would lead them to the DAIDS portal. They tended to associate that more with the overall organizational structure of NIAID. Although an alternate title was not tested, a possible label may include *Divisions & Centers within NIAID,* for example.

Task 2. DAIDS Portal

This is the NIAID DAIDS homepage (figure 3). Please take a moment to look at it and then I'll ask you a few questions about it.

[AFTER ASKED ABOUT THE DAIDS PORTAL]: Please find the DAIDS Clinical Research Policies and Standard Procedures Documents page.

Figure 3. DAIDS Portal http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx.

Findings
Overall, reaction to the DAIDS portal (figure 3) was neutral. There were no negative or positive reactions to the layout or the content. However, most participants had not visited this portal and were not familiar with it. As they looked through it, several participants (3 of 10, both DAIDS staff and extramural researchers) noted the links were interesting. One DAIDS staff member specifically noted it provided her with a clearer *"big picture"* view of the Division.

When asked their general opinion of the left-side menu, all participants noted that the use of acronyms was confusing since they did not know what each represented. Several participants (3 of 10, both DAIDS staff and extramural researchers) suggested writing out the entire Division name.

None of the participants would click on any of the links or tools on the right-side menu. This included the *Website Tools,* the *Stay Connected* icons, the *News Releases* and the *Special Announcements.* Two participants (DAIDS staff) noted they were not able to access the *Stay Connected* tools in the workplace. All participants used the Web browser toolbar to print or bookmark, and nobody reported e-mailing the page or ordering publications. When asked to read through the *News Releases,* the *Special Announcements* and the *See Also* links, most participants found them interesting, but two participants (DAIDS staff) stated they would not click on any of those links.

Two participants (DAIDS staff and an extramural researcher) said they might click on the *See Also* link to *HIV/AIDS.* When they clicked on that link, they were surprised to find themselves in the HIV/AIDS health topics page (figure 4). They remarked that the research information found on that page was well-presented but should be located on the DAIDS portal page.

Once in the DAIDS portal, most participants were able to find the Documents portal (figure 5). When asked to find it from the DAIDS portal, most participants said they preferred to use the *search function* and type in *policies* or *DAIDS policies.* Interestingly, one participant (DAIDS staff) noted this was such a difficult site to find that she bookmarked it so that she would avoid having to find it again.

Recommendations
Although there were no strong negative reactions to the site, we recommend a few changes based on participant feedback:

- Consider replacing the Division acronyms on the left-sided menu with the name of the Divisions written out so they are easily understood by visitors.
- Consider removing or condensing the amount of links on the right-side menu, especially the *News Releases, Special Announcements* and the *See Also* links since most participants had not clicked on those links before and expressed no interest in doing so.
- Consider moving the NIAID's HIV/AIDS Research Program information and links from the HIV/AIDS health topic page to the DAIDS portal page.

Figure 4. HIV/AIDS General Health Topic
http://www.niaid.nih.gov/topics/hivaids/Pages/Default.aspx.

Task 3. Find DAIDS Clinical Research Policies and Standard Procedure Documents portal

This is the homepage for the NIAID DAIDS Clinical Research Policies and Standard Procedures Documents (figure 5). Please take a moment to look at it, and then I'll ask you a few questions about it.

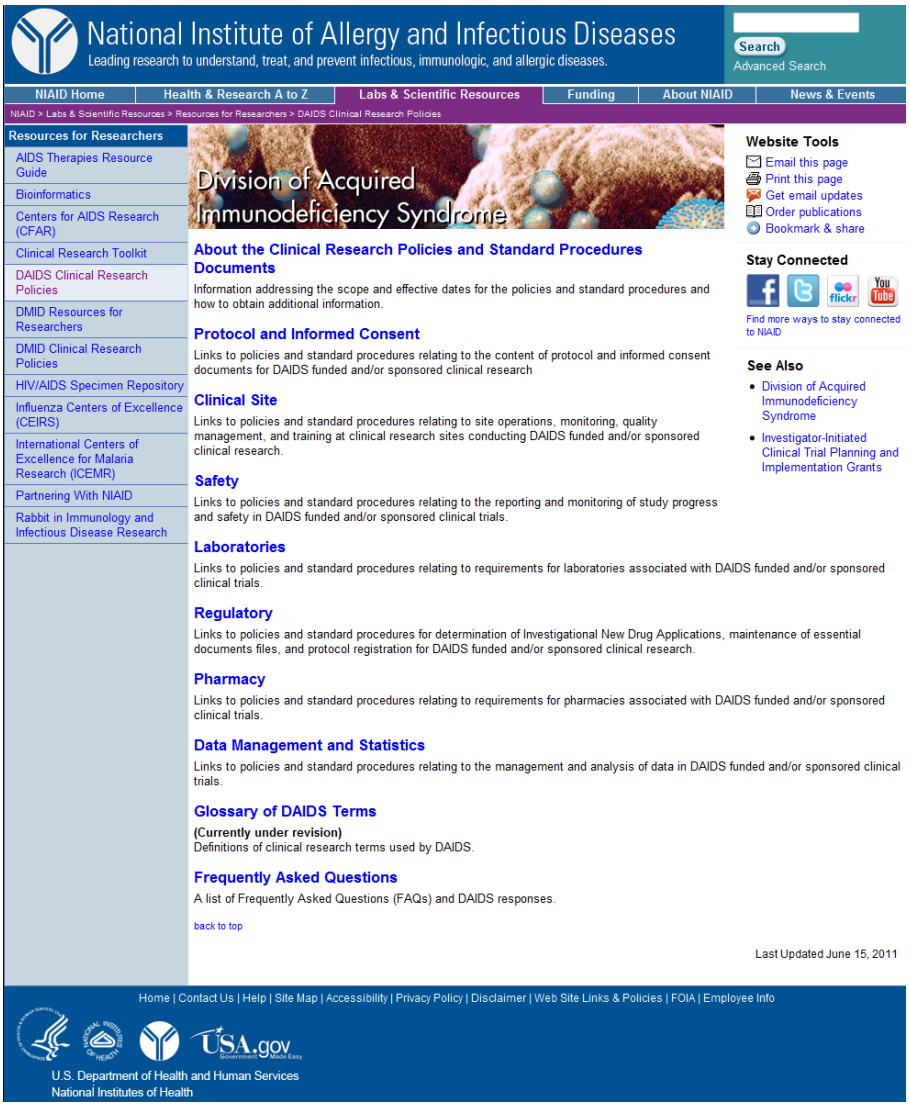


Figure 5. DAIDS Clinical Research Policies and Standard Procedures Documents: Documents Portal http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrchpages/Default.aspx.

Findings

Overall, reaction to the Documents portal (figure 5) was positive. Participants felt the page was not cluttered and that it had useful information. However, when asked about specific elements, they noted a few issues.

Most participants (8 of 10, both DAIDS staff and extramural researchers) found the title of the portal difficult to read due to the background image and the actual font size and color of the text. Similar to earlier findings of the DAIDS portal, participants had not and did not plan to use any of the tools or click on any of the links on the right-sided menu.

Most participants (8 of 10, both DAIDS staff and extramural researchers) did not find the left-sided menu useful and could not see how it related to the main content of the page. One extramural researcher noted it should be a separate page since it seemed the links were useful but did not relate to the content of the Documents portal. Two of the extramural researchers noted that typically the left-sided menu usually is a hierarchical set of links above the main content of the page.

Initially, most participants (8 of 10, both DAIDS staff and extramural researchers) felt the links provided in the middle section of the page were good and useful. However, when asked to find information within those links (Tasks 4–7), they found it difficult. All participants were confused to find policies located under categories they felt were not intuitive. For example, every participant expected the *Child Assent* policy to be found under the *Protocol and Informed Consent* category. Most participants (8 of 10, both DAIDS staff and extramural researchers) were confused that it was located under the *Clinical Site* category. In completing other tasks, several DAIDS staff participants (3 of 7) noted they knew where to find policies because they worked at NIAID and were familiar with the organization of the portal. They also pointed out that anyone outside of NIAID would have difficulties finding those policies.

Recommendations

Although there were no strong negative reactions to the site, we recommend a few changes based on participant feedback:

- Consider revising the left-sided menu so that it has a clear connection to the content on the Documents portal. This could include revising the labels; for example the *Clinical Research Toolkit* can be mistaken for a toolkit for HIV/AIDS research only, although it is actually a toolkit useful for all divisions.
- Consider revising the portal title (font, color and size) as well as the image behind it so that it is easy to read.
- Consider removing or condensing the amount of links on the right-side menu, especially the *Website Tools, Stay Connected* and *See Also* links since most participants had not clicked on those links and expressed no interest in doing so (as noted in the review of the DAIDS portal).
- Consider organizing the policies according to how a researcher would look for the policy, as described in the *Child Assent* example above.

Task 4. About the Clinical Research Policies and Standard Procedures Documents

Let's say that you want to know more about this site. How would you find that?

[IF THEY CANNOT FIND THE *"ABOUT"* LINK]: Please click on the first link: *About the Clinical Research Policies and Standard Procedures Documents* (figure 6). Take a moment to look at it, and I'll ask you a few questions (figure 7).

Now take a look at the section titled "Scope" (figure 7).

Figure 6. DAIDS Clinical Research Policies and Standard Procedures Documents http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

Findings

Most participants (8 of 10, both DAIDS staff and extramural researchers) were able to find more information about the Documents portal by clicking on the first link, *About the DAIDS Clinical Research Policies and Standard Procedures Documents* (figure 6). Two of the extramural researchers did not find the link to information about the documents. After they looked at the Documents portal for several minutes and stated they did not know where to find that information, they were instructed to click on the first link on the page, *About the DAIDS Clinical Research Policies and Standard Procedures Documents.*

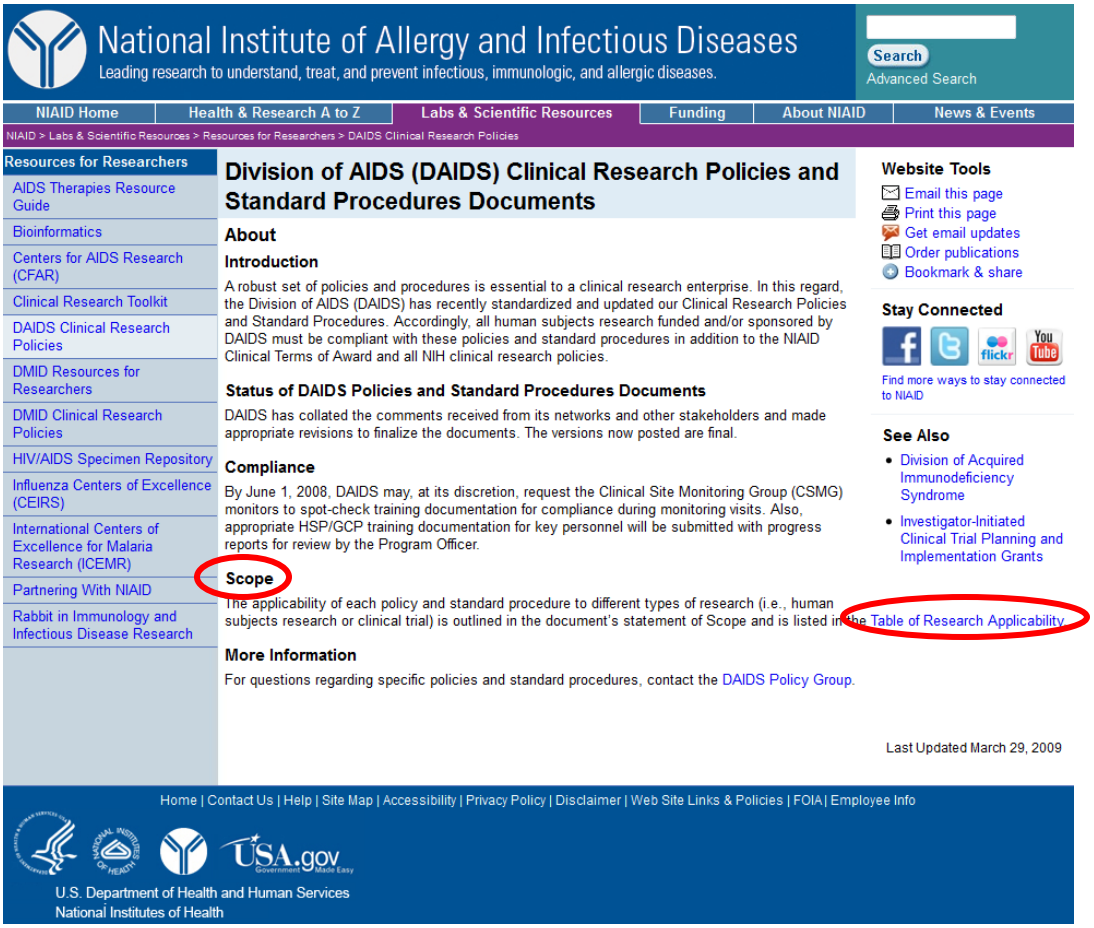


Figure 7. About DAIDS Clinical Research Policies and Standard Procedures Documents
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/about.aspx

All participants (both DAIDS staff and extramural researchers) expected to find an overview of the policies and documents available on the Documents portal and were slightly surprised at the content they actually found (figure 7). They had no negative reaction to it; they understood the content but felt it was not very useful.

Participants were also asked to look at the *Table of Research Applicability* (figure 8). Overall, participants thought it was useful. They felt the table was a good summary of all the policies and how they applied to particular types of research. A few participants (3 of 10, both DAIDS staff and extramural researchers) suggested moving it the main Documents portal since they felt most people would not find it in the *About the DAIDS Clinical Research Policies and Standard Procedures Documents* page. A DAIDS staff member noted it might be helpful to make each of the documents listed hyperlinks so that visitors could quickly access those documents. Some participants (4 of 10, both DAIDS staff and extramural researchers) also thought that the information on the *Scope* section was useful and might be better placed on the Documents portal.

Participants (6 of 10, both DAIDS staff and extramural researchers) thought revising the title of the left column in the table, *Document title,* to *Document or Policy Title* would be helpful to describe what was contained in the table. Other participants (6 of 10, both DAIDS staff and

extramural researchers) noted it might be helpful to list each of the document titles as hyperlinks so that visitors can quickly access those documents.

lth & Research A to Z | Labs & Scientific Resources | Funding | About NIAID

sources for Researchers > DAIDS Clinical Research Policies

Division of AIDS (DAIDS) Clinical Research Policies and Standard Procedures Documents

Table of Research Applicability

Document Title	Research Applicability
Protocol and Informed Consent	
Requirements for Protocol Documents	Applies to clinical trials
Requirements for Informed Consent Development	Applies to human subjects research
Clinical Site	
Requirements for Human Subject Protection (HSP) and Good Clinical Practice (GCP) Training	The HSP requirement applies to all human subject research. The HSP and GCP requirements apply to all clinical trials.
Requirements for Source Documentation	Applies to clinical trials
Requirements for Manual of Operational Procedures (MOP)	Applies to clinical trials
Requirements for Clinical Quality Management Plans	Applies to clinical trials
Requirements for On-site Monitoring	Applies to clinical trials
Safety	
Study Progress and Safety Monitoring	Applies to clinical trials
Expedited Adverse Event Reporting	Applies to clinical trials
Laboratories	
Requirements for DAIDS Funded and/or Sponsored Laboratories	Applies to clinical trials
Regulatory	
Determination of Investigational New Drug Application (IND)	Applies to clinical trials
Requirements for Essential Documents	Applies to clinical trials
Protocol Registration	Applies to clinical trials and to observational studies conducted by the DAIDS-sponsored Clinical Trials Networks
Pharmacy	
Requirements for Pharmacy Facilities	Applies to clinical trials
Requirements for Pharmacy Activities	Applies to clinical trials
Requirements for Pharmacy Personnel	Applies to clinical trials
Data Management and Statistics	
Requirements for Data Management and Statistics	Applies to clinical trials

Figure 8. Table of Research Applicability
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/TableRsrchApp.aspx.

Participants were also asked to find information regarding the *Requirements for Data Management and Statistics* from this page to see if they were able to navigate their way back to the Documents portal. All participants were able to do so by clicking on the *back* arrow of the browser, although all participants looked at the page expecting a *Home* or *Back* button or link.

Recommendations

We recommend a few changes based on participant feedback:

- Consider placing the *Table of Research Applicability* in a more visible location, possibly in the main Documents portal. One possible way to do this is to move the sentence underneath *Scope* to the Documents portal:

  "The applicability of each policy and standard procedure to different types of research (e.g., human subjects research or clinical trial) is listed in the *Table of Research Applicability*."
- Consider adding links to the policies and documents within the *Table of Research Applicability.*
- Consider moving the text on the *About* page to the main Documents portal.
- Consider organizing the policies so they can be found more intuitively from a researcher's viewpoint than they can according to NIAID internal structure.
- Consider revising the link descriptions for the categories in the Document portal to include the types of policies and information that is found in each category.

Task 5. Finding Information: Enrolling Children in Clinical Research

Let's go to the *DAIDS Clinical Research Policies and Standard Procedures Documents* homepage. Let's say that you have received a grant and want to know the requirements for enrolling children in clinical research, specifically information about obtaining the child's assent.

How would you find that information from here?

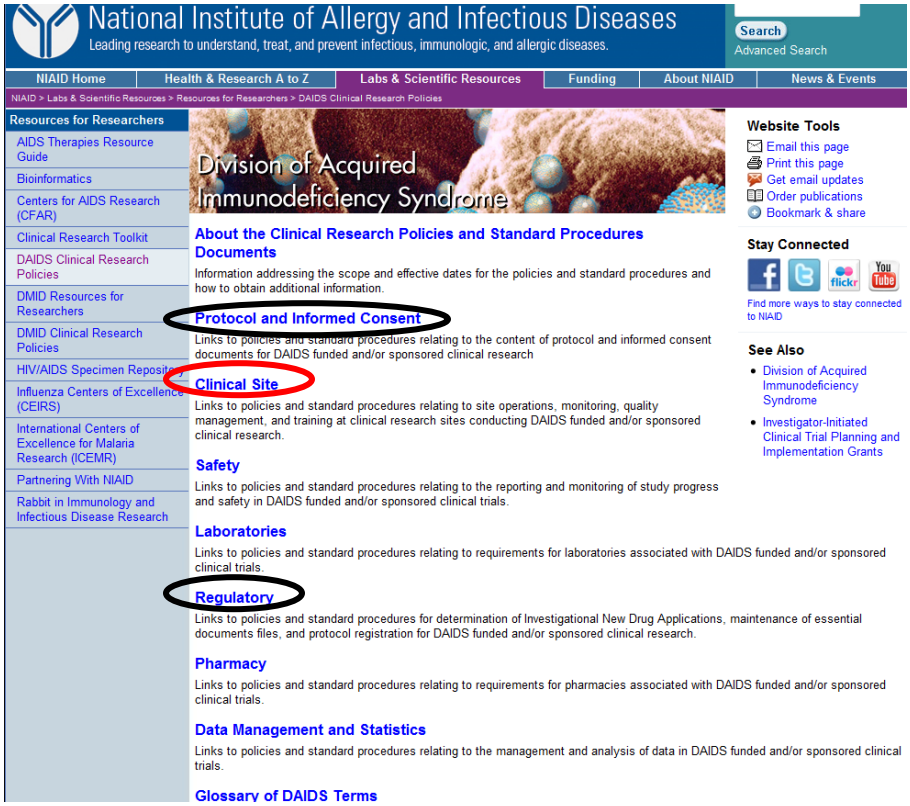


Figure 9. DAIDS Clinical Research Policies and Standard Procedures Documents http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

Findings

All but one of the participants (DAIDS staff member) *incorrectly* expected to find information about the requirements for enrolling children in clinical research under the link *Protocol and Informed Consent* of the Documents portal. One participant thought that information would be there or in the *Clinical Site* link (figure 10), and she noted that she was *more familiar with this page* [Documents portal] *than most people.*

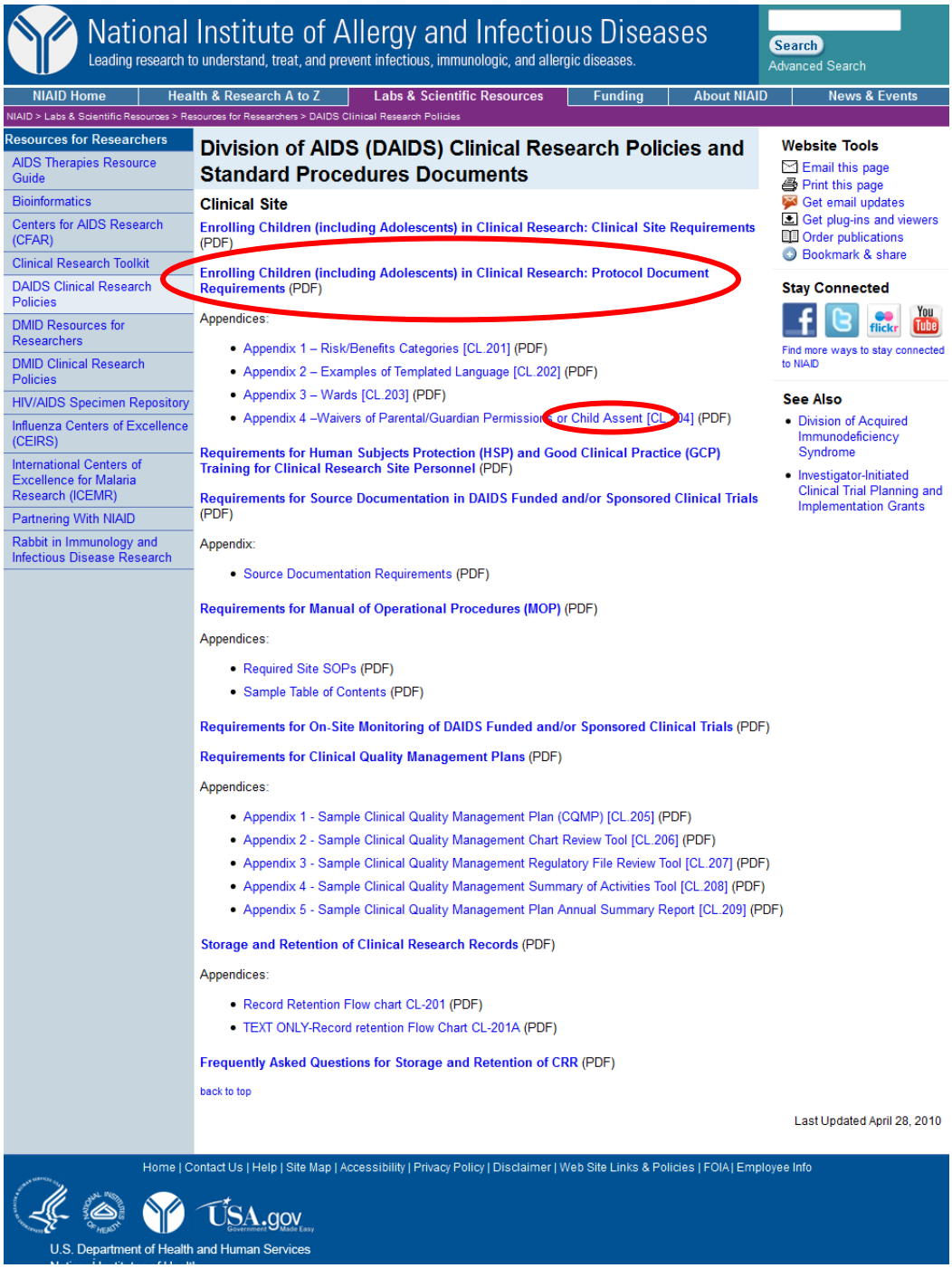


Figure 10. Clinical Site Link (Child Assent information)
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/ClinicalSite.aspx

In general, participants expected information regarding informed consent to be found in the link with the words *informed consent* in the label. Also, the text below each link describing the information available under each link (figure 11) gave participants the same impression.

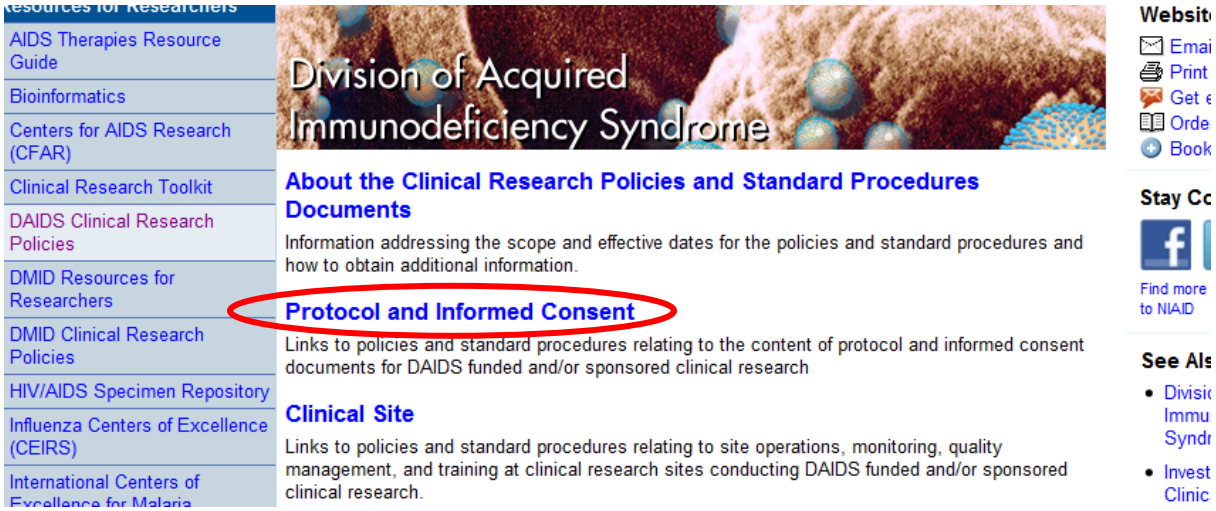


Figure 11. Description of Links in Documents Portal
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

When participants clicked on *Protocol and Informed Consent* and did not find the information about child assent, they were at a loss as to where else on the site that information may be found. They were asked to try other links, and most of the time they tried *Regulatory* but only by a guess when pressed to try another link.

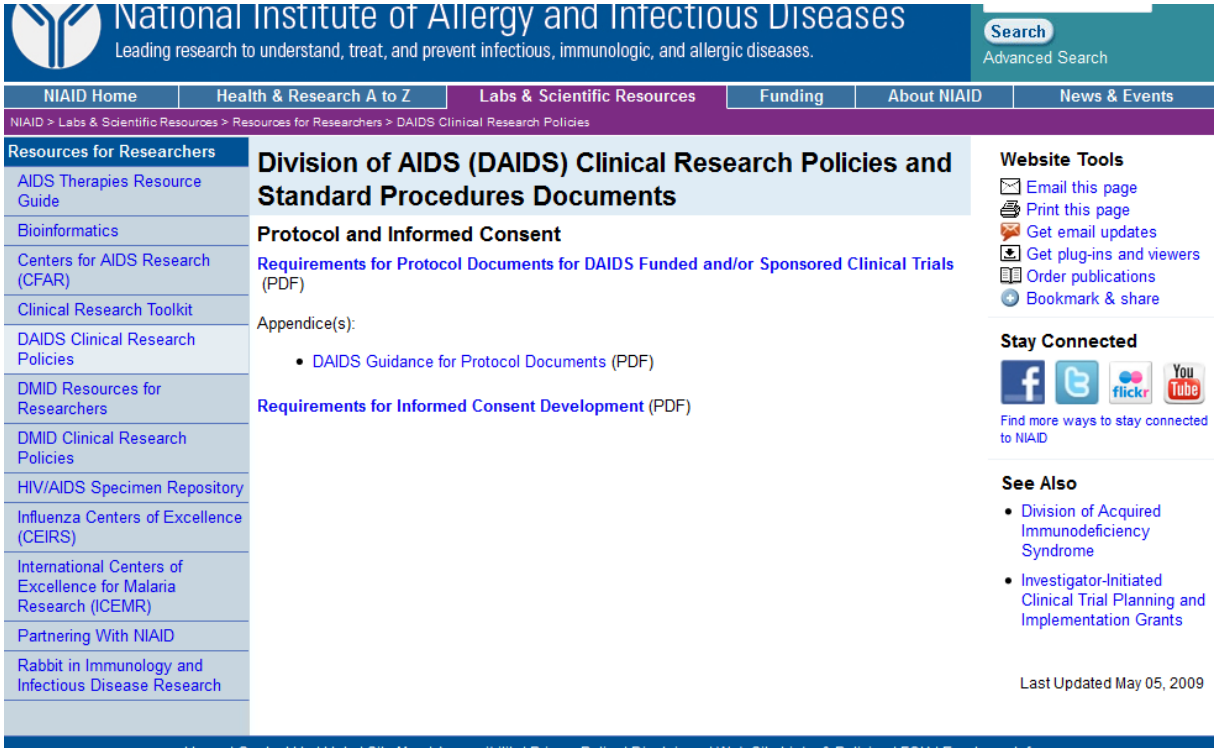


Figure 12. Protocol and Informed Consent
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Protocol.aspx.

Recommendations

We recommend a few changes based on participant feedback:

- Consider revising the description of the links in the Documents portal so that it more accurately depicts the information contained in each (as noted in Task 5).
- Consider placing all documents pertaining to informed consent in the *Protocol and Informed Consent* section.
- Consider renaming the current link labeled *Clinical Site* since all policies and documents in this portal are for clinical research, as noted in the title *Division of AIDS Clinical Research Policies and Standard Procedures Documents.*Besides informed consent for children, the *Clinical Site* link actually contains information about training, operating procedures, quality management, storage and retention of clinical research records.

Task 6. Finding Specific Information: Requirements for Protocol Registration

[STARTING FROM THE DOCUMENTS PORTAL] As you may know, it is DAIDS policy that each participating institution must complete protocol registration with the DAIDS Protocol Registration Office. Please locate information on the requirements for registering study protocols.

How would you find that information from this homepage? (figure 13)

[ONCE THEY FIND THAT INFORMATION] Now please locate the manual with information about protocol registration.

Figure 13. DAIDS Clinical Research Policies and Standard Procedures Documents http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

Findings

Most of the DAIDS staff participants (5 of 7) found the information by clicking on the correct link, *Regulatory* (figure 13). They noted they knew that from past experience, saying, *"it is a policy I use most often,"* or *"because I know how this is organized,"* and *"it's not totally apparent where you would find it."* Although they knew where to find it, they did not know why it was there and not under another link.

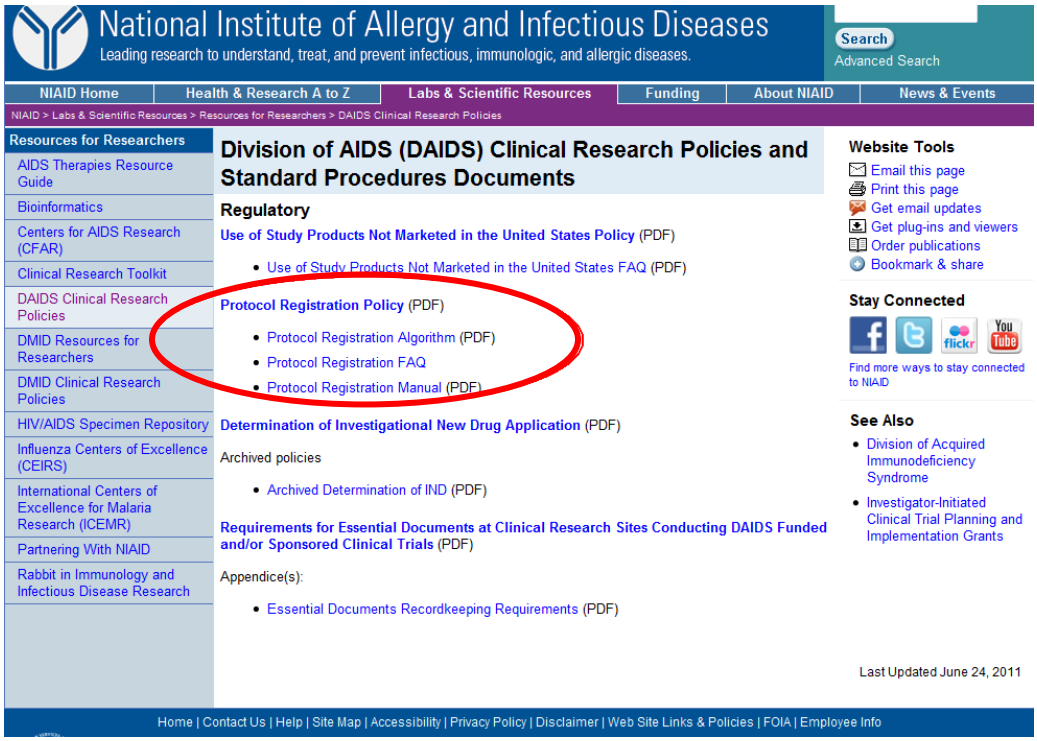


Figure 14. Regulatory link—Protocol Registration Policy
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Regulatory.aspx

All of the three extramural researchers were unable to correctly find the information. Their initial attempt was to click on the link *Protocol and Informed Consent* since they were looking for protocol-related information. Once they realized the information was not where they expected it to be, they did not know where to find it. After some time, two of the researchers clicked on the *Regulatory* link based on the description of the information available in that link.

Recommendations

We recommend a few changes based on participant feedback:

- Consider placing all documents pertaining to protocols in the *Protocol and Informed Consent* (as noted in Task 5).
- Consider renaming the current link labeled *Regulatory* since it is not clear what that means or includes. Determine if current information available under *Regulatory* can be combined into other currently existing links of the Documents portal.

Task 7. Finding Specific Information: FAQs

Let's say that you have a general question about human subject training/good clinical practice training, and you think it is a common question that others may often come to this site to find an answer.

Where do you think you would find answers to questions related to human subject training/ good clinical practice training?

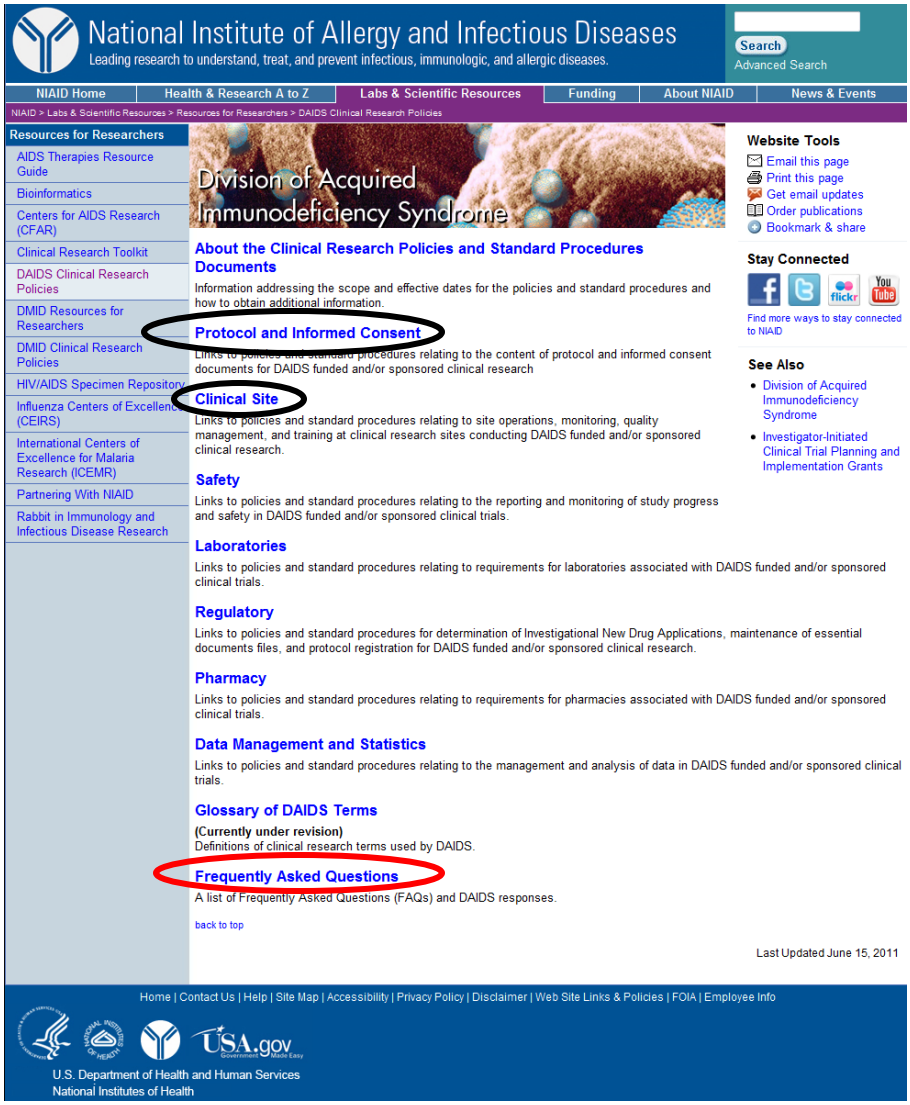


Figure 15. DAIDS Clinical Research Policies and Standard Procedures Documents—FAQs http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

Findings

Most of the DAIDS staff participants (5 of 7) found the information by clicking on the correct link *Frequently Asked Questions* in the Documents portal (figure 15). They usually stated they knew where it was but they preferred it to be located with the policy itself (*Requirements for*

Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training for Clinical Research Site Personnel),

> *"I have clicked on it before, and I know it's a subset of the FAQs available. Which is another pet peeve of mine, ether the FAQs should be a complete list of all the FAQs for each of the policies, or there should be FAQs associated with each policy. I think we have it mixed here."*

All three extramural researchers were unable to correctly find the information. Their initial attempt was to click on either *Protocol and Informed Consent* or *Clinical Site.* As they looked through the page, it took them some time to find the link at the bottom for *Frequently Asked Questions.*

Participants unable to find the correct link were guided to click on the correct link. Once they saw the page (figure 16), all participants reacted positively to the FAQs and liked that they were in HTML format. DAIDS staff participants noted they often answer a lot of these questions, and they felt it was useful that the FAQs were there for researchers.

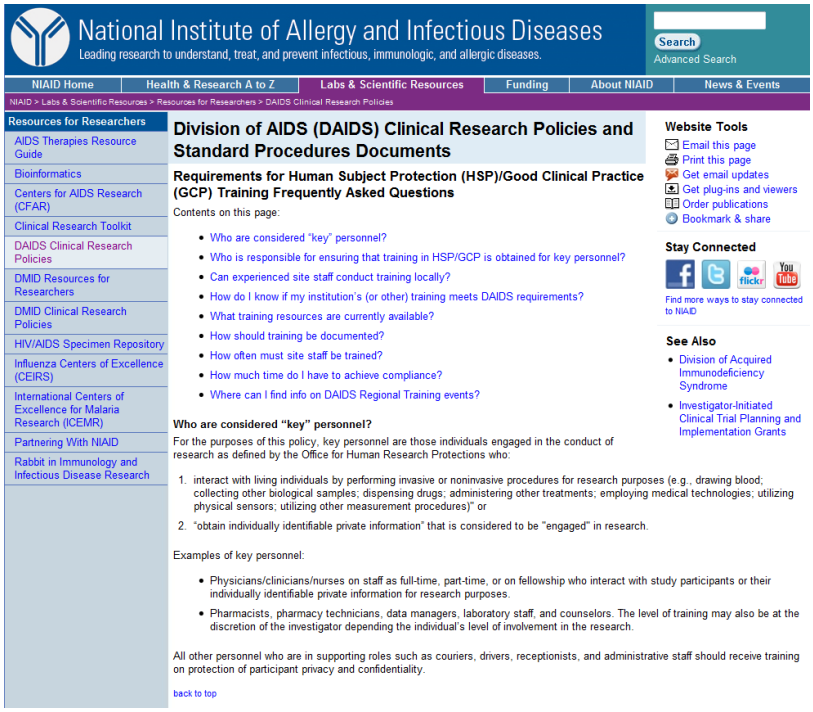
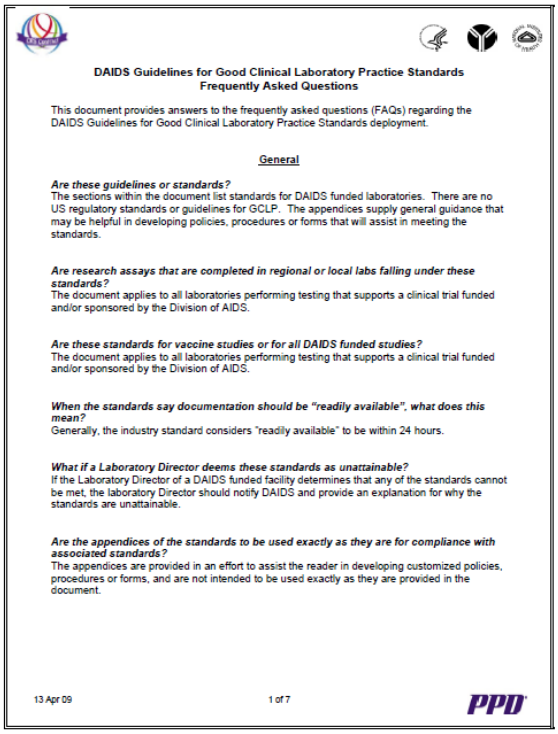


Figure 16. FAQs—Requirements for Human Subject Protection (HSP)/Good Clinical Practice (GCP) Training Frequently Asked Questions
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/faq.aspx.

After seeing the FAQs in HTML format, all participants were shown the FAQs in the *Laboratories* link that are in PDF format (figure 17). Some of the participants (4 of 10, both staff and researchers) thought it was better to have the FAQs as a Web page instead of a PDF file, especially if the questions were hyperlinked to their specific location on the page. They felt having it as a PDF made them have to scroll down and read other responses before getting to any specific question they may want to read. One participant (DAIDS staff) noted that having the

FAQs organized into subsets by category would be very helpful, because in that way she could click on the subcategory of interest and see those questions only.



DAIDS Guidelines for Good Clinical Laboratory Practice Standards
Frequently Asked Questions

This document provides answers to the frequently asked questions (FAQs) regarding the DAIDS Guidelines for Good Clinical Laboratory Practice Standards deployment.

General

Are these guidelines or standards?
The sections within the document list standards for DAIDS funded laboratories. There are no US regulatory standards or guidelines for GCLP. The appendices supply general guidance that may be helpful in developing policies, procedures or forms that will assist in meeting the standards.

Are research assays that are completed in regional or local labs falling under these standards?
The document applies to all laboratories performing testing that supports a clinical trial funded and/or sponsored by the Division of AIDS.

Are these standards for vaccine studies or for all DAIDS funded studies?
The document applies to all laboratories performing testing that supports a clinical trial funded and/or sponsored by the Division of AIDS.

When the standards say documentation should be "readily available", what does this mean?
Generally, the industry standard considers "readily available" to be within 24 hours.

What if a Laboratory Director deems these standards as unattainable?
If the Laboratory Director of a DAIDS funded facility determines that any of the standards cannot be met, the laboratory Director should notify DAIDS and provide an explanation for why the standards are unattainable.

Are the appendices of the standards to be used exactly as they are for compliance with associated standards?
The appendices are provided in an effort to assist the reader in developing customized policies, procedures or forms, and are not intended to be used exactly as they are provided in the document.

13 Apr 09 1 of 7 PPD

Figure 17. DAIDS Guidelines for Good Clinical Laboratory Practice Standards—Frequently Asked Questions
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclpfaqs.pdf.

Recommendations

We recommend a few changes based on participant feedback:

- Consider placing all FAQs in one page divided by category, using the same categories in the Documents Portal.
- Consider having the FAQs as a Web page using HTML instead of a PDF file to make it easier to navigate.

Task 8. Finding Specific Information: Contacting DAIDS or NIAID for help

[STARTING AT THE DAIDS PAGE] Let's say that you have questions about either how to find information you are looking for, or you have additional questions about the information you have found. Please show me where you would find information about where to go for additional help.

Figure 18. DAIDS Clinical Research Policies and Standard Procedures Documents http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Default.aspx.

Figure 19. DAIDS Portal http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx.

Findings

There are two places where this information is found. One is within the *About the Clinical Research Policies and Standard Procedures Documents* link in the Documents portal (figure 18), and the other is within the link *Contact Information* in the DAIDS portal (figure 19).

The DAIDS staff participants were divided as those who could find the link and those who could not. Four DAIDS staff participants were able to find the link: Two found it within the *About*

page, and two found that link in the DAIDS portal. The remaining three DAIDS staff participants were not able to find that information. None of the three extramural researchers found the information, and they were all directed to both links in the *About* page and the DAIDS portal.

All participants felt that information should be easier to find and should be more obvious. Most participants (5 of 6, both DAIDS staff and extramural researchers) noted they would not find the link within the *About* page since they would not think to check there, and because it was at the very bottom of the page (figure 20). All participants felt it made sense to have that information in the DAIDS portal but also felt it should be in the Documents portal.

Figure 20. DAIDS Contact
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/about.aspx.

When asked to click on the *DAIDS Policy Group* link, most participants (8 of 10, both DAIDS staff and extramural researchers) did not like having a pop-up e-mail message with the *To* field already populated (figure 21). The majority (9 of 10, both DAIDS staff and extramural researchers) expected to see the e-mail address and sometimes a phone number as well.

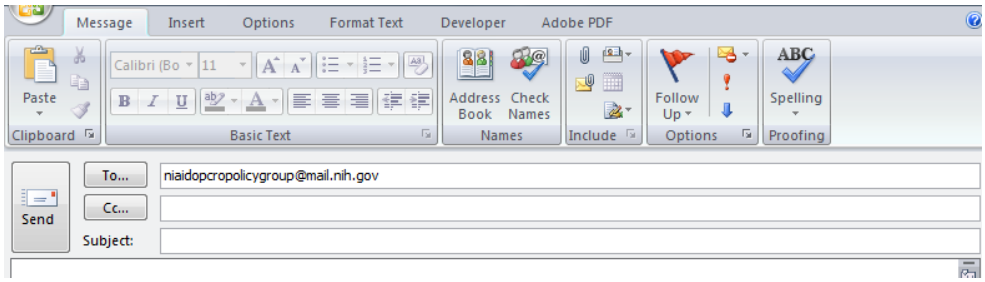


Figure 21. DAIDS Policy Group Contact
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/about.aspx.

After clicking on the *Contact Information* link on the DAIDS portal (figure 22), most participants (8 of 10, both DAIDS staff and extramural researchers) were surprised to see hyperlinked names of people (figure 23). Participants expected to see e-mail addresses and phone numbers. That information was shown (figure 24) but only after clicking on the names, by an additional click. A few participants (3 of 10, both DAIDS staff and extramural researchers) liked seeing the contact information by office.

Figure 22. DAIDS Portal—Contact Information
http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx.

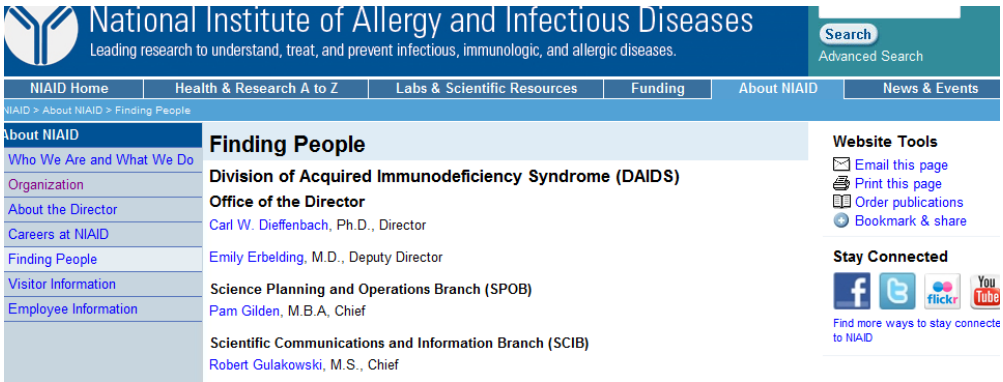


Figure 23. DAIDS Contact Information Page
http://www.niaid.nih.gov/about/findingpeople/Pages/daids.aspx.

Figure 24. Contact Link https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0013210051.

Recommendations

We recommend a few changes based on participant feedback:

- Consider adding a link with information on whom to contact on the Documents portal that is similar (if not the same link) as *Contact Information* in the DAIDS portal.
- Consider removing the contact information within the *About* page, because most people will not find it or use it.

Task 9. Card Sort for Categories and Labeling of Topics and Links

[SHOW WORD DOCUMENT] Let's say that each of these phrases is a link, and you are asked to group together the links you feel belong together. Go ahead and group the links you feel should be together and then give the group of links a name.

I will open up a word document, and you tell me which ones belong together. I'll group them together, and then you can tell me what they should be labeled. Once we go through all of them, you will have an opportunity to make any changes you would like to make before I note your final answers.

The items participants were asked to sort included the following items:

[From Protocol and Informed Consent]

- Requirements for Protocol Documents for DAIDS Funded and/or Sponsored Clinical Trials
- Appendix: DAIDS Guidance for Protocol Documents (PDF)
- Appendix: Requirements for Informed Consent Development (PDF)

[From Clinical Site]

- Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements
- Enrolling Children (including Adolescents) in Clinical Research: Protocol Document
- Requirements for Manual of Operational Procedures (MOP) (PDF)
- Requirements for On-Site Monitoring of DAIDS Funded and/or Sponsored Clinical Trials
- Requirements for Clinical Quality Management Plans (PDF)
- Storage and Retention of Clinical Research Records (PDF)
- Frequently Asked Questions for Storage and Retention of CRR (PDF)

[From Regulatory]

- Protocol Registration Policy (PDF)
- Protocol Registration Algorithm (PDF)
- Protocol Registration Manual (PDF)
- Essential Documents Recordkeeping Requirements (PDF)

[From Pharmacy]

- Requirements for Pharmacy Facilities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Activities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Personnel at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)

[From Data Management and Statistics]

- Requirements for Data Management and Statistics for DAIDS Funded and/or Sponsored Clinical Trials (PDF)
- Appendix: Data Management Requirements for Data Collection Sites (PDF)
- Appendix: Data Management Requirements for Central Data Management Facilities (PDF)

Findings
Due to time limitations, we were only able to do this card sort with 6 of the participants: 3 DAIDS staff and 3 extramural researchers. All participants were shown a word document with 21 links that are currently on the Documents portal (within each of the following categories: *Protocol and Informed Consent, Clinical Site, Regulatory, Data Management and Statistics* and *Pharmacy*). They were not given the existing category titles. They were asked to group them in any order they felt the items belonged and to name each group.

Even with a small sample size, we were able to get a glimpse into their thought process. A card sort does not necessarily provide the final organization of the items sorted, but it can yield useful insight to the participants' thought processes. This can guide an organizational structure that will make sense to the target audience.

Most of the DAIDS staff and extramural researchers grouped the items into five or eight categories. These included the five categories currently on the Documents portal that were included in the card sort with minor modifications and a few additional categories. The table below shows how current categories were modified and show the new categories that participants created.

Table 3. Summary of Card Sort Activity

ORIGINAL CATEGORY	CARD SORT
Protocol and Informed Consent	The links in this section were recategorized into: • Protocol Requirements; Protocol Registration; Protocol Guidelines and Documents • Informed Consent; Human Subject Protection and Informed Consent
Clinical Site	The links in this section were most often recategorized into: • Quality Management • Clinical Site Operations • Records • Operational Procedures • Monitoring Requirements
Regulatory	The links in this section most often were recategorized into: • Protocol Requirements; Protocol Registration; Protocol Guidelines and Documents • Documentation Requirements • Records
Data Management and Statistics	The links in this section remained in the same category, although often it was renamed as: • Data Management
Pharmacy	The links in this section remained in the same category: • Pharmacy

It is interesting to note that one participant divided the 21 items into two categories:

1. Network or nonnetwork site consisting of only the following 3 items:
    a. DAIDS Guidance for Protocol Documents
    b. Appendix: Statistical Requirements
    c. Appendix: Data Management Requirements for Central Data Management Facilities
2. Clinical Site, consisting of the remaining 18 items.

Throughout the interview, two of the DAIDS staff participants noted it would be useful and easier to find information if it was categorized by the type of research conducted: for example, by research networks (both domestic and international), vaccine research through the vaccine research center (VRC) and epidemiological research. However, this was not a thought expressed by any of the three extramural researchers.

Recommendations

- Consider revising the category where participants had the most trouble finding information and where most participants agreed in revising during the card sort: *Protocol and Informed Consent.* This may be best divided into two categories: one for Protocol-related policies and documents and one for Informed Consent–related policies and documents.
- Consider revising the category *Clinical Site* to a more intuitive term.
- Consider revising the descriptive text for each category so that it more accurately reflects the information within each.

Conclusion

The Web usability–testing interviews with DAIDS staff and extramural researchers provided good information that can be used to modify the current site so that visitors can better navigate the site. This will allow visitors to find the information they need quickly and without frustration. Finding the resources they need from the NIAID Web site quickly and easily will fulfill the purpose of this specific section of the site.

Below we summarize the recommendations we suggest based on the participant feedback from the Web usability interviews.

<u>NIAID Homepage</u>

- The link labeled *Resources for Researchers* was not understood by participants. Alternate titles were not tested, but possible labels include *Information for Researchers, Information for Grantees* and *Meeting Grantee Requirements,* to name a few.
- The link labeled *Organization* was not understood by participants either. Although alternate titles were not tested, a possible new label could be *Divisions & Centers within NIAID,* for example.

<u>DAIDS portal</u>

- Consider replacing the Division acronyms on the left-sided menu with the names written out so that they are easily understood by visitors.
- Consider removing or condensing the amount of links on the right-side menu, especially the *News Releases, Special Announcements* and *See Also* links.
- Consider moving the NIAID's HIV/AIDS Research Program information and links from the HIV/AIDS health topic page to the DAIDS portal.

<u>Documents portal</u>

- Consider revising the left-sided menu so that it has a clear connection to the content on the Documents portal.
- Consider revising the portal title (font, color and size) as well as the image behind it so that it is easy to read.
- Consider removing or condensing the amount of links on the right-side menu, similar to the recommendation above for the DAIDS portal.
- Consider revising the description of the links in the Documents portal so that it more accurately depicts the information contained in each.
    - Consider revising the category where participants had the most trouble finding information and where most participants agreed in revising during the card sort: *Protocol and Informed Consent.* This may be best divided into two categories: one for Protocol-related policies and documents and one for Informed Consent–related policies and documents.
        - Consider placing all documents pertaining to informed consent in the *Protocol and Informed Consent* section.
        - Consider placing all documents pertaining to protocols in the *Protocol and Informed Consent* section.

    - Consider renaming the current link labeled *Clinical Site* since all policies and documents in this portal are for clinical research, as noted in the title *Division of AIDS Clinical Research Policies and Standard Procedures Documents.*
    - Consider renaming the current link labeled *"Regulatory"* since it is not clear what that means or includes. Determine if current information available under *Regulatory* can be combined into other currently existing links of the Documents portal.
    - Consider placing all FAQs in one page divided by category, using the same categories in the Documents portal.
- Consider having the FAQs as a Web page using HTML instead of a PDF file to make it easier to navigate.
- Consider organizing the policies so they can be found more intuitively from a researcher's viewpoint than according to NIAID internal structure.

<u>About the DAIDS Clinical Research Policies and Standard Procedures Documents Page</u>

- Consider placing the *Table of Research Applicability* in a more visible location, possibly in the main Documents portal.
- Consider adding links to the policies and documents within the *Table of Research Applicability.*
- Consider moving the text on the *About* page to the main Documents portal.
- Consider adding a link with information on whom to contact on the Documents portal that is similar (if not the same link) as *Contact Information* in the DAIDS portal.
- Consider removing the contact information within the *About* page, because most people will not find it or use it.

APPENDIX A

Participant Screener for Web Usability Interviews (DAIDS Staff)

Summary of Web Usability Testing Interviews by Type and Location

All participants will be 18 years and older. There will be a mix of participants with respect to race/ethnicity, gender, type of researcher, length of time as a staff program officer, and their experience with visiting the NIAID Web site. Testing will be conducted remotely with the interviewer and note taker in Silver Spring, MD.

INTRODUCTION	[RECRUIT 10 PER GROUP (FOR 7-9 TO SHOW)]

Hello, I'm [*FIRST AND LAST NAME*] and I work for American Institutes for Research, a non-profit research institute. Thank you for your interest in the Web usability testing interviews we are conducting to better understand the NIAID Web site as a method of providing information to researchers and program staff. We would like to have you participate so that we can hear your opinion. These interviews will last [ONE HOUR AND A HALF]. My questions today will only take a couple of minutes.

As I said, this should only take a few minutes. At some point, I may end the questions if I find out that you do not meet the requirements for the interview. This has nothing to do with you; we simply want to include a variety of people for the interviews.

Is it OK if I ask you a few questions? ☐ Yes ☐ No → *TERMINATE*

Before we begin, I'd like to let you know that all information you provide will be private. Your help is voluntary, and you do not have to answer every question. If you would rather not answer a question, let me know and you can skip it. You can stop at any time.

1. **How long have you been working as a program officer?**
   - ☐ 1 to 5 years
   - ☐ 6 to 10 years
   - ☐ 11 to 15 years
   - ☐ More than 15 years

2. **What is the highest level of education that you have completed?**
   - ☐ Bachelor's Degree
   - ☐ MPH
   - ☐ PharmD
   - ☐ PhD
   - ☐ DO
   - ☐ MD
   - ☐ Other _____
   - ☐ [NO ANSWER] → *TERMINATE*

3. **Have you used the NIAID Web site before to find any kind of information?**
   ☐ Yes ☐ No
   [IF YES] **3a. What kind of information do you typically look for on the NIAID Web site?**
   _____

4. **In the last month, on how many days did you use the NIAID Web site for any purpose?**
   - ☐ Never
   - ☐ One to two days
   - ☐ Three to five days
   - ☐ Six to Seven days

5. **Are you of Hispanic or Latino origin?** ☐ Yes ☐ No

6. **How would you describe your race?** *[READ AND CHECK ALL THAT APPLY]*
   - ☐ White
   - ☐ Black or African-American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian or Pacific Islander
   - ☐ Another race or multiracial (write in) _____

7. *[RECORD GENDER, ONLY ASK IF UNCLEAR]* ☐ Male ☐ Female

8. **Are you over 18 years old?** _____Years [MUST BE OVER 18 YEARS OF AGE]

TERMINATION SCRIPT

Thank you for answering all of my questions. We are recruiting people from different backgrounds and unfortunately, we have already recruited several individuals with similar characteristics as yours. Again, thank you for the time.

IF NOT SURE WHETHER PARTICIPANT MEETS CRITERIA

We need to have a variety of people in the groups. I need to check my records and I will call you back in a day or two to confirm. THANKS for your interest.

INVITATION SCRIPT (USE IF INDIVIDUAL MEETS RECRUITING CRITERIA)

Thank you for answering all of my questions so far.

9. **The interviews will take place the** week of [INSERT DATES] from *[INSERT TIME]. You will need to be at a computer with internet access and on the phone while we conduct the interview. We will ask you to go to a specific section of the NIAID web site to complete some tasks and we'll ask you questions about it.* **Are you able to participate on one of these days and times? Which ones?**
   - ☐ Yes ☐ No → TERMINATE

Great. As I said, the interview will take about one hour and a half of your time. The interview will be both fun and informative. No one will try to sell you anything. No one will call on you as a result of your participation. This is an important project, and we hope you will be part of it.

10. **Do you agree to participate in one of the interviews?** ☐ Yes ☐ No → TERMINATE

Let me just mention a couple of more things:

1) You will need to be on a computer with internet access
2) You will need to be on a phone during the interview as that is how we will ask you questions.

Let's schedule you for one of the interviews. Which of the following dates and times are you available? [LIST DATES AN TIMES]

We will call you a few days before the interview to remind you of the date and time. If you will **not** be able to participate, please call [NAME AND NUMBER] to let us know as soon as possible, so we can ask someone else. We need to have a certain number of people interviewed.

NAME: _____PHONE:_____EMAIL _____

SCHEDULED FOR:_____*Recruited by:* _____

APPENDIX B

Participant Screener for Web Usability Interviews (Researchers)

Summary of Web Usability Testing Interviews by Type and Location

All participants will be 18 years and older. There will be a mix of participants with respect to race/ethnicity, gender, type of researcher, length of time as a researcher, experience with visiting the NIAID Web site, and whether they have ever received NIAID funding and their research field. Testing will be conducted remotely with the interviewer and note taker in Silver Spring, MD.

INTRODUCTION	[RECRUIT 10 PER GROUP (FOR 7-9 TO SHOW)]

Hello, I'm [*FIRST AND LAST NAME*] and I work for American Institutes for Research, a non-profit research institute. Thank you for your interest in the Web usability testing interviews we are conducting to better understand the NIAID Web site as a method of providing information to researchers. We would like to have you participate so that we can hear your opinion. These interviews will last [ONE HOUR AND A HALF]. My questions today will only take a couple of minutes.

As I said, this should only take a few minutes. At some point, I may end the questions if I find out that you do not meet the requirements for the interview. This has nothing to do with you; we simply want to include a variety of people for the interviews.

Is it OK if I ask you a few questions? ☐ Yes ☐ No → *TERMINATE*

Before we begin, I'd like to let you know that all information you provide will be private. Your help is voluntary, and you do not have to answer every question. If you would rather <u>not</u> answer a question, let me know and you can skip it. You can stop at any time.

1. What is your affiliation?

- ☐ Federal Government
- ☐ State or Local Government
- ☐ Hospital or Clinic_____
- ☐ University/Medical School
- ☐ Military
- ☐ Private/Group Practice
- ☐ Pharmaceutical/Biotech
- ☐ Sales and Marketing

2. How would you define your area of research?

- ☐ Allergy
- ☐ Immunologic disease
- ☐ Infectious diseases [ASK: WHICH ONES?] _____
- ☐ Other [ASK: WHAT TYPE?] _____

3. What is the kind of research you conduct?

- ☐ Clinical Research
- ☐ Basic Research
- ☐ Translational → *TERMINATE*
- ☐ Other [WHAT TYPE?] _____

4. How long have you been working as a researcher from the time your degree was granted?

- ☐ 1 to 5 years
- ☐ 6 to 10 years
- ☐ 11 to 15 years
- ☐ More than 15 years

5. **What is the highest level of education that you have completed?**
   - ☐ Bachelor's Degree
   - ☐ MPH
   - ☐ PharmD
   - ☐ PhD
   - ☐ DO
   - ☐ MD
   - ☐ Other _____

6. **Have you used the NIAID Web site before to find any kind of information?**
   ☐ Yes ☐ No
   [IF YES] **6a. What kind of information do you typically look for on the NIAID Web site?**
   _____

7. **In the last month, on how many days did you use the NIAID Web site for any purpose?**
   - ☐ Never
   - ☐ One to two days
   - ☐ Three to five days
   - ☐ Six to Seven days

8. **Are you of Hispanic or Latino origin?**
   ☐ Yes ☐ No

9. **How would you describe your race***? [READ AND CHECK ALL THAT APPLY]*
   - ☐ White
   - ☐ Black or African-American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian or Pacific Islander
   - ☐ Another race or multiracial (write in) _____

10. *[RECORD GENDER, ONLY ASK IF UNCLEAR]* ☐ Male ☐ Female

11. **Are you over 18 years old?** _____Years [MUST BE OVER 18 YEARS OF AGE]

TERMINATION SCRIPT

Thank you for answering all of my questions. We are recruiting people from different backgrounds and unfortunately, we have already recruited several individuals with similar characteristics as yours. Again, thank you for the time.

IF NOT SURE WHETHER PARTICIPANT MEETS CRITERIA

We need to have a variety of people in the groups. I need to check my records and I will call you back in a day or two to confirm. THANKS for your interest.

INVITATION SCRIPT (USE IF INDIVIDUAL MEETS RECRUITING CRITERIA)

Thank you for answering all of my questions so far.

12. **The interviews will take place the** week of [INSERT DATES] from *[INSERT TIMES]. You will need to be at a computer with internet access and on the phone while we conduct the interview. We will ask you to go to a specific section of the NIAID web site to complete some tasks and we'll ask you questions about it.* **Are you able to participate on one of these days and times? Which ones?**
    ☐ Yes ☐ No → TERMINATE

Great. As I said, the interview will take about one hour and a half of your time. The interview will be both fun and informative. No one will try to sell you anything. No one will call on you as a result of your participation. This is an important project, and we hope you will be part of it.

13. Do you agree to participate in one of the interviews?

☐ Yes ☐ No → TERMINATE. Thank you for speaking with me.

Let me just mention a couple of more things:

1) You will need to be on a computer with internet access
2) You will need to be on a phone during the interview as that is how we will ask you questions.

Let's schedule you for one of the interviews. Which of the following dates and times are you available? [INSERT DATES AND TIMES]

We will call you a few days before the interview to remind you of the date and time. If you will **not** be able to participate, please call [NAME AND NUMBER] to let us know as soon as possible, so we can ask someone else. We need to have a certain number of people interviewed.

NAME: _____PHONE: _____EMAIL _____
SCHEDULED FOR:_____*Recruited by:* _____

APPENDIX C

NIAID DAIDS Clinical Research Policies and Standard Procedures Documents Web Site Usability Testing Protocol (Staff)

DRAFT August 1, 2011

Testing materials

Remote Testing:

- Computer for moderator
- Computer for note-taker
- Computer for participant
- Digital audio recorder, microphone
- Interviewer clock
- Pens and notepads
- Informed consent forms emailed to participant 2 days prior to interview, obtain verbal consent over the phone.
- Copies of the testing protocol for moderator and observers
- GoToMeeting subscription
- Conference call-in number

IMPORTANT:

- Clear the cache after each session and clear browser history
- Screen resolution for laptop should be set at 1024x768
- The URL for the home page is: http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
- We will place a shortcut to the home page on the desktops of the computers.
- Set up interview sessions on GoToMeeting and invite participant plus any observers.

Procedures for obtaining informed consent

Remote Testing: Two days prior to the interview, send the interviewee the consent form by email or fax. Interviewer should go over the consent form with interviewee and obtain verbal consent prior to starting the usability testing.

Testing goals

Testing will use the current Web site, shown to interviewees at the start of the interview. Interviewers will ask participants to accomplish various tasks that focus on specific points or sections – namely, the following:

- *Navigation, design and organization of the Web site:* Do users understand how the information is organized? Can users find the information they need? Are labels and descriptions clear and easy to understand?
- *Search function within the Web site:* Can users search for and find the information they need quickly?
- *Understanding of site content:* Do users understand what information is available to them? Is there any information missing they expect to see? Is the information available useful to users?

Tasks

Task 1: NIAID Home Page
Task 2: DAIDS Home Page
Task 3: Clinical Research Policies and Standard Procedures Documents
Task 4: About the Clinical Research Policies and Standard Procedures Documents
Task 5: Enrolling children (Finding Specific Information)
Task 6: Protocol registration (Finding Specific Information)
Task 7: FAQ's (Finding Specific Information)
Task 8: Contacting DAIDS (Finding Specific Information)
Task 9: Card Sort

Timing 90 minutes total

Approximate time	Topic	Elapsed time
10	Background (and Think Aloud)	10
15	Homepage – Tasks 1 - 4	25
20	Documents – Tasks 5 & 6	45
15	Additional help – Tasks 7 & 8	60
15	Card Sort – Task 9	75
10	Questions	85
5	Closing	90

Key interview questions and probes

Think aloud reminders:

- Remember to tell me your thoughts and reactions as you're looking at the handout.
- Can you tell me what you're thinking about now?

Track where and what participants are looking at:

- What do you see first?

- Can you show me which part you were looking at when you got that reaction?
- Where are your eyes going? What are you looking at?
- What are you looking at now? What are your thoughts?

To elicit further information:

- And you say that because…
- How so?
- In what way?
- Tell me more about that
- Remember, there aren't any right or wrong answers. I just want to know your honest opinion. That's what will help in making improvements to this handout.

Background	**10 min**

- OBTAIN INFORMED CONSENT
- Thank you for agreeing to do this interview. My **name** is [NAME] and I'll be talking with you today. [INTRODUCE NOTE-TAKER]
- I work for a company called the **American Institutes for Research**, which is an independent non-profit research organization.
- Our discussion today is part of a project sponsored by **the National Institute of Allergy and Infectious Diseases (NIAID**). NIAID is one of the 27 Institutes and Centers of the National Institutes of Health (NIH) and is a component of the U. S. Department of Health and Human Services (HHS). NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.
- Today, you will be visiting a section of the NIAID Web site. I will guide you through the session, and ask you about your experience using the Web site. We would like to know what's clear and what's unclear, as well as what you like and don't like. I did not develop the Web site, so please don't worry about offending me. Please just be as honest as possible so that I can tell them about areas that may need to be changed.
- We want you to try your best to find the information we give you today, but please keep in mind that we are testing the Web site, and not you. You may ask me questions while you use the Web site. Sometimes I will answer, but sometimes I won't be able to answer because I'd like you to give it a try on your own. I don't want you to feel frustrated, so if you ever feel like giving up, just let me know and we can stop.
- **Any questions**?

Ground rules

- We'll be here for **an hour and a half today**. We won't be taking any formal breaks, but feel free to let me know if you need a break to go to the restroom [DESCRIBE LOCATION] or to get something to drink.
- Everything you tell me will be **confidential.** To protect your privacy, we won't connect your name with anything that you say.

- Please give us your **honest feedback**. Remember that we're not testing you—we're testing the Web site. My job is just to collect comments about them. If something is unclear or confusing to you, it's bound to be confusing to other people too.
- I would like to **record our discussion** today so that I can make sure I capture all of your feedback. As I mentioned before, your name or identity will not be associated with your comments. Because we're recording, please try to **speak in a voice at least as loud as the one I'm using** now so that we can make sure the tape is picking up our voices.
- We have a lot to talk about today, so there may be times when I need to move the discussion along. Please understand that **when I ask that we move to a new topic, I don't mean to be rude**.
- I'd like to remind you that we will be **recording the session** both for our note taking and for members of the development team who couldn't be here today.
- Do you have any questions before we continue? [ANSWER ANY QUESTIONS, THEN PROCEED.]

Think Aloud

As you navigate the Web site today, I'm going to ask you to think aloud so that I can follow along. This may sound a little strange, so let me demonstrate what I mean by thinking aloud with an example.

[DEMONSTRATE THINK ALOUD AND SHOW THEM THE SAMPLE QUESTION.]

[SAMPLE QUESTION]

Using www.air.org, please find out who is the director of the "International Development" program. [Answer: Janet Robb]

Ask the following questions before beginning the Web usability interview.

Screening

As you record, please state the staff person's name who you are interviewing.

1. **What is your title or position?**

   _____

2. **How long have you been working as a program officer?**
   - ☐ 1 to 5 years
   - ☐ 6 to 10 years
   - ☐ 11 to 15 years
   - ☐ More than 15 years

3. **What is the highest level of education that you have completed?**
   - ☐ Bachelor's Degree
   - ☐ MPH
   - ☐ PharmD
   - ☐ PhD
   - ☐ DO
   - ☐ MD
   - ☐ Other _____

4. **Have you used the NIAID Web site before to find any kind of information?**
   - ☐ Yes
   - ☐ No

   [IF YES] **3a. What kind of information do you typically look for on the NIAID Web site?**

   _____

5. **In the last month, on how many days did you use the NIAID Web site for any purpose?**
   - ☐ Never
   - ☐ One to two days
   - ☐ Three to five days
   - ☐ Six to Seven days

6. **Are you of Hispanic or Latino origin?**
   - ☐ Yes
   - ☐ No

7. **How would you describe your race? [READ AND CHECK ALL THAT APPLY]**
   - ☐ White
   - ☐ Black or African-American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian or Pacific Islander
   - ☐ Another race or multiracial (write in) _____

8. [RECORD GENDER, ONLY ASK IF UNCLEAR]
   - ☐ Male
   - ☐ Female

9. **Are you over 18 years old?**

   _____Years [MUST BE OVER 18 YEARS OF AGE]

Now we are going to move onto a section of the NIAID Web site. There are a series of "tasks" that I will ask you to complete. I will be turning the control of the screen and mouse over to you so you can show me how you would find the information. As you are finding the information, I would like you to tell me your thoughts as you are navigating the Web site, and I will be asking you some questions about the process.

Are you ready to begin?

Tasks

Task 1. NIAID Home Page

This is the homepage for NIAID. Please take a moment to look at it and then I'll ask you a few questions about it.

Let's say you want to find the Division of AIDS. How would you find that from this page?

NOTE: Start with the screen showing the NIAID Web site home page: http://www.niaid.nih.gov/Pages/default.aspx

OBJECTIVES:

- How does this audience prefer content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.

PROBES:

1. **Have you ever visited this page?**
    - IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
    - IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

2. **What do you think about this page? What were your first impressions of this page?**
    - What stands out to you?
    - What you would click on? Why? What would you expect to see?
    - Is there anything you find confusing or unclear?

3. **In your own words, what kind of information do you think you will find by looking at this website?**

4. **What do you think of the banner and title on top of the page?**

Task 2. DAIDS Home Page

This is the NIAID DAIDS homepage.

Please take a moment to look at it and then I'll ask you a few questions about it.

NOTE: Start with the screen showing the NIAID home page Web site:
http://www.niaid.nih.gov/ Pages/Default.aspx

If conducting testing remotely: Direct participant to the URL

OBJECTIVES:

- Does the audience understand the purpose of this page?
- How does this audience prefer for content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.

NOTES [OBSERVE]:

- Note what path they take to find the information using links or the search function?
- CORRECT PATHS:
  USING LINKS:
  A. NIAID Home page→http://www.niaid.nih.gov/Pages/default.aspx
  B. About NIAID Organization →
     http://www.niaid.nih.gov/about/organization/Pages/default.aspx
  C. DAIDS Homepage →
     http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx

PROBES:

5. **How easy or difficult was it to find this page?**
   - What might make it easier to find?
   - Where did you expect to find it? Why is that?

6. **Have you ever visited this page?**
   - IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
   - IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

7. **What do you think about this page ? What were your first impressions of this page?**
   - What stands out to you?
   - What you would click on? Why? What would you expect to see?
   - Is there anything you find confusing or unclear?

8. **In your own words, what kind of information do you think you will find by looking at this website?**

9. **What do you think of the left sided menu?**
   - What does it tell you? Why do you think it's there?

10. What do you think of the banner and title on top of the page?

11. What about the information on the right side, "Web Site Tools"?

- Would you use or click on any of those options listed there?
  - E-mail this page? Why/why not?
  - Print this page? Why/why not?
  - Follow us? Why/why not?
  - Order publications? Why/why not?
  - Bookmark & Share? Why/why not?

12. What about the information below that, "See Also"?

- Would you use or click on the option listed there?

Task 3. Find DAIDS Clinical Research Policies and Standard Procedures Documents Home Page
This is the homepage for the NIAID DAIDS Clinical Research Policies and Standard Procedures Documents.

Please take a moment to look at it and then I'll ask you a few questions about it.

OBJECTIVES:

- Does this audience understand the site has information geared towards clinical and basic researchers?
- Do users understand what types of content they will find in different areas?
- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available? Using the search function?
- Is the information easy to find?
- How does this audience prefer content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information using links or the search function?
- CORRECT PATHS:
  USING LINKS:
  A. NIAID Home page→ http://www.niaid.nih.gov/Pages/default.aspx
  B. About NIAID Organization →
     http://www.niaid.nih.gov/about/organization/Pages/default.aspx
  C. DAIDS Homepage →
     http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx
  D. NIAID Resources for Researchers→
     http://www.niaid.nih.gov/LabsAndResources/resources/Pages/default.aspx
  E. (SUBHEAD) Clinical Research Support and Tools: DAIDS Clinical Research Policies and Standard Procedures Documents→
     http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx

PROBES:

13. How easy or difficult was it to find this page?

- What might make it easier to find?
- Where did you expect to find it? Why is that?

14. Have you ever visited this page?

- IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
- IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

15. What do you think about this page ? What were your first impressions of this page?

- What stands out to you?
- What you would click on? Why? What would you expect to see?
- Is there anything you find confusing or unclear?

16. In your own words, what kind of information do you think you will find by looking at this website?

17. What do you think of the left sided menu?

- What does it tell you? Why do you think it's there?

18. What do you think of the banner and title on top of the page?

19. What about the information on the right side, "Web Site Tools"?

- Would you use or click on any of those options listed there?
  - E-mail this page? Why/why not?
  - Print this page? Why/why not?
  - Follow us? Why/why not?
  - Order publications? Why/why not?
  - Bookmark & Share? Why/why not?

20. What about the information below that, "See Also"?

- Would you use or click on any of those options listed there?
  - Division of Acquired Immunodeficiency Syndrome? Why/why not?
  - Investigator-Initiated Clinical Trial Planning and Implementation Grant? Why/why not?

Task 4 About the Clinical Research Policies and Standard Procedures Documents
Let's say that you want to know more about this site. How would you find that?

[IF PARTICIPANT DOES NOT GO TO "ABOUT THE CLINICAL RESEARCH POLICIES AND STSANDARD PROCEDURES DOCUMENTS" LINK, DIRECT THEM TO IT]

Please click on the first link: About the Clinical Research Policies and Standard Procedures Documents. Take a moment to look at it and I'll ask you a few questions.

Now take a look at the section titled "Scope."

OBJECTIVES:

- Does this audience understand the site has information geared towards clinical and basic researchers?
- Is it clear to the audience what information is available on the site?

PROBES:

21. What kind of information did you expect to find under the heading *"About the Clinical Research Policies and Standard Procedures Documents*" on the homepage?
   - Is the available information what you expected to find?
   - What does that first paragraph tell you? Is it easy to understand? Why/Why not?

22. Who is this page for? Who do you think uses this information?

23. Is this "About Us" information useful to you as a scientist or researcher? Why or why not?
   - IF YES: What is useful about it?
   - IF NO: What would make it more useful?

24. In your own words, what does the section "Scope" say?

25. What do you think the link to the "*Table of Research Applicability*" will show you? Go ahead and click on it.

26. Take a look at it and tell me what is says.
   - Is it what you expected?
   - Who is this for? Who would find this information useful?
   - Is anything missing on this table?

27. If you saw this and wanted to find out more about *Requirements for Data Management and Statistics*, how would you find more about that topic from this page?

Task 5. Finding Information: Enrolling children in clinical research
[STARTING AT THE DAIDS PAGE]Let's go to the homepage. Let's say that you have received a grant and want to know the requirements for enrolling children in clinical research, specifically information about obtaining the child's assent.

How would you find that information from here?

OBJECTIVES:

- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available?
- Can they find the information using the search function?
- Is the information easy to find?
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Clinical Site at:
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/ClinicalSite.aspx →
  C) **Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements** (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/enrollingchildrenprotocol.pdf

  USING SEARCH FUNCTION:
  If they search for "child assent" the second result is correct "**[PDF]** 1.0 PURPOSE 2.0 SCOPE 3.0 BACKGROUND"

IF THEY USE THE SEARCH FUNCTION

28. I notice you are using the search feature, what words are you typing in? Why?

29. Is this list of items found what you expected?

30. Which one would you select? Why?

31. Go ahead and click on that, is that what you expected to find?

- Why/Why not?

32. Is the information you are looking for there?

ALLOW UP TO 3 ATTEMPTS: Go back to the list that came up from the search, and select another document/link.

33. Go ahead and click on that, is that what you expected to find?

- Why/Why not?

34. Is the information you are looking for there?

IF THEY CAN'T FIND THE INFORMATION:

35. Let's see if we can find that from the homepage without using the search function.

IF USING THE LINKS/NAVIGATING:

36. Can you find that information from this page? Don't click on anything yet, just tell me where you would click.

37. Why do you think the information will be there?

38. Go ahead and click on that. Is this what you expected to find? Why/Why not?

ONCE THEY FIND THE PDF FILE:

39. Is this what you expected to find? Why/Why not?

40. What do you think of the format it is in, as a PDF file?

Now that you have found the information, let me ask you a few things.

41. Was it easy or hard to find this information?

- What might make it easier to find?
- Where did you expect to find it? Why is that?

42. What other ways would you look for this information? Which way(s) do you prefer?

43. Is there any other important information they should add this page? Is there anything missing that should be included?

Task 6. Finding Information: Requirements for Protocol Registration
[STARTING AT THE DAIDS POLICIES AND DOCUMENTS PAGE] As you may know, it is DAIDS policy that each participating institution must complete protocol registration with the DAIDS Protocol Registration Office. Please locate information on the requirements for registering study protocols.

How would you find that information from this homepage?

[ONCE THEY FIND THAT INFORMATION, ASK] Now please locate the manual with information about protocol registration.

OBJECTIVES:

- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available?
- Can they find the information using the search function?
- Is the information easy to find?
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Regulatory at: →
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Regulatory.aspx
  C) **Protocol Registration Policy** (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/protocolregpolicy.pdf
  D) Protocol Registration Manual (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/prmanual.pdf
  USING SEARCH FUNCTION:
  If they search for *"Protocol Registration"* none of the results is correct, the closest is the first one which is the FAQs: DAIDS **Protocol Registration** Frequently Asked Questions

PROBES

IF THEY USE THE SEARCH FUNCTION:

44. I notice you are using the search feature, what words are you typing in? Why?

45. Is this list of items found what you expected?

46. Which one would you select? Why?

47. Go ahead and click on that, is that what you expected to find?
- **Why/Why not?**

48. Is the information you are looking for there?

ALLOW UP TO 3 ATTEMPTS: Go back to the list that came up from the search, and select another document/link.

49. Go ahead and click on that, is that what you expected to find?
- **Why/Why not?**

50. Is the information you are looking for there?

IF THEY CAN'T FIND THE INFORMATION:

51. Let's see if we can find that from the homepage without using the search function.

IF USING THE LINKS ON THE HOMEPAGE:

52. Can you find that information from this page? Don't click on anything yet, just tell me where you would click.

53. Go ahead and click on that. Is this what you expected to find? Why/Why not?

54. Tell me a little about this page.
- What information is available here? How do you know that?
- What do you think of the way the information is presented in this page?
- What about the amount of information available? Is it too much, not enough or the right amount?
- Is it easy to understand what information is provided here? Why/ why not?
- Is it easy to read? Why/ why not?

55. Is there any other important information they should add to this page? Is there anything missing that should be included?

ONCE THEY FIND THE PDF FILE:

Now that you have found the information, let me ask you a few things.

56. Was it easy or hard to find this information?
- What might make it easier to find?
- Where did you expect to find it? Why is that?

57. Is this what you expected to find? Why/Why not?

58. What do you think of the format it is in, as a PDF file?

59. What other ways would you look for this information? Which way(s) do you prefer?

60. Is there any other important information they should add this page? Is there anything missing that should be included?

Task 7. Frequently Asked Questions (FAQs)
Let's say that have a general question about human subject training/good clinical practice training and you think it is a common question that others may often come to this site to find an answer.

Where do you think you would find answers to questions related to human subject training/ good clinical practice training?

OBJECTIVES:

- Where do participants expect to find information, where do they look?
- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available? Do they notice the FAQs at the bottom? Is it easy to find?
- Can they find the information using the search function?
- Is the section useful to participants?
- Do they prefer it in HTML or PDF format?

NOTES [OBSERVE]: Note what path they take to find the information.

- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Frequently Asked Questions at: →
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/pages/faq.aspx
  USING SEARCH FUNCTION:
  If they search for *"human subject training"* none of the results include the FAQs link above.
  If they search for *"good clinical practice training"* none of the results include the FAQs link above.

IF THEY USE THE SEARCH FUNCTION

61. I notice you are using the search feature, what words are you typing in? Why?

62. Is this list of items found what you expected?

63. Which one would you select? Why?

64. Go ahead and click on that, is that what you expected to find?
- Why/Why not?

65. Is the information you are looking for there?

DIRECT THEM TO USE THE LINKS FROM THE HOMEPAGE

66. Let's see if we can find that from the homepage without using the search function.

67. Can you find that information from this page?

DIRECT THEM TO SCROLL DOWN. If they don't think they will find it in the FAQs, DIRECT THEM TO CLICK ON FAQS:

Let's see what we find in the Frequently Asked Questions link. Go ahead and click on that.

ONCE PARTICIPANT CLICKS ON FREQUENTLY ASKED QUESTIONS:

68. Do you think the information will be there?

Go ahead and look through this section. [ONCE FIND INFORMATION] Now that you have found the information, let me ask you a few things.

69. Was it easy or hard to find this information?

- What might make it easier to find?
- Where did you expect to find it? Why is that?

70. Is this what you expected to find? Why/Why not?

- What information is available here? How do you know that?
- What do you think of the way the information is presented in this page? Why/ why not?
- What about the amount of information available? Is it too much, not enough or the right amount?
- Is it easy to understand what information is provided here? Why/ why not?
- What do you think of the format it is in, as a PDF file?
- Is it easy to read? Why/ why not?

71. Is there any other important information they should add to this page? Is there anything missing that should be included?

72. What other ways would you look for this information? Which way(s) do you prefer?

COMPARE WITH HMTL FORMATTED FAQs

NOW I WANT YOU TO SEE ANOTHER LIST OF FAQs.
Let's go back to the homepage. Click on "Laboratories." Find the second link of FAQs, and click on that. Take a minute to look at it and then I'll ask you a few questions.
FAQ's (PDF)
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclpfaqs.pdf

73. Is this what you expected to find? Why/Why not?

74. What do you think of the format it is in, as a PDF file?

75. Now that you've seen both formats, which would you prefer?

76. Would you like to be able to find this kind of information using the search function?

77. The FAQs are in different pages, what do you think about that? Would it be useful to have them all in one section, in their own section or in both? Why is that?

Task 8. Contacting DAIDS or NIAID for help

[STARTING AT THE DAIDS PAGE]
Let's say that you have questions about either how to find information you are looking for or you have additional questions about the information you have found. Please show me where you would find information about where to go for additional help.

OBJECTIVES:

- Where do participants expect to find information, where do they look?
- Is it easy to find the information on how to find additional help?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATH:
  A) DAIDS Policies and Documents Homepage → http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) About the Clinical Research Policies and Standard Procedures Documents at → http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/pages/about.aspx
  C) More Information: For questions regarding specific policies and standard procedures, contact the DAIDS Policy Group.

PROBES:

78. Was it easy or hard to find this information?
- What might make it easier to find?

79. Was this information where you expected to find it or not?

80. Is this the information you expected to find or not?

81. Would you prefer to see the email address rather than the link?

82. Was it easy or hard to find this information? Why do you say that?

AN ADDITIONAL COMPARISON OF AVAILABLE CONTACT INFORMATION, IF THERE'S TIME.

Please go to the DAIDS home page and click on Contact Information listed under About DAIDS. http://www.niaid.nih.gov/about/findingpeople/Pages/daids.aspx

83. What do you think about this Contact Information?

84. Do you think this listing is more helpful to researchers?

85. Please select any name. What do you think of this information?

86. Would you prefer to see an email pop-up with the address auto-filled, rather than the link?

Task 9. Card Sort for Categories and Labeling of Topics and Links
[SHOW WORD DOCUMENT]
Let's say that each of these phrases is a link and you are asked to group together the links you feel belong together. Go ahead and group the links you feel should be together and then give the group of links a name.

I will open up a word document and you tell me which ones belong together. I'll group them together and then you can tell me what they should be labeled. Once we go through all of them, you will have an opportunity to make any changes you would like to make before I note your final answers.

Open up a word document with a list of the links available on the site. There are 5 major categories:

- Protocol and Informed Consent
- Clinical Site
- Regulatory
- Pharmacy
- Data Management and Statistics

[INSTRUCTIONS:]

- **Please look these words/phrases over. Each word or phrase is one link.**
- [ASK THEM TO LOOK THEM OVER ONE-BY-ONE AND THEN TO SORT THEM INTO PILES] **After reviewing the list, please put these links into piles or sets that show the links that you think go best with each other. You may designate as many piles as you think are necessary.**
- [NOTE THE CATEGORIES THEY CREATE AND ASK THEM TO EXPLAIN THE CATEGORIES.] **Why did you put these cards together in this pile?**
- [ASK THEM TO NAME OR LABEL EACH OF THE PILES.] **What name would you give this set of links? Why? What about this one?** [and so on…]

OBJECTIVES:

- How do participants expect the information to be organized?
- Do their expectations match the current site organization?

[Protocol and Informed Consent]

- Requirements for Protocol Documents for DAIDS Funded and/or Sponsored Clinical Trials (PDF
- Appendix: DAIDS Guidance for Protocol Documents (PDF)
- Appendix: Requirements for Informed Consent Development (PDF)

[Clinical Site]

- Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements (PDF)
- Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements (PDF)

- Requirements for Manual of Operational Procedures (MOP) (PDF)
- Requirements for On-Site Monitoring of DAIDS Funded and/or Sponsored Clinical Trials (PDF)
- Requirements for Clinical Quality Management Plans (PDF)
- Storage and Retention of Clinical Research Records (PDF)
- Frequently Asked Questions for Storage and Retention of CRR (PDF)

[Regulatory]

- Protocol Registration Policy(PDF)
- Protocol Registration Algorithm (PDF)
- Protocol Registration FAQ
- Protocol Registration Manual (PDF)
- Determination of Investigational New Drug Application (PDF)
- Essential Documents Recordkeeping Requirements (PDF)

[Pharmacy]

- Requirements for Pharmacy Facilities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Activities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Personnel at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)

[Data Management and Statistics]

- Requirements for Data Management and Statistics for DAIDS Funded and/or Sponsored Clinical Trials (PDF)
- Appendix: Data Management Requirements for Data Collection Sites (PDF)
- Appendix: Data Management Requirements for Central Data Management Facilities (PDF)
- Appendix: Statistical Requirements (PDF)

Questions

Thank you for completing all of the tasks. Before we finish up, I would like to ask you to take a few more minutes to answer a few questions.

87. Overall, was it easy or hard to find the information you were asked to find?

- What would make it easier to find?

88. What information is important or useful to you once you get a grant?

- Where do you get that information?
- Are there any other Web sites you visit for that information?
  - Which ones? What information do you find there?
- Have you come to the DAIDS Web site to find information similar to the one I've asked you to find? Why or Why not?

- Now that you know about the kind of information available on the Web site, would you look here or would you look in [REFER TO THEIR ANSWER IN a) ABOVE]?

89. Is there any information or type of information that is missing from the site? Is there any information you would really like to see added?

Thanks and Closing

Thank you for participating in our study today. We have completed all of the tasks and questions. The information you have provided will be very useful in further updating and revising the Web site so that it fits your needs.

APPENDIX D

NIAID DAIDS Clinical Research Policies and Standard Procedures Documents Web Site Usability Testing Protocol (Researchers)

DRAFT August 1, 2011

Testing materials

Remote Testing:

- Computer for moderator
- Computer for note-taker
- Computer for participant
- Digital audio recorder, microphone
- Interviewer clock
- Pens and notepads
- Informed consent forms emailed to participant 2 days prior to interview, obtain verbal consent over the phone.
- Copies of the testing protocol for moderator and observers
- GoToMeeting subscription
- Conference call-in number

IMPORTANT:

- Clear the cache after each session and clear browser history
- Screen resolution for laptop should be set at 1024x768
- The URL for the home page is: http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
- We will place a shortcut to the home page on the desktops of the computers.
- Set up interview sessions on GoToMeeting and invite participant plus any observers.

Procedures for obtaining informed consent

Remote Testing: Two days prior to the interview, send the interviewee the consent form by email or fax. Interviewer should go over the consent form with interviewee and obtain verbal consent prior to starting the usability testing.

Testing goals

Testing will use the current Web site, shown to interviewees at the start of the interview. Interviewers will ask participants to accomplish various tasks that focus on specific points or sections – namely, the following:

- *Navigation, design and organization of the Web site:* Do users understand how the information is organized? Can users find the information they need? Are labels and descriptions clear and easy to understand?
- *Search function within the Web site:* Can users search for and find the information they need quickly?
- *Understanding of site content:* Do users understand what information is available to them? Is there any information missing they expect to see? Is the information available useful to users?

Tasks

Task 1: NIAID Home Page
Task 2: DAIDS Home Page
Task 3: Clinical Research Policies and Standard Procedures Documents
Task 4: About the Clinical Research Policies and Standard Procedures Documents
Task 5: Enrolling children (Finding Specific Information)
Task 6: Protocol registration (Finding Specific Information)
Task 7: FAQ's (Finding Specific Information)
Task 8: Contacting DAIDS (Finding Specific Information)
Task 9: Card Sort

Timing 90 minutes total

Approximate time	Topic	Elapsed time
10	Background (and Think Aloud)	10
15	Homepage – Tasks 1 - 4	25
20	Documents – Tasks 5 & 6	45
15	Additional help – Tasks 7 & 8	60
15	Card Sort – Task 9	75
10	Questions	85
5	Closing	90

Key interview questions and probes

Think aloud reminders:

- Remember to tell me your thoughts and reactions as you're looking at the handout.
- Can you tell me what you're thinking about now?

Track where and what participants are looking at:

- What do you see first?
- Can you show me which part you were looking at when you got that reaction?

- Where are your eyes going? What are you looking at?
- What are you looking at now? What are your thoughts?

To elicit further information:

- And you say that because…
- How so?
- In what way?
- Tell me more about that
- Remember, there aren't any right or wrong answers. I just want to know your honest opinion. That's what will help in making improvements to this handout.

Background	**10 min**

- OBTAIN INFORMED CONSENT
- Thank you for agreeing to do this interview. My **name** is [NAME] and I'll be talking with you today. [INTRODUCE NOTE-TAKER]
- I work for a company called the **American Institutes for Research**, which is an independent non-profit research organization.
- Our discussion today is part of a project sponsored by **the National Institute of Allergy and Infectious Diseases (NIAID**). NIAID is one of the 27 Institutes and Centers of the National Institutes of Health (NIH) and is a component of the U. S. Department of Health and Human Services (HHS). NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.
- Today, you will be visiting a section of the NIAID Web site. I will guide you through the session, and ask you about your experience using the Web site. We would like to know what's clear and what's unclear, as well as what you like and don't like. I did not develop the Web site, so please don't worry about offending me. Please just be as honest as possible so that I can tell them about areas that may need to be changed.
- We want you to try your best to find the information we give you today, but please keep in mind that we are testing the Web site, and not you. You may ask me questions while you use the Web site. Sometimes I will answer, but sometimes I won't be able to answer because I'd like you to give it a try on your own. I don't want you to feel frustrated, so if you ever feel like giving up, just let me know and we can stop.
- **Any questions**?

Ground rules

- We'll be here for **an hour and a half today**. We won't be taking any formal breaks, but feel free to let me know if you need a break to go to the restroom [DESCRIBE LOCATION] or to get something to drink.
- Everything you tell me will be **confidential.** To protect your privacy, we won't connect your name with anything that you say.
- Please give us your **honest feedback**. Remember that we're not testing you—we're testing the Web site. My job is just to collect comments about them. If something is unclear or confusing to you, it's bound to be confusing to other people too.

- I would like to **record our discussion** today so that I can make sure I capture all of your feedback. As I mentioned before, your name or identity will not be associated with your comments. Because we're recording, please try to **speak in a voice at least as loud as the one I'm using** now so that we can make sure the tape is picking up our voices.
- We have a lot to talk about today, so there may be times when I need to move the discussion along. Please understand that **when I ask that we move to a new topic, I don't mean to be rude**.
- I'd like to remind you that we will be **recording the session** both for our note taking and for members of the development team who couldn't be here today.
- Do you have any questions before we continue? [ANSWER ANY QUESTIONS, THEN PROCEED.]

Think Aloud

As you navigate the Web site today, I'm going to ask you to think aloud so that I can follow along. This may sound a little strange, so let me demonstrate what I mean by thinking aloud with an example.

[DEMONSTRATE THINK ALOUD AND SHOW THEM THE SAMPLE QUESTION.]

[SAMPLE QUESTION]

Using www.air.org, please find out who is the director of the "International Development" program. [Answer: Janet Robb]

Ask the following questions before beginning the Web usability interview.

Screening

1. **What is your affiliation?**
   - ☐ Federal Government
   - ☐ State or Local Government
   - ☐ Hospital or Clinic_____
   - ☐ University/Medical School
   - ☐ Military
   - ☐ Private/Group Practice
   - ☐ Pharmaceutical/Biotech

2. **How would you define your area of research?**
   - ☐ Allergy
   - ☐ Immunologic disease
   - ☐ Infectious diseases [Specify:] _____
   - ☐ Other [Specify:] _____

3. **What is the kind of research you conduct?**
   - ☐ Clinical Research
   - ☐ Basic Research
   - ☐ Translational → *TERMINATE*
   - ☐ Other [Specify:] _____

4. **How long have you been working as a researcher from the time your degree was granted?**
   - ☐ 1 to 5 years
   - ☐ 6 to 10 years
   - ☐ 11 to 15 years
   - ☐ More than 15 years

5. **What is the highest level of education that you have completed?**
   - ☐ Bachelor's Degree
   - ☐ MPH
   - ☐ PharmD
   - ☐ PhD
   - ☐ MD
   - ☐ Other _____

6. **Have you used the NIAID Web site before to find any kind of information?**
   - ☐ Yes ☐ No

   [IF YES] **3a. What kind of information do you typically look for on the NIAID Web site?** _____

7. **In the last month, on how many days did you use the NIAID Web site for any purpose?**
   - ☐ Never
   - ☐ One to two days
   - ☐ Three to five days
   - ☐ Six to Seven days

8. **Are you of Hispanic or Latino origin?**
   - ☐ Yes ☐ No

9. **How would you describe your race? [READ AND CHECK ALL THAT APPLY]**
   - ☐ White
   - ☐ Black or African-American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian or Pacific Islander
   - ☐ Another race or multiracial (write in) _____

10. [RECORD GENDER, ONLY ASK IF UNCLEAR] ☐ Male ☐ Female

11. Are you over 18 years old? _____Years

Now we are going to move onto a section of the NIAID Web site. There are a series of "tasks" that I will ask you to complete. I will be turning the control of the screen and mouse over to you so you can show me how you would find the information. As you are finding the information, I would like you to tell me your thoughts as you are navigating the Web site, and I will be asking you some questions about the process.

Are you ready to begin?

Tasks

Task 1. NIAID Home Page

This is the homepage for NIAID. Please take a moment to look at it and then I'll ask you a few questions about it.

Let's say you want to find the Division of AIDS. How would you find that from this page?

NOTE: Start with the screen showing the NIAID Web site home page: http://www.niaid.nih.gov/Pages/default.aspx

OBJECTIVES:

- How does this audience prefer content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.

PROBES:

1. **Have you ever visited this page?**
    - IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
    - IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

2. **What do you think about this page? What were your first impressions of this page?**
    - What stands out to you?
    - What you would click on? Why? What would you expect to see?
    - Is there anything you find confusing or unclear?

3. **In your own words, what kind of information do you think you will find by looking at this website?**

4. **What do you think of the banner and title on top of the page?**

Task 2. DAIDS Home Page

This is the NIAID DAIDS homepage.

Please take a moment to look at it and then I'll ask you a few questions about it.

NOTE: Start with the screen showing the NIAID home page Web site:
http://www.niaid.nih.gov/ Pages/Default.aspx

If conducting testing remotely: Direct participant to the URL

OBJECTIVES:

- Does the audience understand the purpose of this page?
- How does this audience prefer for content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.

NOTES [OBSERVE]:

- Note what path they take to find the information using links or the search function?
- CORRECT PATHS:
  USING LINKS:
  A. NIAID Home page→http://www.niaid.nih.gov/Pages/default.aspx
  B. About NIAID Organization →
     http://www.niaid.nih.gov/about/organization/Pages/default.aspx
  C. DAIDS Homepage →
     http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx

PROBES:

5. **How easy or difficult was it to find this page?**
   - What might make it easier to find?
   - Where did you expect to find it? Why is that?

6. **Have you ever visited this page?**
   - IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
   - IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

7. **What do you think about this page ? What were your first impressions of this page?**
   - What stands out to you?
   - What you would click on? Why? What would you expect to see?
   - Is there anything you find confusing or unclear?

8. **In your own words, what kind of information do you think you will find by looking at this website?**

9. **What do you think of the left sided menu?**
    - What does it tell you? Why do you think it's there?

10. **What do you think of the banner and title on top of the page?**

11. **What about the information on the right side, "Web Site Tools"?**
    - Would you use or click on any of those options listed there?
        - E-mail this page? Why/why not?
        - Print this page? Why/why not?
        - Follow us? Why/why not?
        - Order publications? Why/why not?
        - Bookmark & Share? Why/why not?

12. **What about the information below that, "See Also"?**
    - Would you use or click on the option listed there?

Task 3. Find DAIDS Clinical Research Policies and Standard Procedures Documents Home Page

This is the homepage for the NIAID DAIDS Clinical Research Policies and Standard Procedures Documents.

Please take a moment to look at it and then I'll ask you a few questions about it.

OBJECTIVES:

- Does this audience understand the site has information geared towards clinical and basic researchers?
- Do users understand what types of content they will find in different areas?
- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available? Using the search function?
- Is the information easy to find?
- How does this audience prefer content to be organized?
- Do users understand what types of content they will find in different areas?
- Obtain general feedback on how users feel about the page layout.
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information using links or the search function?
- CORRECT PATHS:
  USING LINKS:
  A. NIAID Home page→ http://www.niaid.nih.gov/Pages/default.aspx
  B. About NIAID Organization → http://www.niaid.nih.gov/about/organization/Pages/default.aspx
  C. DAIDS Homepage → http://www.niaid.nih.gov/about/organization/daids/Pages/default.aspx
  D. NIAID Resources for Researchers→ http://www.niaid.nih.gov/LabsAndResources/resources/Pages/default.aspx
  E. (SUBHEAD) Clinical Research Support and Tools: DAIDS Clinical Research Policies and Standard Procedures Documents→ http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx

PROBES:

13. How easy or difficult was it to find this page?

- What might make it easier to find?
- Where did you expect to find it? Why is that?

14. Have you ever visited this page?

- IF YES: Tell me about one of those times. Why did you visit the page, what were you looking for, did you find it?
- IF NO: Who do you think this page is geared towards? Who is most likely to visit this page? Why would they visit this page?

15. What do you think about this page ? What were your first impressions of this page?

- What stands out to you?
- What you would click on? Why? What would you expect to see?
- Is there anything you find confusing or unclear?

16. In your own words, what kind of information do you think you will find by looking at this website?

17. What do you think of the left sided menu?

- What does it tell you? Why do you think it's there?

18. What do you think of the banner and title on top of the page?

19. What about the information on the right side, "Web Site Tools"?

- Would you use or click on any of those options listed there?
  - E-mail this page? Why/why not?
  - Print this page? Why/why not?
  - Follow us? Why/why not?
  - Order publications? Why/why not?
  - Bookmark & Share? Why/why not?

20. What about the information below that, "See Also"?

- Would you use or click on any of those options listed there?
  - Division of Acquired Immunodeficiency Syndrome? Why/why not?
  - Investigator-Initiated Clinical Trial Planning and Implementation Grant? Why/why not?

Task 4. About the Clinical Research Policies and Standard Procedures Documents

Let's say that you want to know more about this site. How would you find that?

[IF PARTICIPANT DOES NOT GO TO "ABOUT THE CLINICAL RESEARCH POLICIES AND STSANDARD PROCEDURES DOCUMENTS" LINK, DIRECT THEM TO IT]

Please click on the first link: About the Clinical Research Policies and Standard Procedures Documents. Take a moment to look at it and I'll ask you a few questions.

Now take a look at the section titled "Scope."

OBJECTIVES:

- Does this audience understand the site has information geared towards clinical and basic researchers?
- Is it clear to the audience what information is available on the site?

PROBES:

21. What kind of information did you expect to find under the heading *"About the Clinical Research Policies and Standard Procedures Documents*" on the homepage?
    - Is the available information what you expected to find?
    - What does that first paragraph tell you? Is it easy to understand? Why/Why not?

22. Who is this page for? Who do you think uses this information?

23. Is this "About Us" information useful to you as a scientist or researcher? Why or why not?
    - IF YES: What is useful about it?
    - IF NO: What would make it more useful?

24. In your own words, what does the section "Scope" say?

25. What do you think the link to the "*Table of Research Applicability*" will show you? Go ahead and click on it.

26. Take a look at it and tell me what is says.
    - Is it what you expected?
    - Who is this for? Who would find this information useful?
    - Is anything missing on this table?

27. If you saw this and wanted to find out more about *Requirements for Data Management and Statistics*, how would you find more about that topic from this page?

Task 5. Finding Information: Enrolling children in clinical research

[STARTING AT THE DAIDS PAGE]
Let's go to the homepage. Let's say that you have received a grant and want to know the requirements for enrolling children in clinical research, specifically information about obtaining the child's assent.

How would you find that information from here?

OBJECTIVES:

- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available?
- Can they find the information using the search function?
- Is the information easy to find?
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Clinical Site at:
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/ClinicalSite.aspx →
  C) **Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements** (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/enrollingchildrenprotocol.pdf

  USING SEARCH FUNCTION:
  If they search for "child assent" the second result is correct "**[PDF]** 1.0 PURPOSE 2.0 SCOPE 3.0 BACKGROUND"

IF THEY USE THE SEARCH FUNCTION

28. I notice you are using the search feature, what words are you typing in? Why?

29. Is this list of items found what you expected?

30. Which one would you select? Why?

31. Go ahead and click on that, is that what you expected to find?
- Why/Why not?

32. Is the information you are looking for there?

ALLOW UP TO 3 ATTEMPTS: Go back to the list that came up from the search, and select another document/link.

33. Go ahead and click on that, is that what you expected to find?

- Why/Why not?

34. Is the information you are looking for there?

IF THEY CAN'T FIND THE INFORMATION:

35. Let's see if we can find that from the homepage without using the search function.

IF USING THE LINKS/NAVIGATING:

36. Can you find that information from this page? Don't click on anything yet, just tell me where you would click.

37. Why do you think the information will be there?

38. Go ahead and click on that. Is this what you expected to find? Why/Why not?

ONCE THEY FIND THE PDF FILE:

39. Is this what you expected to find? Why/Why not?

40. What do you think of the format it is in, as a PDF file?

Now that you have found the information, let me ask you a few things.

41. Was it easy or hard to find this information?

- What might make it easier to find?
- Where did you expect to find it? Why is that?

42. What other ways would you look for this information? Which way(s) do you prefer?

43. Is there any other important information they should add this page? Is there anything missing that should be included?

Task 6. Finding Information: Requirements for Protocol Registration

[STARTING AT THE DAIDS POLICIES AND DOCUMENTS PAGE]
As you may know, it is DAIDS policy that each participating institution must complete protocol registration with the DAIDS Protocol Registration Office. Please locate information on the requirements for registering study protocols.

How would you find that information from this homepage?

[ONCE THEY FIND THAT INFORMATION, ASK]
Now please locate the manual with information about protocol registration.

OBJECTIVES:

- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available?
- Can they find the information using the search function?
- Is the information easy to find?
- Is the section useful to participants?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Regulatory at: →
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Regulatory.aspx
  C) **Protocol Registration Policy** (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/protocolregpolicy.pdf
  D) Protocol Registration Manual (PDF):
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/prmanual.pdf

  USING SEARCH FUNCTION:
  If they search for *"Protocol Registration"* none of the results is correct, the closest is the first one which is the FAQs: DAIDS **Protocol Registration** Frequently Asked Questions

PROBES

IF THEY USE THE SEARCH FUNCTION:

44. I notice you are using the search feature, what words are you typing in? Why?

45. Is this list of items found what you expected?

46. Which one would you select? Why?

47. Go ahead and click on that, is that what you expected to find?
- **Why/Why not?**

48. Is the information you are looking for there?

ALLOW UP TO 3 ATTEMPTS: Go back to the list that came up from the search, and select another document/link.

49. Go ahead and click on that, is that what you expected to find?
- **Why/Why not?**

50. Is the information you are looking for there?

IF THEY CAN'T FIND THE INFORMATION:

51. Let's see if we can find that from the homepage without using the search function.

IF USING THE LINKS ON THE HOMEPAGE:

52. Can you find that information from this page? Don't click on anything yet, just tell me where you would click.

53. Go ahead and click on that. Is this what you expected to find? Why/Why not?

54. Tell me a little about this page.
- What information is available here? How do you know that?
- What do you think of the way the information is presented in this page?
- What about the amount of information available? Is it too much, not enough or the right amount?
- Is it easy to understand what information is provided here? Why/ why not?
- Is it easy to read? Why/ why not?

55. Is there any other important information they should add to this page? Is there anything missing that should be included?

ONCE THEY FIND THE PDF FILE:

Now that you have found the information, let me ask you a few things.

56. Was it easy or hard to find this information?
- What might make it easier to find?
- Where did you expect to find it? Why is that?

57. Is this what you expected to find? Why/Why not?

58. What do you think of the format it is in, as a PDF file?

59. What other ways would you look for this information? Which way(s) do you prefer?

60. Is there any other important information they should add this page? Is there anything missing that should be included?

Task 7. Frequently Asked Questions (FAQs)

Let's say that have a general question about human subject training/good clinical practice training and you think it is a common question that others may often come to this site to find an answer.

Where do you think you would find answers to questions related to human subject training/ good clinical practice training?

OBJECTIVES:

- Where do participants expect to find information, where do they look?
- Do they prefer to find the information using links or the search function?
- Can they find the information using the links available? Do they notice the FAQs at the bottom? Is it easy to find?
- Can they find the information using the search function?
- Is the section useful to participants?
- Do they prefer it in HTML or PDF format?

NOTES [OBSERVE]: Note what path they take to find the information.

- CORRECT PATHS:
  USING LINKS:
  A) DAIDS Policies and Documents Homepage →
  http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) Frequently Asked Questions at: →
  http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/pages/faq.aspx
  USING SEARCH FUNCTION:
  If they search for *"human subject training"* none of the results include the FAQs link above.
  If they search for *"good clinical practice training"* none of the results include the FAQs link above.

IF THEY USE THE SEARCH FUNCTION

61. I notice you are using the search feature, what words are you typing in? Why?

62. Is this list of items found what you expected?

63. Which one would you select? Why?

64. Go ahead and click on that, is that what you expected to find?

- Why/Why not?

65. Is the information you are looking for there?

DIRECT THEM TO USE THE LINKS FROM THE HOMEPAGE

66. Let's see if we can find that from the homepage without using the search function.

67. Can you find that information from this page?

DIRECT THEM TO SCROLL DOWN. If they don't think they will find it in the FAQs,
DIRECT THEM TO CLICK ON FAQS:
Let's see what we find in the Frequently Asked Questions link. Go ahead and click on that.

ONCE PARTICIPANT CLICKS ON FREQUENTLY ASKED QUESTIONS:

68. Do you think the information will be there?

Go ahead and look through this section. [ONCE FIND INFORMATION] Now that you have found the information, let me ask you a few things.

69. Was it easy or hard to find this information?
- What might make it easier to find?
- Where did you expect to find it? Why is that?

70. Is this what you expected to find? Why/Why not?
- What information is available here? How do you know that?
- What do you think of the way the information is presented in this page? Why/ why not?
- What about the amount of information available? Is it too much, not enough or the right amount?
- Is it easy to understand what information is provided here? Why/ why not?
- What do you think of the format it is in, as a PDF file?
- Is it easy to read? Why/ why not?

71. Is there any other important information they should add to this page? Is there anything missing that should be included?

72. What other ways would you look for this information? Which way(s) do you prefer?

COMPARE WITH HMTL FORMATTED FAQs

NOW I WANT YOU TO SEE ANOTHER LIST OF FAQs.
Let's go back to the homepage. Click on "Laboratories." Find the second link of FAQs, and click on that. Take a minute to look at it and then I'll ask you a few questions.

FAQ's (PDF)
http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclpfaqs.pdf

73. Is this what you expected to find? Why/Why not?

74. What do you think of the format it is in, as a PDF file?

75. Now that you've seen both formats, which would you prefer?

76. Would you like to be able to find this kind of information using the search function?

77. The FAQs are in different pages, what do you think about that? Would it be useful to have them all in one section, in their own section or in both? Why is that?

Task 8. Contacting DAIDS or NIAID for help

[STARTING AT THE DAIDS PAGE] Let's say that you have questions about either how to find information you are looking for or you have additional questions about the information you have found. Please show me where you would find information about where to go for additional help.

OBJECTIVES:

- Where do participants expect to find information, where do they look?
- Is it easy to find the information on how to find additional help?

NOTES [OBSERVE]:

- Note what path they take to find the information.
- CORRECT PATH:
  A) DAIDS Policies and Documents Homepage → http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx
  B) About the Clinical Research Policies and Standard Procedures Documents at → http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/pages/about.aspx
  C) More Information: For questions regarding specific policies and standard procedures, contact the DAIDS Policy Group.

PROBES:

78. Was it easy or hard to find this information?

- What might make it easier to find?

79. Was this information where you expected to find it or not?

80. Is this the information you expected to find or not?

81. Would you prefer to see the email address rather than the link?

82. Was it easy or hard to find this information? Why do you say that?

AN ADDITIONAL COMPARISON OF AVAILABLE CONTACT INFORMATION, IF THERE'S TIME.

Please go to the DAIDS home page and click on Contact Information listed under About DAIDS. http://www.niaid.nih.gov/about/findingpeople/Pages/daids.aspx

83. What do you think about this Contact Information?

84. Do you think this listing is more helpful to researchers?

85. Please select any name. What do you think of this information?

86. Would you prefer to see an email pop-up with the address auto-filled, rather than the link?

Task 9. Card Sort for Categories and Labeling of Topics and Links

[SHOW WORD DOCUMENT]
Let's say that each of these phrases is a link and you are asked to group together the links you feel belong together. Go ahead and group the links you feel should be together and then give the group of links a name.

I will open up a word document and you tell me which ones belong together. I'll group them together and then you can tell me what they should be labeled. Once we go through all of them, you will have an opportunity to make any changes you would like to make before I note your final answers.

Open up a word document with a list of the links available on the site. There are 5 major categories:

- Protocol and Informed Consent
- Clinical Site
- Regulatory
- Pharmacy
- Data Management and Statistics

[INSTRUCTIONS:]

- **Please look these words/phrases over. Each word or phrase is one link.**
- [ASK THEM TO LOOK THEM OVER ONE-BY-ONE AND THEN TO SORT THEM INTO PILES] **After reviewing the list, please put these links into piles or sets that show the links that you think go best with each other. You may designate as many piles as you think are necessary.**
- [NOTE THE CATEGORIES THEY CREATE AND ASK THEM TO EXPLAIN THE CATEGORIES.] **Why did you put these cards together in this pile?**
- [ASK THEM TO NAME OR LABEL EACH OF THE PILES.] **What name would you give this set of links? Why? What about this one?** [and so on…]

OBJECTIVES:

- How do participants expect the information to be organized?
- Do their expectations match the current site organization?

[Protocol and Informed Consent]

- Requirements for Protocol Documents for DAIDS Funded and/or Sponsored Clinical Trials (PDF
- Appendix: DAIDS Guidance for Protocol Documents (PDF)
- Appendix: Requirements for Informed Consent Development (PDF)

[Clinical Site]

- Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements (PDF)
- Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements (PDF)

- Requirements for Manual of Operational Procedures (MOP) (PDF)
- Requirements for On-Site Monitoring of DAIDS Funded and/or Sponsored Clinical Trials (PDF)
- Requirements for Clinical Quality Management Plans (PDF)
- Storage and Retention of Clinical Research Records (PDF)
- Frequently Asked Questions for Storage and Retention of CRR (PDF)

[Regulatory]

- Protocol Registration Policy(PDF)
- Protocol Registration Algorithm (PDF)
- Protocol Registration FAQ
- Protocol Registration Manual (PDF)
- Determination of Investigational New Drug Application (PDF)
- Essential Documents Recordkeeping Requirements (PDF)

[Pharmacy]

- Requirements for Pharmacy Facilities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Activities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)
- Requirements for Pharmacy Personnel at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks (PDF)

[Data Management and Statistics]

- Requirements for Data Management and Statistics for DAIDS Funded and/or Sponsored Clinical Trials (PDF)
- Appendix: Data Management Requirements for Data Collection Sites (PDF)
- Appendix: Data Management Requirements for Central Data Management Facilities (PDF)
- Appendix: Statistical Requirements (PDF)

Questions

Thank you for completing all of the tasks. Before we finish up, I would like to ask you to take a few more minutes to answer a few questions.

87. Overall, was it easy or hard to find the information you were asked to find?

- What would make it easier to find?

88. What information is important or useful to you once you get a grant?

- Where do you get that information?
- Are there any other Web sites you visit for that information?
  - Which ones? What information do you find there?

- Have you come to the DAIDS Web site to find information similar to the one I've asked you to find? Why or Why not?
- Now that you know about the kind of information available on the Web site, would you look here or would you look in [REFER TO THEIR ANSWER IN a) ABOVE]?

89. Is there any information or type of information that is missing from the site? Is there any information you would really like to see added?

Thanks and Closing

Thank you for participating in our study today. We have completed all of the tasks and questions. The information you have provided will be very useful in further updating and revising the Web site so that it fits your needs.

I would like to get your mailing address so that we may send you a $50 gift card as a thank you for your participation and time.

[CONTACT INFORMATION:]
Name _____

Institution and Address: _____

City, State, ZIP Code: _____

E-mail:_____Telephone: _____