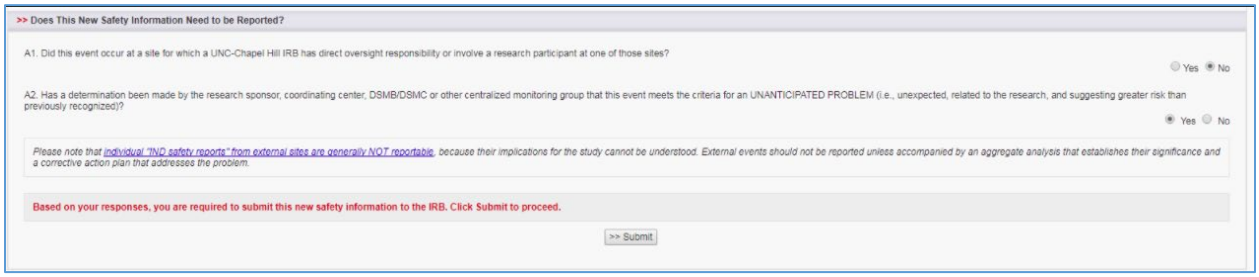
IRBIS 5.09.04 Update:

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

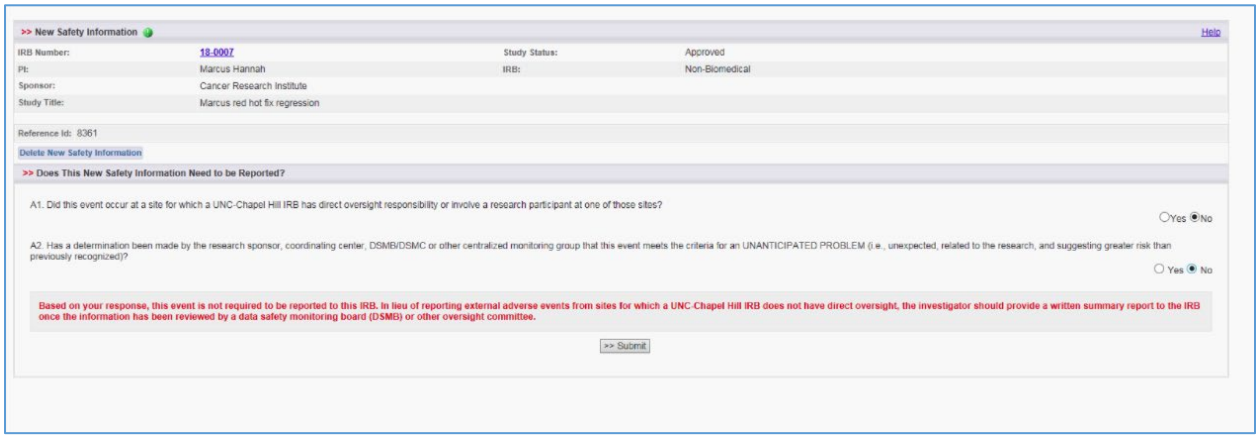
> *Please note that individual IND safety reports from external sites are generally NOT reportable, because their implications for the study cannot be understood. External events should not be reported unless accompanied by an aggregate analysis that establishes their significance and a corrective action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



Revised:



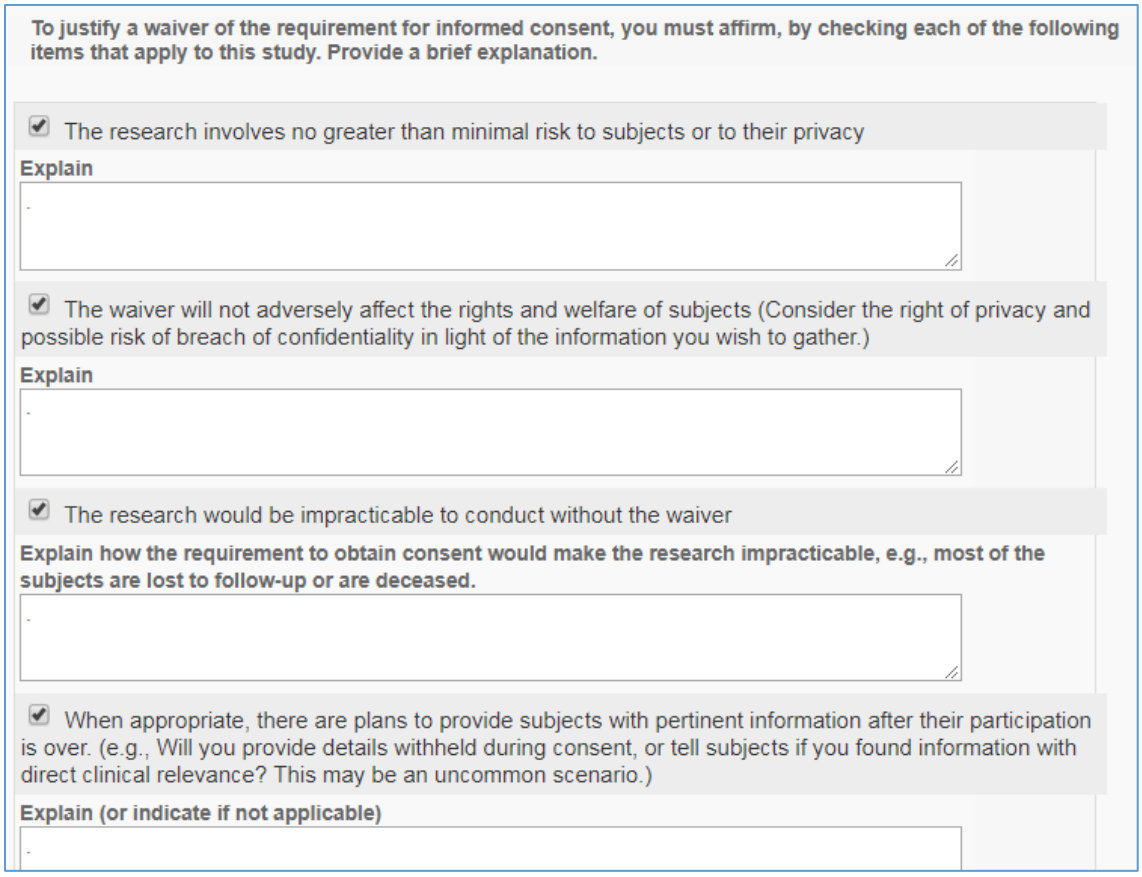
Changes to D.3, Full or partial waiver of consent

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:



Revised: