	Office of Sponsor and Regulatory Oversight	Document #: <b>3B</b>
	<b>Dose Escalation Determination – Frequently Asked Questions</b>	Revision #: <b>1</b>
		Effective Date: <b>15SEP2023</b>

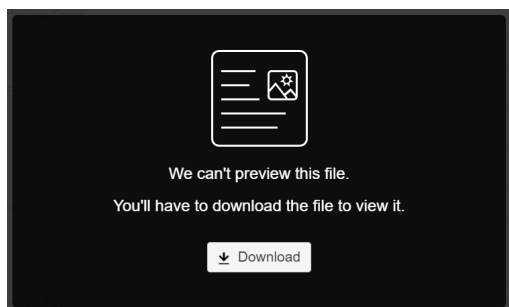
**Questions**

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**Answers**

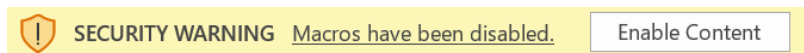
**1. How do I get a working copy of F01-303-S01 Dose Escalation Determination?**

- 1.1. Go to the OSRO Wiki page, [Forms and Instructions - Forms and Instructions - CCR Wiki \(cancer.gov\)](#).
- 1.2. Click on the hyperlink titled Dose Escalation Determination Form.
- 1.3. Click the Download button in the dialog box.




**2. How do I enable the Microsoft Word form fields?**

You must use the desktop version of Microsoft (MS) Word and click Enable Content on the yellow caution bar.



If a Security Warning asks if you want to make the file a Trusted Document, click Yes. The form fields should now be active.

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### 3. Why can't I email the file?

The working file of F01-303-S01 Dose Escalation Determination is a macro-enabled MS Word document, designated with the suffix .docm. Due to cybersecurity concerns, this type of file is treated with increased caution as compared to normal .docx Word files. Updated NIH security policy blocks .docm files from being emailed between users. Emailing the file as an attachment will result in a system undeliverable error.

Users can send the Word document to team members via a Teams Chat (see Question 4).

### 4. How can I collaborate with others on filling out the form?

Emailing a .docm file is not allowed by the NIH IT security. You may share the file via MS Teams. Open a Chat with the intended collaborator(s). Upload the file from your device to the Chat and click Send.

If you receive the file via a Teams Chat, download the file to your computer and open it using the desktop MS Word application. The form will not function as intended in the web-based MS Word version.

### 5. Can the PI sign the form in Microsoft Word?

Signing the form in MS Word is no longer accepted by OSRO because the file cannot be submitted to OSRO Safety by email. The form must be converted from .docm to .pdf. The digital signature is applied to the pdf. Be sure to add all the information and supporting data to the form *before* converting the form to .pdf.

### 6. How should the PI sign the form?

After the form is completed in MS Word and ready for the PI's attestation signature, convert the form to PDF. Send the PDF to the PI.

The PI opens the Certificates tool, selects Digitally Sign, and follows the dialog box prompts.


Detailed steps for signing the PDF may be found in the following NCI IT Knowledge articles.

[Digitally Sign Documents in Adobe Acrobat or Reader \(Windows\) - Tutorials & Service Descriptions \(cancer.gov\)](#)

[Digitally Sign Documents in Adobe Acrobat or Reader \(Mac\) - Tutorials & Service Descriptions \(cancer.gov\)](#)

### 7. Can I submit my supporting information as a separate file to the F01-303-S01 instead of putting it in Appendix A and B?

No. The OSRO Safety reviewers require that only one file be submitted for their review. If preferable to inserting the information in the MS Word document, you may append pages to the PDF prior to the PI signature.

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**8. Where do I email my completed, signed F01-303-S01?**

Email the completed, signed F01-303-S01 Dose Escalation Determination to OSRO Safety at [NCIOSROSafety@mail.nih.gov](mailto:NCIOSROSafety@mail.nih.gov). Remember to add all information to the macro-enabled MS Word document then convert the .docm file to .pdf for signing digitally.

**Change Summary**

Revision Number	Effective Date	Description of Change
1	15SEP2023	New Document