

4605.7041 CLINICAL MATERIALS SUBMISSION MODIFICATION.

Subpart 1. **Modification due to circumstances or situations.** The commissioner may modify clinical materials submission requirements under part 4605.7040 if the commissioner determines that one of the following circumstances exists and the modification does not risk the public's health. The circumstances are:

A. laboratory testing methods or capabilities are not sufficient or adequate to determine the presence of the pathogen of concern;

B. surveillance needs have changed; or

C. evolving pathogen knowledge indicates that either the pathogen is no longer a concern or advances in diagnostic testing provide the necessary information to public health.

Subp. 2. **Notification.** The commissioner must issue an order that notifies submitters that the commissioner is altering normal submission requirements under part 4605.7040. The commissioner's order must identify the circumstance in subpart 1 that warrants the suspension, the need for different submission requirements, and the situation-specific directions for clinical submission necessary to correct the situation. The directions must identify the following:

A. the submissions of clinical materials that are suspended entirely, if any; or

B. the reduced number of clinical materials that must be submitted; and

C. other specific changes in required procedures that correspond to the altered requirements.

Subp. 3. **Removal of modification.** The commissioner must issue an order rescinding the modified procedures when the criteria for the circumstances no longer apply.

Statutory Authority: *MS s 144.05; 144.12*

History: *43 SR 415*

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