Updated Guidance – 11th November 2020

Sponsor Monitoring guidelines:

The UK will be going into a national lockdown effective on the 5th of November 2020. As all non-essential visits will be stopped at the point of the lockdown, monitors will not be permitted to attend a RFL site unless their attendance is **critical** to manage a specific safety issue. Therefore, as of Thursday 5th November all monitoring visits will now take place remotely even if a date has already been booked. Should a sponsor feel that an onsite visit continues to be necessary, requests for attendance should be sent to the relevant Theme Lead Research Nurse. The process for obtaining remote access is covered in Appendix 2 of this guidance document.

Process for booking visits – if deemed critical:

Monitoring visits will take place in a number of possible locations. Only those areas previously approved as locations for monitoring visits can be used. These may change over the time but the current permitted spaces are:

ROYAL FREE

Location	Named Contact for Booking
Academic Oncology (1 monitor)	Nicola Johnson
IIT (preference will be given to pharmacy visits) (1 monitor)	Aarti Nandani for Pharmacy visits Normal booking spreadsheet for IIT for site visits
South House (1 monitor)	Normal booking calendar for HIV
3rd Floor (Renal) (1 monitor)	Vashist Deelchand
Rheumatology except Haemophilia Monitoring LG room 253 (1 monitor)	Stephanie Davey
Haemophilia - Haemophilia centre (1 monitor)	Cecilia Garcia
Room 1/485/2 (Centre for Cell Gene and Tissue Therapeutics) (1 monitor)	Owen Bain
NAC Monitoring room 1 (1 monitor)	Sarah Louth or Angelique Smit
NAC Monitoring room 2 (1 monitor)	Sarah Louth or Angelique Smit
LG/242 (1 monitor)	Francesca Gowing
Child Health G 387 room 4 (1 monitor)	Cynthia Diaba

BARNET

Please contact Claire Singh.

Research staff wishing to arrange monitoring visits must liaise with the named contact for the room booking as detailed in the tables above. Visiting monitors from more than one Pharmaceutical company or Clinical Research Organisation will not be permitted to share a monitoring room on the same day.

Process 24 hours before monitoring visit

The monitor will be requested to complete a wellbeing symptom screening questionnaire (Appendix 1). The study team member responsible for the monitor must ensure that they have received the completed form no more than 24 hours before the scheduled visit. This should be filed in the site file records.

Where the monitor is intending to see both the study team and pharmacy, the study team must forward a copy of the completed symptom questionnaire to pharmacy for their records.

If any answers to the questionnaire are answered as Yes, the visit should be cancelled, and the monitor advised to self-isolate as per national guidance and to arrange a Covid-19 test as per the national screening process.

Process on day of monitoring visit

Monitors will be met by a member of the study team at the main entrance to the hospital. The monitor must ensure that they have a printed copy of the email from the study team confirming the monitoring visit with them.

They will be provided with a mask to wear on entry to the hospital and ask to put this on. The staff member meeting the monitor will also be wearing a mask. They will be asked to verify that the answers that they provide in the questionnaire remain correct. Their temperature will also be taken. If the individual displays any possible signs of Covid or the answers to the well-being questionnaire have changed, the monitoring visit will be cancelled. They will be advised to self-isolate as per national guidance and to arrange a Covid-19 test as per the national screening process. If answers to the wellbeing symptom screening questionnaire

remain unchanged the monitoring visit can proceed as planned and they will be escorted to the monitoring area by the research staff. Wearing of masks is mandatory in the hospital

On arrival to the department the monitor will be asked to continue wearing the mask. As per current Trust policy, masks must be worn at all times. This also applies within Covid secure offices.

Attention must be paid to the following points:

1) Prior to the visit research staff are required to clean the work area to be used by the Monitor with Clinell disinfection wipes. This should be repeated at the end of the visit.

2) Staff should exercise caution when two people are required to review a document together. In this situation masks should always be worn.

3) Sponsor staff are requested not to visit additional hospitals on the day of the visit to a Royal Free London site. They will be asked to confirm this is not the case.

4) At the end of the visit a member of the research staff will accompany the study monitor to the exit of the hospital and ensure the correct exit door is used.

5) At all times current government guidelines should be adhered to.

Other points to consider

- Monitors should be shown where the closest restroom facilities are and consideration should be taken as to whether this will require staff to escort them, ie swipe controlled access.

- Monitors are not authorised to be unescorted while on hospital premises. The allocated research staff should be available to escort them as needed.

- Masks must be worn at all times.

- Should the monitor need to leave the monitoring room for example, for lunch, the work area must be cleaned on their return with Clinell disinfection wipes.

- Where possible, the number of people interacting with the monitor should be kept to a minimum.

- The monitors should have access to EDRM so they can verify records themselves - the study team should be available for queries but should not expect to be in the monitoring room for the length of the visit.

- The canteen is currently only for RFL staff.

Appendix 1:

Well-being symptom screening questionnaire for COVID-19

This screening questionnaire is to be used to screen for symptoms of COVID-19 when sponsor monitors arrive onsite. A temperature is requested for everyone. Checks will be performed daily.

Name of monitor:	
Sponsor Company:	

Do you have any of the following symptoms?

Major criteria	Yes	No
Fever ≥37.8°C Check with infrared thermometer if a raised temperature is recorded check with tympanic thermometer to confirm reading		
New, persistent cough		
New loss of, or change in, normal sense of taste or smell (anosmia)		
New shortness of breath		
New headache plus muscle aches*		

If the individual being tested has one or more of the above symptoms regardless of minor criteria:
- Send home immediately. The individual will be asked to leave the hospital. Research staff should ensure that this can be done safely, e.g – discourage use of public transport.
- Advise to self-isolate and arrange Covid swab test.
  *11.06.20: Both are indicators of possible COVID (ref: ID team); feedback will be monitored regarding these two criteria prior to further updates of the form.

Minor criteria	Yes	No
New hoarseness		
Non-persistent cough		
New nasal discharge or congestion		
New wheeze		
New headache		
New muscle aches		
Nausea or vomiting or diarrhoea		

If monitor has no major criteria symptoms but one or more minor criteria symptoms:
- Advise individual to arrange a COVID test.
- Send home immediately. The individual will be asked to leave the hospital. Research staff should ensure that this can be done safely, e.g – discourage use of public transport.

Person completing the form	
Name	
Signature	
Date	

Appendix 2: Process for Obtaining Access for Remote Access

Remote monitoring is currently the preferred method of monitoring across the RFL sites. There is an agreed two-part process. If a monitor already has an existing RLF user account, proceed to step 2.

Step One: User account

The research staff member should verify the monitor's details through a video Teams meeting.

The monitor should complete the code of conduct form for remote monitoring (RFLRDDOC0070).

The completed code of conduct form should be returned to the research staff member and filed in the site file records.

The research staff member should raise a ticket through the self-service helpdesk requesting a user account and access to the relevant EDRM systems.

The monitor will be required to complete mandatory Information Governance training. This can either be the Trust's standard MAST IG Training module, an appropriate external data security and awareness course or the data security and awareness module level 1 available at https://www.e-lfh.org.uk

As part of their process, IT will seek confirmation from HR that the monitor is permitted to attend and from the study team member that IG training has been completed by the monitor.

Step Two: Remote access account

The research staff member should email the R&D Manager the following information along with a copy of evidence of IG training within the last year.

Name:

Username:

email:

Study:

Role: Monitor

Site: RF or Barnet

Systems that will be accessed:

Department: R&D

Reporting to: Lucy Parker, R&D Manager (study team member xx)

Evidence of IG training within the last year:

Expected length of required access:

The R&D Manager will then raise a ticket through the self-service helpdesk requesting remote access. Once access has been granted, the R&D Manager will email the study team member to inform them that access has been given and also email the monitor the information provided by IT on how to log on.

If the monitor no longer requires access, the Sponsor contact should inform the R&D Manager so that access to RFL systems are removed for that monitor.