

## Amendment SmartForm changes – December 2023

The format of the Amendment (AME) SmartForm has been revised with new questions and sections. Additionally, a feature called View Differences will be implemented that allows research teams and IRB reviewers to easily identify what changes have been made to the SmartForm. These changes will remove the need for research teams to list each change being made to the PRO SmartForm and simplify the description of the impact of the changes being introduced with the Amendment.

**These changes to the layout and functionality of the Amendment SmartForm are being implemented on 12/16/23. These changes will be automatically applied to every Amendment that is open and not yet submitted for review. These changes will cause the loss of some information in certain sections of the Amendment SmartForm. Please either submit the Amendment, withdraw the Amendment, or save a pdf copy of the Amendment SmartForm before 12/16/23.**

**If you have questions or need assistance completing the AME SmartForm, please contact the IRB Coordinator for your project.**

### Changes to the AME SmartForm

A new question was added, “1.3 **Who initiated this Amendment:**” to differentiate between Investigator-Initiated and Sponsor-Initiated amendments and a new sub-question was added to indicate when the amendment was received.

Section 2 was reformatted to combine several existing sections and uses a table to identify the changes being made and the processes and documents that the changes affect.

The screenshot displays the Amendment SmartForm interface. On the left is a navigation menu with four items: '1. Amendment Identification', '2. Amendment Details' (highlighted in orange), '3. Supporting Documents', and 'Submission Instructions'. The main content area is titled '2.1 \*Enter each change proposed in this Amendment:' and features a table with three columns: 'What change is being made?', 'What is the rationale for this change?', and 'What will this change impact?'. The table contains two rows of data. The first row shows 'Dear Investigator Letter' with the rationale 'New information about the study drug' and the impact 'Consent Form (includes parental permission forms, assent forms, informational letters, consent addendums, etc)'. The second row shows 'IB update to version 3' with the rationale 'Annual update' and the impact 'Consent Form (includes parental permission forms, assent forms, informational letters, consent addendums, etc), Investigator's Brochure, PRO SmartForm Protocol, Other: testing'. Below the table is question '2.2 \*Which subjects will be notified of these changes?' with six checkboxes: 'Currently enrolled subjects', 'Subjects in follow-up', 'Subjects who have completed all activities', 'Other (examples: subjects in screening or withdrawn subjects)', 'None – subjects have not been enrolled to date', and 'This project (or a portion of this project) does not involve direct contact with subjects'. Below that is question '2.5 \*In your opinion, will the proposed change(s) affect the risk-benefit ratio of the research?' with radio buttons for 'Yes' (selected) and 'No', and a 'Clear' link. A sub-question '2.5.1 Please explain how the risk benefit-ratio may be affected...' is followed by a text input field. At the bottom right are buttons for 'Exit', 'Save', and 'Continue'.

2.1 \* Enter each change proposed in this Amendment:

+ Add

What change is being made?	What is the rationale for this change?
Dear Investigator Letter	New information
IB update to version 3	Annual update

2.2 \* Which subjects will be notified of these changes?

Currently enrolled subjects  
 Subjects in follow-up  
 Subjects who have completed all activities  
 Other (examples: subjects in screening or withdrawn subjects)  
 None – subjects have not been enrolled to date  
 This project (or a portion of this project) does not involve direct contact with subjects  
 Subjects will not be notified

2.5 \* In your opinion, will the proposed change(s) affect the risk/benefit ratio?  
 Yes  No [Clear](#)

\* If Yes:  
 2.5.1 Please explain how the risk/benefit ratio may be affected by their participation:

\* Required

OK OK and Add Another Cancel

Question 2.2 was added to differentiate between notifying subjects and re-consenting subjects. It also provides flexibility for different research project designs and stages. Subsequent questions will display based upon the selections.

**2.2 \* Which subjects will be notified of these changes?**

- Currently enrolled subjects
- Subjects in follow-up
- Subjects who have completed all activities
- Other (examples: subjects in screening or withdrawn subjects)
- None – subjects have not been enrolled to date
- This project (or a portion of this project) does not involve direct contact with subjects
- Subjects will not be notified

Question 2.3 was added to identify if subjects will be re-consented.

2.3 \* Will subjects be re-consented?

Yes  No [Clear](#)

2.4 \* Describe the notification process:

2.3 \* Will subjects be re-consented?

Yes  No [Clear](#)

*If some subjects will only be notified and not re-consented, then include the notification process in the descriptions below.*

\* 2.3.1 Describe which subjects will be re-consented:

\* 2.3.2 When will the subjects be re-consented?

\* 2.3.3 Describe the re-consenting process:

Section 3, The directions in this section have been changed to reflect that documents that were revised or new documents being added no longer need to be identified in this section. New and revised documents should be added in Section 52.1.2 of the PRO SmartForm.

View differences will show changes made to the AME SmartForm and the PRO SmartForm. These changes can be viewed by selecting, “View Differences” in the AME Workspace.

The screenshot displays the IRB workspace interface. At the top, there are navigation tabs: Dashboard, Animal Use, Funding, Human, Biosafety, Agreements, and Researcher Profile. Below these are sub-tabs: All Submissions, Ancillary/Safety Approvals, Department Reviews, and Reliance on an External IRB. The main header shows the project path: Human > AE Testing—E1412: Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma > Testing new amendment functionality. There are 'Follow' and 'Help' icons in the top right.

The left-hand navigation menu is titled 'Pre Submission' and includes the following items: Edit Amendment, Printer-Friendly Version, View Differences (highlighted with a red arrow), View / Edit PRO SmartForm, View PRO Change Log, Printer-Friendly PRO, and another View Differences (highlighted with a red arrow). Below this menu is the 'Activities' section with 'Submit Application' (P1) and 'Withdraw' (P1&S) buttons.

The main workspace area is titled 'AME00028470 Workspace' and 'Testing new amendment functionality'. It contains the following details:

<b>Project ID:</b>	PRO00020951 ( Approved )	<b>Project Short Title:</b>	AE Testing—E1412: Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma
<b>Principal Investigator:</b>	Timothy Fenske	<b>Primary Contact:</b>	Mary Emanuelson
<b>Review Type:</b>		<b>Department / Division:</b>	Medicine / Hematology and Oncology - Medicine
<b>Committee:</b>	MCW Institutional Review Board #2	<b>IRBC2:</b>	
<b>Meeting Date:</b>			


Below the details is the 'Submission Instructions - Please read these entire instructions before proceeding' section. It states: 'Before submitting this Amendment you will need to:'

1. Complete the Amendment SmartForm. Use the "Edit Amendment" link in the left-hand navigation area to enter the Amendment SmartForm and complete all sections.
2. Make necessary changes to the PRO SmartForm. You can go to the PRO SmartForm to make necessary changes or to upload revised or new documents at any time by:
  - Using the "Exit" link at the top of each page of the Amendment SmartForm.
  - Using the "View/Edit PRO SmartForm" link in the left-hand navigation area of the Amendment Workspace to open an editable copy of the PRO SmartForm.
3. Finish the Amendment SmartForm. Once all sections of the Amendment SmartForm are completed, click "Go to Workspace". This will take you to the Amendment Workspace.
4. Submit the Amendment to the IRB. If the Amendment SmartForm has been completed, the necessary changes to the PRO SmartForm have been made, and/or new or revised documents have been uploaded, click "Submit Amendment".

The sections with the pencil icon in the left navigation pane will indicate which sections have been changed.

☰ Compare <<

▼ **Inclusion/Exclusion Criteria**

15. Inclusion/Exclusion Criteria 

▼ **Recruitment Plan**

17. Recruitment Strategies

18. Subject Compensation/Reimbursement

▼ **Biospecimen Information**

25. Biospecimen Collection

▼ **Banking**


26. Connecting with a Bank

▼ **Project Proposal**

28. Purpose

29. Hypothesis and Objectives

▼ **Project Procedures**

30. Procedures and 

## Reading: PRO00020951\_MS\_11

**1. Project Identification**

1.1 \* **Short Title:** ⓘ  
AE Testing---E1412: Randomized Phase II Open Label Study of L (Prednisone) in Patients with Newly Diagnosed Diffuse Large B Ce

1.2 \* **Full Title of Project:** ⓘ  
E1412: Randomized Phase II Open Label Study of Lenalidomide I with Newly Diagnosed Diffuse Large B Cell Lymphoma

1.3 \* **Principal Investigator (PI):** ⓘ  
Timothy Fenske

1.3.1 \* **Does the Principal Investigator, their immediate family with the sponsors of this research or that might affect the res**  
 Yes  No

1.3.2 \* **Does the Principal Investigator need to access Froedtl**

\* **Does the Principal Investigator need to access Childre**

1.3.3 \* **Will the Principal Investigator be involved with any of t**

Screening subjects for entry into a magnetic environment for

Entry into a magnetic environment for MRI

**None of the above**

1.4 \* **Will there be other project team members in addition to the I**  
 Yes  No

Newly added information will be highlighted in green and deleted information will be highlighted in red.

Compare

28. Purpose

29. Hypothesis and Objectives

▼ Project Procedures

30. Procedures and Analysis

31. Procedures and Expenses for Subjects

▼ Risks

32. Risks and Safeguarding Against Risks

▼ Oversight of Subject Safety

33. Oversight of Subject Safety

34. Privacy and Data Confidentiality

35. Benefits

▼ Consent - Adults

38. Informed Consent

39. Informed Consent Process – Part I

- Anemia which may require blood transfusion
- Constipation, diarrhea
- Tiredness
- Bruising, bleeding
- Abnormal unpleasant sensation, body movement**

**OCCASIONAL, SOME MAY BE**

**SERIOUS**  
In 100 people receiving lenalidomide (CC-5013), from 4 to 20 may have:

- Nausea, heartburn, vomiting
- Chills, fever
- Swelling of the body
- Infection, especially when white blood cell count is low
- Weight loss, loss of appetite
- Pain
- Muscle weakness
- Dizziness, fainting
- Headache
- Difficulty sleeping
- Cough, shortness of breath
- Increased sweating
- Itching, rash
- Sores on the skin
- Blood clot which may cause swelling, pain, shortness of breath
- Low blood pressure
- High blood pressure which may cause headaches, dizziness, blurred vision
- Nose bleed
- Change in mood
- Feeling of "pins and needles" in arms and legs
- Numbness, tingling or pain of the arms and legs
- Change in past
- Dehydration
- Fall
- Dry mouth, skin
- Blurred vision
- Cloudiness of the eye, visual disturbances
- Added new risks**

Go to forms menu Print Icons Help

Exit

Compare

28. Purpose

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- Feeling of "pins and needles" in arms and legs
- Numbness, tingling or pain of the arms and legs
- Change in past
- Abnormal unpleasant sensation, body movement**
- Dehydration
- Fall
- Dry mouth, skin
- Blurred vision
- Cloudiness of the eye, visual disturbances

**RARE, AND SERIOUS**  
In 100 people receiving lenalidomide (CC-5013), 3 or fewer may have:

- Abnormal heartbeat
- Heart failure, heart attack which may cause shortness of breath, swelling of ankles, and tiredness
- Liver damage which may cause yellowing of eyes and skin, swelling

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Exit