

IRBIS 5.09.04 Update:

Following Question A2 on the NSI form, a text box appears which has now been removed:

Please note that individual IND safety reports from external sites are generally NOT reportable, because their implications for the study cannot be understood. External events should not be reported unless accompanied by an aggregate analysis that establishes their significance and a corrective action plan that address the problem.

This item only appears if you select “NO” to the UNC-Chapel Hill IRB Direct oversight questions and yes to the determination questions. This text box has been removed completed as it is not accurate per the new SOP.

Original:

The screenshot shows a web form titled ">> Does This New Safety Information Need to be Reported?". It contains two questions, A1 and A2, each with radio button options for "Yes" and "No". Question A1 asks if the event occurred at a site with direct oversight. Question A2 asks if a determination has been made by the research sponsor, etc. Below the questions is a text box containing the instruction: "Please note that individual 'IND safety reports' from external sites are generally NOT reportable, because their implications for the study cannot be understood. External events should not be reported unless accompanied by an aggregate analysis that establishes their significance and a corrective action plan that addresses the problem." Below the text box is a red instruction: "Based on your responses, you are required to submit this new safety information to the IRB. Click Submit to proceed." and a "Submit" button.

Revised:

The screenshot shows a web form titled ">> New Safety Information". At the top, it displays study information: IRB Number: 18-0007, Study Status: Approved, PI: Marcus Hannah, IRB: Non-Biomedical, Sponsor: Cancer Research Institute, and Study Title: Marcus red hot fix regression. Below this is a "Reference Id: 8361" and a "Delete New Safety Information" link. The main section is titled ">> Does This New Safety Information Need to be Reported?". It contains the same two questions, A1 and A2, with radio button options for "Yes" and "No". Below the questions is a red instruction: "Based on your response, this event is not required to be reported to this IRB. In lieu of reporting external adverse events from sites for which a UNC-Chapel Hill IRB does not have direct oversight, the investigator should provide a written summary report to the IRB once the information has been reviewed by a data safety monitoring board (DSMB) or other oversight committee." and a "Submit" button.

Changes to D.3, Full or partial waiver of consent

The waiver of informed consent section has been reworded to remove the checkboxes and explain textboxes to only required explanations of each item.

Additionally, a new data element has been added which did not previously exist:

- Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9.) *

Original:

To justify a waiver of the requirement for informed consent, you must affirm, by checking each of the following items that apply to this study. Provide a brief explanation.

The research involves no greater than minimal risk to subjects or to their privacy

Explain

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The waiver will not adversely affect the rights and welfare of subjects (Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)

Explain

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The research would be impracticable to conduct without the waiver

Explain how the requirement to obtain consent would make the research impracticable, e.g., most of the subjects are lost to follow-up or are deceased.

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When appropriate, there are plans to provide subjects with pertinent information after their participation is over. (e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)

Explain (or indicate if not applicable)

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Revised:

To justify a waiver of the requirement for informed consent, you must provide a complete explanation for how each of the following items that apply to this study.

Explain how the research involves no greater than minimal risk to subjects or to their privacy *

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Explain how the waiver will not adversely affect the rights and welfare of subjects (Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.) *

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Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9.) *

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Explain how the requirement to obtain consent would make the research impracticable, e.g., most of the subjects are lost to follow-up or are deceased. *

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