| FACT Virtual Inspection Agenda Example |
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| FACT Renewal InspectionHospital and Medical CenterWashington DC, USA |
|  |
| DAY/TIME | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 0 December 31, 2020 |
| TBD | Inspection Team Pre-Inspection MeetingZoom 5 | All inspectors |
|  |
| DAY 1 January 1, 2021 |
| 08:00  | Introductory MeetingZoom 1 | All inspectors, Program Director, Director/Med Director – Clinical, Apheresis, Cell ProcessingQuality Managers, Managers, SupervisorsOther leadership |
| 08:45 | Clinical InspectionZoom 2 | Clinical inspectorClinical coordinator for inspectionTechnical support person, assistant |
|  | Apheresis InspectionZoom 3  | Apheresis inspectorClinical coordinator for inspectionTechnical support person, assistant |
|  | Cell Processing InspectionZoom 4  | Processing inspectorClinical coordinator for inspectionTechnical support person, assistant |
| 10:30 | Break |
| 10:45 | Resume |  |
| 12:00 | Lunch break | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | Resume individual inspections | Scheduled interviews |
| 14:40 | BREAK |
| 15:00 | Resume |  |
| 16:30 | Inspectors’ closed meetingZoom 5 | Review progress |
| 16:40 | Inspectors meet with Program;notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2021 |
| 08:00 | Introduction to Day 2Zoom 1 | Inspectors and applicant participants |
| 08:30 | Resume individual meetings |  |
| 10:00 | Break |
| 10:30 | Resume |  |
| 12:00 | Lunch BREAK | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | Resume |  |
| 15:00 | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 | EXIT INTERVIEWZoom 1 | All inspectorsApplicant participants and guests |

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| Contact Information |
| **ROLE** | **NAME** | **CELL PHONE NUMBER** |
| Team Leader |  |  |
| Clinical Inspector – Adult  |  |  |
| Clinical Inspector – Pediatric |  |  |
| Apheresis Inspector |  |  |
| Cell Processing Inspector |  |  |
|  |  |  |
|  |  |  |
| Program Director |  |  |
| Clinical Program Quality Manager |  |  |
| Marrow Collection Facility Medical Director |  |  |
| Apheresis Medical Director |  |  |
| Apheresis Quality Manager |  |  |
| Cell Processing Director |  |  |
| Cell Processing Medical Director |  |  |
| Cell Processing Quality Manager |  |  |
|  |  |  |
| FACT Coordinator |  |  |

| AGENDA: Virtual Clinical Facility Inspection |
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| FACT Renewal InspectionHospital and Medical CenterWashington DC, USA |
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| DAY/TIME | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 1 January 1, 2021 |  |  |
| 08:00  | Introductory MeetingZoom 1 | All inspectors, Program Director, Director/Med Director – Clinical, Apheresis, Cell ProcessingQuality Managers, Managers, SupervisorsOther leadership |
| O8:45 | Clinical InspectionReview Tour / Facility issuesEnvironmental / maintenance records.Zoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 10:30 | BREAK |
| 10:45 | B4: Quality ManagementReview records, minutes [ID documents:]Zoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Quality Manager [NAME: \_\_\_\_\_\_] |
| 12:00 | Lunch Break | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | B3: Personnel records, training recordsZoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 13:15 | NursingReview mock product administrationZoom 2 | Interview inpatient nurse [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:20 | OutpatientZoom 2 | Interview outpatient nurse [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:25 | Advanced Practice Providers; review training records, call schedule, access to attending physicianZoom 2 | Interview APP [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:35 | PharmacyTour pharmacy, verify availability of tocilizumab, other medications; SOPs and protocols, involvementZoom 2 | Interview Pharmacist [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:55 | Data Management; Complete Data Management form, identify commendable practices, verify CIBMTRZoom 2 | Interview Data Manager [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:15 | ICU; Mini-tour; verify safe environment, SOPs, transfer capacityZoom 2 | Interview ICU Staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:25 | ERZoom 2 | Interview ER staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:30 | Radiation OncologyZoom 2 | Interview radiation oncology staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:35 | Clinical ResearchZoom 2 | Interview Clinical Research Coordinator [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:45 | BREAK |
| 15:00 | Document ReviewZoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 16:30 | Adjourn inspectionZoom 5  | Inspection Team meeting |
| 16:40 | Inspectors meet with Program; notify applicant of expectations and schedule for the next day Zoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2021 |
| 08:00 | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 | Medical Record reviewZoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 10:00 | BREAK |
| 10:30 | Outcomes AnalysisZoom 2 | Interview Physician [NAME: \_\_\_\_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | Marrow Collection review – if applicable; complete checklist(s)Zoom 2 | Clinical inspectorClinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]Technical support person, assistant [NAMES: \_\_\_\_\_\_]Marrow Collection Facility Medical Director – if applicable[NAME: \_\_\_\_\_\_\_]  |
| 15:00 | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 | EXIT InterviewZoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Apheresis Collection Facility Inspection |
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| FACT Renewal InspectionHospital and Medical CenterWashington DC, USA |
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| DAY/TIME | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2021 |  |  |
| 08:00  | Introductory MeetingLocation:Zoom 1 | All inspectors, Program Director, Director/Med Director – Clinical, Apheresis, Cell ProcessingQuality Managers, Managers, SupervisorsOther leadership |
| O8:45 | Apheresis InspectionReview Tour / Facility issues Environmental / maintenance recordsZoom 3 | Apheresis inspectorApheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_] |
| 10:30 | BREAK |
| 10:45 | Mock procedure: discussion, clarification | Apheresis inspectorApheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors  |
| 13:00 | C3: Personnel records, training records Zoom 3 | Apheresis inspectorApheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 13:15 | NursingReview mock product administrationZoom 3 | Interview collection nurse [NAME:\_\_\_\_\_\_\_\_\_\_\_\_] |
| 13:45 | C4: Quality Management:Zoom 3 | Quality Manager [NAME:\_\_\_\_\_\_\_\_\_\_\_\_] |
| 14:40 | BREAK |  |
| 15:00 | Continue Quality Management: C4Zoom 3 | Quality Manager [NAME:\_\_\_\_\_\_\_\_\_\_\_\_] |
| 16:30 | Adjourn inspection Zoom 5 | Inspection Team meeting |
| 16:40 | Inspectors meet with Program; notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participants |
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| DAY 2 January 2, 2021 |
| 08:00 | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 | Review donor recordsZoom 3 | Apheresis inspectorApheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 10:00 | Break |
| 10:30 | Zoom 3 | TBD |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | Review labeling and shipping; complete checklist Zoom 3 | Apheresis inspectorApheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 15:00 | Inspectors’ meeting; plan Exit InterviewZoom 5 | All inspectors |
| 16:00 | EXIT Interview. Zoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Processing Facility Inspection |
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| FACT Renewal InspectionHospital and Medical CenterWashington DC, USA |
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| DAY/TIME | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2021 |  |  |
| 08:00  | Introductory MeetingZoom 1 | All inspectors, Program Director, Director/Med Director – Clinical, Apheresis, Cell ProcessingQuality Managers, Managers, SupervisorsOther leadership |
| O8:45 | Cell Processing InspectionReview Tour / Facility issues; Environmental / maintenance records; Facilities, equipment, materials managementZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 10;30 | BREAK |
| 10:45 | Mock processing and cryopreservation procedure: discussion, clarificationZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 12:00 | Lunch Break | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | D3: Personnel / training records Zoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:15 | OperationsZoom 4 | Interview operations staff [NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_] |
| 13:45 | D4: Quality ManagementZoom 4 | Quality Manager [NAME: \_\_\_\_\_\_\_\_] |
| 14:40 | BREAK |
| 15:00 | Review processing recordsZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 16:30 | Adjourn inspectionZoom 5 | Inspection Team meeting |
| 16:40 | Inspectors meet with Program; notify applicant of expectations and schedule for the next dayZoom 1 | All inspectors and applicant participants |
|  |
| DAY 2 January 2, 2021 |
| 08:00 | Introduction to Day 2 Zoom 1 | Inspectors and applicant participants |
| 08:30 | Review records/labelingZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 10:00 | BREAK |
| 10:30 | Finish records/labelingZoom 4 | Processing inspectorProcessing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meetingZoom 5 | All inspectors |
| 13:00 | Off-site storage checklistZoom 4  | Off-site storage staff – if applicable [NAME: \_\_\_\_] |
| 15:00 | Inspectors’ meeting; plan Exit Interview Zoom 5 | All inspectors |
| 16:00 | EXIT Interview. Zoom 1 | All inspectors, applicant participants and invited guests |

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| Persons Interviewed During the Inspection |
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| Cellular Therapy Clinical Program |
| **NAME** | **POSITION / ROLE IN PROGRAM** |
|  | Program Director |
|  | Clinical Program Medical Director |
|  | Marrow Collection Facility Medical Director |
|  | Attending Physician |
|  | Advanced Practice Provider (APP) |
|  | Quality Manager |
|  | Inpatient Nurse |
|  | Outpatient Nurse |
|  | Pharmacist |
|  | Data Manager |
|  | ICU Staff |
|  | ER Staff |
|  | Radiation Oncology |
|  | Clinical Research Coordinator |
|  |  |
|  |  |
|  |  |
| Cellular Therapy Product Collection: Bone Marrow |
|  | Marrow Collection Medical Director |
|  | Operating Room Nurse |
|  |  |
| Cellular Therapy Product Collection: Apheresis |
|  | Apheresis Facility Director |
|  | Apheresis Facility Medical Director |
|  | Quality Manager |
|  | Collection Staff (nurse) Lead |
|  | Collection Staff |
|  |  |
|  |  |
| Cell Processing Facility |
|  | Cell Processing Facility Director |
|  | Cell Processing Facility Medical Director |
|  | Quality Manager |
|  | Processing Staff |
|  | Processing Staff |
|  |  |
|  |  |