

GW OHR Guidance: Writing Stipulations

This guidance document outlines general best practices and strategies for writing clear and concise stipulations. This document should be used by IRB members and designees who would like more information about writing stipulations. For information about recording stipulations in the iRIS system, please see the iRIS help tool “Reference Guide: Reviewing an IRB Application” in the iRIS help menu.

Why is the formatting and writing of stipulations important?

Stipulations are a critical part of the IRB review process and the way we communicate concerns and requested changes to the research team. Stipulations are the formal communication to the study team, while comments and notes can inform stipulations.

After an IRB designee or member saves stipulations, the IRB analysts send the stipulations to the research team. The stipulation process is most efficient when the IRB designee writes stipulations clearly; ready to be sent to the investigator and including specific instructions for the investigator to assuage reviewer concerns and achieve compliance. This helps avoid analysts needing to re-write stipulations which can increase confusion and delay reviews.

Who is responsible for writing stipulations?

Minimal Risk Studies reviewed by expedited procedures

- The IRB member or designee reviewing the study is responsible for writing stipulations for minimal risk expedited studies

High Risk Studies reviewed by Full Board

- The full committee votes on stipulations during the meeting
- The IRB Administrator writes stipulations that were stated at the IRB meeting

Best practices:

1. **Write your stipulation directly to the investigator.** Rather than directing your stipulation to the analyst, write as if you are communicating directly with the investigator.
2. **Put as much detail in the stipulation as possible.** If the comment is regarding a specific section, write the section and page number before your comment.
3. Remember to **mark each stipulation as “minor” or “major”** at the end of the reviewer page. This helps direct the investigators response to stipulations.
 - a. “Minor” stipulations are simple directives that the investigator can follow and will be finalized by the IRB Analyst or Administrator
 - b. “Major” stipulations are questions that need answers, clarifications, requests for additional materials, or other requests that will elicit information necessary for the review itself. Major stipulations must be reviewed by the designee once met by the investigator.
4. If you have a question for the analyst during your review please feel free to **call or send an email to the analyst to resolve questions quickly.**
5. **Write politely-** please and thank you goes a long way!
6. If you **have changes to specific language in a section, please suggest new language** and clearly write out the correction.
7. When possible, **give a clear explanation of why you are requesting the change.** Making the stipulation educational is beneficial to the investigators long-term and provides helpful context regarding the rationale for the request. Ideally, reference the criteria of approval 45 CFR 46.11 & 21 CFR 56.11

Examples of Stipulations

EXAMPLE 1: This example highlights the following best practices: (i) detailed description of where to make the requested correction, (ii) use of polite language, (iii) changes requested are specific, and (iv) an explanation is provided for why the stipulation is being requested.

- **Do Not Stipulate:** *Don't like how they wrote the information about pregnancy risks*
- **Stipulate:** *Consent form page 3, section “Risks,” Please rephrase the following sentence: “The experiment won't hurt a pregnancy or fetus” “The **procedures in this experiment research may** hurt a pregnancy or fetus **in unknown ways**” since the study drug has not been tested on pregnant women and risks are unknown.*

TIP: *The above example is a minor stipulation.*

EXAMPLE 2: This example highlights the following best practices: (i) a specific section is listed, (ii) instructional stipulation is directed to research team, and (iii) clear direction is provided and full sentences are used.

- **Do Not Stipulate:** *They say survey will take 30 minutes in one place but 60 minutes in another - clarify*
- **Stipulate:** *In the IRB Application section 9.1 you state that the survey will take 30 minutes, but in the Informed Consent Form page 2, section “how long will I be in the study?” you state the survey will take 60 minutes. Please rectify and make sure the duration is consistent between study documents.*

TIP: The above example is a minor stipulation provided the designee is not concerned if the survey takes 30 or 60 minutes; either is fine but consistency is necessary. It could be made a major stipulation if the designee believes the length of the survey affects human subject welfare. In that case, the language of the stipulation would be changed from “rectify” the inconsistency to “clarify” the length of the survey. That information would then be considered by the designee once provided by the investigator.

EXAMPLE 3: This example highlights the following best practices: (i) clear direction and (ii) instructional stipulation is directed to research team.

- **Do Not Stipulate:** *Didn’t submit the IB*
- **Stipulate:** *Please submit the most recent IB for the study drug.*

TIP: The above example is a major stipulation as it is requesting a document necessary for review.

These small corrections increase compliance with federal regulations, save our analysts precious time during the review process, and help reduce questions returned to you. We thank you for your service as an IRB designee!

Questions?

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