**Quality Control Document:**

site initiation checklist

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| --- | --- |
| **Supersedes:** | Site Initiation Checklist (UoB-SMA-QCD-002, v1.0) |
| **Last reviewed:** | Jul 2024 |
| **Next review in:** | 2027, Quarter 3 (Jul-Sep) |

Access the [Clinical Research e-Pathway](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/e-pathway/overview.aspx) for a roadmap to help navigate a complete project lifecycle.

# Purpose

The purpose of this quality control document (QCD) is to provide a site-initiation checklist template to help ensure a site’s full preparedness to conduct a study/trial. This checklist has been designed to document evidence of site-initiation activities undertaken as part of clinical trials of investigational medicinal products (CTIMPs), but it can be adapted for use in other trials or studies. Refer to Investigator Site Management SOP (UoB-SMA-SOP-001) for guidance on site initiation.

# Scope

This is an optional QCD and may be used to support the development of a site initiation checklist in all clinical research.

# Implementation plan

The QCD will be implemented in line with this document’s effective date.

# Stakeholders

Any staff member involved the managing the site initiation process (e.g. trial staff in a clinical trials unit).

# Instructions

1. Save a copy of this QCD.
2. Update the document’s footer details (e.g. with local filename and version number), retaining the document reference information to this QCD.
3. When using this site-initiation checklist, customise it to the specific needs and requirements of your project.
* This may involve adding/adapting/removing entries/sections on the checklist. Any red instructional text should be removed from the document.
* There are various methods that can be used to initiate a site, and this may influence the content of the checklist. For example, a site-initiation visit may be conducted via a telephone conference. Preparation for the site initiation will vary depending on the method employed. Therefore, you may want your checklist to include additional information such as ‘prepare handouts and send to site prior to site-initiation date’.
* If representatives from pharmacy, radiology, laboratories etc. are involved in the study/trial, ensure that representatives from these supporting departments are present for the site initiation. The checklist can be adapted to incorporate this check.
1. Ensure appropriate version control to manage the document when changes are made.
2. When ready, delete these introduction pages (i.e., pages 1 to 4).

## how to complete the form

1. Insert the project, site, PI and visit details as prompted.
2. Complete site initiation attendance log.
3. For each entry on the checklist, provide a ‘Yes/No/Not Applicable’ option for completion. Where required, ‘comments’ can be added in the box at the end of each section.
4. The form signed off by the person conducting the visit.
5. File completed versions of this site initiation checklist in the relevant study/trial master file and site/pharmacy/lab file as applicable.

# Related documents

## Associated QMS documents

UoB-SMA-SOP-001 Investigator Site Management

UoB-SMA-QCD-001 Site Signature and Delegation Log

Access to the full UoB QMS for clinical research is available via the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx).

# Document contributors

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| --- |
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# Document history

## Document version log

The table below summarise the changes made to this document compared to its superseded versions. For information on earlier versions not shown, please email the CRCT (crct@contacts.bham.ac.uk).

| **Version** | **Reason for update** |
| --- | --- |
| 2.0(05-Aug-2024) | * Transferred to new QCD template.
* Additional information provided in the instructions.
* Layout of checklist updated.
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## Document revision log

The table below summaries the reason for any revisions made to the latest version of this document. Revisions do not affect the key content and/or requirements outlined in the document.

| **Revision** | **Reason for revision** | **Editor/reviewer** | **Authoriser** |
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| - | - | - | - |

< start of the template – delete this red text and the pages above when you are ready to use this template >

# Project details

|  |  |
| --- | --- |
| **Name of project** |  |
| **Name of site** |  |
| **Principal investigator** |  |
| **Name of person(s) conducting site initiation** |  |
| **Date(s) of site initiation** |  |
| **Comments** |
|  |

# METHOD SELECTED FOR INITIATION OF SITE

|  |  |
| --- | --- |
| **Method of site initiation** | Visit / Investigator meeting (IM) 1 |[ ]
|  | Web / Teleconference 1 |[ ]
|  | Postal 2 |[ ]
|  | Email 2 |[ ]
| **Justification for method of site initiation selected** |
|  |
| **Please tick to confirm whether the following has been completed** | YES | NO | N/A |
| Site visit log signed (where applicable) |[ ] [ ] [ ]
| **Comments** |
|  |

*1 Please continue to complete the remainder of this document.*

*2 Use the remainder of this document to ensure the training pack provided fulfils all the relevant details.*

# SITE INITIATION ATTENDance log

Documentation must be available to support who took part in the site initiation activities.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of personnel**  | **Project-specifc role** | **Visit** | **Remote** | **Date** |
|  |  |[ ] [ ]   |
|  |  |[ ] [ ]   |
|  |  |[ ] [ ]   |
|  |  |[ ] [ ]   |
|  |  |[ ] [ ]   |
|  |  |[ ] [ ]   |

# Site Initiation checks

Discuss the delegation of roles with the PI and the importance of the delegation of responsibilities/authority log. How PI oversight and involvement will be documented/evidenced in the project should be discussed.

## Project & Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Document version control |[ ] [ ] [ ]
| Protocol overview, study conduct |[ ] [ ] [ ]
| Participant eligibility criteria  |[ ] [ ] [ ]
| Protocol design, rationale, aims of the research |[ ] [ ] [ ]
| Study flow chart (schedule of visits, procedures, timelines)  |[ ] [ ] [ ]
| PI oversight and delegation of duties |[ ] [ ] [ ]
| Enrolment procedure, screening and randomisation  |[ ] [ ] [ ]
| Instructions on testing procedures/treatment plan |[ ] [ ] [ ]
| Adverse event (AE) reporting procedures including timelines for reporting, reporting mechanism and sign-off of completed serious adverse event (SAE) forms  |[ ] [ ] [ ]
| Pregnancy reporting procedures  |[ ] [ ] [ ]
| 24hr emergency contact arrangements |[ ] [ ] [ ]
| Procedure for breaking the blind  |[ ] [ ] [ ]
| Procedure for participant/trial discontinuation and withdrawal |[ ] [ ] [ ]
| Timeframes for expedited reporting to the MHRA and the REC |[ ] [ ] [ ]
| Protocol deviations and notification of Serious Breaches  |[ ] [ ] [ ]
| Procedure for reporting urgent safety measures |[ ] [ ] [ ]
| Email correspondence |[ ] [ ] [ ]
| Informed consent procedure |[ ] [ ] [ ]
| Approved PIS |[ ] [ ] [ ]
| Approved consent form and completion of, including signatory |[ ] [ ] [ ]
| Documentation of consent in patients’ notes and ongoing willingness to continue |[ ] [ ] [ ]
| Notification to GP  |[ ] [ ] [ ]
| Filing consent forms |[ ] [ ] [ ]
| Patient confidentiality |[ ] [ ] [ ]
| **Comments** |
|  |

## Case report forms (CRFS) and data handling

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| CRF completion training and responsibilities for review |[ ] [ ] [ ]
| Highlight important issues |[ ] [ ] [ ]
| Study identifiers, study no. patients’ initials |[ ] [ ] [ ]
| Data entry & correction procedures including self-evident corrections, where appropriate, and documented agreement of this |[ ] [ ] [ ]
| Visit schedule |[ ] [ ] [ ]
| Source documents (highlighting any data items not normally captured in the source data) |[ ] [ ] [ ]
| Documented review of incoming clinical data (e.g. laboratory results, imaging) |[ ] [ ] [ ]
| Filing, storage and security |[ ] [ ] [ ]
| DCF process and return CRFs |[ ] [ ] [ ]
| **Comments** |
|  |

## Investigator site file (ISF)

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Overview of ISF and maintenance |[ ] [ ] [ ]
| Essential documents and amendments |[ ] [ ] [ ]
| Check all documentation is present |[ ] [ ] [ ]
| Site delegation log has been completed |[ ] [ ] [ ]
| Evidence of appropriate qualification and training, including GCP training of all staff listed on the delegation log (e.g. signed and dated CV, GCP certificates) has been filed in the ISF |[ ] [ ] [ ]
| **Comments** |
|  |

## Monitoring, audits and inspection

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Participant recruitment and recruitment targets |[ ] [ ] [ ]
| Site monitoring visit attendance |[ ] [ ] [ ]
| Monitors access to source data including medical notes and CRFs |[ ] [ ] [ ]
| Audit/inspections |[ ] [ ] [ ]
| **Comments** |
|  |

## IMP/Medicine

This section may also be applicable/adapted for use of food and/or nutritional components.

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Product information: supply, handling, receipt, storage, location, labelling |[ ] [ ] [ ]
| Temperature logs and monitoring  |[ ] [ ] [ ]
| IB/ SmPC |[ ] [ ] [ ]
| Dose modification plans: treatment, duration, side effects |[ ] [ ] [ ]
| Dispensing logs and accountability procedures  |[ ] [ ] [ ]
| Recall procedures |[ ] [ ] [ ]
| **Comments** |
|  |

## Site equipment

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Accreditation, calibration and maintenance programmes |[ ] [ ] [ ]
| **Comments** |
|  |

## Archiving

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Responsibilities of the site |[ ] [ ] [ ]
| Timeframes |[ ] [ ] [ ]
| Archiving facilities |[ ] [ ] [ ]
| **Comments** |
|  |

## Training

Project-specific training should be delivered as required. Training may be delivered face to face or using an alternative method such as an online training video, PowerPoint WebEx, postal pack or CD etc.

|  |  |  |  |
| --- | --- | --- | --- |
| **Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff** | YES | NO | N/A |
| Were any training requirements identified during the visit? |[ ] [ ] [ ]
| Was training provided during the visit? |[ ] [ ] [ ]
| **If applicable, training was provided in the areas listed below.** |
|  |
| **Comments** |
|  |

## Other departments

Where other departments are involved in the project (e.g. pharmacy, radiology, laboratories), responsibilities are expected to be discussed. Amend this section accordingly to ensure any protocol-specific requirements are addressed.

|  |
| --- |
| **Have any additional training requirements been identified?** |
|  |
| **Has the site been provided with a file containing the essential documents for the project?** |
|  |
| **Comments** |
|  |

## Follow-up actions (where applicable)

|  |
| --- |
| **Comments** |
|  |

## Sign off by person performing visit

For CTIMPs, prior to site activation, once site initiation is complete, please ensure the regulatory green light has been completed and the site is notified in writing of the authorisation to commence.

|  |  |
| --- | --- |
| **Name:** |  |
| **Signature:** |  |
| **Date (dd-mmm-yyyy):** |  |