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Issue 28, October 2017

Non-Compliance Report: Lapses in Subject Recruitment Procedures

Here we feature two case studies on non-compliances submitted to the Domain Specific Review Board (DSRB). These non-compliances involved lapses in subject recruitment procedures which resulted in subject complaints.

Case Study 1

Study site ABC utilises a database to store contact details of volunteers who have previously given consent to be kept informed of future clinical studies that might be of interest to them. Identifiers kept in this database included the names and email addresses of these volunteers.

Recently, a study team member at site ABC sent out a routine recruitment email to the volunteers. The usual practice was to enter the volunteers' email addresses under the "bcc" field. On this occasion however, all volunteers' email addresses were accidentally entered into the "cc" list. As a result, the email addresses and potential identities of all the volunteers in the email were inadvertently revealed and made visible to others in the email chain.

When the study site staff realised the error, they attempted to recall the email and offered an apology to the volunteers concerned. In the recall process, the same mistake was repeated; volunteers' email addresses were again entered into the "cc" field instead of the "bcc" list. Similarly, a second attempt was made to recall the email. In addition, the recall email also contained responses from a few volunteers, including a particular volunteer's contact information.

Subsequently, a few individuals contacted the site to express their unhappiness and one volunteer requested to have his data permanently removed from the database. Study site ABC promptly notified the DSRB and the Personal Data Protection Commission of this incident.

To prevent future recurrences, site ABC has committed to retraining its staff on handling recruitment emails and putting a process in place to check all drafted emails before dissemination.

This incident underscores the ease with which personal data can be erroneously circulated and highlights the importance of vigilance to protect the identities of research volunteers The lesson learnt here is that when recruiting subjects, study sites must ensure that all study staff are adequately trained on subject recruitment processes and appropriate management of research volunteers' personal and study data. All subjects and study data, as well as study-related documents should be safeguarded and kept confidential at all times.

References

- *PCR SOP 501-C02 Subject Recruitment and Screening*
- *PCR SOP 501-B08 Data Collection and Handling*
- *PCR SOP 501-C05 Unanticipated Problems Involving Risks to Subjects or Others*
- *PCR SOP 501-B04 Interactions with Domain Specific Review Board*

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Case Study 2

Recently, DSRB received a subject complaint. The subject, Ah Hua, had contracted a urinary tract infection during her stay in a hospital and her lab samples had been sent for further testing. After she was discharged, Ah Hua received a phone call from a study team member to recruit her into a research study as her lab results had fulfilled the study's inclusion criteria.

Prior to this call, the primary physician had not contacted Ah Hua to either explain her diagnosis or inform her about the research study. Emotionally, it was unsettling for Ah Hua to have the study team member disclose the diagnosis, particularly when the latter was unable to address her concerns regarding the diagnosis.

This incident was later determined by DSRB as a serious non-compliance, as the subject's permission was not obtained prior to direct contact by study team members.

After investigation, various factors were identified that could have attributed to this incident.

- Firstly, the study team member might have approached the wrong primary physician before contacting Ah Hua.
- Secondly, the primary physician might have mistakenly assumed that he had explained the study to Ah Hua and referred Ah Hua to the study team.
- Thirdly, the study team member might have mistakenly assumed that the primary physician had already explained the study to Ah Hua, and proceeded to contact her.

The lesson learnt here is that it is important that study teams should work in synergy with the primary physicians tasked with referring patients to the study team. Study teams should remind primary physicians to explain the research study to their patients before referring them to study teams. Study team members should only initiate contact with the subjects after subjects have been duly informed about the study and have consented to being approached.

References

- Personal Data Protection Commission Singapore. Advisory Guidelines for the Healthcare Sector. 28 March 2017. Accessed from: https://www.pdpc.gov.sg/docs/default-source/public-consultation-4---education-healthcare-social-services-photography-submissions/advisory-guidelines-for-the-healthcare-sector-(28-mar-2017).pdf?sfvrsn=2
- PCR SOP 501-C02 Subject Recruitment and Screening

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