Human Research Ethics Training Tips

How to Write Stipulations

#1. Write stipulations in a professional, respectful manner.

Original stip: The details and discussion of *X* were poorly written and ambiguous.

Guidance: Remember, the IRB correspondence is directed to the study PI. Write, "Please revise…" instead of, "The researcher should revise…"

Revised stip: Please provide a more robust discussion of *X* with particular attention to the details and of *Y*.

#2. Write stipulations as complete sentences, using proper grammar and correct spelling. Do not use abbreviations that may be unclear to the researcher.

Original stip: Will need non-English consents, if applicable.

Revised stip: Because you plan to enroll non-English speaking subjects, please submit non-English consent forms.
If the researcher used the abbreviations in the application, you may use those in your stipulations; do not use abbreviations that may be unfamiliar to the researcher.

#3. Write stipulations as clear, *directive* sentences. If a stipulation is a *recommendation*, clearly state that.

Original stip: Because of the renal toxicity associated with Cisplatin, a GFR measurement rather than 1.5X ULN creatinine would be more realistic as a measure of renal function.

Revised stip: Because of renal toxicity associated with Cisplatin, the IRB recommends using a GFR measurement rather than creatinine. Please either revise or provide a strong rationale for retaining urine creatinine as a measure of renal function.

#4. Pair each stipulation with the appropriate IRBIS question.

Original stip: A.4.2 (Study design): Please describe who will read the ultrasound and their qualifications for using and evaluating an ultrasound.

Recommendation: Move stip to A.4.7 (Specialized training) Refrain from entering stipulations as *global stipulations* if the stipulation is in reference to a specific IRBIS question.

Acceptable global stipulation: *Please spell out all acronyms the first time they are used.*

This is very important. It takes a lot of extra time on the part of the IRB coordinator to move stipulations to the proper sections of the application. Remember, that in most cases, the researcher not only responds to the stipulation but is also required to revise that section of the application. If you stip in the wrong section, their revisions will also be in the wrong section.

#5. Combine similar or duplicate stipulations

Original stips:
1. Please provide additional comment on minimizing potential risks regarding disclosure of illegal activity.
2. Please mark "disclosure of illegal activity" as drug testing may identify individuals using illegal drugs.

Combined stip:
As drug testing may identify individuals who use illegal drugs, please mark “disclosure of illegal activity” and describe what will be done to minimize this risk.

If someone else has already entered a similar stipulation, either do not add a second stip be clear that your stipulation is meant to add the first stip.

#6. Provide context to support stipulations.

Original stip: Please respond “yes” to this question Revised stip: The master protocol states that you will be collecting HIV status at baseline therefore you should change your response here to “yes”.

Very important! Without context, the research may not understand why you are asking for Ú change. Whenever possible, provide context or reference to protocol or application. (e.g., Daster protocol, page 27, states, "abc..." but here you state "def...", please revise for concordance.)

#7. If the information is complete and accurate, refrain from *stipping* about *how* the information is presented.

Original stip: The response is written in second person (as if consenting a participant). Please revise the response to 3rd person. Although this information appears to be copied from the consent form, if accurate and complete, do not stip.

WHAT information is provided is much more important that **HOW** the information is provided.

#8. Do not offer options that cannot be approved

Original stip: On page 10 of the ICD, subjects are told they can decline the pharmacogenetic blood draw at Visit 1 and still be in the study. The ICD for stored samples does not list a "no blood draw" option. Will the pharmacogenetic blood draw opt-out be a verbal decline? Please clarify/reconcile.

Guidance: Delete underlined sentence as this is not a viable option (i.e., not approvable). Instead, if optional, instruct PI to add “yes/no” option for pharmacogenetic blood draw on the signature page.

Revised stip: If the pharmacogenetic blood draw is optional, please add a “yes/no” option on the signature page of the main consent form.

If you are unsure about whether or not something is permissible under the regulations or UNC policy, consult with your IRB Coordinator, Chair or Charlotte Coley, (chcoley@unc.edu or 919-966-1594)

#9 Anticipate more than one response and write stipulation to cover all possibilities.

Original stip: Will parents be notified of positive pregnancy tests of those <18 years old? If so, this should be specifically stated in the Assent forms and Parental consent forms.

Guidance: NC law does not require that parents be informed of the results of pregnancy testing of minors. However, if pregnancy testing is conducted as part of a research study, we require both parents/guardians and minor subjects be informed about whether or not the results will be shared.

Revised stip: Will parents be notified of positive pregnancy tests of those <18 years old? Please include a statement in both the parental permission and minor assent forms *whether or not* pregnancy test results will be shared with parents.

This is one of the more difficult things to do. In most cases, if you know that changing a 'no' Response to 'yes', opens up additional questions, you should include information about this part of your stipulation. An easy way to become familiar with the IRBIS application is to play" by opening a new application in IRBIS at irbis.unc.edu. ...just don't submit the application. also, Charlotte emailed you a copy of the annotated application a few weeks ago. If you need this again, please email Charlotte at chcoley@unc.edu or 919-966-1594.