Humber Health Partnership

Use of Microsoft Copilot Within Research for the Review of Study Documentation SOP

Document control use only	
Reference	R&D GCP SOP 23
Directorate / Care Group	Research & Development
Version	Version 1
Result of last review	Not Applicable 1st Version
Issue date	21/05/2026

Author / Owner Use Only	
Group or Trust specific document	HHP (Group) – Hull University Teaching Hospitals NHS Trust and Northern Lincolnshire and Goole NHS Foundation Trust (Group)
Date approved by owner (for minor changes only outside committee)	N/A
Date approved	22/05/2026
Approving body	R&D Sponsor Oversight Group / RDI Committee
Next full review date	22/05/2029
Lead Director	Professor Sathyapalan – R&D Director James Illingworth – R&D Manager
Document type	Standard Operating Procedure
Author / Contact	Leanne Cox – R&D QA Manager
Key words	GCP, SOPs, R&D, Research & Development, AI Tool

Distribution:	HHP R&D internet Click on GCP SOPs for HHP-sponsored CTIMPs https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

When this document is viewed as a paper copy, the reader is responsible for checking that it is the most recent version.
Printed copies valid only if separately controlled

AI update statement: This Standard Operating Procedure (SOP) was reviewed and updated with the assistance of a HHP approved Artificial Intelligence (AI) tool. The AI output was used to support drafting and editing only; all content was verified, amended where required, and approved by the document owner/author in accordance with the Trust's document control and governance requirements.

Working in partnership:
Hull University Teaching Hospitals NHS Trust
Northern Lincolnshire and Goole NHS Foundation Trust

United by Compassion:
Driving for Excellence

Authorized by		Sign	Date
R&D Director	Professor Thozhukat Sathyapalan	DocuSigned by: 4C017C4E8DDA44B...	21/5/2026
R&D Manager	James Illingworth	DocuSigned by: 3DDA0F96873F430...	22/5/2026

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, (21/05/2026)	L. Cox	First SOP approved by R&D Committee on

This page details the version history and the main changes made for each new version.

Contents List

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs.

Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HHPR&D GCP SOPs are available at:

https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps

1. Purpose

This SOP describes the controlled and appropriate use of Microsoft Copilot within HHP-sponsored research for the purpose of supporting the review of study documentation, including but not limited to:

- Clinical Trial Protocols
- Participant Information Sheets (PIS)
- Informed Consent Forms (ICF)
- Investigator Brochures
- Study Manuals and Plans
- Regulatory submissions and correspondence

The SOP ensures that use of Copilot is compliant with ICH GCP E6(R3), MHRA expectations, HRA guidance, and HHP Information Governance (IG) requirements.

2. Scope

This SOP applies to:

- HHP R&D staff
- HHP Sponsor Representatives
- Chief Investigators and Delegated Research Teams
- Clinical Trials Pharmacy (where applicable)
- External research staff adopting HHP SOPs

This SOP covers use of Copilot as a supportive tool only. It does not replace human review, sponsor oversight, or regulatory responsibility.

3. Responsibilities

3.1 Sponsor (HHP – HUTH / NLaG)

- Ensures Copilot use is risk-proportionate and compliant with IG and GCP.
- Ensures staff are trained in this SOP.
- Ensures no confidential, commercially sensitive or identifiable participant data is entered into Copilot.

3.2 Chief Investigator / Delegated Research Team

- Use Copilot only for permitted activities defined in this SOP.
- Maintain responsibility for accuracy, completeness, and regulatory compliance of study documents.
- Always document Copilot use

3.3 R&D QA

- Request and receive confirmation from CI/PI that they are happy for the study review to be supported using the group approved AI Tool (Copilot)
- Provide guidance on appropriate use In line with the approvals that are in place from the HHP IG and IT Departments.
- Review compliance during monitoring, audit, and inspection preparation.
- Update this SOP in line with regulatory changes.

4. Definitions

Microsoft Copilot
A Microsoft-integrated AI assistant used to support summarisation, comparison, clarity checking, and quality review of text-based documents.

AI-Assisted Review
Use of Copilot to support human review by generating summaries, identifying inconsistencies, or suggesting improvements.

Prohibited Content
Any identifiable participant data, confidential sponsor/vendor information, or unpublished intellectual property not authorised for external processing.

5. Procedure

5.1 Permitted Uses of Copilot in Research

Copilot may be used for non-confidential, non-identifiable, non-commercially sensitive content, including:

- Summarising sections of a protocol
- Checking clarity, readability, or consistency of PIS/ICF wording
- Comparing versions of documents for changes
- Identifying ambiguous or unclear phrasing
- Supporting preparation of sponsor-level oversight documentation
- Drafting training materials or checklists
- Generating regulatory comparison tables (e.g., E6(R2) vs E6(R3))
- Supporting quality-by-design review activities

Copilot may be used to support, but not replace:

- Sponsor review
- CI scientific review
- Regulatory compliance checks
- Risk assessment

- Ethical considerations

5.2 Prohibited Uses

Copilot must not be used for:

- Entering identifiable participant data
- Entering screening logs, enrolment logs, or clinical data
- Entering confidential sponsor/vendor documents not authorised for external processing
- Drafting or approving final versions of regulatory submissions
- Making decisions that impact participant safety, eligibility, or data integrity

Copilot must not be used as:

- A substitute for human judgement
- A substitute for GCP-mandated review processes
- A decision-making tool for clinical or regulatory determinations

5.3 Information Governance Requirements

Before using Copilot, staff must:

1. Ensure the document contains no identifiable data.
2. Ensure the content is appropriate for processing under HHP IG rules.
3. Use only HHP - approved Microsoft accounts and devices.
4. Ensure permission has been obtained from the Investigator for the use of Copilot to support the study documentation review.
5. Avoid uploading full protocols or documents containing confidential third-party content unless consent has been explicitly sort (including consent from Funders, vendors and third parties as appropriate).

5.4 How to Use Copilot for Document Review

Staff may use Copilot to:

- Request concise summaries of detailed documents or sections
- Ask for readability improvements
- Ask for identification of inconsistencies
- Request comparison between two text excerpts
- Generate training explanations for complex regulatory concepts
- Produce sponsor-level justifications or oversight wording

All outputs must be:

- Reviewed by a human
- Checked for accuracy
- Checked for regulatory alignment
- Documented where required (see Section 5.6)

5.5 Quality and GCP Considerations

Copilot outputs must be:

- Treated as draft suggestions
- Verified against the protocol, regulations, and SOPs
- Not accepted without human review

ICH E6(R3) emphasises:

- Critical thinking
- Proportionate oversight
- Human accountability

Copilot supports these principles but does not replace them.

5.6 Documentation Requirements

Copilot use must be documented when:

- Used during Sponsor review of key documents during the RDI QA Verification process (protocol, PIS/ICF)
- Used to support risk assessment or oversight activities
- Used to generate content included in the TMF or Sponsor Oversight File

Documentation may include:

- A note in the review log
- Acknowledgement on the Sponsor QA Verification Form Review that the Investigator is happy for AI to be used in the review of the study documentation.
- A statement in the oversight report
- A comment in the document version history

Example wording:

“AI-assisted review (Microsoft Copilot) used to support summarisation and clarity checking. All outputs reviewed and verified by Sponsor Representative.”

6. Training Requirements

All staff using Copilot must complete:

- Training on this SOP
- HHP IG and Data Security training
- GCP training (where applicable)
- Local induction on appropriate AI use

7. Deviations

Any deviation from this SOP must be:

- Reported to R&D QA
- Documented in the Deviation Log
- Assessed for impact on data integrity, participant safety, or confidentiality
- Subject to CAPA where required

8. Related Documents

- HHP GCP SOPs (current versions)
- HHP Information Governance Policies
- ICH E6(R3)
- MHRA GCP Guide (2026)
- HRA Guidance on Use of AI in Research
- RDI SOPs for Document Control, Risk Assessment, and Sponsor Oversight

9. Implementation

- Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs.

10. Appendices

10.1. NHS.net Connect Guardrails for M365 Copilot

Use Copilot only within approved organisational configurations. Apply sensitivity labels and do not paste identifiable data into prompts unless your organisation's IG process explicitly permits it.

- Ensure prerequisites such as appropriate licensing, MFA, and managed devices are in place before enabling M365 Copilot.
- Use sensitivity labels to restrict Copilot access to sensitive content; label content before storage/sharing.
- Treat Copilot output as a draft; maintain human review and file audit-ready evidence of decisions.
- Prefer summarisation and structuring prompts; request citations to source sections and explicit assumptions.

10.2. 'Do / Don't' cheat sheet and Prompts

• DO: Ask Copilot to reference protocol section numbers and document versions.

• DO: Use Copilot to generate action trackers, checklists, and filing manifests.

• DO: Keep prompts inside your tenant and labelled repositories.

Examples:

- "Summarise this section of the protocol focusing on safety reporting."
- "Identify any unclear or ambiguous statements in this PIS."
- "Compare these two versions of the consent form and list changes."
- "Explain the difference between substantial and non-substantial amendments."

• DON'T: Use Copilot for clinical decision-making or participant care decisions.

• DON'T: Paste identifiable patient data into prompts unless explicitly approved and controlled.

• DON'T: Submit Copilot-generated regulatory documents without competent review.

Examples:

- "Review this participant's screening data."
- "Check this SAE narrative for accuracy."
- "Assess eligibility for this patient."
- "Upload this confidential vendor document and summarise it."