Improvement of Phase I Clinical Trial Informed Consent Document Readability

A Capstone Paper Submitted to the Krieger School of Arts and Sciences Advanced Academic Programs in Partial Fulfillment of the Degree of Master of Science in Research Administration

by

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Abstract

When seeking the consent of a patient to participate in a clinical trial, the Informed Consent Document (ICD) is a substantial part of the informed consent process to review and discuss significant aspects of research with the prospective study participant. This document and process must ensure that the prospective participant is fully aware of the objectives of the research, its risks and benefits, requirements for study eligibility and activities, and other study-specific information. The informed consent process is used to convey clinical trial information to the prospective participant and to document that the participant has formally agreed to participate in the clinical trial. A component of a study participant’s comprehension of the ICD is the document’s readability.

For this capstone project, the author examined the readability levels of both study-specific ICDs and the ICD template utilized in a Phase I Clinical Research Unit (CRU) (“Institution”) in 2017. It was found that the average readability levels exceeded the 8th grade threshold, a threshold generally accepted by most Institutional Review Boards (IRBs) for the Protection of Human Subjects. In order to better understand the Institution’s participant population, the author conducted a survey to obtain data regarding the participants’ educational background. Data gathered from this survey were used to support the project’s objectives. The project objectives were to (1) provide recommendations to improve the readability of the Institution’s ICD template for the purpose of increasing participant comprehension of consent documents, (2) to reduce the readability level of the Institution’s ICD template to an 8th grade level or lower, (3) to review and lower the readability level of both the
ICD document as a whole, as well as the specific sections of the ICD which comprise the document, and (4) to determine the appropriate readability level for the Institution’s volunteer population.

By adhering to recommendations provided by both Federal and private bodies to improve document readability, it was found that achieving a readability level of 8th grade or lower was feasible. Additionally, it was found that such a level is suitable for the Institution’s participant population, as evidenced by the education and background information gathered in the participant survey. Recommendations provided by the author to improve the Institution’s ICD template to a readability level less than 8th grade have been derived. Furthermore, the author recommends additional research to better understand and possibly improve participant overall comprehension of Institutional ICDs.
Table of Content

Abstract ............................................................................................................................... ii

Figures ................................................................................................................................. vi

Tables .................................................................................................................................. vi

Glossary .............................................................................................................................. vii

Chapter 1: Introduction ........................................................................................................ 1
  1.1 Background ...................................................................................................................1
  1.2 Statement of the Problem ............................................................................................2
  1.3 Research Questions ......................................................................................................3
  1.4 Research Objectives ......................................................................................................4
  1.5 Significance ...................................................................................................................4
  1.6 Exclusions and Limitations ............................................................................................5

Chapter 2: Literature Review ................................................................................................ 7
  2.1 National and Global ICD Readability and Comprehension Issues .............................7
    2.1.1 National Concerns ..............................................................................................7
    2.1.2 Global Concerns ...............................................................................................10
  2.2 Recommendations for Improvement of Readability .................................................. 11
    2.2.1 Recommendation Resources ............................................................................12
    2.2.2 Compiled Recommendations .............................................................................14

Chapter 3: Project Description ............................................................................................. 16

Chapter 4: Need Assessment ............................................................................................... 17
  4.1 Overview of Need Assessment ................................................................................... 17
  4.2 Need Analysis .............................................................................................................. 17
  4.3 Review and Confirmation of Need .............................................................................. 18

Chapter 5: Methodology ...................................................................................................... 20
  5.1 Methodology Design ................................................................................................... 20
    5.1.1 Technical ICD Readability Improvements .......................................................20
    5.1.2 Participant Survey .............................................................................................22
  5.2 Study Participants ....................................................................................................... 22
  5.3 Survey Design .............................................................................................................. 23
  5.4 Institutional Review Board .......................................................................................... 23

Chapter 6: Project Results and Discussion ............................................................................ 24
  6.1 Survey Results and Discussion .................................................................................... 24
  6.2 Informed Consent Document Readability Improvements and Discussion .................. 33

Chapter 7: Recommendations and Conclusions .................................................................... 42
  7.1 Introduction ................................................................................................................ 42
Figures

Figure 1. Participants’ Highest Level of Education ................................................................. 24
Figure 2. Participants’ Primary Language ................................................................................. 26
Figure 3. Participants’ Medical Background .............................................................................. 28
Figure 4. Participants’ Familiarity with ICDs ........................................................................... 30
Figure 5. Participants’ Suggested ICD Changes by Category .................................................. 31
Figure 6. Example of Proposed Formatting Revision ............................................................. 36

Tables

Table 1. Identified Recommendations to Improve ICD Readability Level ............................... 15
Table 2. 2017 Average ICD Readability Grade Level ............................................................... 19
Table 3. ICD Sections with Readability Levels >8th Grade ..................................................... 21
Table 4. Examples of Proposed Terminology and Vocabulary Revisions ................................. 34
Table 5. Examples of Proposed Revisions with Readability Grade Level Comparison ............ 37
Table 6. Comparison of ICD Template Readability Grade Level with Proposed Revisions ...... 39
Glossary

**Clinical Research Unit (CRU).** Facility which conducts clinical trial activities, from clinical trial subject recruitment, through investigational product administration, follow-up activities, and data reporting. In this paper CRU is used interchangeably with *Institution*.

**Healthy Volunteer.** A person who volunteers to participate in a research study with no known clinically significant health issues. ¹

**Informed Consent Document (ICD).** The document used in the informed consent process to review and discuss clinical research study objectives, procedures, benefits and risks with prospective participants. The ICD serves to document authorization from the study participant or their legal representative to voluntarily agree to participate in the study.²

**Readability.** Used in this paper to discuss the ease to which a reader is able to understand written text. Readability in this paper has been derived using the Flesch-Kincaid Grade Level tool through Microsoft Word. This tool is used to calculate a reading level corresponding to a United States school-grade in which a student would be at an appropriate level to understand the text.³

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Chapter 1

Introduction

1.1 Background

Informed Consent Documents (ICD) are elements of “a process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial.”\(^4\) This process is used to convey clinical trial information to prospective participants and document authorization for their participation in research. A component of a study participant’s comprehension of the ICD is the document’s readability. It is generally accepted that a 6\(^{th}\)-8\(^{th}\) grade readability level is appropriate for most clinical trial ICDs, and is required by most Institutional Review Boards (IRB) for the Protection of Human Subjects.\(^5\) Achieving a readability level in this range is a challenge due to reasons such as the complexity of the clinical trial, and required language for legal purposes. Readability levels of ICDs can vary, but levels must be suitable for the language and educational level of the prospective participant.\(^6\) IRBs require this in order to protect the welfare of the participant and meet federal mandates in the Code of Federal Regulations (CFR) 45 Part 46.116, requiring that ICDs be understandable to the


prospective participant or their representative.\textsuperscript{7} This capstone project aimed to provide recommendations for improving the readability of the ICD template used in a Phase I Clinical Research Unit (CRU) (hereby “Institution”). By improving ICD readability, it is believed that the Institution will be better able to remain compliant with federal and IRB requirements and better serve its participant population.

In addition, this project sought to gather information regarding the educational background of healthy volunteer participants who participated in a clinical trial at the Institution, as well as general feedback of the Institution’s ICDs. Prior to this project, this information had not been solicited by the Institution. This information was believed to be beneficial for the Institution to better understand the participant population it serves, and help to identify any potential unmet needs.

1.2 Statement of the Problem

In 2017, the Institution conducted 21 Phase I clinical trials. Of these trials, 11 used ICDs with an average readability level greater than 8\textsuperscript{th} grade. While the average readability level of the ICD as a whole is used to determine suitability for participant use, many of these documents contained specific sections with readability levels far greater than the 8\textsuperscript{th} grade threshold. When assessing individual sections of these documents it was found that certain sections had content with a readability level more appropriate for high school and even college-level students. The sections with higher readability levels included those which discussed: specific information about the investigational product, objectives of the study, study eligibility

requirements, study procedures and restrictions, laboratory sample collection and testing (including genetic testing), possible side effects of the investigational product and study procedures, contraception requirements, and study compensation. The primary ICD template used to create the majority of these study-specific ICDs (18 out of 21) was itself found to have a readability level of 9th grade. As templates serve as the foundation for the final study-specific ICDs, it is suggested that templates be written at an appropriate readability level, which in turn have the potential to promote study-specific ICD compliance with federal and IRB requirements.\(^8\,^9\) Additionally, the socioeconomic and educational profiles of the participants, who are the recipients of the Institution’s ICDs, are unknown. It is difficult to develop ICDs with a readability level that is appropriate for the intended audience without an understanding of the participants’ educational levels.

1.3 Research Questions

This capstone project was developed to answer the following research questions:

1. Is it possible to create an ICD template with a readability grade level suitable for federal and IRB requirements while still appropriately conveying content related to study-specific and legal requirements?

2. What is the educational background of the Institution’s healthy volunteer population?

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3. How familiar is the Institution’s healthy volunteer population with ICDs?

4. Does the Institution’s healthy volunteer population need assistance in comprehending ICDs?

5. Does the Institution’s healthy volunteer population have suggestions on how to improve ICDs?

1.4 Research Objectives

The first objective of this capstone project was to provide recommendations to improve the readability of the Institution’s ICD template for the purpose of increasing participant comprehension of consent documents. The second objective was to reduce the readability level of the Institution’s ICD template to an 8th grade level or lower. The third objective was to review and lower the readability level of both the ICD document as a whole, as well as the specific sections of the ICD which comprise the document. Lastly, the fourth objective was to gather new data regarding the participants’ education, primary language spoken, exposure to medical terminology, exposure to ICDs, and ICD feedback in order to determine the appropriate readability level for the Institution’s volunteer population.

1.5 Significance

ICDs are a substantial part of the informed consent process to review and discuss significant aspects of research with prospective study participants. This document and process must ensure that the prospective participant is fully aware of the objectives of the research, its risks and benefits, requirements for study eligibility and activities, and other study-specific
information. The ICD serves as documentation for the participant’s willingness to participate in the research voluntarily. As required by 45 CFR Part 46.116, this document must only be signed once the prospective participant or the legally authorized representative has been given as much time as needed to consider their voluntary participation, has reviewed the informed consent in a manner that is not coercive, and documents that the ICD is understandable to the prospective participant or their representative. Part of ensuring participant comprehension of the ICD is developing a document that is understandable, promotes ease of reading, and does not contain jargon or technical terms. Developing an ICD that has a readability level no higher than an 8th grade level not only meets most IRB requirements, but increases the likelihood that the document will be more understandable to prospective participants.

1.6 Exclusions and Limitations

This project did not look at participants’ overall comprehension of ICDs. This project strictly focused on ICD readability as a factor which has the potential to influence ICD comprehension.

In addition, this project only assessed ICDs for studies conducted at the Institution in 2017. In order to examine possible correlations with the ICD readability level and participant survey results, only volunteers who participated in a clinical trial at the Institution in 2017 were included in the survey. As the majority of clinical trials conducted by the Institution are performed in healthy volunteer populations (20 out of 21 studies in 2017), only participants in

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11 NIH, “How do I develop consent forms and who reviews them?”.  

healthy volunteer-population trials were included in the survey. Therefore, patient-volunteers were omitted from the pool of participants to be selected at random to take part in the survey.

Lastly, as this project’s objective was to provide recommendations on how to improve the Institution’s ICD template, recommendations were not submitted to the Institution’s Legal and Genetics departments for review prior to the completion of this project. Primarily due to the extensive time needed for review by these departments, recommendations from these departments will be provided following the completion of this project.
Chapter 2

Literature Review

The following literature topics pertaining to ICD readability and comprehension were examined: (1) national and global issues of inappropriate ICD language and readability levels, and (2) recommendations for improvement of readability.

2.1 National and Global ICD Readability and Comprehension Issues

Concerns for ICD complexity and increased readability levels continue to exist on both a national and global scale. Literature reviewed pertaining to ICD readability and participant comprehension establish the need to strive for improvements to simplify ICDs and ultimately to better ensure that the reason for informed consent, as intended by the founding Nuremberg Code of 1947 and the Declaration of Helsinki of 1964, has been successfully met.

2.1.1 National Concerns

Over the past few decades, numerous studies have been conducted to assess ICD readability. In particular, from 2003-2013 Dr. Michael Paasche-Orlow and colleagues have conducted such readability studies.\textsuperscript{12,13} These studies assessed the readability levels of publically available ICD templates obtained from numerous United States medical school IRBs using the Flesch-Kincaid tool. ICDs assessed included those with which the IRB also provided

\textsuperscript{12} Paasche-Orlow, Taylor, and Brancati, “Readability Standards for Informed-Consent Forms as Compared with Actual Readability,” (2003).
local standards such as grade level or suggested language. In 2003, the authors found that out of 114 ICDs the average readability grade level was 10.6, a finding which exceeded the IRBs’ own standard for an appropriate grade level by nearly three grades. The standards varied from a 5th grade readability level to 10th grade, with an 8th grade readability standard being the most common.\textsuperscript{14} Ten years later, the authors conducted the study again in order to determine if readability improvements had been made, and whether or not the newly required Health Insurance Portability and Accountability Act (HIPAA) privacy language had any impact on readability levels. During this time, the authors were able to sample 106 ICD templates available from medical school IRBs and determined that the average readability grade level was 9.8, and exceeded their standards by just over two grade levels. While the average readability level of ICD templates slightly improved, the authors’ conclusion remains that ICD readability level is too high and does not meet the IRB standards established. Furthermore, they recommend that the readability level of an IRB’s ICD template must meet their own established standards, and that IRBs ensure that reviewed ICDs are checked for appropriate readability levels.\textsuperscript{15}

In addition to ICD templates, the readability of actual IRB-approved ICDs used in research has also been assessed. Simonds et al. examined ICDs used in research performed in underserved communities to determine their readability grade level and the overall health literacy requirement based on the ICD’s layout, graphics and readability level.\textsuperscript{16} In their review

\textsuperscript{14} Paasche-Orlow, Taylor, and Brancati, “Readability Standards for Informed-Consent Forms as Compared with Actual Readability,” (2003).
of 97 ICDs the authors found that the average readability grade level was 12 using the Simple Measure of Gobbledygook (SMOG) tool, and that all ICDs exceeded the required 8th grade readability level. Acknowledging that some may attribute a higher ICD readability level to complex language for legal reasons and documentation of participant agreement, the authors poignantly state “their ICDs are designed to protect research institutions rather than communities”. Additionally, their findings led them to suggest that a shift in researcher and institutional mindset may be needed to view ICDs as educational tools rather than simply means to document a person’s authorization to participate in the research. Similarly, a separate study conducted by Larson et al. also reviewed IRB-approved ICDs for readability, but examined their length as well. In their review of 100 ICDs the authors found an average readability grade level of 11.6 using the Flesch-Kincaid tool, including average readability levels of 10th grade for pediatric documents. In addition, the authors found the average ICD page length to be 10.3 pages, with an upward limit of 28 pages. From this, the authors have concluded that ICDs must be simplified to reduce readability grade levels as well as document length. However, support is needed for researchers and institutions to improve their ICDs while still adhering to regulatory requirements established in 45 CFR 46.116.

17 Ibid., 688.
18 Ibid.
20 Ibid.
2.1.2 Global Concerns

The concern with high ICD readability levels is not isolated to just research institutions within the United States. ICD readability and comprehension studies can be found conducted throughout the world, with results showing that readability levels remain too high. Villafranca et al. performed reviews of ICD templates publically available on the websites of Research Ethics Boards (REBs), equivalent to the United States’ IRBs, in English-speaking medical schools around the world. These schools were located in Australia, New Zealand, Canada, South Africa, the United Kingdom, and the United States.21 Readability levels were calculated on 94 ICDs in order to assess ICDs for more than simply quantitative readability. Villafranca et al. used the Flesch-Kincaid tool to analyze readability, and used the Coh-Metrix linguistic software to examine linguistic elements as they pertained to readability. In addition, ICDs were compared to their corresponding REBs’ standards, if available. In this review, the authors found that none of the 94 ICDs met the 8th grade level readability standard but instead were more appropriate for a 12th grade level and above. The linguistic analysis of word familiarity, imagability, and word length also did not meet the 8th grade standard. The only element which met this standard was sentence length.22 From these findings, the authors suggest that ICD template readability must be improved in order to improve actual ICD readability derived from such templates. In particular, they suggest that more familiar vocabulary that is short and easy to

22 Ibid.
visually look at is needed to improve readability. In addition, the authors recommend that IRBs review ICD readability using linguistic software.\textsuperscript{23}

Global assessment of ICD readability has also been examined in comparison to participant comprehension. Paris et al. conducted a study of 200 participants in Phase I clinical research who were randomized to review one of four types of ICDs followed by an assessment for comprehension.\textsuperscript{24} Each recipient received one of the four different ICDs available for the study. The different ICDs included: (1) unchanged ICD, (2) ICD with a reduction in word and sentence length, (3) ICD which had been reviewed and altered by a group (comprised of a nursing, IRB, and volunteer representative), and (4) a combination of both (2) and (3). The authors found that improving ICD readability, regardless of the method, increased participant comprehension. They also found that participants who had a professional background in a medical field also had better ICD comprehension. Based on their results, the authors recommend that ICD improvements be made in all Phase I clinical research in order to reduce readability and therefore increase participant comprehension.\textsuperscript{25}

\textbf{2.2 Recommendations for Improvement of Readability}

Over the past few decades, both federal and private resources have been created to support readability improvement of health-related public materials. Recommendations from these resources are both specific to ICD development, and to general public document creation.

\textsuperscript{23} Ibid.


\textsuperscript{25} Ibid.
Together, these resources can support initiatives to improve ICD readability and ultimately participant comprehension.

### 2.2.1 Recommendation Resources

In 2009, the Agency for Healthcare Research and Quality (AHRQ), an organization within the United States Department of Health and Human Services (HHS), developed the *Informed Consent and Authorization Toolkit for Minimal Risk Research*. This resource was created to support researchers and IRBs in obtaining informed consent and meeting regulatory requirements, while also presenting information to research participants in a manner in which they can better understand.26 While the toolkit is intended for minimal risk research, the use of many of its recommendations has been accepted for all levels of research. 27

In addition to AHRQ, the Centers for Disease Control and Prevention (CDC) has been proactive in creating materials to reduce readability levels. In 1998, the agency created the *Consent for CDC Research* as a reference to support their efforts in creating research materials for participants that could be more easily understood.28 The guide discusses recommendations that can be used to lower the readability levels of ICDs and simplify documents so that they are more approachable for potential participants.29 *Simply Put*, now in its third edition, was also created by the agency as a guide to support the creation of public materials that are audience-

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29 Ibid.
appropriate, clear, and convey necessary health messages more easily.\textsuperscript{30} In 2016, the CDC also created \textit{Everyday Words for Public Health Communication} as a glossary for healthcare providers to minimize the use of medical jargon. The resource is intended to offer alternative words which are more common to people who may not be familiar with medical terminology, and who therefore may be better able to understand the material being presented to them.\textsuperscript{31}

The National Institutes of Health (NIH) \textit{Clear & Simple} initiative focuses on providing clear communication to individuals with low literacy.\textsuperscript{32} The program is intended to help healthcare providers in creating written materials that are effective and audience-focused. The program acknowledges that while found among all races and ethnicities, lower literacy is associated with lower income and less education.\textsuperscript{33} Additionally, the program focuses on understanding the audience in order to be able to better communicate necessary information by both content and visual aspects of the material.

In addition to federal resources, IRBs at Institutions of Higher Education also provide recommendations to support the improvement of ICD readability and comprehension. Johns Hopkins Medicine (JHM) IRB provides a guidance document for their researchers and staff to assist them in creating an ICD that is comprehensible to study participants, and meets the IRB’s recommended 8\textsuperscript{th} grade reading level.\textsuperscript{34} The recommendations focus on how to make ICD

\begin{itemize}
  \item \textsuperscript{33} Ibid.
\end{itemize}
content more familiar to a prospective participant in both the language used and the visual layout of the document.\textsuperscript{35} Additionally, Quorum Review IRB, a central IRB located in the United States, has made their recommendations available to research personnel which address ways to simplify ICDs while maintaining compliance, and promoting participant comprehension.\textsuperscript{36,37} The IRB acknowledges the need for ICD creators to remain cognizant of literacy challenges, suggesting to “shape communication on the assumption that participants may have low literacy” in order to better ensure ICD comprehension.\textsuperscript{38}

\textbf{2.2.2 Compiled Recommendations}

In review of the resources discussed in Section 2.2.1, Table 1 lists the most predominant recommendations identified for improving ICD readability levels.

\textsuperscript{35} Ibid.
\textsuperscript{36} Quorum Review, “How to Simplify Your Consent Form: Streamline Without Compromising Compliance.”
\textsuperscript{38} Ibid, 4.
Table 1. Identified Recommendations to Improve ICD Readability Level

- Write the document at no greater than an 8th grade reading level
- Reduce the use of polysyllabic (3 or more syllables) words
- Keep sentences short (no more than about 10 words per sentence)
- Keep sentences simple and direct
- Remove irrelevant details
- Use everyday words
- Minimize the use of technical terms and medical jargon
- Provide clear definitions when complex terms and acronyms are used
- Use active voice and verbs
- Limit 1 idea per sentence and per paragraph
- Order sentences, paragraphs and ideas in a logical sequence
- Avoid repetition
- Understand who the target audience is and educate contributors about this audience
- Use electronic readability tools
- Use at least 12-point font and increase based on the target audience’s need
- Utilize pictures, graphs and tables
- Utilize white space on the page and avoid largely condensed areas of text
Chapter 3

Project Description

In order to meet this project’s objectives, two primary components of the project were designed. The first focused on the technical readability aspects of the Institution’s current ICD template. In order to better understand these aspects, an examination of the Institution’s current ICD readability levels was conducted in both their actual IRB-approved clinical trial ICDs, as well as the ICD template. The ICD template was then reviewed for the technical aspects which can impair the document’s readability. Recommendations for ICD readability improvements were then derived from literature suggestions and applied to the ICD template.

The second component of this project was a telephone survey to volunteers who previously participated in a clinical trial at the Institution. This survey aimed to gather information to better understand the educational background of the Institution’s volunteer population, and to solicit feedback of the volunteer’s response to the ICD and recommendations for ICD improvement. To date, this information has not been gathered by the Institution. Such information is considered to be beneficial in better understanding the Institution’s ICD target audience and identifying any potential unmet needs.
Chapter 4
Need Assessment

4.1 Overview of Need Assessment

Historically, it has been a challenge for Institutional ICD authors to develop an ICD which adheres to the IRB requirements of a readability level no greater than 8th grade. Many of the Institution’s ICD authors attribute this to complex clinical trial design, legal language requirements, and genetic research language requirements. While average document readability levels of 8th grade have been achieved, analysis of the readability level of specific ICD sections has not been examined. In order to achieve this project’s objective, a review of ICD readability of all clinical studies conducted by the Institution in 2017 was performed.

As the Institution utilizes multiple IRBs depending on specific study needs, the review of this need assessment and the overall project focus was on studies reviewed and approved by the Institution’s primary IRB. In 2017, 18 out of the 21 clinical trials conducted at the Institution were reviewed and approved by the primary IRB; the remaining 3 clinical trials were reviewed and approved by a secondary IRB. For consistency in analyzing ICD language and making recommendations for template improvements, this project has focused on studies reviewed by and template versions used for the Institution’s primary IRB.

4.2 Need Analysis

To remain consistent with current Institutional practices, the Flesch-Kincaid Grade Level tool offered through Microsoft Word was utilized by the author to calculate the readability level
of 18 clinical trials which took place at the Institution during 2017. Table 2 (presented in Section 4.3) lists the average readability level of the 18 clinical trials conducted in 2017 which were reviewed and approved by the Institution’s primary IRB. The author examined average readability in both the document as a whole, as well as each specific section defined in the current Institutional ICD template. Comparisons have been made to the average readability level of the ICD template.

4.3 Review and Confirmation of Need

As evidenced by Table 2, the use of an ICD template with a readability level which exceeds the 8th grade requirement correlates to an increased readability grade level in the final document submitted for IRB approval and participant use. While all clinical trial protocols can differ, the use of a simpler, reduced readability grade level template has the potential to improve final ICD readability levels and ultimately aid in participant comprehension.
<table>
<thead>
<tr>
<th>Specific ICD Section</th>
<th>Clinical Trial ICDs (N=18)</th>
<th>ICD Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>8.5</td>
<td>8.6</td>
</tr>
<tr>
<td>Information about the Study Drug</td>
<td>8.5</td>
<td>9.8</td>
</tr>
<tr>
<td>Purposes of the Study</td>
<td>12.5</td>
<td>8.9</td>
</tr>
<tr>
<td>How Long the Study Will Last and How Many People Will Be In the Study</td>
<td>5.2</td>
<td>4.8</td>
</tr>
<tr>
<td>When Are You Eligible to Participate in Another Drug Study</td>
<td>8.2</td>
<td>8.0</td>
</tr>
<tr>
<td>To Be In the Study (Eligibility)</td>
<td>11.7</td>
<td>11.4</td>
</tr>
<tr>
<td>What Will Happen During the Study (screening phase)</td>
<td>6.5</td>
<td>6.6</td>
</tr>
<tr>
<td>What Will Happen During the Study (dosing phase)</td>
<td>9.3</td>
<td>9.3</td>
</tr>
<tr>
<td>HIV and Hepatitis Testing</td>
<td>9.0</td>
<td>8.9</td>
</tr>
<tr>
<td>Dosing Schedule</td>
<td>7.4</td>
<td>7.6</td>
</tr>
<tr>
<td>Blood Sample Collection</td>
<td>8.8</td>
<td>9.1</td>
</tr>
<tr>
<td>Your Responsibilities (Activity and Diet Restrictions)</td>
<td>9.7</td>
<td>9.4</td>
</tr>
<tr>
<td>Possible Side Effects and Risks of the Study Drug and Procedures</td>
<td>9.3</td>
<td>9.0</td>
</tr>
<tr>
<td>Additional Risks (study-specific tests/genetic testing)</td>
<td>10.8</td>
<td>10.9</td>
</tr>
<tr>
<td>Genetic Information Nondiscrimination Act (GINA)</td>
<td>14.9</td>
<td>14.5</td>
</tr>
<tr>
<td>Additional Risks (study-specific procedures)</td>
<td>7.4</td>
<td>8.2</td>
</tr>
<tr>
<td>Birth Control, Dangers of Pregnancy and Breastfeeding</td>
<td>9.5</td>
<td>9.8</td>
</tr>
<tr>
<td>Possible Benefits of the Study and Alternatives to Participating In the Study</td>
<td>7.9</td>
<td>7.5</td>
</tr>
<tr>
<td>Release of Your Medical Records and Privacy (Confidentiality)</td>
<td>8.5</td>
<td>8.6</td>
</tr>
<tr>
<td>Payment for Injury Related to the Study</td>
<td>11.7</td>
<td>10.8</td>
</tr>
<tr>
<td>Legal Rights and Whom to Contact</td>
<td>10.6</td>
<td>10.7</td>
</tr>
<tr>
<td>Payment For Being In the Study</td>
<td>9.1</td>
<td>9.0</td>
</tr>
<tr>
<td>Your Decision to Be In the Study</td>
<td>5.8</td>
<td>6.0</td>
</tr>
<tr>
<td>Additional Costs to Participation and New Findings</td>
<td>7.4</td>
<td>7.6</td>
</tr>
<tr>
<td>The Reason for IRBs and Informed Consent</td>
<td>8.5</td>
<td>8.5</td>
</tr>
<tr>
<td>Agreement To Be In the Study</td>
<td>7.2</td>
<td>8.5</td>
</tr>
<tr>
<td>Additional Consent Request- Banked Biospecimen</td>
<td>10.6</td>
<td>10.5</td>
</tr>
</tbody>
</table>

**Average of Entire Document** | 9.3 | 9.3 |
Chapter 5
Methodology

5.1 Methodology Design

Two primary components of the project were formed to meet the study objectives: (1) technical ICD readability improvements and (2) administration of a participant survey.

5.1.1 Technical ICD Readability Improvements

In order to narrow the scope of this project, and identify and propose recommendations to improve ICD readability levels, the analysis of ICD readability focused on studies reviewed and approved by the Institution’s primary IRB. In 2017, 18 of the 21 Phase I clinical trials conducted by the Institution were reviewed and approved by the Institution’s primary IRB. ICD readability levels were calculated using the Flesch-Kincaid Grade Level tool offered through the Microsoft Word software. The use of this tool to determine readability levels did not deviate from the Institution’s usual practice. Table 2 previously presented in Chapter 4 outlines the average readability levels of 2017 clinical trials as compared to the ICD template. The average entire-document readability level for both the actual clinical trial ICDs and the ICD template was grade 9.3 level. Based on these findings, Table 3 lists the ICD sections which presented readability levels greater than 8th grade. As the reading level was higher in these sections, the author placed emphasis on these areas to improve their readability.
Table 3. ICD Sections with Readability Levels >8th Grade

<table>
<thead>
<tr>
<th>Specific ICD Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information about the Study Drug</td>
</tr>
<tr>
<td>Purposes of the Study</td>
</tr>
<tr>
<td>To Be In the Study (Eligibility)</td>
</tr>
<tr>
<td>What Will Happen During the Study (dosing phase)</td>
</tr>
<tr>
<td>HIV and Hepatitis Testing</td>
</tr>
<tr>
<td>Blood Sample Collection</td>
</tr>
<tr>
<td>Your Responsibilities (Activity and Diet Restrictions)</td>
</tr>
<tr>
<td>Possible Side Effects and Risks of the Study Drug and Procedures</td>
</tr>
<tr>
<td>Additional Risks (study-specific tests/genetic testing)</td>
</tr>
<tr>
<td>Genetic Information Nondiscrimination Act (GINA)</td>
</tr>
<tr>
<td>Birth Control, Dangers of Pregnancy and Breastfeeding</td>
</tr>
<tr>
<td>Payment for Injury Related to the Study</td>
</tr>
<tr>
<td>Legal Rights and Whom to Contact</td>
</tr>
<tr>
<td>Payment For Being In the Study</td>
</tr>
<tr>
<td>Additional Consent Request- Banked Biospecimen</td>
</tr>
</tbody>
</table>

Proposed changes to the Institution’s ICD template were based on the recommendations outlined previously in Table 1. The ICD sections listed in Table 3 were examined particularly for their use of polysyllabic words, sentence length, and complex syntax. Sentences that were lengthy and used complex terminology were revised to be broken-down into short, simple structures focusing on one idea per sentence. Identification of complex terminology included pinpointing areas where medical and clinical research terminology were used. Sentences with more than ten words were considered to be lengthy, and revisions aimed to reduce sentence length as close as possible to ten words or less. In addition, words that were more abstract were replaced with vocabulary more familiar in every-day conversations.
5.1.2 Participant Survey

In order to better understand the Institution’s Phase I volunteer population, data regarding the volunteers’ educational background and general feedback of the Institution’s ICDs were gathered by administering a telephone survey. Information gathered from this survey was used to better understand the Institution’s volunteer population, the ICD target audience, to develop clinical trial ICDs suitable to the participants’ readability level, and to assist in identifying potential unmet participant needs.

5.2 Study Participants

50 participants were selected at random to participate in the telephone survey. Participants were eligible to participate in the survey if they (1) participated in a clinical trial at the Institution in 2017, (2) participated in a healthy volunteer trial, (3) were an adult volunteer (age 18-55) in the clinical trial, and (4) were willing to participate in an approximately 5-minute survey. Participants were selected at random by utilizing a Microsoft Excel extract derived from the clinical database which listed all study participants in 2017. The Microsoft Excel randomization function was then used to order participants at random. Participants were then contacted based on the randomization provided. Appendix 1 includes the Telephone Script which was communicated to all participants upon contact. Surveys were only conducted with participant’s verbal agreement to voluntarily participate.
5.3 Survey Design

The survey presented to participants consisted of seven questions. Questions consisted of both quantitative and open-ended responses. Survey questions presented to volunteers are included in Appendix 2. Responses to survey questions did not contain identifying information in order to protect participant privacy. In this survey, questions 1, 2, and 4 focused on the participant’s educational background. Questions 3, 5, and 6 focused on the participant’s response to the ICD and overall familiarity with ICDs. Lastly, question 7 offered the participant an opportunity to provide open-ended feedback regarding their ideas for possible ICD improvements.

5.4 Institutional Review Board

Review and approval for the conduct of this participant survey was received from Johns Hopkins University Homewood IRB (Appendix 3). IRB approval was received on February 12, 2018 and participant surveys were conducted from February 19, 2018 to February 23, 2018.
6.1 Survey Results and Discussion

The survey conducted offered a random sampling of the Institution’s population to better understand their educational background, familiarity with ICDs, and identify potential unmet needs. The following results were obtained from the survey. 50 participants who met the eligibility criteria and provided verbal consent to participate completed the survey. All 50 participants completed the survey and none declined to answer a question.

Questions 1, 2, and 4 in the survey were intended to obtain information regarding the participants’ educational background. Figure 1 summarizes the findings regarding the participant’s highest level of education, the first question in the survey. 33 of the participants

**Figure 1. Participants’ Highest Level of Education**

- 66% Elementary School (kindergarten-5th grade)
- 32% Middle School (6th- 8th grade)
- 2% High School (9th- 12th grade)
- 2% Undergraduate Degree (associate's or bachelor's)
- 2% Graduate Degree (master's or higher)
(66%) reported having completed high school (9th to 12th grade) as their highest level of education, while 16 (32%) reported completing an undergraduate (associate’s or bachelor’s) degree, and one participant (2%) reported completing a graduate (master’s or higher) degree. None of the participants reported completing elementary school (kindergarten to 5th grade) or middle school (6th to 8th grade) as their highest level of education. These findings demonstrate that the majority of the Institution’s volunteer population has a highest level of education that does not exceed a high school level, and therefore ICD readability levels of 8th grade or lower would be considered appropriate for this population. Furthermore, these data support the need to ensure that specific sections within ICDs do not exceed a readability level greater than 12th grade. As demonstrated previously in Table 2, sections of both the ICD template and actual ICDs utilized in 2017 exceeded a 12th grade level. By reducing ICD readability levels to 8th grade or lower, the Institution would be better able to ensure an appropriate reading level for their volunteer population, and therefore potentially increase participant overall comprehension of consent documents.

The second question in the survey asked participants about their primary language spoken. Figure 2 demonstrates that the majority of the participants stated that English was their primary language (80%), followed by Spanish (14%), and French, Russian and Creole, equally (2%).
Prior to conducting the survey, the author anticipated that the majority of participants would report English to be their primary language, and that Spanish would also be prevalent. However, it was surprising to the author to find that the Institution had volunteers who reported French, Russian and Creole to be their primary language. It is important to note that the ability to read and write English was a requirement for these volunteers to participate in the Institution’s clinical trial, and that all participants in this study were capable of doing so. While these findings provide additional insight into the demographics of the Institution’s volunteer population, changes were not made to the ICD template’s readability as a result of them, particularly because all participants were capable of reading and writing English. However, these data demonstrate that the population of respondents in this survey was diverse in background. Additionally, these data have made it apparent that 20% of the Institution’s volunteer population has a primary language other than English, and that the languages which
comprise this percentage are quite diverse. These findings could be beneficial in encouraging
the Institution to conduct further research to understand if there is a correlation between a
participant’s primary language spoken and their overall comprehension of the ICD.

The fourth question in the survey inquired about participants’ exposure to formal
medical training and work experience in a medical setting. As demonstrated in Figure 3, the
majority of the participants denied having formal medical training (86%). 7 of the participants
(14%) reported previously receiving medical training, and of these respondents only one
participant (2%) stated that they had applied this formal training to working in a medical
setting, while the remaining participants had not (12%). These results support this project’s
effort to minimize the use of the medical jargon in the Institution’s ICD template as the majority
of participants have not worked in a trained capacity in a medical setting (98%), and do not
have formal medical training backgrounds (86%).
Questions 3, 5, and 6 in the survey pertained to the participants’ responses to the ICD and overall familiarity with ICDs. None of the participants reported having difficulty understanding the medical terminology in the ICD, question 3 in the survey. Additionally, 49 of the participants (98%) reported not requiring help to read or understand the ICD before they signed it, question 6 in the survey. One participant (2%) reported needing assistance in understanding the ICD prior to signing it, and stated that the clinical staff who provided this assistance was the person who reviewed and signed the ICD with this participant. It was surprising to the author to find that none of the participations reported having difficulty understanding the medical terminology in the ICD, as this finding was inconsistent with some of the open-ended responses participants provided in the final question of the survey (discussed in detail later in this section). In the open-ended responses, participants commented on the need to improve ICD terminology and clarify information, including medical terminology. As
one of the significant challenges identified in this project was the length of time from when the survey was administered and when participants last read the ICD, it would be beneficial to administer the questionnaire following participants’ initial exposure to ICDs. In turn, this could provide participants with the opportunity to answer questions when they are more familiar with ICD content, and therefore potentially eliminate inconsistencies between survey answers. Consequently, changes to the ICD template’s readability were not made as a result of these findings. However, as one participant reported requiring assistance in understanding the ICD prior to signing the document, it would be beneficial for the Institution to conduct additional research into participants’ overall comprehension of the ICD, and to further identify what content is or is not understood by participants. Furthermore, it would be beneficial to obtain this information following initial exposure to the ICD, when participants are better able to recall ICD content.

The sixth question in the survey inquired about participants’ overall familiarity with ICDs. As demonstrated in Figure 4, a slight majority of the participants (24%) reported having previously read and signed 2-5 ICDs in their lifetime. 22% of the participants reported having read and signed over 20 ICDs in their lifetime, closely followed by 6-10 ICDs and 11-20 ICDs, equally (20%). 7 of the participants (14%) reported that it had been their first time reading and signing an ICD. None of the participants reported that they were unsure of their prior exposure to ICDs.
It is possible that the participants’ lack of need for assistance in ICD comprehension, discussed previously, correlates to their familiarity with ICDs, as the majority of participants (86%) had read and signed ICDs previously, nearly half of which (42%) have read and signed 11 or more ICDs in their lifetime. However, it is important to note that 14% of the participants reported that they had not been exposed to an ICD previously. For these participants, language used in an ICD may be new to them. Reducing ICD readability levels to 8th grade or lower would not only be appropriate for the educational level of the Institutional participants, but could potentially increase participant overall comprehension, particularly for volunteers who have little to no prior exposure to consent documents. These data could be beneficial in supporting the need for the Institution to conduct further research to understand if there is a correlation between a participant’s familiarity with ICDs and their overall comprehension of the ICD.
The final question of the survey was open-ended and asked participants if they had suggestions for changes that they believed the Institution should make to the ICD. 17 of the participants (34%) provided responses, while the remaining (66%) stated that they did not have suggestions for change at the time of the telephone call. Of the suggestions that were provided, five broad categories were identified: (1) terminology used in the ICD and need for clarification of information, (2) length of the ICD and need for concision, (3) visual layout or format of the ICD, (4) clinical presentation of the ICD, and (5) repetition of information in the ICD. Figure 5 summarizes the prevalence of these categories mentioned in participant feedback.

**Figure 5. Participants’ Suggested ICD Changes by Category**
The majority of suggestions provided pertained to the need to reduce the length of the ICD and make the information more concise (35%), as well as to improving the terminology used and clarifying information presented (26%). Additionally, participants commented on the need to reduce repetition of information, improve the visual format or layout of the ICD, and enhance the clinical presentation of the ICD, equally (13%). The verbatim responses which comprise the response summary presented in Figure 5 are listed in Appendix 4. The majority of these responses provided general feedback; however, 3 respondents were able to provide content-specific feedback: two respondents specifically commented on the need to reduce the repetitiveness of contraception information, and one respondent commented on the need for clearer information regarding what, if any, blood sample collections are optional for the volunteer.

The open-ended responses to the final survey question are considered to be particularly beneficial in this project. However, when asked to provide feedback, many of the participants commented that they were unable to provide general or specific feedback because of their difficulty recalling the ICD content, and not having the physical document available to refer to at the time of the telephone call. Since it had been up to a year since some of these participants read and signed the ICD, it would likely be more beneficial to request such feedback from volunteers closer to the time that they initially read and sign the ICD in the future. This may provide the Institution with not only a greater amount of feedback, but with more content-specific responses as well.

Of the suggestions provided in response to the final survey question, many of the changes were incorporated into the ICD template to improve its readability. In particular, those
regarding repetition of information, reduction of technical terms, better use of everyday
type of language, and removal of non-essential information were addressed. Discussion of these
specific changes can be found in Section 6.2. As this project did not focus on ICD length or
clinical presentation of the ICD, further research and improvements are recommended to
assess and possibly improve these elements.

6.2 Informed Consent Document Readability Improvements and Discussion

Utilizing the recommended strategies outlined previously in Table 1, the readability of
the Institution’s ICD template was improved both within the specific ICD sections, as well as the
overall average document.

The changes incorporated to reduce readability levels and promote ease of reading
consisted of numerous elements. To begin, language consisting of highly technical and medical
terminology was identified and replaced with suggestions provided in the sources identified in
the literature review. Readability levels were also improved by identifying complex vocabulary
and replacing it with more common, everyday language that participants are more likely to be
familiar with. Samples of these proposed replacements are provided in Table 4.
Table 4. Examples of Proposed Terminology and Vocabulary Revisions

<table>
<thead>
<tr>
<th>Current Terminology/Vocabulary Used (underlined)</th>
<th>Proposed Revision (underlined)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...metabolite identification (by-products or end products of a drug produced as the body processes a drug)...</td>
<td>...test for metabolites of the study drug. These are sometimes made when the body processes a drug...</td>
</tr>
<tr>
<td>...human immunodeficiency virus (HIV), Hepatitis B surface antigen (HepBsAg), Hepatitis B core antibody (HepBcAb), or Hepatitis C antibody (HCVAb)...</td>
<td>...HIV, Hepatitis B, or Hepatitis C...</td>
</tr>
<tr>
<td>The following modifiers mean that the study drug is absorbed by your body over a period of time instead of all at once.</td>
<td>The following terms are used to describe how the study drug is absorbed by your body over a period of time. This is different from it being absorbed all at once.</td>
</tr>
<tr>
<td>Postmenopausal (at least 12 consecutive months without a period)</td>
<td>Postmenopausal (at least 12 months in a row without a period)</td>
</tr>
<tr>
<td>You will be confined to the unit for X days. If a prolonged drug effect is noted and your safety is a concern, you may need to remain in the unit longer.</td>
<td>You will need to stay in the unit for X days. You may need to stay in the CRU longer if you experience a longer drug effect. This is for safety reasons.</td>
</tr>
<tr>
<td>Study assessments</td>
<td>Study procedures</td>
</tr>
<tr>
<td>...the average person receives from background radiation...</td>
<td>...the average person gets from radiation in the environment...</td>
</tr>
<tr>
<td>Fetus</td>
<td>Unborn child</td>
</tr>
<tr>
<td>Contraception</td>
<td>Birth control</td>
</tr>
<tr>
<td>Unforeseeable risks</td>
<td>Risks that cannot be predicted</td>
</tr>
</tbody>
</table>

Additionally, sentences exceeding 10 words and using polysyllabic words were identified and deconstructed to achieve short, simple sentences, addressing only one primary idea per sentence. For example, the following sentence contains an average words per sentence count of 32.0, as calculated by the Flesch-Kincaid formula:

“You must not have a history of sensitivity to heparin (a substance that stops blood from clotting) or of low platelets (cells that help with blood clotting) as a result of heparin.”
Instead, this sentence can be reconstructed to maintain same intent, but have an average of 11.5 words per sentence:

“You must not have a history of sensitivity to, or side effects from heparin. Heparin is a substance that stops blood from clotting.”

By reducing the number of words in a sentence, information within the ICD is presented to the participant in a more concise and direct manner.

Furthermore, areas of the ICD where information was found to be repeated were identified and consolidated to one section, ensuring that topics are discussed once throughout the document. Particularly, areas where contraception requirements were discussed were removed and instead primarily addressed in the *Birth Control, Dangers of Pregnancy and Breastfeeding* section. Such changes reduced redundancy and wordiness, and can allow for clinical trial participants to locate critical information in just one location within the document. These changes also addressed the content-specific feedback provided by participants in the survey, discussed previously. In addition, superfluous information was also removed from the document if it was not considered to be critical. For instance, the use of the word “*supine*” was removed from “*Your vital signs will be collected (supine)*”, as this information was not considered to be critical to the volunteer’s decision to participate in the clinical trial, and was felt to only add to the wordiness of the document.

Lastly, formatting changes were also applied to the ICD template in response to the participant feedback received. First, the author restructured the discussion around what types of specimens would be collected from a paragraph-format to bullet-format. In addition, text that notified volunteers of samples that were optional for them to provide was changed to have the font bold and underlined. The following is an example of this change:
“You are also being asked to give a (specimen name) sample.
• Providing this sample is optional for you.”

Making such changes allowed for better streamlining and clarity of information. In the second formatting change, tables were inserted to present information more clearly, reduce the number of words needed, and create more white-space. This proposed layout revision was applied to sections where the ICD content was appropriate for such changes, such as the Payment For Being In the Study section of the ICD template. In this section, payment for participation was previously discussed in a sentence-format. To reduce the use of words and present information more directly, a table was inserted to list the overall stipend and how it is composed. An example of this is shown in Figure 6 below.

**Figure 6. Example of Proposed Formatting Revision**

<table>
<thead>
<tr>
<th>Type of Activity</th>
<th>Payment per Activity</th>
<th>Total Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overnight Stays</td>
<td>$XXXX.XX</td>
<td>XX</td>
</tr>
<tr>
<td>Follow-up Visit</td>
<td>$XXXX.XX</td>
<td>X</td>
</tr>
<tr>
<td><strong>Total Payment</strong></td>
<td><strong>$XXXX.XX</strong></td>
<td></td>
</tr>
</tbody>
</table>

Samples of the changes incorporated to reduce the document’s readability are included in Table 5. For confidentiality purposes, the entire ICD template with proposed changes incorporated has not been provided in this publication.
Table 5. Examples of Proposed Revisions with Readability Grade Level Comparison

<table>
<thead>
<tr>
<th>ICD Section</th>
<th>Current Template Language</th>
<th>Readability Grade Level</th>
<th>Proposed Revision</th>
<th>Readability Grade Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information about the Study Drug</td>
<td>If the dose is tolerated without significant side effects and the levels in the blood are acceptable, then the doses in later periods/later groups may be increased to a maximum of X mg taken X times a day for X days.</td>
<td>17.6</td>
<td>The dose may increase up to X mg taken X times a day for X days. The dose will only increase if it’s believed to be safe. How well the study drug is tolerated and blood tests will help us to decide if it is safe.</td>
<td>3.9</td>
</tr>
<tr>
<td>To Be In the Study (Eligibility)</td>
<td>You must not have a history of sensitivity to heparin (a substance that stops blood from clotting) or of low platelets (cells that help with blood clotting) as a result of heparin.</td>
<td>14.5</td>
<td>You must not have a history of sensitivity to, or side effects from heparin. Heparin is a substance that stops blood from clotting.</td>
<td>7.3</td>
</tr>
<tr>
<td>What Will Happen During the Study (on-Study)</td>
<td>As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for metabolite identification (by-products or end products of a drug produced as the body processes a drug) and/or evaluation of the laboratory tests used to measure the study drug, as well as for other internal exploratory purposes.</td>
<td>28.0</td>
<td>These samples may also be used to test for metabolites of the study drug. These are sometimes made when the body processes a drug. This test helps us to better understand how the body absorbs, distributes, and gets rid of the study drug. These samples can also be used to check the laboratory test(s) which measure the study drug, and for other internal research purposes.</td>
<td>8.5</td>
</tr>
</tbody>
</table>
### Table 5. Examples of Proposed Revisions with Readability Grade Level (cont.)

<table>
<thead>
<tr>
<th>Blood Sample Collection</th>
<th>During the study, blood samples will be taken by individual needle-sticks or by a catheter put directly into a vein in your arm. The catheter procedure consists of putting a small tube in your arm to take blood when required. Catheters are used at the judgment of the study investigator or when required by the study plan, not at the request of the subject.</th>
<th>10.6</th>
<th>Blood samples will be taken by individual needle-sticks or by a catheter placed in a vein in your arm. A catheter is a small tube that is placed in your arm to take blood when required. They are used at the judgment of the study investigator or when required by the study plan. They are not used at the request of the subject.</th>
<th>6.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth Control, Dangers of Pregnancy and Breastfeeding</td>
<td>If abstinence (not having sexual intercourse at all) is your usual and preferred lifestyle and both you and your study investigator agree that it is your selected method of contraception, you must continue not to have sexual intercourse or you may become pregnant.</td>
<td>20.9</td>
<td>Please tell us if abstinence (not having sexual intercourse at all) is your chosen lifestyle. If so, both you and the study investigator must agree that this is your selected method of birth control. You must continue not to have sexual intercourse or you may become pregnant.</td>
<td>8.8</td>
</tr>
</tbody>
</table>

The changes that the author has made to the Institution’s ICD template are consistent throughout the document with the samples provided in Table 5, and have aided in improving the document’s readability. At the time of this publication, changes to the Institution’s ICD template have not been implemented. Due to the need for subject matter expert and legal counsel review, the changes discussed in this publication will be recommended to the Institution by the author as proposed revisions.
The proposed revisions discussed previously enabled a reduction in readability level of the ICD template as a whole, as well as specific sections of the ICD, as outlined in Table 6.

Table 6. Comparison of ICD Template Readability Grade Level with Proposed Revisions

<table>
<thead>
<tr>
<th>Specific ICD Section</th>
<th>ICD Template</th>
<th>Proposed Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>8.6</td>
<td>6.9</td>
</tr>
<tr>
<td>Information about the Study Drug</td>
<td>9.8</td>
<td>7.4</td>
</tr>
<tr>
<td>Purposes of the Study</td>
<td>8.9</td>
<td>6.8</td>
</tr>
<tr>
<td>How Long the Study Will Last and How Many People Will Be In the Study</td>
<td>4.8</td>
<td>4.8</td>
</tr>
<tr>
<td>When Are You Eligible to Participate in Another Drug Study</td>
<td>8.0</td>
<td>6.5</td>
</tr>
<tr>
<td>To Be In the Study (Eligibility)</td>
<td>11.4</td>
<td>8.1</td>
</tr>
<tr>
<td>What Will Happen During the Study (screening phase)</td>
<td>6.6</td>
<td>6.3</td>
</tr>
<tr>
<td>What Will Happen During the Study (dosing phase)</td>
<td>9.3</td>
<td>6.6</td>
</tr>
<tr>
<td>HIV and Hepatitis Testing</td>
<td>8.9</td>
<td>6.9</td>
</tr>
<tr>
<td>Dosing Schedule</td>
<td>7.6</td>
<td>5.3</td>
</tr>
<tr>
<td>Blood Sample Collection</td>
<td>9.1</td>
<td>6.6</td>
</tr>
<tr>
<td>Your Responsibilities (Activity and Diet Restrictions)</td>
<td>9.4</td>
<td>6.8</td>
</tr>
<tr>
<td>Possible Side Effects and Risks of the Study Drug and Procedures</td>
<td>9.0</td>
<td>6.7</td>
</tr>
<tr>
<td>Additional Risks (study-specific tests/genetic testing)</td>
<td>10.9</td>
<td>7.4</td>
</tr>
<tr>
<td>Genetic Information Nondiscrimination Act (GINA)</td>
<td>14.5</td>
<td>9.6</td>
</tr>
<tr>
<td>Additional Risks (study-specific procedures)</td>
<td>8.2</td>
<td>7.8</td>
</tr>
<tr>
<td>Birth Control, Dangers of Pregnancy and Breastfeeding</td>
<td>9.8</td>
<td>7.2</td>
</tr>
<tr>
<td>Possible Benefits of the Study and Alternatives to Participating In the Study</td>
<td>7.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Release of Your Medical Records and Privacy (Confidentiality)</td>
<td>8.6</td>
<td>7.2</td>
</tr>
<tr>
<td>Payment for Injury Related to the Study</td>
<td>10.8</td>
<td>8.2</td>
</tr>
<tr>
<td>Legal Rights and Whom to Contact</td>
<td>10.7</td>
<td>7.9</td>
</tr>
<tr>
<td>Payment For Being In the Study</td>
<td>9.0</td>
<td>7.2</td>
</tr>
<tr>
<td>Your Decision to Be In the Study</td>
<td>6.0</td>
<td>5.3</td>
</tr>
<tr>
<td>Additional Costs to Participation and New Findings</td>
<td>7.6</td>
<td>7.6</td>
</tr>
<tr>
<td>The Reason for IRBs and Informed Consent</td>
<td>8.5</td>
<td>7.6</td>
</tr>
<tr>
<td>Agreement To Be In the Study</td>
<td>8.5</td>
<td>8.2</td>
</tr>
<tr>
<td>Additional Consent Request- Banked Biospecimen</td>
<td>10.5</td>
<td>8.8</td>
</tr>
<tr>
<td><strong>Average of Entire Document</strong></td>
<td><strong>9.3</strong></td>
<td><strong>7.3</strong></td>
</tr>
</tbody>
</table>
All sections of the ICD identified to have particularly high readability levels (previously listed in Table 3) were improved, as well as the average overall readability grade level of the ICD template which was reduced by approximately two grade levels.

The revisions discussed reduced the readability grade level of all sections of the ICD to an 8th grade level or lower with the exception of one section, the Genetic Information Nondiscrimination Act (GINA). While the readability level of this section started at a grade level of 14.5, improvements made reduced this level to 9.6, still exceeding the 8th grade readability level threshold. This section of the ICD remained to be a challenge particularly due to the complex concepts reviewed in the section, as well as the requirements indicated by the Institution’s legal counsel. Further discussion and collaboration with the Institution’s legal counsel will be required to reduce the readability level to at least 8th grade, while still maintaining the necessary intent of the information conveyed to volunteers.

As evidenced by the survey results discussed in Section 6.1, these proposed template changes enable the creation of an ICD that is more appropriate for the Institution’s volunteer population. The proposed revisions have improved the overall ICD template readability to a 7th grade level, and the readability level of each specific section, with the exception of one, to an 8th grade level or lower. As a result of this project, it is now understood that the majority of the Institution’s volunteer population does not have an educational level that exceeds high school, and does not have formal medical training. Therefore, the proposed ICD template changes discussed are more suitable for this population. Additionally, by reducing the ICD template readability the Institution may be better able to present clinical trial information more clearly to
volunteers in their population who have never read and signed an ICD previously, and may be less familiar with clinical trials.
Chapter 7
Recommendations and Conclusions

7.1 Introduction

The following chapter provides recommendations for the Institution to improve its ICD template readability and identify areas for further research based on the findings outlined in Chapter 6. It concludes with a summary of the project’s ability to meet its objectives.

7.2 Recommendations

Through examination of the Institution’s ICD template, and administration of the participant survey, the following recommendations have been derived:

1. Reduce the Institution’s ICD template and all study-specific ICDs to a readability level no greater than 8th grade.
2. Conduct further research to solicit participant feedback on ICD readability following initial presentation of the ICD to participants.
3. Conduct further research to better understand participants’ overall comprehension of the ICD.
4. Conduct further research to better understand the best visual layout and clinical presentation of ICDs to possibly improve participant comprehension.

Recommendation #1: Reduce the Institution’s ICD template and all study-specific ICDs to a readability level no greater than 8th grade.

As outlined previously in Table 2, both the Institution’s ICD template and study-specific ICDs in 2017 had an average readability level of 9th grade. Furthermore, specific sections of these ICDs contained content with a readability level more appropriate for a college-level student. This project’s survey, conducted in a random selection of Institutional clinical trial participants,
found that the majority of the Institution’s population has a highest educational level of high school (9th-12th grade). Maintaining the current readability levels is not appropriate for this population. Rather, a readability level no greater than 8th grade would be suitable for both the population and would sufficiently meet federal and IRB requirements.

In order to reduce the ICD template’s readability level to an 8th grade level or lower, it is recommended that the Institution follow the suggestions provided by both Federal and private bodies previously outlined in Table 1. Specifically, it is recommended that the Institution make the following improvements to the ICD template: reduce the use of polysyllabic words, deconstruct sentences which are long and address more than one idea, reduce the use of medical and clinical research terminology and instead use everyday words when possible, eliminate repetition, remove unnecessary information, and utilize tables or charts where appropriate for the content. Reducing the use of complex terminology and vocabulary is not only suitable for the Institution’s volunteer population based on their highest level of education, but also because the majority of the population does not have formal medical training and work experience in a medical setting. Furthermore, while the majority of the Institution’s volunteer population had prior exposure to ICDs, 14% of the population did not. Reducing ICD readability levels to 8th grade or lower would not only be appropriate for the educational level of the Institutional participants, but could potentially increase participant overall comprehension, particularly for the Institution’s volunteers who have little or no prior exposure to consent documents.

In addition to recommendations outlined in the literature review, responses provided by the survey participants also support these changes. Of the suggested changes provided by
participants, over one-third addressed the need to reduce the length of the ICD and make the
information more concise, and slightly over one-quarter pertained to improving the
terminology used and clarifying information presented. Furthermore, participants also
commented on the need to reduce repetition of information in the ICDs (13%).

Tables 4 and 5 (presented earlier) provide examples which demonstrate that changes
reducing the readability level as documented in the literature are feasible and can make
significant improvements to readability levels. When applied to the entire template, these
changes can improve the overall readability level of the ICD template to less than an 8th grade
level, as evidenced previously in Table 6.

Recommendation #2: Conduct further research to solicit participant feedback on ICD
readability following initial presentation of the ICD to participants.

The open-ended responses provided by survey participants with regards to ICD
improvement suggestions were considered to be particularly beneficial in identifying areas
where change may be needed. One challenge identified in this project was the timing of when
the telephone survey was conducted and when the participant initially signed the ICD in 2017.
For some participants it is possible that this length of time was up to a year. While conducting
the survey many participants commented that it was difficult to recall exactly what was in the
ICD. While the data obtained in this survey is still considered to be very beneficial in identifying
and supporting readability improvements to the Institution’s ICDs, the level of detailed
responses may be more substantial should the survey be conducted in a shorter timeframe
following initial presentation of the ICD to participants. It is therefore recommended that the
Institution solicit feedback regarding ICD readability immediately following the participant’s initial review of the ICD.

**Recommendation #3:** Conduct further research to better understand participants’ overall comprehension of the ICD.

This project strictly focused on improving the Institution’s ICD template readability using a quantitative method, the Flesch-Kincaid Grade Level tool through Microsoft Word, with the intent to improve ICD comprehension. The project did not analyze the participants’ overall comprehension of the ICD in relation to its readability. In order to further understand whether the terminology and vocabulary used in the ICD are appropriate for the population, it is recommended that further research be conducted into the participants’ overall comprehension of the ICD. This recommendation is further supported by the results obtained in the participant survey. In this survey, one respondent reported needing assistance in reading and understanding the ICD prior to signing it. Although this was not the case for a majority of the participants, further understanding of the specific information that was not understandable could be beneficial for all of the Institution’s clinical trial participants. Furthermore, it is recommended that participants’ overall comprehension of an ICD be assessed in relation to their primary language spoken, as it has been identified that one-fifth of the Institution’s population has a primary language other than English. By assessing overall comprehension of the ICD, the Institution can better determine if ICD readability improvements enhance ICD comprehension.

**Recommendation #4:** Conduct further research to better understand the best visual layout and clinical presentation of ICDs to possibly improve participant comprehension.
This project strictly focused on improving the Institution’s ICD template readability; therefore, an analysis of improvements to the visual layout and clinical presentation of the ICD was not performed. Through the literature review performed and feedback obtained in the participant telephone survey, the need to further examine the visual and clinical presentation of the Institution’s ICDs has been identified. Just over one-quarter of the comments received from the survey participants’ open-ended responses pertained to the visual format or layout of the ICD and need for enhancement of the clinical presentation of the ICD. Based on this, further research is recommended to investigate whether or not different visual formats of the paper ICD, or different visual clinical presentations of the ICD could improve participant comprehension of the ICD.

7.3 Conclusions

The objectives of this capstone project were to provide recommendations to improve the readability of the Institution’s ICD template for the purpose of increasing participant comprehension of consent documents, to reduce the readability level of the Institution’s ICD template to an 8th grade level or lower, and to review and lower the readability level of both the ICD document as a whole, as well as the specific sections of the ICD which comprise the document. By utilizing recommendations provided by both Federal and private bodies, all objectives have been met with the exception of one section of the ICD which continues to exceed an 8th grade readability level. Furthermore, the recommendations for ICD improvements that have been derived are supported by the suggestions provided in the participant survey. Lastly, recommendations provided to improve the readability of the
Institution’s ICD template can be considered appropriate for the Institution’s population, as evidenced by data gathered in the participant telephone survey. This meets the fourth and final objective of this project.

In addition to reducing the Institution’s ICD template and all study-specific ICDs to a readability level no greater than 8th grade, it is recommended that the Institution conduct further research to better understand and possibly improve participant comprehension of ICDs. By improving ICD readability and obtaining a better understanding of participant comprehension, it is believed that the Institution can better ensure that the prospective participant voluntarily participates in the clinical trial under full autonomy and with a thorough understanding of all research participation elements.
Bibliography


Appendix 1: Participant Survey Telephone Script

Telephone Survey of Phase I Clinical Trial Volunteer’s Educational Background

Telephone Script

Good Morning/Afternoon,

My name is Stephanie Dean and I am calling from [redacted]. I am working on a project for my Master’s degree and am looking to find ways to improve our consent forms to make them more user-friendly and understandable. I am reaching out to 50 volunteers who participated in our clinical trials in 2017 to ask them general questions about their education and background, and you have been selected at random. Up to 7 questions would be asked, and this would take about 5 minutes. You may stop at any point if you do not feel comfortable answering. You may also decline to participate and this will have no impact on your ability to participate in future studies at our unit.

By completing this survey or questionnaire, you are consenting to be in this research study. Your participation is voluntary and you can stop at any time.

Would you be willing to participate in this survey?

[if yes, proceed to asking survey questions]

[if no] Okay, thank you for your time. Have a nice day.
Appendix 2: Participant Survey Questions

Telephone Survey of Phase I Clinical Trial Volunteer’s Educational Background

Survey Questions

1. What is your highest level of education?
   a. Elementary (kindergarten- 5th grade)
   b. Middle school (6th grade- 8th grade)
   c. High school (9th grade- 12th grade)
   d. Undergraduate degree (associate’s or bachelor’s)
   e. Graduate degree (master’s or higher)

2. What is your primary language spoken at home? (open-ended)

3. Did you have any difficulty understanding the medical language used in the consent form?
   a. No
   b. Yes

4. Do you have any formal medical training?
   a. No
   b. Yes
   i. If yes, have you worked in a medical setting?
      1. No
      2. Yes

5. Did you need help from someone in reading or understanding the consent form before you signed the form?
   a. No
   b. Yes
   i. If yes, who provided that help to you? (open-ended)

6. Was the clinical trial that you participated in with us in 2017 the first time that you have read and signed an Informed Consent document?
   a. Yes
   b. No
   i. If no, about how many clinical trial Informed Consent documents have you read and signed?
      1. 2-5
      2. 6-10
3. 11-20
4. Over 20
5. I’m not sure

7. Although you do not have the consent form in front of you, can you please tell me if there are changes that you think we should make to the form? (open-ended)
Appendix 3: Johns Hopkins University Institutional Review Board Approval

**JOHNS HOPKINS UNIVERSITY**

Homewood Institutional Review Board  
3400 N. Charles Street  
Baltimore MD 21218-2685  
410-516-6580  
http://web.jhu.edu/Homewood-IRB/

Michael McCloskey, PhD  
Chair

**Date:** February 14, 2018

**PI Name:** Marianne Woods  
**Study #:** HIRB000006904  
**Study Name:** Telephone Survey of Phase I Clinical Trial Volunteer’s Educational Background

**Date of Review:** 2/12/2018  
**Date of Approval:** 2/12/2018  
**Expiration Date:** 2/12/2021

The above referenced study has been approved.

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Please keep in mind that it is your responsibility to inform the HIRB of any adverse consequences to participants that occur in the course of the study, as well as any complaints from participants regarding the research. In conducting this research, you are required to follow the requirements listed in the HIRB Policies and Procedures Manual.
Approved Documents:

Recruiting Materials:
Telephone Script

Study Team Members:
Stephanie Dean

APPROVAL IS GRANTED UNDER THE TERMS OF FWA00000834 FEDERAL-WIDE ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS FOR PROTECTION OF HUMAN RESEARCH SUBJECTS
Appendix 4: Participant Suggestions for Changes to ICD (verbatim)

"What the risks are and what the dose is are the most important things to me. I think it would be helpful to have the risks really clear and in both layman's terms and technical terms so I could look it up if I wanted to."

"Some of them [ICDs] are too long. There are too many pages. With too much information people don't feel like reading it and they'll just end up signing it. On the last page the blood testing should be really clear that it is optional- either separate it from the actual ICD or just make it clearer."

"You could make the font a little bigger. It's pretty long and there's a lot of information, just get to the point."

"It was a little too long."

"Maybe also do PowerPoint presentation or video presentation to make it more engaging."

"Some of the information is repeated too much, like the contraception stuff."

"It's helpful when it is really specific about what the drug treats."

"It's a lot of information, but as long as it's important information it's fine."

"There's a lot of information and it's very long. It's helpful to go through it in a group rather than one-to-one since people ask different questions."

"Sometimes it can be a little lengthy, but that's okay as long as it's what we need to know for safety reasons."

"To a point there's too much information- just get down to the facts, you don't have to have 50 pieces of paper."

"You repeat a lot of information, like when to use a condom. Also, don't talk about something later in the consent if it was talked about in the beginning. If it's not important just take it out."

"Maybe you could talk about the main points of the study at the end of it before you sign: the main things to take from the study like as the purpose, the dose, how the dose will be given, like a quick review."

"Sometimes there's too much information in the form, maybe a little too wordy."

"Sometimes you use a little too many medical and technical terms, and some information you go over and over again."

"Maybe you could include a summary page, like bullet points for the main objectives or takeaways from the whole consent, like the purpose of it, if it's FDA approved or not, side effects, your in-house stay or how many outpatient visits you have, and then the compensation. Like a 1-page summary since you've just looked through like 20 pages."

"You could highlight or underline the things that are really important like the medication, side effects, how many doses we're going to take."
Curriculum Vitae

Stephanie Dean is a graduate of the Master of Science in Research Administration program at Johns Hopkins University where she focused in compliance, legal, and regulatory issues pertaining to research administration, as well as program administration and facilitation. She performed her undergraduate studies at the University of Vermont where she received a Bachelor of Science degree in Nursing. She has worked as a research nurse in Phase II and III oncology patient clinical trials, and currently works in a Phase I clinical research unit primarily involved in healthy volunteer clinical trials. Aside from her academic studies and professional work, she enjoys being involved in outdoor recreational activities and spending time with family and friends.