RESEARCH CONSENT FORM READABILITY

Benjamin Munley¹, Joseph Breault²,³,⁴, Stephanie Gaudreau²
¹Department of Epidemiology, Tulane School of Public Health; ²Institutional Review Board, Ochsner Clinic Foundation; ³Department of Family Medicine, Ochsner Health System; ⁴Senior Lecturer, School of Medicine, University of Queensland.

Problem

Most research involving human subjects must first obtain informed consent from study participants. Informed consent is an ongoing process that starts with an approved informed consent form (ICF) usually supplemented with an in-person consultation between study staff and individual study participants. Recent studies measuring the readability of ICFs and their templates supplied by sponsors and research institutions show that the average reading level is several grade levels higher than the recommended eighth grade reading level. While this has long been the case, there is little published research on the factors responsible for the high reading levels observed in ICFs.

Purpose

The purpose of this study is to elucidate factors associated with lower readability, especially those that are actionable on the part of the investigators or regulating institutional review boards (IRB). The outcome measure employed in this study is the Flesch-Kincaid Reading Grade Level (RGL), a common measure used in previous studies involving the readability of ICFs and their templates. The primary variables in this study are the sponsor of the study (National Cancer Institute (NCI) vs. Commercial/Investigator Initiated), the clinical trial phase of the study (I, II, III, II/III, III, IV), and the year in which the IRB approved the study (2010-2015). The objective of this study is to identify the relationship if any between study sponsor, phase, and approval year by the IRB and the study’s main ICF readability as measured by the RGL score.

Methods

Using a comprehensive list of one institution’s IRB approved oncology studies obtained through the IRB Electronic database, studies approved after 1/1/2010 and before 3/1/2015 were included in the initial list of eligible studies. Studies without an approved main ICF were excluded from the analysis. Studies with ICFs which did not contain a HIPAA section were also excluded from the analysis.

The primary variable, study sponsor, was dichotomized as sponsored by NCI or by a private entity defined as either an independent investigator or a commercial body. The secondary variable, study phase, was also dichotomized into two groups (I, II/III, II/III, III, IV) and the initial approval date of the ICF was used for the third variable, approval year.

The HIPAA section which is a standardized section added to each ICF regardless of sponsor, phase, or year of approval was removed prior to readability scoring. This was done to obtain a more accurate study specific measure of readability of the ICF for each study.

Similar to previous studies looking at readability scores of ICFs, the RGL score for each study’s ICF was calculated using text analysis tools provided in Microsoft Word 2011. RGL scores were compared between sponsor, study phase, and approval year for all studies with complete data on all variables using a multiple linear regression model.

Results

Of the 166 oncology studies approved by the IRB between 1/1/2010 and 3/1/2015, 143 were included in the initial data analysis. Twenty-two studies were excluded due to lack of an approved or main ICF. One study was excluded due to lack of a HIPAA section within the approved ICF, and 33 studies were excluded from the final analysis to missing data on one of the variables.

A multiple regression model (n = 110) was used was used using SAS software. The mean RGL scores were found to be significantly different when comparing sponsor groups and controlling for study phase and approval year (p-value < 0.0001). Also of significance, the mean RGL score for approval years 2011 and 2014 were found to be different from the mean RGL score of approval year 2010 when controlling for sponsor group and study phase (p-values = 0.0279 and 0.0399, respectively). Mean RGL scores for study phase and all other approval years were not found to be significantly different.

Discussion

The ICF development process typically includes 3 stages. First, there is usually an ICF template provided by a study sponsor, which must be used by local study staff. Second, local study staff must draft an ICF for IRB submission based on the ICF template provided by the sponsor. Generally an IRB will have its own ICF template, which must be synthesized with the sponsor template to include institution required language and preferred formatting. Third, there is often back and forth negotiations between the study sponsor and the local study staff in order to finalize ICF wording that is acceptable to both parties as well as approvable by the IRB.

This study measured one institution’s Oncology ICF readability scores and found a strong association (p < 0.0001) between study sponsor and ICF readability indicating that stage 1 above is a primary factor in ICF readability. NCI sponsored studies were found to have a RGL score nearly one whole grade level lower than private entity sponsored studies. Given the results of this study, a systematic approach within Oncology departments which targets improving the readability of ICFs which are privately sponsored could be beneficial in improving the readability of future ICFs.

While the ICFs of NCI sponsored studies were found to have a lower RGL score than those of privately sponsored studies, both were found to have RGL scores over the recommended eighth grade reading level. Therefore, the ICFs of all studies could benefit from the results of this study to encourage improved readability as a focus at all three of the above stages of ICF development.

There were several limitations in conducting this study that prevents the results being generalized to all research departments nationwide. First, this study only looked at ICFs written in English, so the results of this study do not reflect those ICFs currently in use at this institution which are written in other common languages such as Spanish. Second, this study did not take into account the role of the CRC and other local study staff during ICF development and negotiations with study sponsor and IRB. Third, this study only looked at studies from the Oncology Department and therefore the results may not be generalizable to other departments. Lastly, this study only looked at one institution in the Gulf South, so the results may not be generalizable to other institutions within or outside of this region.

Despite these limitations, this study had several strengths which include the large sample of studies included in the analysis from 2010 to 2015. This is the first study that has looked at the readability of Oncology ICFs in relationship to sponsor type, study phase, and study approval year.

References


Note: This study was deemed to be not human subject research as it only involved consent forms and not human subjects.