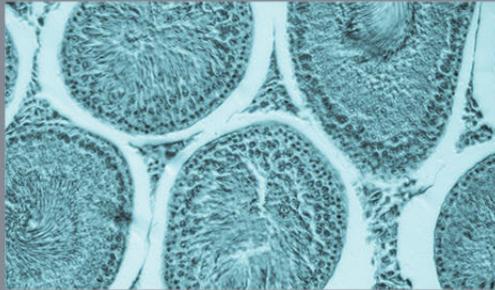


The future starts now.



WCG Smart Forms / December 2015



INTRODUCING WCG SMART FORMS:

The Smarter Way to Work

- ◆ WIRB-Copernicus Group® (WCG™) is excited to announce the December 21 release of six SMART Forms that will streamline your IRB submissions and help to reduce the amount of paperwork you need to complete in order for WCG to review your research.
- ◆ Our new SMART Forms are just that: they are dynamic, responsive PDFs that auto-populate based on the information you enter. Based on your responses, our SMART forms will automatically remove fields that don't apply to your research. Faster and easier to use than our original submission forms, our new SMART Forms will also allow you to save frequently entered information - or data from previously completed forms - to help you accelerate future submissions.

WCG SMART FORMS:

The Smarter Way to Work

Available starting **Monday, December 21st**, six new SMART Forms will replace 20 of our older forms, including:

- Initial Review Form
- Modification/Change in Research Form
- Promptly Reportable Information (PRI) Form
- Continuing Review Site Report
- Continuing Review Sponsor Report
- Closure Report

WCG Smart Forms

Where are they located?

- On **December 21**, the new forms will be available on the WIRB and CGIRB web sites for download. The forms posted on the two websites are the same.
- The forms must be completed using Adobe's free Reader or Acrobat (version 9.1 or newer).
- Important: Use of a program other than Adobe to view the forms or complete the forms will result in missing questions and nonfunctional fields. You can download the free Adobe Reader from Adobe.com (<https://get.adobe.com/reader/>).
- If you don't have access to the free Adobe Reader or Acrobat, WCG will be making available versions of the form that do not require access to Adobe (look for these in early 2016). In the interim, you may continue to submit the old-style Word versions of the forms. Please contact us if you need any of those forms, as they will not be available on the web sites after December 20.

WCG Smart Forms

Submissions to CGIRB and WIRB:

- ◆ Please be sure to select the correct IRB in this section of each form to prevent processing delays caused by selecting the wrong IRB –

Submission Information

*To whom are you submitting this study?

- Copernicus Group IRB (CGIRB)
- Western IRB (WIRB)

- ◆ The questions asked in the Closure form and the PRI form do not vary depending on which IRB you select; however, some questions in the other forms vary based on which IRB you are submitting to.
- ◆ The new forms ask some brand new questions, ask some questions differently, and don't ask some questions at all anymore.

WCG Smart Forms

What do I need to know about the new forms?

- Because the forms adjust dynamically as you answer questions in them, they must be completed electronically – you cannot print them out and complete them on paper.
- Required questions are marked with an asterisk:

Submission Source

*Indicate the type of submission

- Sponsor/CRO submission of a new protocol
- Site being added to existing protocol
- Investigator submitting a new protocol
- Physician submitting for approval of the on-label use of a Humanitarian Use Device (HUD)

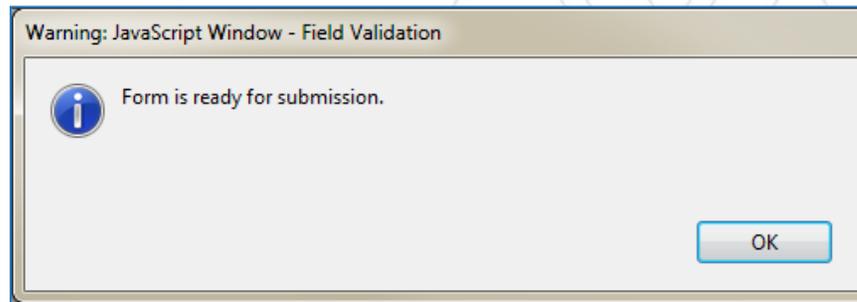
- When you have completed all the required fields, use the button at the end of the form to verify that all the required fields have been completed:

Check fields for submission

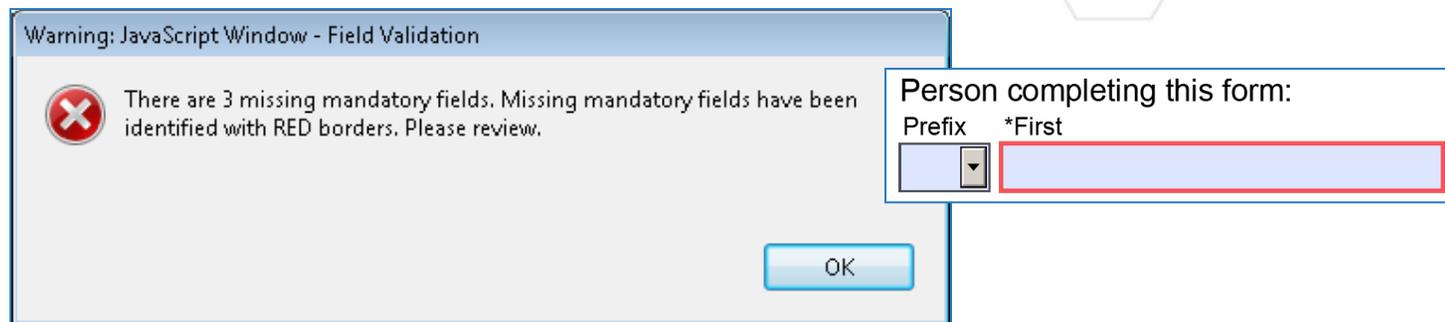
WCG Smart Forms

Filling out the forms:

- When you click the “Check fields for submission” button and all the required fields are completed, a message will pop up, indicating the form is ready to submit:



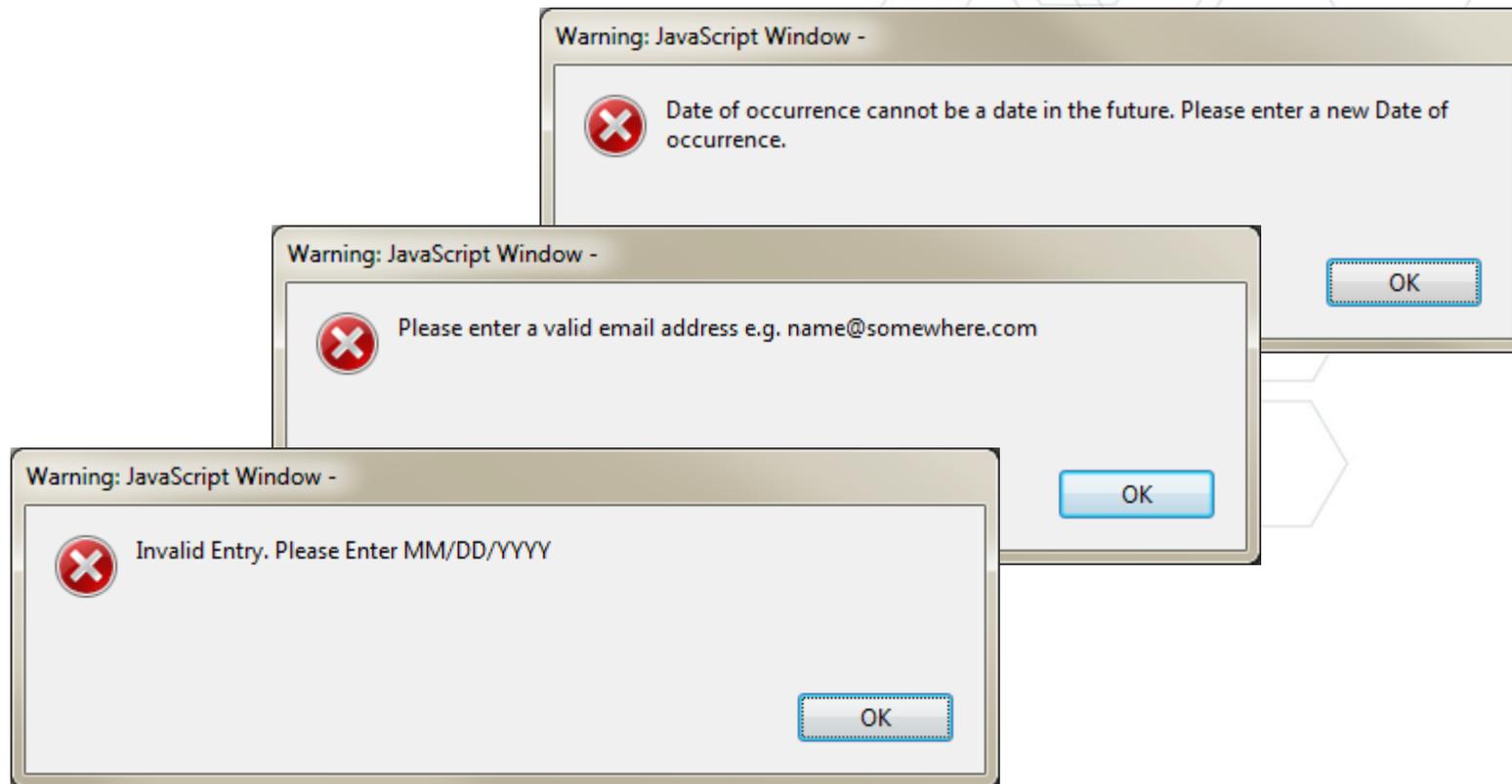
- If any required fields are not completed, a message will pop up telling you how many required fields are not yet complete and those fields will be rimmed in red:



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Filling out the forms:

- Some questions will only accept certain types or formats of data:



WCG Smart Forms

Filling out the forms (cont.)

- When a +/- combination of buttons like the ones pictured below are present, you can add as many more sections as you need, but you cannot remove the last one – there will always be one instance of the section present in the form.

To Add/Remove Additional CROs

Add/Remove Site Section

*Select the languages needed
Bengali

WCG Smart Forms

Initial review form:

- All the forms will let you change your answer to a question as many times as necessary; however, each time you change an answer, the form may reconfigure itself and add or remove questions based on your answer.
- The initial review form will seem quite empty until the user makes an initial selection here:

 **Initial Review Submission Form**

Note: Form must be completed in Adobe version 9.1 or later (Reader or Acrobat). All fields with an asterisk (*) are required.

Submission Source

*Indicate the type of submission

Sponsor/CRO submission of a new protocol

Site being added to existing protocol

Investigator submitting a new protocol

Physician submitting for approval of the on-label use of a Humanitarian Use Device (HUD)

WCG Smart Forms

Documents referenced in the forms:

At the end of the initial review form, there are two sections listing documents that need to be submitted.

- One list is static – it lists the documents required for most initial review submissions:

Required Attachments

Please submit the following additional documentation with your application

- Final signed protocol
- Supporting documents
- All information intended to be seen or heard by subjects in Microsoft Word format, including:
 - Consent documents
 - Information sheets
 - Recruitment scripts
 - Advertisements

- The second list is dynamic – it populates based on the answers you entered. Be sure to review this list carefully when you are preparing your submission:

Attachments Required Based on Your Answers

Based on your answers, please submit the following additional documentation with your application

- A copy of the complete grant or contract if you or your institution is the awardee of the grant.

WCG Smart Forms

Saving the forms:

- ◆ The forms can be partially completed, saved, and returned to later. If you find that you always fill out a section the same way (e.g., site information, contact names and information), you can pre-fill the form, save it, and use it as the starting point for future submissions.
- ◆ As with any form, you should save often.

WCG Smart Forms

Final thoughts:

- We hope you find the new forms easier to use and more efficient than our prior forms!
- Feel free to wrap up any submissions you already have in process using the old forms – we will continue to accept them until April 4, 2016.
- If you have questions about the forms, you may contact anyone at WIRB or CGIRB for assistance or submit your questions to info@wcgclinical.com.
- If you have suggestions for improving the forms, we'd like to hear about those as well!