Clinical Research Study Coordinators' Training - A Deep Dive into Informed Consent: An Assessment of CRC Knowledge

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ABSTRACT

Clinical research coordinators (CRC) need continuous trainings in Human Protection Research, Ethics, and Regulatory Updates. This training workshop was designed for clinical study coordinators but was open to clinical research personnel at all levels. The workshop was held to provide a deep dive and continuing education about informed consent processes. We promoted the in-person workshop through the communication systems within member institutions. This in-person session was critical due to regulatory changes that had occurred as a result of the COVID pandemic. A detailed flyer was emailed using a list serve to all levels of clinical researchers. A registration form created on the REDCap platform provided a link for registration and the means to capture data. A follow-up email reminder was sent every two weeks. The training was organized in modules, each of which included didactic materials, hands-on training, case studies, and teach-back sessions. A Jeopardy game was conducted at the end of the workshop to reiterate the information that was covered during the training. A survey pertinent to regulatory and informed consent processes was developed. The survey, which contained a 15-item questionnaire, was provided to the attendees pre- and post-workshop to assess knowledge gained. A total of 42 people registered, and 30 people attended the event. Of the 30 attendees, 21 (70%) were study coordinators. Of the study coordinators, 8 (38%) had been a study coordinator for less than 1 year, 2 (10%) had been a study coordinator for 1-2 years, 4 (19%) had been a study coordinator for 3-4 years, and 7 (33%) had been a study coordinator for more than 4 years. Other attendees included investigators, administrators, nurses, and regulatory personnel. Many of the questions that focused on consent elements were answered correctly by the participants prior to the workshop. Conversely, only 14% initially knew the correct Human Health Service regulations for the Common Rule. This number increased to 33% post-workshop. Additionally, knowledge of the required reading grade level language on informed consent forms (ICFs) improved from 71% pre- to 100% post- workshop. All responses to the survey questionnaire items were anonymous and were not connected in any way. Thus, a person-by-person comparison (pre- vs. post- workshop) was not able to be performed. Overall, there was a significant improvement in the number of correct responses to the questionnaire items post-workshop. The improvement shows that study coordinators benefit from continuous review of informed consent form elements. This includes a discussion on the information required in ICFs, government agencies that oversee clinical trials, and the reading grade levels for ICFs. Of importance, study coordinators need further guidance on where to find specific federal regulations for informed consent processes. Responses to a 6-Month Follow-Up also reflect these findings. As such, it may be beneficial to hold clinical research coordinator training workshops every 6-12 months to ensure knowledge is retained and correct practices are implemented.

BACKGROUND

The duties of clinical research coordinators (CRCs) make it necessary for them to require continuous trainings in Human Protection Research, Ethics, and Regulatory updates. As such, we designed a training workshop with the goal of educating CRCs about the different aspects of the ICF. To assess the level of knowledge among CRCs when it comes to the ICF process, we conducted pre-and post-workshop surveys. To evaluate information retention, we sent out the same survey to attendees six months after the workshop.

The training workshop was designed for clinical study coordinators, although it was open to clinical research personnel at all levels.

MATERIALS & METHODS

We promoted the in-person workshop through the communication systems within our hub's member clinical institutions (Georgetown University, Howard University, MedStar Health Research Institute, and the Washington DC Veterans Affairs Medical Center). Using a list serve, a detailed flyer and the registration link were emailed to all levels of clinical researchers. The registration form was created via the RedCap platform. To maximize outreach efforts, we sent follow-up reminder emails every two weeks.

The workshop was organized into modules, each of which included didactic materials, hands-on training, case studies, and teach-back sessions. A Jeopardy game was conducted at the end of the workshop to reiterate and reinforce the information that was covered during the training.

A survey pertinent to regulatory and informed consent processes was developed. The survey, which consisted of 15 question items, was provided to the attendees pre-and post-workshop to assess knowledge gained. The survey contained a mix of multiple choice, fill-in-the-blank, and true/false questions.

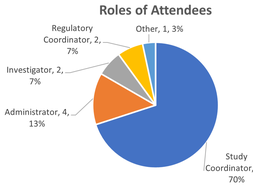
6 months after the training workshop, we sent the same 15-question items to attendees to determine whether the knowledge gained through the training session was retained.

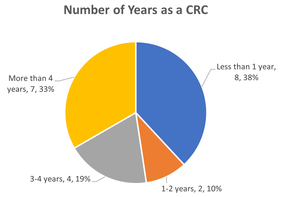
SURVEY QUESTIONS

1. What are the Health and Human Services (HHS) current regulations for the protection of human subjects' research?
2. What does GHUCCTS stand for?
3. What is an e-consent?
4. What agency governs clinical trials of devices and drugs?
5. At what reading grade level should informed consents be written?
6. The informed consent needs to list a 24-hour number that study participants can contact in case of an emergency. TRUE or FALSE
7. The informed consent does not need to list the name of the Principal Investigator since the role of Principal Investigator can change during the course of the study. TRUE or FALSE
8. Even if the participant is unable to read or comprehend the information stated in the informed consent, it is acceptable for the study coordinator to enroll them in the study. TRUE or FALSE
9. The study coordinator does not have to thoroughly explain the contents of the informed consent before the participant signs it because the participant will receive a copy of the informed consent that they can read at their leisure. TRUE or FALSE
10. A participant must completely sign and date the informed consent form before they can participate in ANY study activities. TRUE or FALSE
11. It is preferred to have an informed consent form that is brief and lacking information because participants are not likely to read it if it is too long. TRUE or FALSE
12. The informed consent form must list the location of the site in which study activities will be conducted. TRUE or FALSE
13. The participant does not need to be given a copy of the signed consent form. TRUE or FALSE
14. If the participant fails to date the informed consent form but correctly signs it, the participant cannot proceed with study activities until it is corrected. TRUE or FALSE
15. It is the responsibility of the PI and/or study coordinator to ensure that the informed consent form is properly completed before the study participant proceeds with study activities. TRUE or FALSE

RESULTS

42 clinical research personnel registered for the training workshop, but only 30 registrants attended the event.

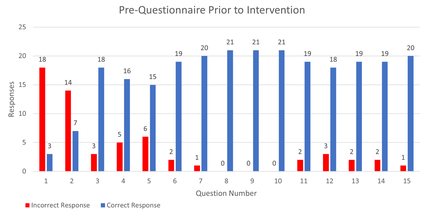


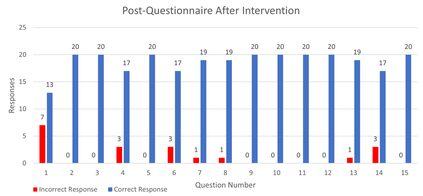


Questions (Q) that focused on consent elements (Q3, 5-15) were predominantly answered correctly by participants prior to the workshop. Interestingly, 91% answered Q6 correctly pre-workshop, but this decreased to 85% correct post-workshop. Additionally, knowledge of the required reading grade level language on informed consent forms (Q5) improved from 71% pre- to 100% post-workshop.

Moreover, only 14% knew the correct Human Health Service regulations for the Common Rule (Q1) pre-workshop, but it increased to 65% post-workshop. 76% knew the correct agency that governs clinical trials (Q4) pre-workshop, and this increased to 85% post-workshop.

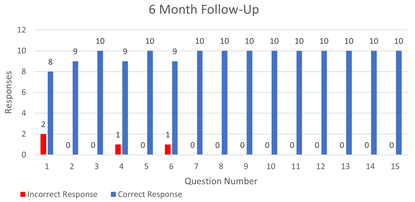
There were 21 responses to the pre- questionnaire and 20 responses to the post-questionnaire, and while the respondents to both pre- and post- questionnaires were largely the same individuals, we were unable to capture individual knowledge gained because the questionnaires were not linked.





RESULTS (Continued)

Of the 10 responses to the 6-month follow-up survey (assessing retention of workshop information), 80% knew the correct Human Health Service regulations for the Common Rule – an improvement compared to 14% correct pre-workshop and 65% correct post-workshop. Q4 and Q6 (90% correct) also showed slight improvements during follow-up compared to post-workshop responses (85% correct).



LIMITATIONS

All responses to the survey questionnaire items were anonymous. The pre-post responses were not matched as to assess individual knowledge gained (i.e., T1-T2 analysis not conducted). About half of the initial respondents responded to the 6-month follow-up survey.

DISCUSSION

Overall, significant improvements were seen in the numbers of correct responses post-workshop. A comparison of pre-workshop vs. post-workshop responses shows that CRCs benefit from continuous review of ICF elements. This includes a discussion on the information required in all ICFs (i.e., 24-hour number listed), government agencies that oversee clinical trials, and the reading grade levels for ICFs.

Responses to the 6-month follow-up showed even more improvement compared to the post-workshop questionnaire. The improvements demonstrate that the majority of the information discussed during the workshop was retained. However, we need to further stress the importance of the 24-hour emergency contact listed on ICFs. These aspects of ICFs need to be reviewed frequently to ensure appropriate conduct of the ICF process. Also, CRCs need further guidance on where to find specific federal regulations.

It is beneficial to conduct CRC training workshops every 6-12 months to ensure that knowledge and information discussed during these sessions is adequately retained and implemented. Such workshops will continue to be open to all research team members (not limited to CRCs) because everyone can benefit from refresher trainings.

In future workshops, we plan to incorporate more case studies to enhance interactive discussions so that both novice and experienced research individuals can learn from each other's experiences.

REFERENCES

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- Belmont Report - *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* : https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- CITI Program Comprehensive CRC: https://about.citiprogram.org/course/crc-foundations-and-advanced/

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