

## Submitting Contingencies

In some cases, submissions may be approved with contingencies. Study teams are required to submit additional information to satisfy the contingencies prior to full approval. The study team is informed of pending contingencies via a Contingencies Letter email notification, which also includes a link to the study. The **Outstanding Issues** table at the bottom of the Study Workspace lists all contingencies that must be addressed. The Current State of the study is **Contingencies Pending**.

### eResearch Study Workspace

**Current State**  
Contingencies Pending

**Activities**  
 Edit Study 2  
 Printer Friendly Version  
 Application Checklist  
 Error Check  
 Submit Contingencies 3  
 Notify Study Team Members to Accept Roles  
 Withdraw Application  
 Post Correspondence

Section	Identified Issue
05 Research Design	There are only two people listed on this study in Q1-3, the PI and a study coordinator, yet Q5-1.5 references three investigators. "Three investigators will review transcripts independently. The three will then meet to finalize themes." Please make sure to list all study personnel involved in this study in Q1.3 and Q5-1.4. The focus group script also refers to people helping and they also need to be listed as study personnel. If the study sites involve interaction/intervention, then they are engaged. Please change all the focus group location sites as "yes" they are engaged.
05 Research Design	The inclusion criteria in Q5.4 states that only caregivers will be included, yet Q8-2.4 states that "all caregivers and people with developmental disabilities enrolled in the agencies will be eligible to participate...". Please be clear and consistent; these directly contradict one another.
08 Subject Participation	The number 38 should be repeated in 8.1.1 and then in section 8.2 should be listed in the adult category.
10-1 Informed Consent Documents	Paula Burgess-Byrne is listed as the study coordinator on the eResearch application (Q1-3), as a Co-Investigator on the first page of the consent form, and then as study coordinator (again) on page 5 of the consent form. Which is correct? Please reconcile. If she is conducting the focus groups as it states on the consent form, please list her expertise in Q5-1.4 as it asks for her qualifications. It also needs to be clear in the eResearch application who is conducting the focus groups. Furthermore, if there are other investigators involved, they need to be listed in Q1.3 and Q5-1.4 as well.
10-1 Informed Consent Documents	Section 4.3 of the consent form states that the participants' participation will be over "after completion of the interview and medication dispensing knowledge test", yet there is no mention of the survey referred to in eResearch 5-1.5. Is the knowledge "test" the medication administration hassles survey? Is there an interview prior to the focus group? If so, where are these questions/ interview guide? Or is the interview the focus group? Where does the focus group fall in the order? Please be extremely clear in section 4.3 because it sounds as if there will be an interview and a test and I'm not sure where the focus group comes in. After the test? Before the test? The focus group script doesn't mention the test anywhere - only refers to two parts: questions (i.e., focus group) and then the hassles survey. If I were a study participant, I would want to know when the "test" was going to be given as it said on the consent form.

1. Locate the **Outstanding Issues** table at the bottom of the Study Workspace and review all **Identified Issues**.

2. Click **Edit Study** from the Activities menu and make all necessary changes to the study application.

**Note:** If available, you can also click the blue **Section** links in the Outstanding Issues table to navigate directly to those sections of the study application.

3. Click **Submit Contingencies** from the Activities menu.

**Note:** The system validates that all required fields on the study application are complete. Any errors must be addressed before submitting contingencies.

### Submit Contingencies Window

**Submit Contingencies**

**Qualitative Study of Medication Use Process for People with Intellectual Developmental Disabilities** (HUM00059674)

**Outstanding Identified Issues:**

Section	Identified Issue
05 Research Design	There are only two people listed on this study in Q1.3, the PI and a study coordinator, yet Q5-1.5 references three investigators: "Three investigators will review transcripts independently. The three will then meet to finalize themes." Please make sure to list all study personnel involved in this study in Q1.3 and Q5-1.4. The focus group script also refers to people helping and they also need to be listed as study personnel. If the study sites involve interaction/intervention, then they are engaged. Please change all the focus group location sites as "yes" they are engaged.
05. Research Design	The inclusion criteria in Q5.4 states that only caregivers will be included, yet Q8-2.4 states that "all caregivers and people with developmental disabilities enrolled in the agencies will be eligible to participate...". Please be clear and consistent; these directly contradict one another.
08 Subject Participation	The number 38 should be repeated in 8.1.1 and then in section 8.2 should be listed in the adult category.
10-1 Informed Consent Documents	Paula Burgess-Byrne is listed as the study coordinator on the eResearch application (Q1.3), as a Co-Investigator on the first page of the consent form, and then as study coordinator (again) on page 5 of the consent form. Which is correct? Please reconcile. If she is conducting the focus groups as it states on the consent form, please list her expertise in Q5-1.4 as it asks for her qualifications. It also needs to be clear in the eResearch application who is conducting the focus groups. Furthermore, if there are other investigators involved, they need to be listed in Q1.3 and Q5-1.4 as well.
10-1 Informed Consent Documents	Section 4.3 of the consent form states that the participants' participation will be over "after completion of the interview and medication dispensing knowledge test" yet there is no mention of the survey referred to in eResearch 5-1.5. Is the knowledge "test" the medication administration hassles survey? Is there an interview prior to the focus group? If so, where are these questions/ interview guide? Or is the interview the focus group? Where does the focus group fall in the order? Please be extremely clear in section 4.3 because it sounds as if there will be an interview and a test and I'm not sure where the focus group comes in. After the test? Before the test? The focus group script doesn't mention the test anywhere - only refers to two parts: questions (i.e., focus group) and then the hassles survey. If I were a study participant, I would want to know when the "test" was going to be given as it said on the consent form.

**\* Indicate the changes you have made in response to the identified issues.** Any changes to supporting documents will require that you attach the new document in the proper section of the application. Clicking on the section will open the application section that needs to be modified.

**4**

Made all requested changes in both application and supporting documents  
 Made some of the requested changes (comment required)  
 Did not make any changes (comment required)

Clear

**Comments:**

**5**

**6**

OK Cancel

- Click the applicable radio button to **indicate the changes made in response to the identified issues.**
- Enter **Comments** in the field provided, if necessary.
- Click **OK.**

After submitting contingencies, the study application returns to the applicable committee for review and the Current State of the study changes to reflect this (e.g., **Core Committee Staff Contingency Review**).