April 2015 IRB Member Training
Diane Towle

#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 or 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 a change. Whenever possible, provide context or reference to protocol or application. (e.g., Master 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 pharmacogentic 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, IRB Training Coordinator.

#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 as 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 Charlottee at chcoley@unc.edu.

#10 The IRB application is no longer a “stand alone” document

- Since moving from paper to an electronic application, the application is no longer a “stand alone” document (i.e., all reviewers have access to the protocol, IB, consent forms, etc.)
- As long as the response is complete, do not stip if the researcher references a specific section of the protocol for additional where additional information/details can be found
- Do not stip requesting that the Schedule of Events be included in the application

Primary Reviewer Summary RECOMMENDATIONS

Summary should include:

- PI name
- Funding source
- Primary and secondary objects
- Study population
- Study design
- Brief discussion of overall concerns, inconsistencies
- Summary of consent form recommendations
- Approval recommendation, including regulatory findings and approval period

Summary should **not** include:

- Stipulations

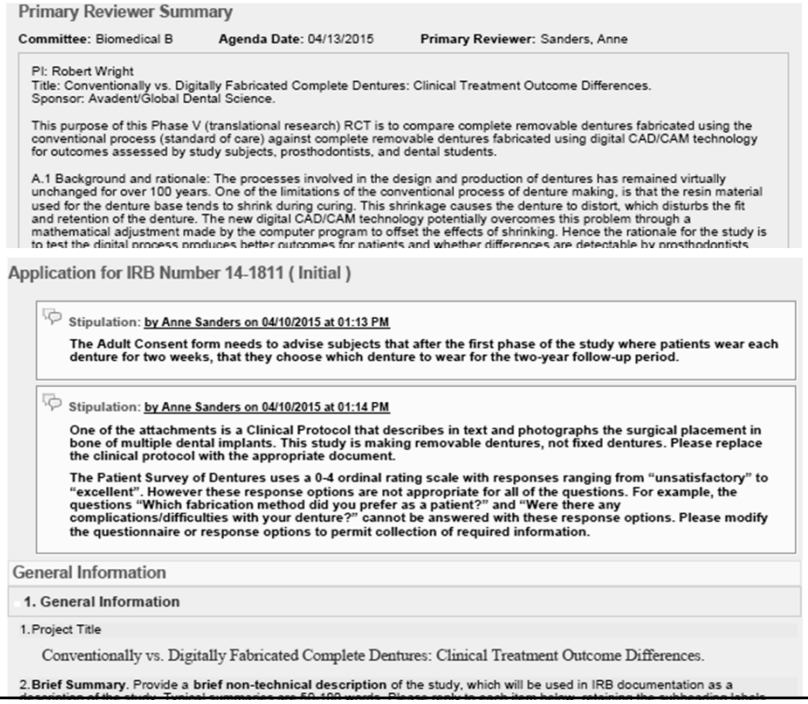
The purpose of the 'Primary Reviewer Summary' is to prepare a clear, concise presentation for the committee. If you typically type your summary using Word, please copy and paste into the Primary Reviewer Summary text box. Also, please note that any "recommendations" for regulatory findings, vote, etc. are just that--recommendations. You do not need to modify your summary after the study is reviewed by the committee.

Beginning May 4, 2015…

- All reviews should be completed by 8 a.m. on the morning of the meeting.
- Primary reviewer summaries are ***required*** for reconsiderations and initial studies.
- Primary reviewer summaries are ***optional*** for renewals and modifications.
- If you've prepared a summary, it should be entered into the Reviewer Summary text box.

Why are we changing the process?

- 8 a.m. deadline allows office staff to download copies of all applications to a jump-drive (serves as back up)
- Primary Reviewer Summary serves as official documentation
- Access to all necessary documents should IRBIS/Internet go down during a meeting
- Reformatted PDF application:
  - Primary Reviewer Summary
  - Full application with stips embedded
  - Reconsideration: Includes all stips and PI responses



Primary Reviewer Summary

Committee: Biomedical B **Agenda Date:** 04/13/2015 **Primary Reviewer:** Sanders, Anne

PI: Robert Wright
Title: Conventionally vs. Digitally Fabricated Complete Dentures: Clinical Treatment Outcome Differences.
Sponsor: Avadent/Global Dental Science.

This purpose of this Phase V (translational research) RCT is to compare complete removable dentures fabricated using the conventional process (standard of care) against complete removable dentures fabricated using digital CAD/CAM technology for outcomes assessed by study subjects, prosthodontists, and dental students.

A.1 Background and rationale: The processes involved in the design and production of dentures has remained virtually unchanged for over 100 years. One of the limitations of the conventional process of denture making, is that the resin material used for the denture base tends to shrink during curing. This shrinkage causes the denture to distort, which disturbs the fit and retention of the denture. The new digital CAD/CAM technology potentially overcomes this problem through a mathematical adjustment made by the computer program to offset the effects of shrinking. Hence the rationale for the study is to test the digital process produces better outcomes for patients and whether differences are detectable by prosthodontists

Application for IRB Number 14-1811 (Initial)

Stipulation: by Anne Sanders on 04/10/2015 at 01:13 PM

The Adult Consent form needs to advise subjects that after the first phase of the study where patients wear each denture for two weeks, that they choose which denture to wear for the two-year follow-up period.

Stipulation: by Anne Sanders on 04/10/2015 at 01:14 PM

One of the attachments is a Clinical Protocol that describes in text and photographs the surgical placement in bone of multiple dental implants. This study is making removable dentures, not fixed dentures. Please replace the clinical protocol with the appropriate document.

The Patient Survey of Dentures uses a 0-4 ordinal rating scale with responses ranging from "unsatisfactory" to "excellent". However these response options are not appropriate for all of the questions. For example, the questions "Which fabrication method did you prefer as a patient?" and "Were there any complications/difficulties with your denture?" cannot be answered with these response options. Please modify the questionnaire or response options to permit collection of required information.

General Information

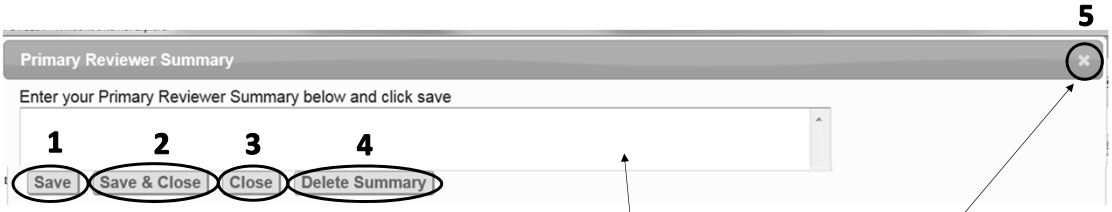
1. General Information

1.Project Title

Conventionally vs. Digitally Fabricated Complete Dentures: Clinical Treatment Outcome Differences.

2.**Brief Summary.** Provide a **brief non-technical description** of the study, which will be used in IRB documentation as a

To “Save and Close” or “Exit”?



1. Click on “Save” every few minutes to ensure that your work is saved.
2. Click on “Save & Close” once you have completed entering your summary to save your work and close the Reviewer Summary text box.
3. “Close”=“Cancel” (This is being changed.) Click on Close/Cancel to cancel your most recent entry.
4. Click on “Delete Summary” to delete the entire summary. Delete (or revise) your own summary only.
5. Click on **x** to close the Review Summary window.

Any questions or comments about this presentation should be directed to Diane Towle at towle@unc.edu.