Chicken Soup for the Busy Coordinator

NHG Health

JANUARY 2026

Protecting Research and Participant Data: Best Practices

About Data Protection

Personal information includes any identifiable details about an individual, such as personal data, medical conditions, and information gathered during healthcare or research.

Protecting the privacy and confidentiality of this information means securely managing this information to protect individuals' confidentiality.

For more information on the types of identifiable data, click **here**.

Scenario #1: Case of "Hidden" Identifiers

1. Clinical Research Coordinator (CRC) X removed visible identifiers and uploaded several imaging files onto a vendor's central imaging platform for independent tumour assessment.

2. A few days later, the vendor notified the study team that the metadata still contained personal data such as patient's name, date of birth, age etc.

3. This results in a research data breach that requires immediate notification to the IRB, institution data protection authorities and sponsor (where applicable). Subject's confidentiality is compromised.

Reminder: In the event of a research data breach, researchers should report the breach in the accordance to their institution policy (e.g., NHG Health Research Data Policy).

Tips on removing personal information from imaging file copies to be sent to vendor

1. Right click to select 'Properties'
2. Select 'Details' tab
3. Select 'Remove properties and personal information'
4. Send to vendor

Please consult with your institutional Data Protection Office (DPO) on the appropriate steps to remove "hidden" identifiers (where applicable).

Scenario #2: Audible traces.. Don't give them away!

1. CRC Y is working on a research study which requires audio recordings from participants.

2. These audio recordings are to be uploaded to the sponsor's portal for transcription by an external vendor.

What does the CRC need to do?

Audio recordings are considered identifiable data. When collected and shared for the purpose of the research, the study team should:

- **1. Ensure IRB has approved this study procedure**
- **2. Consult with respective institutional DPO to ensure compliance with institutional practices.**
- **3. Ensure there is a signed service agreement with any third-party vendors to protect institutional interests and participant's rights.**

Where de-identification is required, it is best practice to have a 2nd pair of eyes to countercheck if the document or files are redacted accurately.

References: NHG Health Investigator's Manual Chapter 2.3: The Personal Data and Protection Act and Chapter 7: Study Conduct
PCR SOP 501-B05 Documentation and 501-B08 Data Collection and Handling
1601-B01 NHG Health Research Data Policy
HealthTech Instruction Manual

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