

Section 6: Substance Administration

Slide 2

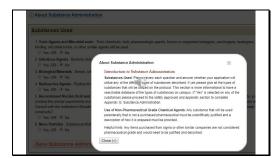


Section 6 of the online application focuses on substances that may be administered as part of the protocol. It contains two sections – classifying the substances used, and a question regarding the use of non-pharmaceutical grade chemical agents.

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At the top of the screen, you will find the link containing additional information regarding the section.



As mentioned earlier, this section contains two portions. For the Substances Used portion, please review the six substance categories listed here. If you will utilize any substances that may fall into these categories, you can select "Yes" and list these agents. The Use of Non-Pharmaceutical Grade Chemical Agents portion focuses on any substance that is not purchased pharmaceutical grade and will be used parenterally. These substances must be scientifically justified, and a description of their preparation must be provided.

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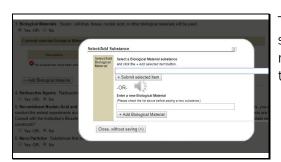


Focusing on the Substances Used portion first, if you answer "Yes" to any of the sections, you see that a selection box appears to add agents to the appropriate sections.



A red X appears for the substances that you have answered "Yes" to. Add the substance to the section by clicking either the link outlined in red, or the corresponding button. Once the substance is added, the red X will disappear.

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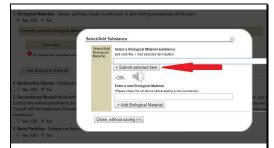


This generates a pop-up for you to select an agent from a drop-down menu, or to add a substance to that list if you do not see it listed.

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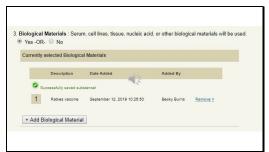


The list of substances for most categories is extensive, so please always review the list prior to adding a new substance.



If you find the correct agent, you can add it to the protocol by clicking the "Submit selected item" button. Alternatively, if you do not find the correct agent you can enter it into the field below and click the corresponding button to add. For example, this substance pop-up is for biological materials. If the material is not found in the drop-down, enter it into the field and click "Add Biological Material".

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As you can see, once a substance is added to the question the red X has turned into a green check. All red Xs must be removed before you can complete this section and move to the next.

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A non-pharmaceutical grade product is a chemical or compound that does not meet requirements of USP/NF/BP and may have higher levels of impurities that can introduce unwanted variables or toxic effects. As a reminder, sterile pharmaceutical grade preparations that are reconstituted, diluted, mixed, or have other non-pharmaceutical grade substances added are also considered non-pharmaceutical grade. All items purchased from Sigma are classified as nonpharmaceutical grade. If nonpharmaceutical grade chemical

agents will be used as part of this protocol, please answer "yes" to the question in the second portion of this section. In the text field provided, please address the first four items listed. The fifth item, Appendix G, can be found in Section 8 of this online application which we will discuss later in this tutorial.

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When this section is completed and a green check is shown under the section on the right side, you can proceed to the next section by clicking the button outlined in red.

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This concludes this portion of the video tutorial. If you have additional questions or suggestions to improve this tutorial, please feel free to call 540-231-0931 or email iacuc@vt.edu. The ACUP staff is happy to assist you as you complete the protocol submission process. Thank you for watching.