Covid-19 Onsite Monitoring Reminders Checklist

Meeting Date: _____
Attendees: _____
Notes:
_____
_____
_____
_____

Confirm Onsite:

- *Can site continue to see patients onsite?*
- *Confirm if any changes to Site Staff working schedules*
- *Confirm if site staff are working remotely*
- *Any changes to site equipment? If yes:*
    - *Update Study Trackers*
    - *Inform Study team (if applicable)*
    - *Add to trip report*
- *Any changes to site personnel? If yes:*
    - *Collect updated Site Delegation of Authority Log*
    - *Collect updated FDA 1572 Form (if applicable),*
    - *Confirm Training Documentation for new site personnel*
    - *Collect Site Personnel documents (CV, ML, IATA, etc.)*
    - *Update CTMS System/ Study Site Staff Trackers with changes*
- *Are there any changes to IP/Lab Kit/ Study Equipment delivery schedule?*

CRA To Do List:

- *Confirm how site is adapting and maintaining patient safety during Covid-19 (temperature checks, PPE, etc.).*
  ***Reminder: Add to trip report*
- *Confirm Backup Site staff is fully trained and have vendor portal access*
- *In case of site closures, confirm backup plan for shipment and delivery of IMP/Laboratory Equipment, etc. to subjects:* _____
- *Site Equipment Calibration Review:*
  *Due Date:*_____
  Equipment Reviewed: _____
- *To confirm any health or medication changes, be sure there is documentation of frequent contact with subjects (if applicable per site SOP)*
- *Review medical records to confirm if any Covid-19 related AEs occurred (if applicable)*

PI Meeting:

- *Any changes to PI onsite schedule?*
- *Any issues with Recruitment/ Patient retention due to Covid-19?*
- *Question/concerns?*

  _____

Please Note: *This checklist is a working checklist consisting of CRA monitoring questions/topics to discuss onsite that relate to the Covid-19 pandemic. This checklist is designed to be used to supplement the discussion of regular monitoring activities and shall not be used to replace any FDA, GCP, Sponsor, IRB, and CRO guidelines, or any other such standards within the clinical research profession.*

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