

PROTOCOL WAIVERS

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1 Introduction

- 1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).
- 1.2 A Protocol Waiver may be defined as the sponsor approval for a prospective protocol deviation. Such deviations can often involve (but may not be limited to) the active recruitment to a study of one or more participants who do not meet the inclusion/exclusion criteria as detailed in the study protocol.
- 1.3 In the context of possible prospective approval of a protocol deviation by a sponsor, the following regulatory statements should be considered:
 - I. Regulation 29 of Statutory Instrument 2025:538 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 - via altering regulation 29 as stated in The Medicines for Human Use (Clinical Trials) Regulations, (SI 2004 No. 1031) - stipulates that, subject to regulation 30 (relating to urgent safety measures) "no person shall conduct a clinical trial otherwise than in accordance with the protocol relating to that trial, as may be modified from time to time in accordance with regulations 20 to 22C".
 - II. According to ICH-GCP E6(R3) (ICH Guideline for Good Clinical Practice):
 - Section 2.5.2: The investigator should comply with the protocol;
 - Section 2.5.4 The investigator should follow the protocol and deviate only where necessary to eliminate an immediate hazard(s) to the trial participants.

2 Scope

- 2.1 This Policy applies to all researchers participating in or running research studies sponsored by NHSL and/or the UoE.

- 2.2 This Policy also applies to all members of ACCORD who manage, co-ordinate or advise on clinical research sponsored by NHSL and/or the UoE.

3 Policy

- 3.1 It is ACCORD policy that sponsor approval will NOT be granted for a prospective protocol deviation and, as such, Protocol Waivers will not be approved for studies sponsored by NHSL and/or the UoE.
- 3.2 Investigators must not use systems of prospectively approving protocol deviations, in order to effectively widen the scope of a protocol. Protocol design must be appropriate to the populations required and if the protocol design is defective, the protocol must be amended.
- 3.3 It should be noted that GCP does permit deviations from the protocol without prior agreement when necessary to eliminate immediate hazards to the participants. However, such deviations are not prospectively approved by the sponsor and do not therefore result in a Protocol Waiver.

4 References and related documents

- The Medicines for Human Use (Clinical Trials) Regulations, (SI 2004 No. 1031).
- Statutory Instrument 2025:538 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
- ICH-GCP E6(R3) Guidelines

5 Document History

Version Number	Effective Date	Reason for Change
1.0	01 MAR 2013	First version of new document
2.0	18 APR 2016	New Policy template and title.
3.0	04 JUL 2018	Update to the ICH-GCP E6(R2) Guidelines
4.0	31 JUL 2020	Minor changes to reference citations in the SOP text.
5.0	11 OCT 2024	Broken link removed from section 1.3. New ACCORD branding added.
6.0	06 OCT 2026	Update regulatory and guidance citations.

6 Approvals

Sign	Date
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<i>Heather Charles</i> Heather Charles (22-Sep-2026 09:47:45 GMT+1) APPROVED: Heather Charles, Deputy R&D Director, NHS Lothian, ACCORD	22-Sep-2026
<i>Gavin Robertson</i> Gavin Robertson (22-Sep-2026 11:01:45 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	22-Sep-2026

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Final Audit Report

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