

WRITING FOR AN IRB REVIEW

TEACHERS COLLEGE INSTITUTIONAL REVIEW BOARD
STEPHANIE SHEEHAN-BRAINE, RESEARCH ETHICS & WRITING INTERN



PROTOCOL OVERVIEW

Research with human subjects is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46). A project requires Institutional Review Board (IRB) review if it includes both research and human subjects.

An **IRB protocol** is a group of documents that conveys all the necessary information about your research with human subjects to IRB reviewers (e.g., consent form, IRB application). Your protocol will be reviewed by IRB administrators to ensure that your study follows principles of sound scientific design, and that your study is conducted in accordance with federal regulations, state law, and institutional policies.

Often, researchers mistakenly use the same **writing style** in materials for both the IRB reviewer and study participant. Remember, **there is a difference between academic writing and writing for a general audience**. Below are some considerations to take into account when writing protocols and participant materials.

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WRITING FOR YOUR AUDIENCE

When constructing documents for your protocol- ask yourself- **Who is my audience?**

While members of the **IRB committee** have the professional experience to provide scientific and ethical review, they are of various backgrounds. Discipline-specific language or jargon should be defined to clearly communicate the goals, objectives, and procedures of your study.

Further, discipline-specific language or jargon may not be appropriate for use with your **participants**. Documents provided to participants should be written using language they can understand and feel comfortable with- which means you, as a researcher, should know your population of interest's preferences. Take your participants' current level of education into account. When working with individuals of culturally and linguistically diverse backgrounds, it is important to strive for cultural competence and sensitivity.

Here is a resource from the CITI Programs Good Clinical Practice (GCP) course that provides examples of [Protocol vs Participant Language](#).

Here are some **guiding questions** from [plainlanguage.gov](#) that may help you in writing for your audience:

- 1 Who is my audience?
- 2 What does my audience already know?
- 3 What does my audience need to know?
- 4 What questions will my audience have?
- 5 What's the best outcome for my research?
What do I need to say to get this outcome?
- 6 What's the best outcome for my audience?
What do I need to say to get this outcome?

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CULTURAL COMPETENCE & SENSITIVITY

When working with individuals of culturally and linguistically diverse backgrounds, it is important to strive for **cultural competence and sensitivity**.

Cultural competence describes a concerted effort to incorporate special knowledge about individuals and groups of people into standards, policies, procedures, and practices. In research, cultural competence plays a key role when developing research ideas, conducting research, and exploring the applicability of findings. **Cultural competence is critical for researchers to ensure: (1) effective communication and interaction between researchers and participants, (2) adequate analysis and interpretation of results, and (3) appropriate engagement in study design and implementation.**

While cultural competence is a learned experience that takes time, effort, and commitment, researchers can consider the following **goals**:

- ✦ Strive to learn and understand the moods, values, and motivations of others.
- ✦ Incorporate cultural knowledge into daily practices.
- ✦ Establish values, procedures, systems, and principles that recognize diversity.
- ✦ Include accessibility in research practices, and provide accessibility options for individuals.
- ✦ Demonstrate behaviors, attitudes, policies, and structures to value diversity, and enable others to work effectively in cross-cultural contexts.
- ✦ Conduct regular self-assessments in order to ensure sensitivity to cultural and linguistic characteristics.
- ✦ Recognize limitations, and acknowledge misunderstandings if they arise.
- ✦ Aim to improve upon missteps, miscommunications, or digressions.
- ✦ Adapt to diversity and the cultural contexts of communities.

To learn more about initiatives concerning community, diversity, civility, equity, and anti-discrimination, visit TC's [Office for Diversity and Community Affairs](#).

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WRITING FOR IRB SUBMISSIONS

A **well written protocol** should address all scientific and research ethics issues. When writing your IRB protocol, you should answer all questions on the TC IRB Application Template and use the [TC Reviewer Questions](#) as a guide for what IRB reviewers will look for in your protocol. Overall, the following points should be included and clearly stated in your protocol:



WRITING FOR PARTICIPANT MATERIALS

Writing for participants is different from writing for an IRB protocol. When **writing for participants**, it is important to consider the following points:



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READABILITY OF PARTICIPANT MATERIALS

Most importantly, it is critical that your documents are **“readable”** for your target population. There are two common tests that score readability and determine how difficult it is to understand your writing that can be done in Microsoft Word. These are the **Flesch Reading Ease test** and the **Flesch-Kincaid Grade Level score**.

To conduct readability tests in Microsoft Word, follow these steps:

- 1** After typing your document into Word, click the following: File menu > Options > Proofing tab.
- 2** Under the “When correcting spelling and grammar in Word” heading, check the box labeled “Show readability statistics.”
- 3** Then, exit the options menu and return to your document text.
- 4** Next, run a standard spelling and grammar check and review your readability scores. The first score is the Flesch Reading Ease test, and the second is the Flesch-Kincaid Grade Level score.

If your document scores at least 60 on the Flesch Reading Ease test, it should be relatively easy to read, although you can aim for higher scores to improve readability. The higher your score, the higher the readability of your document. The second score, the Flesch-Kincaid Grade Level score, is equivalent to the reading level of grade students. An 8, for example, would mean that the material is appropriate for an 8th-grade reader. A score of 8 is typical for adults competent to consent.

One commonly used guideline is to **write adult participant documents at a 6th-8th grade reading level to ensure comprehension**. If working with children, it is beneficial to write assent forms at or one grade level below their current reading level.

If working with populations who are multilingual, you should translate all participant materials to their preferred language. Below are some examples of translated participant forms:

- [English to Spanish Translated Site Permission Form](#)
- [English to Chinese Translated Parental Permission Form](#)
- [English to Portuguese Translated Parental Permission Form](#)

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KEEPING IT CLEAR & CONCISE

Overall, no matter your audience, it is important to keep your writing **clear and concise**. **Proofread** your documents more than once to ensure clear language use, concise communication, and proper grammar and spelling.

To learn more about the writing process, you can visit [TC's Graduate Writing Center](#).

THE 5 TYPES OF IRB WRITERS

Typically, there are **five types of writers** TC IRB administrators encounter when reviewing IRB documents: **the struggling writer, the erudite writer, the “more is better” writer, the superhero writer, and the academic writer**. Below, you will find the description of each, and resources that can help.



I. **The Struggling Writer**

These writers struggle with grammar, spelling, and punctuation. The documents submitted from struggling writers are often difficult to read, and require a large amount of revision. Keep in mind: If the IRB reviewer cannot understand what is being asked of participants, the IRB cannot assess the risk of the study or work to mitigate it.

Resource: [5 Tips for Effective Proofreading](#)

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II. The Erudite Writer

These writers typically do well, but write far above the general population's understanding. For example, the content form should clearly convey the study purpose and what is expected from a participant in the study. . Keep in mind: For this kind of writer, it is recommended to focus on information-sharing, avoid jargon, and keep the writing simple.

Resource: Visit [Writing for an IRB Review](#) to review writing for your audience & writing with cultural competence

III. The “More is Better” Writer

These writers include far too much information on their documents. These writers typically submit multiple page documents, explaining every single study activity in minute detail. Too much detail can be overwhelming to an individual interested in your a and they may tune out, become distressed, or experience cognitive overload. Keep in mind: If a participant cannot understand what is asked of them, how can they fully consent to be in the study?

Resource: [7 Tips for Clear and Concise Writing](#)

IV. The Super Hero Writer

These writers tend to think that their study can “save the world.” This is problematic, as these writers often overstate study benefits and downplay the risks. These writers need to remember that their research is for testing, inquiry, or exploration, and that they do not know how their study will end. Keep in mind: A general rule of thumb is to inform potential participants about the study risks in a clear and concise way, and not to cheer or promote participation. Every potential participant has the right to say “no”, even after they have received information or expressed interest.

Resource: [Conducting Risk-Benefit Assessments](#)

V. The Academic Writer

These writers often do well when writing for class assignments, journal writing in their field, and overall are content-knowledge specialists. However, this type of writer

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struggles with taking their elevated knowledge and explaining it to a general audience. Keep in mind: When writing, consider using examples that make the study relatable to the general audience. Ask yourself, can my neighbor, grandma, niece, or colleague understand my study activities? If the answer is yes, then your content is written at the appropriate level for your audience.

Resource: [Write for your audience.](#)

SAMPLES

In addition to writing style, new researchers may struggle with knowing how to frame their research study within a TC IRB application. To assist researchers in the writing process, the TC IRB has created sample applications and consent documents with relevant explanations.

- [Existing Data Sample Protocol](#)
- [Multi-Activity Study Sample Protocol](#)
- [Online Survey Consent Sample Form](#)
- [Audio Recorded Individual Interview and Focus Group Sample Form](#)



Final Takeaways

While writing is tough, there are so many resources available at TC to help you! Reach out to the [Graduate Writing Center](#) or the [IRB department](#) with any questions. Sign up for [TC IRB Office Hours](#) if you need individualized guidance or assistance!