TAYSIDE MEDICAL SCIENCE CENTRE POLICY

CO-ENROLMENT

POLICY NUMBER:	TASC POLICY 011 v4
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EFFECTIVE DATE:	04 March 2024
REVIEW DATE:	04 March 2026

1. Co-enrolment Definition

Co-enrolment is the process of consenting participants into more than one research project either concurrently or sequentially.

2. Background

There are no direct statements concerning co-enrolment in the Medicines for Human Use (Clinical Trials) Act SI 2004/1031 (as amended) - transposed from EU Directive 2001/20/EC.

Tayside Medical Science Centre (TASC) requires careful consideration of the impacting factors of co-enrolment, including the retention of patients' freedom of informed choice before this may be sanctioned for studies sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST).

3. Purpose of the Policy

To describe the factors to be considered to ensure that safety, rights and wellbeing of research subjects are protected and respected and to ensure reliability, transparency and robustness of trial results.

4. Applicability

Relevant to all personnel who facilitate, manage, co-ordinate or advise on clinical healthcare research sponsored by UoD and/or NHST where individual participant consent is received.

5. Communication of Co-Enrolment Plans

Clinical Trial of Investigative Medicinal Products (CTIMP)

Co-enrolment may be approved in a NHST/UoD sponsored CTIMP.
This would follow the Sponsor's risk assessment evidencing compliance with the Relevant Safety Information for all Investigational Medicinal Products (IMP) to be administered as well as the relevant Protocols.

Co-enrolment must be approved by the Research Ethics Committees (RECs), Medicine and Healthcare products Regulatory Agency (MHRA) and other approving bodies as relevant to the studies concerned.

NonCTIMP

Consideration shall be given on a case-by-case basis for nonCTIMPs sponsored by UoD and/or NHST.

- Details of co-enrolment may entail identifying specific studies with which co-enrolment will be permitted, alternatively generic circumstances may be described.
- Co-enrolment may be permitted, for example, in studies that involve only the collection of questionnaire data or blood samples.
- Where follow-up is required, consideration will need to be given to evaluate the impact on outcome measures, especially where an intervention is involved.

6. Assessment of Co-enrolment Plans

In all cases of co-enrolment, planned or accidental (i.e. where a participant has not declared their participation in another study at informed consent), the safety of the participant, the interventions involved, participant burden and impact on study endpoints must be considered.

7. Interventional Trials

Sponsor representatives should consider the opinion of a Clinical Pharmacologist, (independent to the studies where possible) in relation to Pharmacokinetics and Pharmacodynamics of both CTIMPs involved and the likelihood of clinically meaningful interactions.

Similar expertise should be considered for other non-pharmaceutical interventions such as diagnostic, radiation, device, or surgical intervention.

8. Participant burden

Consideration must be given to the burden on participants of self-reporting activities including the risk that participants may become non-compliant due the frequency and complexity of questionnaires.

9. Study Design and Outcomes

Consideration must be given as to whether co-enrolment is likely to influence the outcome measures and endpoints of the trials or compromise the overall study design and delivery.

For observational studies, consideration must be given to determine any impact that responses given for one study may impact on the other.

The opinion of the study statisticians is recommended to determine if outcomes could be affected.

It is recommended that co-enrolment proposals be provided to the Trial Steering Committee and/or Data Monitoring Committees for each study to consider:

- Participant safety
- Biological and scientific rationale
- The introduction of bias
- Participant burden
- Compatibility of Protocols i.e. inclusion/exclusion criteria and prohibited medications
- Recruitment plans
- Logistical and organisational issues.

10. Safeguards/Risk

Co-enrolment will not be permitted where one of the studies concerned has been classified as First-in-Human or Phase 1 Trial.

Failure to declare cases of co-enrolment may result in the Clinical Trial Liability Insurance being invalid.

11. Clinical Trials of an Investigational Medicinal Product (CTIMP)

Enrolment of a participant in the interventional phase of more than one CTIMP is not recommended.

In exceptional circumstances and following risk assessment involving Sponsor representatives for the trials concerned, a co-enrolment agreement may be required, and legal implications be fully described.

1. CTIMP-CTIMP. In cases where participants are in follow-up (data collection only), co-enrolment may be permitted. In such cases the CTIMP-CTIMP Co-enrolment Checklist shall be completed by Research Governance.
2. NonCTIMP-CTIMP. Participants who are active in the interventional phase of a nonCTIMP may be co-enrolled in a CTIMP. In such cases the nonCTIMP-CTIMP Co-enrolment Checklist shall be completed by Research Governance.
3. NonCTIMP-NonCTIMP co-enrolment does not typically require formal documentation.

12. Co-Enrolment Agreement

In exceptional circumstances, for example at the request of the Insurer, proposals for co-enrolment between active CTIMPs may require to be captured by written,

authorised agreement between the Sponsoring organisations and the Chief Investigators for each trial.

The Co-Enrolment Agreement will be drafted by the UoD Legal team and the finalised agreement signed by the Sponsors and the CIs of the CTIMPs concerned.

13. Accidental Co-enrolment

Accidental co-enrolment may be identified at any time, including data cleaning stage and by routinely asking participants if they are in another study.

The Sponsor representatives (Research Governance) require that these be notified through the Breach reporting system to determine the appropriate course of action.

DOCUMENT HISTORY

History prior to 2021 is in the archived Policies available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
3	Patricia Burns (Senior Research Governance Manager)	04/03/2022	Sections 5 and 9 rewritten to provide clarity.
4	Patricia Burns (Senior Research Governance Manager)	04/03/2024	Scheduled review, no changes required.

APPROVALS

Approved by:	Date:
Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	26/02/2024
Approved by:	**Date:**
Professor Russell Petty, R&D Director, NHS Tayside	29/02/2024