UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 26

Clinical Research Study Activation, Location/Site Selection and Initiation

Version:	6.0
Approval Date:	08/07/2026
Effective Date:	22/07/2026
Review Date:	21/07/2028
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Revision Chronology:	**Effective date:**	**Reason for change:**
Version 6.0	22 July 2026	Triggered review: Request via the Feasibility Working Group to update to include current terminology and best practice. New template used and text reviewed to improve flow. Reference to support EDI considerations
Version 5.0	07 Jul 2025	Multiple minor changes throughout document. Addition of further information relating to processes in the devolved nations.
Version 4.0	17 May 2023	Biennial Review: change to new format. Minor amends to text.
Version 3.0	18 February 2021	Biennial Review: change to new format. Minor amends to text.
Version 2.2	8 January 2019	Updates to guidance and additions to process text. Clarification regarding evidence of qualifications and training. Clarification between Green light for commencing the study and green light for individual recruitment sites.
Version 2.1	3 May 2016	Minor changes to text. Change to new format
Version 2.0	9 December 2013	Addition of text to include site selection and change of title.
Version 1.1	5 March 2012	Biennial review: Format change to comply with SOP 1.
Biennial review February 2010		No changes.
Version 1.0	29th February 2008	

UNIVERSITY OF WARWICK

CONTENTS

1 Purpose and Scope

To describe the procedure for permissions required for a University of Warwick clinical research study to commence (Green Light), the process for selection of suitable trial delivery locations and delivering training to ensure all investigators and local teams have the capacity to participate in the study and are prepared to commence recruitment.

This SOP is applicable to all UoW staff involved in the set-up of a new research study or new research sites.

Staff working on non-Warwick sponsored studies must ensure they are compliant with the external sponsor requirements.

The terms *location* or *site* may be used interchangeably in this text dependent upon context.

2 Acronyms

ARSAC	Administration of Radioactive Substances Advisory Committee
CI	Chief Investigator
CRF	Case Report Form
CV	Curriculum Vitae
GCP	Good Clinical Practice
EDC	Electronic Data Capture
ETC	Excess Treatment Costs
HCRW	Health Care Research Wales
HRA	Heath Research Authority
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
ISF	Investigator Site File
LIP	Local Information Pack
MHRA	Medicines and Healthcare products Regulatory Agency
mNCA	Model Non-Commercial Agreement
MRC	Medical Research Council
NIHR	National Institute for Health and Care Research
NRS PCC	NHS Research Scotland Permissions Co-ordinating Centre
OID	Organisation Information Document
PI	Principal Investigator
PIC	Participant Identification Centre
QA	Quality Assurance
RDN	Research Delivery Network
REC	Research Ethics Committee
R&D	Research & Development
R&IS	Research & Impact Services
SIV	Site Initiation Visit
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
TM/C	Trial Manager/Coordinator
TMF	Trial Master File

TMG	Trial Management Group
WCTU	Warwick Clinical Trials Unit

3 Definitions

Clinical study	A research study involving human volunteers (participants) that is intended to add to medical knowledge.
Recruitment site/location	A place at which research study participants are enrolled into a study.
PIC	NHS/HSC organisations that identify potential participants for a study and refer them to recruiting centres (e.g., through search of patient databases). PICs have no other involvement in the research.
PI	The person responsible for the conduct of a research study at any location.

4 Background

ICH GCP E6R3 outlines the expectation that sponsors will have arrangements in place to ensure selection of suitable locations and training of investigators.

The sponsor of a clinical trial is responsible for authorising a study to commence.

In studies involving multiple locations, strong communication between the coordinating centre and study locations, especially new or inexperienced ones, is essential to ensure readiness, appropriate documentation is maintained, and timely recruitment of participants.

Any delegated responsibilities must be clearly defined and documented.

5 Responsibilities

Sponsor	• Ensure all required approvals are in place to commence the study • Sign Green Light form (**T18**) to commence protocol activities • Review and sign localised mNCA agreement for each location • Approve amendments for the addition of new trial delivery locations.
CI	• Support TM/C to identify recruitment locations • Attend SIVs where possible to provide clinical/scientific information • Delegate study management tasks to appropriately trained and qualified individuals. • Sign Green Light form
TM/TC/Research Facilitators	• Identify potential recruitment locations • Develop and distribute feasibility questionnaires • Prepare the Site Initiation Visit (SIV) presentation • Arrange SIV meetings • Deliver SIV presentation • Prepare essential documents to obtain green light from sponsors • Ensure site activation checklist is completed (C09) • Communicate with research locations to activate to recruitment • Where applicable, work with external study sponsors to ensure appropriate 'green lighting' of the study including agreement on required documentation
TMG	• Support TM/C with site selection

	• Review/assess feasibility questionnaires • Document decisions on site selection in meeting minutes
QA Team	• Review study-specific green light form • Review site initiation presentation slides (and significant updates)

6 When

This should be considered at the early stages of setting up a new study, although additional sites may be identified after recruitment has commenced.

The permissions required for a clinical research study to commence (Green Light) form (**T18**) must be completed prior to any protocol required activities commencing and requires Sponsor approval.

Individual site activation checklists (**C09**) must be completed before site initiation confirmation letters/emails are sent to activate a site.

7 How

7.1 Activation of a clinical research study

It is essential that the following documentation is in place at the coordinating centre and the Sponsor has given their written approval for recruitment to begin:

1. Written agreement for sponsorship or co-sponsorship of the trial	See SOP 3
2. CI Signed and dated acceptance of responsibilities	Contact R&IS sponsorship@warwick.ac.uk for Warwick Sponsored Studies
3. Evidence of financial arrangements	
4. Appropriate insurance to cover the whole study period	See SOP 10
5. Written REC/HRA approval	See SOP 5 (part 1)
6. Unconditional written approval from MHRA (if applicable)	See SOP 5 (part 2)
7. Any other relevant third-party contracts/agreements	

Documentation of RCT activation should be via a green light form, a template is available to adapt to suit the needs of the study (**T18**). It is also good practice to use this for all clinical research studies. The Sponsor should have oversight of its contents and final approval to commence activity. External sponsors may require the study coordination centre to use the sponsor's own green light form, but it should be ensured that the requirements are consistent with the minimum requirements of the Warwick form.

For Warwick-Sponsored research, QA should review the form and its associated documents in preparation for a request for approval submitted to sponsorship@warwick.ac.uk.

The CI must delegate study management tasks to appropriately trained and qualified individuals and retain oversight of this throughout the study. A template coordination centre delegation log can be located on the WCTU website (**T23**).

7.2 Site/location selection

Effective feasibility assessment supports the achievement of recruitment targets while enhancing data quality and ensuring the inclusion of diverse and representative participant populations. Identification may involve:

- contacting investigators with previous experience in the therapeutic area
- recommendations by colleagues
- publications
- professional groups
- conferences
- NIHR RDNs
- NIHR Reporting Platform
- NIHR Scoping Locations for Research tool
- Feasibility Service - NHS England Digital [NB Funding is required for this]

An 'expression of interest' form can be used. This usually outlines the study, summarises the participant population, study timelines and the expectations.

A feasibility questionnaire (see **T71**) should be sent to assess suitability to participate in a study against the protocol requirements. It may be appropriate to arrange an online meeting with the site R&D, PI, and any other members of staff who will be involved with study related activities to assess feasibility. T71 provides a list of questions to consider.

Feasibility responses should be reviewed to identify potential issues with regards to capability and capacity and any limitations posed by the study. Responses may need consideration by the TMG to assess the site's capacity and capability to recruit, and where there is any area of concern regarding a site's ability to participate, this should be taken into account in the decision to continue. Guidance may be sought from other study teams who have experience of working with a site.

When a site is rejected at the feasibility stage, this should be sensitively discussed with the Principal Investigator and local team. It may be possible to support the site and to reconsider the decision if the local concerns are resolved.

Any decision making around the inclusion or rejection of sites at the feasibility stage should be clearly documented in TMG meeting minutes or alternative location in the TMF, along with the completed feasibility documentation.

Reserve investigator sites or PICs should be considered as part of proactive study planning (so that the study may be extended to these sites if recruitment issues arise).

Once it is confirmed that the site is suitable and all necessary considerations have been addressed, site setup can begin.

7.3 Site set up, initiation & activation

7.3.1 Timelines: 150-day metric

This measures the time from initial regulatory submission to First Participant First Visit (FPFV). The study-level metric is calculated centrally using the first participating location to achieve the relevant milestone(s) and is not applied as an individual performance metric for each participating location.

Participating locations are subject to location-level study set-up and recruitment expectations. Locations should complete study set-up within 60 calendar days and recruit the first participant within 30 calendar days of being confirmed as Ready to Start (sponsor green light), in accordance with national guidance. These timelines shall be considered during feasibility assessment, resource planning, contracting, and study delivery activities.

Study teams should be aware that these timelines may impact the anticipated opening date of new sites and should factor this into feasibility assessments, recruitment projections and site activation planning.

Where delays to site opening may impact study delivery or recruitment targets, the impact should be recorded and these risks documented, and regularly reviewed by the TMG, with mitigation actions agreed and recorded.

7.3.2 Ethical approval:

All clinical research studies will gain ethical and site level approvals via the HRA approval system.

If recruitment is planned in Scotland or Northern Ireland and where the lead R&D nation is England, additional approvals may be required. A separate form may be required for submission to a Scottish REC. Where a submission to a Scottish REC is required, please check the available guidance for applicants with regards to patient-facing documentation – changes to terminology used may be needed before a submission would be considered for approval.

7.3.3 Local Information Pack (LIP):

The local information pack provides a consistent package to support study set-up and delivery across the UK and should be used for all studies with participating NHS/HSC organisations. It contains the OID and the SoECAT and should be submitted via email to the following once the Sponsor has received the Initial Assessment Letter or Approval Letter from HRA/HCRW:

- PI*
- Local research staff/study coordinators*
- NHS R&D office*
- Lead RDN contact.

Full details of the content of the LIP can be found here: IRAS Help - Preparing & submitting applications - Site specific information as well as the email template for sharing local information packs with NHS/HSC organisations.

Full details of the requirements for site set up can be found via the IRAS website 'Help' section.

** Where the study has an NHS/HSC Sponsor, and the Sponsor and the participating NHS/HSC organisation are the same, there is no need for the NHS/HSC Sponsor to share the UK Local Information Pack with itself.*

7.3.3.1 Organisation Information Document (OID):

The OID is used for non-commercial funded research which details NHS/HSC site activities. The OID details information that will be common to all participating organisations that are undertaking the same activities within the study. Different OIDs may be generated for a single study where institutions are undertaking differing activities (e.g. intervention-only; recruitment-only). For Warwick Sponsored studies, the OID must be approved by the Sponsor before sharing with sites.

For help, guidance and suggested pack and email templates for England and Wales visit:

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/ or for Scottish and Northern Irish sites visit:

https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Sharing

Guidance for research in Scotland is available here:

https://www.nhsresearchscotland.org.uk/services/uk-wide-working/enter-title-here

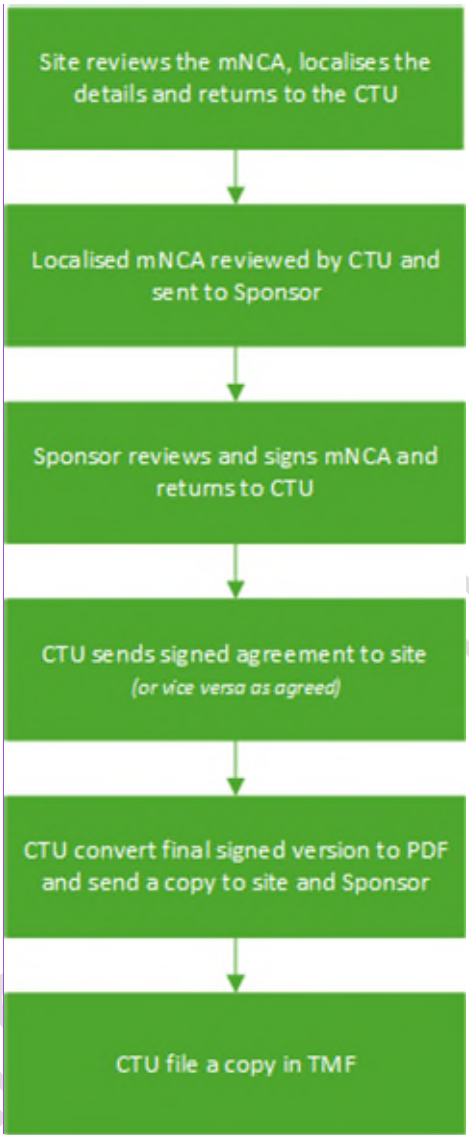
7.3.3.2 Schedule of Events Cost Attribution Template (SoECAT):

The SoECAT form is used to attribute research costs. However, is not intended primarily as a study costing tool. It details the ETCs.

7.3.4 Contract/Agreement

The study sponsor (or their delegate) will commence negotiations with each location once their involvement is confirmed and provide contracts/agreements to exchange. For non-commercial studies, the model Non-Commercial Agreement (mNCA) will be used. The intended agreement and any potential amendments must be approved by the HRA prior to use in site set-up.

Completion of a model Non-Commercial Agreement



N.B. For non-commercial studies that are not clinical trials or clinical investigations, the agreed final Organisation Information Document (taken together with the documents in the Local Information Pack and the exchange of correspondence) forms the agreement between the participating NHS/HSC organisation and the Sponsor, once confirmed by the participating NHS/HSC organisation. For all other non-commercial studies, it is expected that the mNCA is used as the agreement (although the localised OID is still needed in the LIP, for the information it contains).

For University of Warwick sponsored studies, siteagreements@warwick.ac.uk should be used as a contact point to request review and signature on all site agreements. If the site uses DocuSign for contract execution, the site will be required to initiate the approval process.

7.3.5 Investigator Site File (ISF)

Once the site agreement is in place or nearing completion, the ISF may be sent to sites. The ISF can be paper or electronic. A template ISF index is available (**T08**).

7.3.6 Capacity and Capability

The R&D offices at each site will assess and confirm their capacity and capability (England and Wales) or local approval (Scotland and Northern Ireland) to undertake the study and recruitment can commence as soon as the contract/agreement has been signed.

As a minimum, the following documentation should be in place at the study site prior to the site being opened to recruitment:

- ✓ Written HRA/HCRW approval (England & Wales)
- ✓ Confirmation of site's capability and capacity
- ✓ Principal Investigator's (PI) CV and evidence of GCP training*
- ✓ Fully executed site agreement signed by all parties
- ✓ Appropriately completed and signed Site Signature and Delegation Log (see **T22** & **G15**)
- ✓ Documented evidence of relevant site training
- ✓ Any additional essential approvals (e.g. MHRA, ARSAC)
- ✓ Essential Honorary Research Contracts or Research Passports (See SOP 38)

**A CV, proportionate GCP and/or relevant training is expected to be in place for all other staff named on the delegation log. Unless deemed necessary, these should be retained at site and made available on request. However, if evidence of specific training is required for any member of staff based on the study risk assessment, this should be sent to the coordinating team to confirm the training has been completed.*

Following site activation, new members of staff working on the study must be added to the site signature & delegation log and a CV and training evidence retained at the site.

Where the lead R&D nation is in England, the following process will need to be followed in order to share the LIP and receive C&C for sites in the following nations;

- For sites in Scotland, the study documentation will need to be submitted to the NRS PCC, which serves as a single point of contact to coordinate NHA research permissions. The lead board will facilitate the sharing of the LIP across relevant participating boards in Scotland, and will reduce the time required to gain NHS permissions at each site. See Permissions | NHS Research Scotland | NHS Research Scotland for further details
- For sites in Northern Ireland, the study documentation will be shared with the HSC R&D Approvals Service automatically using the documentation submitted in IRAS. An HSCNI R&D Approvals Assessor will be assigned to undertake the NI participating nation research governance review of the study. A 'Completion of Northern Ireland Governance Assessment' will then be provided upon approval to proceed with setup with each NI site locally. Please note, the sharing of the LIP and related setup correspondence will still need to be done with each NI site individually in order for setup to commence.

7.3.7 Site initiation

When a site is close to signing the agreement/contract, a mutually convenient time for the initiation should be arranged. The format will depend on the complexity of the study and the experience of the site staff but could include:

- Site visit
- Remote Teams meeting,
- Detailed written instructions
- Presentation at a study launch meeting
- Regularly hosted site initiation drop in sessions

- Online or refresher packages for new members of the team who join after initiation (It is the responsibility of the site PI to ensure any new members of their team have received the relevant training before being added to the delegation log)

For WCTU managed studies, Site Initiation slides should be prepared by the TM/C, and reviewed by the following prior to use:

- the QA team
- CI and/or TMG members (to ensure clarity of message)

A Site Initiation Visit (SIV) Checklist (**C05**) is available to guide expected content of the initiation. Additional site initiation guidance (**G14**) is also available.

The site initiation presentation should be delivered by an appropriate member of the coordinating team. It may be appropriate for different members of staff to deliver different sections according to expertise. It may be appropriate to provide staff with pre-recorded site initiation materials and to supplement this with a brief question and answer session.

Where possible, all members of the study team should attend the site initiation, but it can be done in a number of sessions or parts to accommodate individuals or specialties. Attendance at the site initiation meeting should include:

- PI
- Co-investigators
- Research staff
- Staff who will be involved with study related activities. Additional personnel e.g., pharmacists, radiologists etc. should be included as required.

Attendance of site staff at initiation visits/teleconferences should be recorded (e.g. using an attendee's signature log, attendance log recorded via a Teams meeting, or detailed in the site activation letter) and a copy should be stored in both the TMF and ISF.

7.3.8 Site Activation

A summary of the initiation should be sent to the site and should include:

- who attended and when
- issues discussed
- questions raised with responses showing resolution
- confirmation the site is now ready to start recruitment.

If there is a delay between the initiation meeting and site activation, steps should be taken to ensure the ISF is up to date with current documentation and any additional staff training requirements have been addressed. This may include repeated training if major changes have been made or if new staff members join the team.

Prior to confirming that a site can open to recruitment, the TM/TC must complete the site activation checklist (checklist **C09**) to document that all the required documentation and approvals are in place.

All Site activation confirmation correspondence should be filed in the ISF and a copy filed in the TMF.

The original site signature and delegation log should be stored in the ISF. If an electronic delegation log is used, the process should ensure electronic signatures are attributable to the individual, and filed in the

TMF. Amended/updated versions should be retained alongside the original in the ISF and available for storage in the TMF.

8 Associated Templates and Documents

T08	ISF Index
T18	Permissions Required to Commence a Clinical Research Study (Green Light Form)
T22	Site signature and delegation log
T23	Coordinating centre delegation log
T71	Site Feasibility Questionnaire
C05	SIV presentation checklist
C09	Site activation checklist
G13	Site training and qualification Guidance
G14	SIV guidance
G15	Delegation Log review guidance