



IRB GUIDANCE:

**Review Of Injury Language For Sponsored Studies That Are Greater
Than Minimal Risk.**

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INTRODUCTION

This guidance is written for Investigators, the Downstate (DS) Institutional Review Board (IRB), and Sponsored Programs Administration (SPA). This guidance provides information related to the review of injury language provided within an Informed Consent Form (ICF) for a sponsored study that is greater than minimal risk to ensure it is congruent with any corresponding study Agreement (i.e. Clinical Trial Agreement [CTA], or other similar agreement) executed by SPA.

When the DS IRB approves or activates a research study, standard language is included in the DS IRB determination letter indicating the investigation cannot start until all agreements are executed. Federal regulations require injury language be included in the informed consent for studies that are greater than minimal risk. This language must be reviewed by the Director of Contracts to ensure consistency with an Agreement executed by SPA. A study cannot take place unless the agreement is executed and IRB approval is granted. DS IRB activation is also required for studies approved by a Reviewing (External) IRB.

This guidance represents the IRB's and SPA's current thinking on this topic; however, the use of the word "must" in this document means the concept is a Downstate policy or regulatory requirement. The use of the word "should" in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements. For more information, please contact the Downstate IRB Office at irb@downstate.edu

AGREEMENT REVIEW

The agreement review process by SPA should not delay the IRB review process. In general, the Director of Contracts reviews the injury language in the final IRB approved ICF when executing an Agreement; however, if the injury language in the ICF is not congruent with the Agreement, either the Agreement or the ICF requires amending. If SPA requires changes to an IRB approved ICF prior to Agreement execution, an amendment must be submitted to the IRB which has oversight of the research.

The Director of Contracts may recommend changes to the ICF to be congruent with the Agreement and may suggest changes to the language; however, only the IRB with oversight for the study may approve changes to the ICF.

AGREEMENT REVIEW BY SPONSORED PROGRAMS ADMINISTRATION PRIOR TO RECEIVING COPY OF INFORMED CONSENT FROM IRB

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If Sponsored Programs obtains an Agreement prior to receiving a copy of the ICF from the IRB, the Director of Contracts will reach out to the IRB Assistant to request a copy.

The IRB Assistant will check IRBNet to see if the ICF has been submitted and share the latest copy with the Director of Contracts and provide the following:

- Study status
- Level of risk, if assessed at the time of inquiry
- Name of IRB with oversight

The IRB Assistant will include a copy of the correspondence with the Associate IRB Administrator tagged on the submission in IRBNet and attach a copy in the reviewer notes section of IRBNet.

PROCESS FOR REVIEW OF INJURY LANGUAGE FOR NEW IRB SUBMISSIONS

The Associate IRB Administrator tagged on a new submission in IRBNet sends the latest consent form to Director of Contracts, and provide the following:

- Study status
- Level of risk, if assessed at the time of inquiry
- Name of IRB with oversight

The steps in the process for the review of injury language depends on the type of IRB oversight.

DOWNSTATE IRB OVERSIGHT

If the study has **DS IRB oversight**, the following steps will take place:

- 1) As noted above, the Associate IRB Administrator sends a copy of the ICF to the Director of Contracts, as soon as possible, so that feedback can be provided.
- 2) If any changes are required to be consistent with the CTA, Director of Contracts will notify the PI and IRB that changes are needed.
 - a. If the study is not yet reviewed or approved by the IRB, the IRB may include conditions for approval, when applicable.
 - b. If the study has already been reviewed and either approved or approved with conditions by the full board, the PI must submit an amendment to the DS IRB.
Note: The PI can request an amendment for minor changes to a response for conditional approval and the IRB can approve such minor changes or defer it back to full board review.
 - c. A final IRB approved copy of the consent will be shared with Director of Contracts for Agreement execution.

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REVIEWING (EXTERNAL) IRB OVERSIGHT

If the study has oversight by a **Reviewing (External) IRB**, the following steps take place:

- 1) If there is **no pre-preview by the DS IRB Office**:
 - a. As noted above, the Associate IRB Administrator sends a copy of the final external IRB approved consent to the Director of Contracts.
 - b. If any changes are required to the consent to make it consistent with the Agreement the Director of Contracts notifies the PI to submit an amendment to the external IRB and once approved, the DS IRB will acknowledge it. See amendment process below for more details.
- 2) If there is an opportunity for **pre-review by the DS IRB Office**:
 - a. As noted above, the Associate IRB Administrator sends a copy of the non-IRB approved consent as soon as possible, so that feedback can be provided by the Director of Contracts.
 - b. The Director of Contracts notifies the DS IRB and PI if any changes are required to the injury language in the ICF in order to be congruent with the Agreement.
 - c. The IRB will advise the PI of next steps depending on the review process and the IRB Reliance Agreement with the Reviewing IRB.
 - d. A final external IRB approved copy of the consent will be shared with Director, Contracts, when the DS IRB acknowledges the study.

Note: If SPA review of the consent or agreement is delayed it is possible that the consent may be approved by the IRB and acknowledged by the DS IRB, prior to agreement execution. If any changes are required to the consent by SPA to make it consistent with the Agreement, before the Agreement can be executed, the PI must be notified by the Director of Contracts to submit an amendment to the Reviewing (External) IRB for subsequent acknowledgement by the Downstate IRB. See amendment process below for more details.

AMENDMENTS TO IRB APPROVED CONSENT INJURY LANGUAGE

Whenever the injury language within a consent form is amended and approved by the IRB, it must be submitted to Director of Contracts for review.

The process for amending the injury language within an informed consent document depends on the which IRB has oversight of the study.

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DOWNSTATE IRB OVERSIGHT

If the study has **DS IRB oversight**, the following steps take place:

- 1) PI submits amendment to the DS IRB.
- 2) The Associate IRB Administrator tagged on the submission in IRBNet sends the revised consent to the Director of Contracts, for opportunity for pre-review.
- 3) The Director of Contracts sends any necessary feedback to the Associate IRB Administrator who sent the consent to SPA.
NOTE: If the IRB approves the consent prior to receiving any feedback an amendment may be required before the Agreement can be executed.
- 4) The Associate IRB Administrator tagged on the submission in IRBNet sends a copy of approved consent to Director of Contracts.
- 5) SPA will consider the final approved revised consent for execution of the agreement.

REVIEWING (EXTERNAL) IRB OVERSIGHT

If the study has oversight by a **Reviewing (External) IRB**, the following steps take place:

- 1) PI submits amendment to external IRB in accordance with their policies and procedures.
- 2) PI submits the approved amendment to the DS IRB for acknowledgement.
- 3) The Associate IRB Administrator tagged on the submission in IRBNet sends the revised approved consent to Director of Contracts, when it is acknowledged by the DS IRB.
- 4) SPA will consider the final approved revised consent for execution of the agreement.

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Date Reviewed & Approved	Revision Required	Responsible Staff Name and Title	

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	Yes	No		
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