| FACT Virtual Inspection Agenda Example | | |
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| FACT Renewal Inspection  Hospital and Medical Center  Washington DC, USA | | |
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| DAY/TIME | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 0 December 31, 2020 | | |
| TBD | Inspection Team Pre-Inspection Meeting  Zoom 5 | All inspectors |
|  | | |
| DAY 1 January 1, 2021 | | |
| 08:00 | Introductory Meeting  Zoom 1 | All inspectors,  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |
| 08:45 | Clinical Inspection  Zoom 2 | Clinical inspector  Clinical coordinator for inspection  Technical support person, assistant |
|  | Apheresis Inspection  Zoom 3 | Apheresis inspector  Clinical coordinator for inspection  Technical support person, assistant |
|  | Cell Processing Inspection  Zoom 4 | Processing inspector  Clinical coordinator for inspection  Technical support person, assistant |
| 10:30 | Break | |
| 10:45 | Resume |  |
| 12:00 | Lunch break | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | Resume individual inspections | Scheduled interviews |
| 14:40 | BREAK | |
| 15:00 | Resume |  |
| 16:30 | Inspectors’ closed meeting  Zoom 5 | Review progress |
| 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 | Resume individual meetings |  |
| 10:00 | Break | |
| 10:30 | Resume |  |
| 12:00 | Lunch BREAK | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | Resume |  |
| 15:00 | Inspectors’ meeting; plan Exit Interview  Zoom 5 | All inspectors |
| 16:00 | EXIT INTERVIEW  Zoom 1 | All inspectors  Applicant 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 Inspection  Hospital and Medical Center  Washington 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 Meeting  Zoom 1 | All inspectors,  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |
| O8:45 | Clinical Inspection  Review Tour / Facility issues  Environmental / maintenance records.  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 10:30 | BREAK | |
| 10:45 | B4: Quality Management  Review records, minutes [ID documents:]  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Quality Manager [NAME: \_\_\_\_\_\_] |
| 12:00 | Lunch Break | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | B3: Personnel records, training records  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 13:15 | Nursing  Review mock product administration  Zoom 2 | Interview inpatient nurse [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:20 | Outpatient  Zoom 2 | Interview outpatient nurse [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:25 | Advanced Practice Providers; review training records, call schedule, access to attending physician  Zoom 2 | Interview APP [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:35 | Pharmacy  Tour pharmacy, verify availability of tocilizumab, other medications; SOPs and protocols, involvement  Zoom 2 | Interview Pharmacist [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:55 | Data Management; Complete Data Management form, identify commendable practices, verify CIBMTR  Zoom 2 | Interview Data Manager [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:15 | ICU; Mini-tour; verify safe environment, SOPs, transfer capacity  Zoom 2 | Interview ICU Staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:25 | ER  Zoom 2 | Interview ER staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:30 | Radiation Oncology  Zoom 2 | Interview radiation oncology staff [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:35 | Clinical Research  Zoom 2 | Interview Clinical Research Coordinator [NAME: \_\_\_\_\_\_\_\_\_] |
| 14:45 | BREAK | |
| 15:00 | Document Review  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 16:30 | Adjourn inspection  Zoom 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 review  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_] |
| 10:00 | BREAK | |
| 10:30 | Outcomes Analysis  Zoom 2 | Interview Physician [NAME: \_\_\_\_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | Marrow Collection review – if applicable; complete checklist(s)  Zoom 2 | Clinical inspector  Clinical coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Marrow Collection Facility Medical Director – 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 |

| AGENDA: Virtual Apheresis Collection Facility Inspection | | |
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| FACT Renewal Inspection  Hospital and Medical Center  Washington 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 Meeting  Location:  Zoom 1 | All inspectors,  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |
| O8:45 | Apheresis Inspection  Review Tour / Facility issues Environmental / maintenance records  Zoom 3 | Apheresis inspector  Apheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_] |
| 10:30 | BREAK | |
| 10:45 | Mock procedure: discussion, clarification | Apheresis inspector  Apheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | C3: Personnel records, training records  Zoom 3 | Apheresis inspector  Apheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_] |
| 13:15 | Nursing  Review mock product administration  Zoom 3 | Interview collection nurse [NAME:\_\_\_\_\_\_\_\_\_\_\_\_] |
| 13:45 | C4: Quality Management:  Zoom 3 | Quality Manager [NAME:\_\_\_\_\_\_\_\_\_\_\_\_] |
| 14:40 | BREAK |  |
| 15:00 | Continue Quality Management: C4  Zoom 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 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 | Review donor records  Zoom 3 | Apheresis inspector  Apheresis 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 meeting  Zoom 5 | All inspectors |
| 13:00 | Review labeling and shipping; complete checklist  Zoom 3 | Apheresis inspector  Apheresis coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [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 |

| AGENDA: Virtual Processing Facility Inspection | | |
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| FACT Renewal Inspection  Hospital and Medical Center  Washington 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 Meeting  Zoom 1 | All inspectors,  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |
| O8:45 | Cell Processing Inspection  Review Tour / Facility issues; Environmental / maintenance records; Facilities, equipment, materials management  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 10;30 | BREAK | |
| 10:45 | Mock processing and cryopreservation procedure: discussion, clarification  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 12:00 | Lunch Break | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | D3: Personnel / training records  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 13:15 | Operations  Zoom 4 | Interview operations staff [NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_] |
| 13:45 | D4: Quality Management  Zoom 4 | Quality Manager [NAME: \_\_\_\_\_\_\_\_] |
| 14:40 | BREAK | |
| 15:00 | Review processing records  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [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 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 | Review records/labeling  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 10:00 | BREAK | |
| 10:30 | Finish records/labeling  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_] |
| 12:00 | LUNCH BREAK | Everyone |
| 12:30 | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 | Off-site storage checklist  Zoom 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 |
|  |  |
|  |  |