UCLH Standard Operating Procedure for on-site external research visits during COVID-19

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For Trust-wide SOPs, please check this is the **latest version of the SOP** on the Joint Research Office website: www.ucl.ac.uk/joint-research-office.

For Departmental SOPs, please check this is the **latest version of the SOP** with the Research Unit QA Manager.

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1	28/10/2020	Initial release of SOP for standardised use across UCLH Contributors: • UCLH Infection Prevention and Control Team (lead: Professor Peter Wilson, acting DIPC) • Cancer Clinical Trials Unit (Celia St Clair, Sajida Adam, Marcin Wolakiewicz) • Clinical Research Facility (Kirsty Adams) • Research Division Leads and Representatives	Mona Hassan, JRO Research Quality & Safety Manager
2	03/12/2020	SOP updated with corrected myUCLH weblinks; close out visits (on-site) have also been included within the remit of this SOP.	Mona Hassan, JRO Research Quality & Safety Manager

ACRONYMS

CCTU	Cancer Clinical Trial Unit
CRF	Clinical Research Facility
CRO	Contract Research Organisation
EHRS	Electronic Health Records System
IMP	Investigational Medicinal Product
IPC	Infection Prevention and Control
JRO	UCLH/UCL Joint Research Office
QA	Quality Assurance
R&D	Research and Development Department /Research Directorate
RN	Research Nurse
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
UCL	University College London
UCLH	University College London NHS Foundation Trust

DEFINITIONS

Monitoring	Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring it is conducted, recorded and reported in accordance with the protocol and any amendments, Sponsor and UCLH SOPs and Policies, the principles of ICH Good Clinical Practice (GCP), and the applicable regulatory requirements.
Audits	A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). The purpose of an audit is to identify if there is a quality system; the system can meet the criteria and the activities and results are in compliance with this system. Audit is not part of quality control and monitoring.
Site Initiation Visits (SIVs)	Site initiation is the process by which the sponsor is assured that the Principal Investigator is sufficiently trained in the following protocol, understands the instructions and the site is ready to commence the study.
Close out Visits	Close-out is defined as the act of ensuring that all clinical trial related activities are appropriately reconciled, recorded, and reported at the end of a trial in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).
Infection Prevention and Control (IPC)	Infection prevention and control (IPC) is a scientific approach and practical solution designed to prevent harm caused by infection to patients and health workers. It is grounded in infectious diseases, epidemiology, social science and health system strengthening

1. BACKGROUND

Suspension to all on-site external research visits due to COVID-19

On 23rd March 2020, all on-site sponsor visits to University College London NHS Foundation Trust (UCLH) were suspended by the Research Directorate in response to the COVID-19 pandemic. This included all monitoring, auditing, site initiation visits (SIVs) and close out visits led by research sponsors, Contract Research Organisations (CROs) or other authorised delegates (hereafter referred to as "research visitors"). UCLH approved remote sponsor activities via Trust-approved methods, including remote access to electronic patient medical records and the use of Microsoft Teams and Circuits for virtual meetings with sponsors. UCLH is also in the unique position in that it has a Trust-wide electronic health records system, Epic, which can be accessed securely and remotely by sponsors via EpicCare Link UCLH, thereby allowing them to complete activities such as source data verification, source document reviews and adverse event reviews (refer to the *UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)* for further information).

The Research Directorate obtained the necessary approvals (MHRA GCP Inspectorate, Information Governance, EHRS SIRO) to allow sponsors to access EpicCare Link remotely for the purpose of monitoring and auditing activities, in line with COVID-19 regulatory guidance, and by signing the "*Remote Monitoring – UCLH Research Monitors Code of Conduct*" document, which sets out the regulatory, R&D, UCLH information Governance and EHRS conditions of use, per study/trial. Where required, patient consent was

also sought to allow sponsors to review their records off-site. This has been successfully implemented and well-utilised; to date, over one hundred remote monitoring requests have been authorised. As research recruitment and activity was also suspended, and the majority of the UCLH research workforce were working from home or redeployed, the interruption was minimal.

Restarting sponsor visits at UCLH

As of 19th June 2020, research activity and recruitment began to resume at UCLH, subject to adequate risk assessments and approvals (*UCLH SOP for Restarting Studies paused due to COVID-19*). Upon consultation with the UCLH Executive Board, the UCLH Infection Prevention and Control (IPC) COVID-19 team, policy, and research departments, the Research Directorate have prepared this SOP outlining what is required for urgent on-site research visits to resume safely across UCLH sites. This guidance is applicable to studies in receipt of 'UCLH Confirmation of Capacity and Capability' and 'Authorisation to Continue Research Activity at UCLH' **only** (i.e. the study has received all necessary NHS and regulatory approvals and approval from the JRO to either continue or restart research activity during COVID-19).

This SOP is applicable to external research visits taking place **in non-clinical areas and rooms only;** external visitors continue to be restricted from clinical areas in UCLH.

- **Clinical Areas**: defined as rooms or areas where patients are seen by nurses or doctors for the purpose of a consultation, assessment or treatment. Examples: wards, clinics, inpatients, outpatients, etc.
- **Non-clinical areas:** defined as rooms or offices that are used by staff only, restricted access, and are not used for the purpose of patient consultations, assessments or treatments. Examples: offices, meeting rooms.

2. PURPOSE

This SOP is for restarting on-site external research visits (e.g. monitoring, auditing, restricted site initiation visits, and close out visits), which has been permitted by the Trust in **non-clinical areas only**, subject to strict IPC measures and risk assessments being implemented by research departments. Study teams are responsible for assessing their capacity in hosting on-site research visits, and are encouraged to prioritise urgent external research visits only, as outlined below:

Prioritisation of on-site research visits:

Visit Type	Essential criteria to be met:
Monitoring visits	Can be conducted on-site when no alternative options are available (i.e. cannot be conducted remotely). E.g.: • study is due to complete (or has started yet no monitoring has been conducted) • there is an imminent database lock • recruitment thresholds have been met • significant protocol deviations or safety events • preparation for upcoming regulatory inspections or sponsor audits.

Audit visits	Will be considered at the discretion of the study team/research department. Triggered, for-cause, or pre-regulatory inspection audits should be prioritised. All other audits (e.g. routine) will be agreed at the discretion of the study team, depending on capacity and non-clinical room availability.
Site Initiation Visits (SIVs)	On-site SIVs will be allowed subject to strict criteria being met, and mixed delivery. Study team meetings and training should be conducted remotely via video-conferencing software such as MS Teams or Circuits (UCLH-approved systems). Only activities deemed essential to conduct on site should proceed, with one sponsor representative allowed on site only. Permitted activities include ensuring UCLH has received the correct ISF and associated documents; ensuring that the required kits/equipment have been received; signing training documentation. Visitors will **not** be allowed to tour or inspect facilities in clinical areas, or hold in person meetings with the study team.
Close out visits	On-site close out visits will be allowed subject to strict criteria being met, and mixed delivery. Close out meetings and discussions should take place remotely via video-conferencing software. Only activities deemed essential to conduct the visit on site should proceed, where there are no alternative options.

This SOP should be read in conjunction with UCLH staff and visitor guidance, which may be subject to change at short notice in response to the evolving pandemic, as well as any related departmental policies.

It is the responsibility of hosting research staff to ensure that all IPC measures are always followed by external research visitors.

SOP exclusions:

- This SOP is not applicable to UCLH pharmacy monitoring visits, which is separately managed by the Pharmacy Clinical Trials team. Please contact uclh.PharmacyCT@nhs.net for further information on arranging these.
- This SOP is not applicable to restarting UCLH research studies; refer to the *UCLH SOP for Restarting Research Studies paused due to COVID-19* for further information.
- This SOP is not applicable to patient visitors (e.g. friends or family). Refer to the *UCLH visitors policy* for further information.
- This SOP is not applicable to UCL premises; refer to UCL policy *Visitors to the UCL Campus during COVID-19 for* further information.

It is the responsibility of the UCLH study team to arrange and coordinate on-site visits with the external research visitors. This SOP outlines the procedure with which all UCLH study teams must comply in order to maintain personal, patient and staff safety whilst hosting on-site research visits with sponsors or their representatives.

3. PROCEDURE

This document outlines the requirements for resuming on-site monitoring and auditing visits safely, and should be read in conjunction with the UCLH *COVID-19 Infection Prevention and Control Framework* SOP and departmental policies (where applicable). This document should also be read in conjunction with the *UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)* and its associated documents. The process for requesting monitor access to EpicCare Link is detailed in the SOP; study teams should ensure all monitors are signing the most up to date version of the "*UCLH Research Visitor EpicCare Link Code of Conduct*" document (Version 2 and subsequent amendments), available on myUCLH Research pages, which has been updated to reflect the responsibilities of external research visitors during COVID-19. **All UCLH staff and visitors are expected to always comply with UCLH social distancing and infection control and prevention measures.**

The general UCLH requirements are:

- Hold all meetings and conversations remotely. Where this is absolutely unavoidable, no more than five people should meet together and must maintain a two-metre distance between each other. It is sensible not to have all members of a team/specialty in the room at the same time
- When on-site, you will need to wear a face mask
- If you need to travel in a lift, please follow the markings on the floor regarding maximum capacity
- Maintain a two-metre distance between yourself and others as you move around. This will help keep each other and UCLH patients safe.
- Carefully plan your route to and from buildings and areas so that you reduce the number of people you meet and avoid touching door handles etc.
- In open plan offices do not sit next to or opposite colleagues. For example, desk work areas should be at least 50 per cent empty
- Wash hands regularly and clean desk areas, with wipes provided, when using a workstation.
- If you have symptoms of COVID-19, have tested positive or are required to isolate due to COVID 19, do not come on-site until safe to do so, per government guidance.

Requirements for resuming on-site research visits:

There are several factors each study team needs to consider before arranging any external research visits:

1)	**Availability of on-site research staff to facilitate external research visits** (e.g. escorting on-site to rooms, provide access to documents for review, book rooms, provide face masks/alcohol wipes/hand sanitiser). I.e. this can only be permitted where the study teams are available on site and cannot be conducted remotely.
2)	**Availability of non-clinical space and access to non-clinical rooms** that can be booked for maximum 4 days (in non-clinical buildings, e.g. 250 Euston Road, Maple House, etc., or non-clinical meeting rooms or offices). Study teams should consult with their divisions for guidance if required, as length of visit times may be shorter. Study teams are responsible for identifying and booking rooms in advance of research visits, and ensuring these room bookings are appropriate sizes for 2m social distancing to be effective, and comply with current Trust policy. IPC recommends that monitors conduct their visit alone in a room, rather than in open shared spaces (where possible).
3)	**External visitors must have or be provided with adequate PPE** e.g. arrive with adequate face masks and alcohol wipes should be provided to visitors during their visit. Visitors should be

	signposted to hand sanitiser stations and handwashing facilities (where not immediately obvious). These must always be used during the visit.
4)	**Sign in/sign out log for identifying and tracking all external research visitors** (e.g. each department has a standard sign in and out sheet/ID checks for external visitors, for track and trace purposes).
5)	**Numbers of on-site research visits conducted at any one time are limited within research departments** (e.g. there aren't multiple research monitors attending on the same day). E.g. shared calendar which identifies when monitoring visits have been arranged.
6)	**Assessment of priority and urgency** e.g. prioritising monitoring visits due to imminent database locks, meeting recruitment thresholds, significant site protocol deviations, and upcoming regulatory inspections.
7)	**Limiting numbers of external research visitors**. Maximum 1 external research visitor allowed per visit.
8)	**Meetings with the PI/study team should continue virtually** (e.g. via MS Teams); on-site activities should be restricted to activities that can't be conducted remotely (e.g. review the paper Investigator Site Files, paper source documents, storage facilities, etc.).
9)	**Sponsors/visitors are responsible for adhering to the timelines set by the UCLH study team**; it is recommended that external research visits are booked at least 2 weeks in advance, to provide adequate time to arrange. If EpicCare Link access is required, this should also be arranged by the UCLH study team with UCLH IT Services minimum 2 weeks in advance of the visit.

Research departments based within clinical areas:
If UCLH study teams or research departments are based within a clinical area, staff are expected to identify suitable non-clinical rooms as an alternative. UCLH room bookings can be located via Outlook's shared calendar function. Study and patient documents should be securely contained and transported to rooms appropriately, with confidentiality always maintained.

All UCLH study teams must ensure locally that the above measures are in place, and that the external research visitors are able to adhere to these requirements. This should be managed via completion of the following **prior** to the visit taking place:

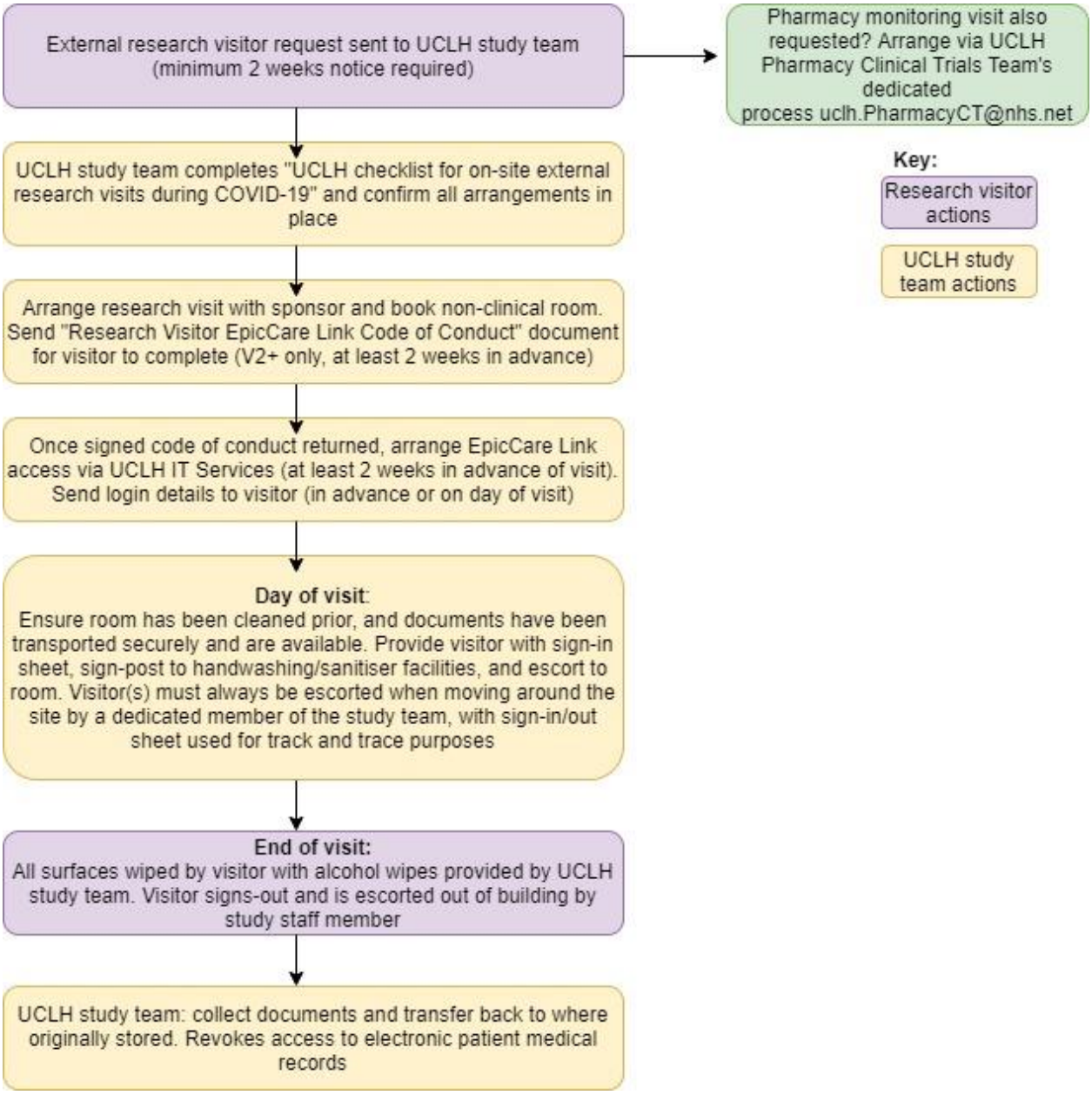
1) 'UCLH checklist for on-site external research visits during COVID-19' (Appendix 1)
2) If access to patient medical records is required: Signing the updated "*Research Visitors EpicCare Link Code of Conduct* (Version 2)"and subsequent amendments document, which includes an additional COVID-19 section. No other/previous codes of conduct will be accepted.

These documents only need to be completed once, per external research visitor. If there are subsequent visits during the pandemic, then the original checklist may be re-used, and the second signature box completed to verify that there have been no changes. If there have been changes, a new form needs to be completed.

External research visits may commence provided these have been completed adequately, and measures have been put in place by the UCLH study team and agreed by the visitor. No separate approval from the JRO will be required provided the requirements of this SOP have been met, however queries or concerns may be directed to research-incidents@ucl.ac.uk.

As a reminder, it is the responsibility of the UCLH study team to ensure that the external research visitor adheres to IPC measures at all times during their visit. On-site access to UCLH will be removed if these measures are not followed adequately.

Diagram 1: Procedure for arranging on-site research visits during COVID-19



4. PUBLICATION & COMMUNICATION

The latest version of this SOP is authorised and published on the myUCLH Research SOP pages. Staff are reminded to frequently check the websites to ensure they are using the latest SOP and associated templates.

The original fully signed master copy is maintained by the JRO Research Quality & Safety Manager.

5. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)	MyUCLH Research Page: https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=13495
2.	External Research Visitors Code of Conduct template (on-site visits)	MyUCLH Research Page: https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=13495
3.	UCLH checklist for on-site external research visits during COVID-19	MyUCLH Research Page: https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=16348

6. REFERENCES

UCLH Infection Prevention and Control (IPC) Framework: Key Principles for Opening Services
UCLH SOP for Restarting Research Studies Paused due to COVID-19
UCL guidance for returning to campus and reopening buildings (including their visitors to UCL policy)
UCLH [patient] visitors' policy
UCLH/UCL Joint Research Office COVID-19 guidance: important updates for researchers
UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)

7. APPENDICES

Appendix 1: *UCLH On-Site External Research Visit during COVID-19 Checklist*
Appendix 2: *UCLH On-Site External Research Visit during COVID-19 Checklist – CCTU only*