Medical Communications and Writing for Patients

Editorial

Dear all,

As I'm sure you are aware, EMWA's Special Interest Groups (SIGs) have been hard at work hosting "Meet & Share" sessions throughout the year. These sessions aim to encourage open and honest discussion between medical writers on a variety of topics (usually identified ahead of the session). It's an invaluable resource for EMWA members, since we are lucky enough to have a lot of very experienced and talented medical writers in our community, so I strongly encourage you to look out for the Meet & Share sessions and get involved!

The Communicating with the Public SIG's latest Meet & Share session delved into the issues surrounding the roles and responsibilities of ethics committees in the UK and US. This was the first of a two-part series on "Protecting the public from undue harm during research studies", and was developed in response to a need to educate medical writers about how ethics committees function and how effective medical writing can really make a difference to an ethics committee submission. It's a fascinating area of medical writing, and is often overlooked, so it's a great honour to have presentations from Alison Rapley and Art Gertel, who are both hugely experienced in this area, and were able to compare and contrast the UK and US ways of doing things. A special thanks to the SIG's ever-trusty and talented reporter Sam Rappaz, for another engaging and very readable article.

SECTION EDITOR

Lisa Chamberlain James
lisa@trilogywriting.com

The session could have continued for a lot longer than we had, so I encourage you all to join Part 2!

As 2023 draws to a close, I hope that it has been a good year for you all, and that you and your loved ones remain healthy and happy. Enjoy the upcoming Christmas break – may you dodge the snowballs, and may Santa be kind.

See you in 2024!

Bestest,
Lisa

Meet and Share session on protecting the public from undue harm during research studies: A report

Sampoorna Rappaz
Academic Writing Tutor, University of Bern
Independent medical writer and editor
sampoorna.satheesha@gmail.com

doi: 10.56012/qxky3990

In September 2023, the Communicating with the Public Special Interest Group (SIG) held a Meet and Share session on the roles and responsibilities of ethics committees in the UK and the US, the first of a two-part series on "Protecting the public from undue harm during research studies". The purpose of the series is to educate medical writers about how ethics committees function and how effective medical writing can add value to a submission to an ethics committee. Freelance medical writing trainer and consultant Alison Rapley gave an introduction to Research Ethics Committees (RECs), which review submissions for studies in the UK. She was followed by Art Gertel (principal consultant of MedSciCom LLC), who introduced the US-centric ethics review committees, the Institutional Review Boards (IRBs). The session was moderated by SIG Chair Lisa Chamberlain James.

The ethics committees' main objectives, irrespective of where they function, is to protect the public by:

1. Thoroughly reviewing the background information of and justification for a proposed research study that is provided to them by the investigators, funders, or sponsors; and
2. Ensuring that participants can truly understand what they are agreeing to when they sign an Informed Consent Form (ICF).

Effective and ethical writing of study documents helps ethics committees fulfil their objectives, making the approval process easier and leading to a useful and successful study. Below are highlights of the information presented.

Research Ethics Committees

How are RECs organised?

There are 60 RECs currently active in the UK, co-ordinated by the Health Research Authority. The REC is made up of volunteers. Each REC must have a minimum of 7 members and can have up to 18 members; the average membership size is about 8 to 10. One-third of the membership must be "lay" and the rest "expert". Lay members are currently defined as those who are not registered healthcare professionals and whose primary professional interest is not in clinical research. (This means that medical writers are considered lay members, despite having extensive specialist knowledge!) Expert members include specialists, such as doctors, hospital medical staff, other healthcare professionals, statisticians with expertise in clinical research, and others. While there is no legal requirement for the membership to be culturally diverse or to include members with varied perspectives, (such as patient advocates, research staff), an REC functions best when its membership includes people who are representative of the participant community and general population.

What are the roles of the REC?

The REC has two main roles:

1. Balance the rights, safety, and wellbeing of research participants against the wishes of researchers. At times, researchers seek information that may not be ethically justified, so the REC steps in on behalf of potential participants to make researchers reassess their goals.
2. Ensure "true" informed consent has been sought. The REC will check if the potential participants know everything that will happen to them during the course of the study and what that means to their health and wellbeing.

What does the REC review?

RECs review the following aspects of a study:

1. **Social or scientific value:** Does the research support the study objectives? Is the study necessary? Will the outcomes be useful?
2. **Recruitment:** Is the participant selection fair? Is any community excluded? Are there any barriers for participation, such as language, technology? Why is a certain vulnerable community (such as children, pregnant people, people with cognitive problems) being recruited, or not being recruited?
3. **Informed consent process:** Is the information adequate and complete?
4. **Risk-benefit ratio:** What are the anticipated benefits? What are the risks and have they been clearly explained? Are adverse effects explained using clear, accurate language?
5. **Care and protection of participants:** Is the welfare and dignity of the participants being prioritised? Will study expenses be paid? Is the language coercive? Will the participants be provided with the trial results?
6. **Suitability of applicant and supporting staff:** Will the trial be conducted by capable and competent people?
7. **Suitability of supporting information:** Is the language in the Patient Information Sheet, posters, participant diary, etc., appropriate and understandable? (Ms Rapley highlighted that this is a common objection raised by RECs as the language is often not appropriate.)

Institutional Review Boards

How are IRBs organised?

An IRB is a committee that reviews and approves research in accordance with US federal regulations and institutional policies. The Common Rule (45 CFR 46, Subpart A, effective from 2018)[1] requires that an IRB reviews and approves certain studies involving human participants. Only "non-exempt" studies require an IRB review, and some "exempt" categories require a "limited IRB review". Ethics review in the US is two-tiered: Submission is reviewed by an IRB that is affiliated with the institution whose staff will conduct the study or where the study will be conducted and by an independent IRB that is non-affiliated. An independent IRB review is required; however, an institutional IRB review could be done in addition to the independent review. The purpose of an independent review is to mitigate bias and corruption; the review is done upon payment and these IRBs work on a for-profit business model.

An IRB must have at least 5 members. The membership has varied background and qualifications; however, as in the UK, there are no legally required diversity quotas that need to be met. There are central IRBs that provide a national perspective and local IRBs that provide a local one, and these perspectives may not dovetail. Single-gender memberships and single-profession membership are not allowed. There is no guidance yet on how to classify people who are undergoing a gender transition. Each IRB must consist of at least one member who is not in any other way affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. A member who has a conflict of interest must not participate in the review. When an IRB's membership does not have the expertise to conduct a thorough review, it can bring in an expert as a non-voting member.

What are the roles of the IRB?

The overarching role of the IRB is to protect the study participants. IRBs are heavily regulated; they follow the FDA's Criteria for IRB Approval of Research (21 CFR §56.111).[2] Their review is continuous. To approve the research, IRBs must determine in its initial review that all of the following criteria are met:

1. Participants give their time and put their wellbeing at risk for benefits that may not be realised. Hence, the risks to participants must be minimised and be reasonable in relation to the anticipated benefits and the importance of resulting knowledge.
2. Selection of participants must be equitable, and thus must consider language, socio-economic, and technological barriers to participation.
3. Informed consent must be sought and appropriately documented. The ICF must be understandable.
4. Research plan must include a data monitoring plan to record data signals on risk.
5. Privacy of the participants must be protected.
6. Vulnerable participants must be protected by installing appropriate safeguards.

When new information is available that affects the IRB's prior finding on the research, the IRB conducts a continuing review in accordance with the above criteria (21 CFR §812.64).

What does the IRB review?

IRBs review the following materials:

- Protocol and informed consent document(s) in use at the study site and any proposed modifications to these documents
- Summary of amendments to the research since the last review
- Investigator's Brochure, including any modifications
- New and relevant information, especially about the risks associated with the research. This could be gathered from various sources, such as new information on competitors' products, newly described relevant syndromes, and other published and unpublished sources.
- Relevant regulatory actions that could affect safety and risk
- Other significant information, such as reports from data monitoring committees
- Summary of withdrawal of participants from the research since last review
- Summary of complaints by the participants about the research since last review

Ethics review of decentralised clinical trials

During the peak of the coronavirus disease 2019 (COVID-19) pandemic, regulatory authorities and trial sponsors were motivated to establish and follow decentralised trial processes to mitigate virus spread. Although presently only used in a few cases, decentralised clinical trials (DCTs) have many advantages that could make them the "new normal".[3] A DCT, also called remote clinical trial, is defined as: "A clinical trial utilising technology, processes, and/or services that create the opportunity to reduce or eliminate the need for participants to physically visit a traditional research site."[4] So, when participants do not visit a site what information does the ethics committee review?

> Ethics committees scrutinise all patient-facing information for understandability.

Good Clinical Practice (GCP) guidelines (ICH E6 R2)[5] require the written information that is provided to patients to be submitted for ethical review. This would include the electronic ICF and screenshots of the patient-facing screen. But, if adaptive design is used, the information on the screen can change from one day to the next. Dr Gertel noted that if every possible screen had to be reviewed it would greatly increase the effort and time required by ethics committees to adequately review all material. So the initial library of screenshots submitted for review may not be the full library. Dr Gertel confirmed that the IRBs are not given a software demonstration, only screenshots. As for RECs, Ms Rapley said that they are lagging behind in how to carefully review DCTs. Both agreed that screenshots are not adequate to understand the patient perspective. Ms Rapley said that RECs are sometimes sent weblinks to help them experience the platform, but there is no clear guidance on how to submit such information.

Both the speakers highlighted the questions raised by ethics committees concerning equity and digital literacy when reviewing DCTs, such as "Will the participants be provided with a device?", "Do the participants know how to use the device?", "Can they access the internet?", "Do they have an option to use a facility to access the program?". Ms Rapley suggested that it is good practice to provide options so as to not inadvertently hinder participation.

Problems facing ethics boards

The speakers agreed that one of the main problems faced by ethics committees is diversity, both when considering study recruitment and its own membership. The participant population should be a representative one, but participation is hindered by cultural norms and historical injustices that have eroded trust in clinical research for some communities. Also, it is difficult to balance benefit and risk when it comes to deciding if vulnerable participants should be recruited. While these issues would benefit from having an ethics committee that represents the participant community, organising such a committee has proved difficult.

Not enough people are volunteering to join ethics committees as it requires a large time commitment, a good understanding of clinical research and related issues, and possibly some qualifications. Being a member of an ethics committee entails a lot of reading and may require travel although most of the committee meetings are now virtual for the sake of convenience. Even so, as Ms Rapley pointed out, membership mainly consists of White, older people, who have the time and luxury to participate. Also, as there are no legal requirements in the UK or in the US to have an adequately diverse membership, there is less motivation to persuade people from underrepresented communities to volunteer.

An attendee raised the question of whether ethics committees can offer remuneration to its members. Dr Chamberlain James, who had been an REC member, said that ethics committees run on a small budget so they cannot offer compensation. Dr Gertel explained that ethics committees need to be careful about receiving and making payments as it may lead to a conflict of interest. People participate in ethics committees "out of the goodness of their heart", according to Ms Rapley. She noted that a REC's chair and vice chair do get a small annual payment as they have a lot more work than the others.

Role of medical writers in ethics review

Writing in plain language

Medical writers must use plain language principles[6] when developing written materials for patients. Ethics committees scrutinise all patient-facing information for understandability. A plain language glossary is a needed resource when translating complex scientific terms into the more understandable and familiar terms that a study participant will encounter. A widely recommended plain language glossary is the

Multi-Regional Clinical Trials (MRCT) Center Clinical Research Glossary,[7] which is now being expanded and maintained in collaboration with Clinical Data Interchange Standards Consortium (CDISC) as one of its global clinical research standards.[8] Dr Gertel, who along with Dr Chamberlain James is one of the current workgroup members for the MRCT glossary, gave an overview of how the glossary was developed. He spoke about the extended discussions the workgroup had on defining "plain"; the problem is that what is "plain" for one person may not be for another. He advised medical writers who wish to write in plain language to let go of some precision while embracing accuracy and understandability. What is important is to not be misunderstood. A glossary is especially useful to achieve these goals, as it ensures that terms are used accurately and consistently across all communications. Giving patients information in plain language empowers them to participate in decision making, which leads to them making informed decisions.

Becoming an ethics reviewer

Speakers strongly encouraged medical writers to join ethics committees. Medical writers would bring valuable insight to the review. They understand clinical research and know the ethical principles that govern it. Those who are trained in plain language writing are especially suited to reviewing the appropriateness of written materials for patients. Medical writers in turn would benefit professionally as they would learn the intricacies of how an ethics review is conducted, what documentation is needed, and how discussions take shape. You can learn more about ethical practices in the EMWA workshop "DDF17: Ethical considerations in clinical trials".

If you live in the UK, you can join an REC. More details can be found on the Health Research Authority website: www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/.

Thank you

The Communicating with the Public SIG thanks the speakers and all those who attended the Meet & Share session. The SIG welcomes you to join the next Meet & Share (the second part of the series), which will cover sections of an ethics submission in the UK that require writing for the public, specifically what RECs want to see in the Lay Summary, the Application Form and participant facing documents such as the Patient Information Sheet, ICF, recruitment posters, etc.

Acknowledgements

I would like to thank Lisa Chamberlain James, Art Gertel, and Alison Rapley for their helpful review of this article.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. US Code of Federal Regulations. Title 45. Part 46. Subpart A – Basic HHS policy for protection of human research subjects. 19 January 2017. Available from: https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46
2. US Code of Federal Regulations. Title 21. Part 56. Subpart C. §56.111 Criteria for IRB approval of research. Available from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-C/section-56.111
3. Alemayehu D, Hemmings R, Natarajan K, Roychoudhury S. Perspectives on virtual (remote) clinical trials as the "new normal" to accelerate drug development. Clin Pharmacol Ther. 2022;111(2):373–81. doi:10.1002/cpt.2248.
4. Decentralized Trials & Research Alliance (DTRA). Glossary of Industry Terms and Definitions [cited 2023 Oct 03]. Available from: https://www.dtra.org/glossary
5. ICH guideline for good clinical practice E6(R2). Step 5. 01 December 2016. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf
6. Plain Language Association International (PLAIN). What is plain language? [cited 2023 Oct 04] Available from: https://plainlanguagenetwork.org/plain-language/what-is-plain-language/
7. Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Clinical Research Glossary. Available from: https://mrctcenter.org/clinical-research-glossary/glossary-words/
8. CDISC. CDISC and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital (MRCT Center) collaborate to offer plain language clinical research definitions as a new standard 24 Mar 2023 [cited 2023 Oct 04]. Available from: https://www.cdisc.org/news/cdisc-and-multi-regional-clinical-trials-center-brigham-and-womens-hospital-mrct-center

Author information

Sampoorna Rappaz, PhD, teaches scientific and plain language writing at the University of Bern, Switzerland. She also works as an independent medical writer and editor. She is a supporting member of the Medical Communications SIG and the Communicating with the Public SIG.

ORCiD: https://orcid.org/0000-0002-7330-7586

Google Scholar: https://scholar.google.com/citations?user=E9nHIqkAAAAJ&hl=en