| FACT Virtual Inspection Agenda Example | | |
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| FACT Renewal Inspection  Cord Blood Bank  Washington DC, USA | | |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 0 December 31, 2021 | | |
| TBD | Inspection Team Pre-Inspection Meeting  Zoom 5 | All inspectors |
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| DAY 1 January 1, 2022 TIME ZONE | | |
| 08:00 CT | Introductory Meeting  Zoom 1 | All inspectors,  CBB Director  CBB Medical Director  CBB Collection Director(s)  CBB Processing Facility Director  Quality Unit Manager, Managers, Supervisors  Other leadership  Interpreters |
| 08:45 CT | Central Bank Inspection  Zoom 2 | Bank inspector  Bank coordinator for inspection  Technical support person, assistant  Interpreter |
|  | Collection Inspection  Zoom 3 | Collection inspector  Collection coordinator for inspection  Technical support person, assistant  Interpreters |
|  | Processing Inspection  Zoom 4 | Processing inspector  Processing facility coordinator for inspection  Technical support person, assistant  Interpreters |
| 10:30 CT | Break | |
| 10:45 CT | Resume individual inspections |  |
| 12:00 CT | Lunch break | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors  Interpreters |
| 13:00 CT | Resume individual inspections |  |
| 14:40 CT | BREAK | |
| 15:00 CT | Resume individual inspections |  |
| 16:30 CT | Inspectors’ closed meeting  Zoom 5 | Review progress |
| 16:40 CT | Inspectors meet with Bank;  notify applicant of expectations and schedule for the next day  Zoom 1 | All inspectors and applicant participants  Interpreters |
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| DAY 2 January 2, 2022 TIME ZONE | | |
| 08:00 CT | Introduction to Day 2  Zoom 1 | Inspectors and applicant participants  Interpreters |
| 08:30 CT | Resume individual inspections |  |
| 10:00 CT | Break | |
| 10:30 CT | Resume individual inspections |  |
| 12:00 CT | Lunch BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Resume individual inspections |  |
| 15:00 CT | Inspectors’ meeting; plan Exit Interview  Zoom 5 | All inspectors |
| 16:00 CT | EXIT INTERVIEW  Zoom 1 | All inspectors  Applicant participants and guests  Interpreters |

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| Contact Information | | |
| **ROLE** | **NAME** | **CELL PHONE NUMBER** |
| Team Leader |  |  |
| Bank Inspector |  |  |
| Collection Inspector |  |  |
| Processing Inspector |  |  |
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|  |  |  |
| CBB Director |  |  |
| CBB Medical Director |  |  |
| CBB Collection Director(s) |  |  |
| CBB Processing Facility Director |  |  |
| Quality Unit Manager |  |  |
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| FACT Accreditation Coordinator |  |  |

| AGENDA: Virtual Central Bank Inspection | | |
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| FACT Renewal Inspection  Cord Blood Bank  Washington DC, USA | | |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Links | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE | | |
| 08:00 CT | Introductory Meeting  Zoom 1 | All inspectors,  CBB Director  CBB Medical Director  CBB Collection Director(s)  CBB Processing Facility Director  Quality Unit Manager, Managers, Supervisors  Other leadership  Interpreter |
| O8:45 CT | Central Bank Inspection  Review Tour / Facility issues  Environmental / maintenance records  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:30 CT | BREAK | |
| 10:45 CT | B2: Quality Management  Review records, minutes [ID documents:]  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Quality Unit Manager [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | Lunch Break | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | B1: Personnel records, training records  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:45 CT | BREAK | |
| 15:00 CT | Document Review Part B  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspection  Zoom 5 | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; 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, 2022 TIME ZONE | | |
| 08:00 CT | Introduction to Day 2  Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review of relevant standards in Part E  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | BREAK | |
| 10:30 CT | Review of relevant standards in Part E  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Complete review  Zoom 2 | Bank inspector  Bank coordinator for inspection [NAME: \_\_\_\_\_\_\_]  Technical support person, assistant [NAMES: \_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit Interview  Zoom 5 | All inspectors |
| 16:00 CT | EXIT Interview  Zoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Collection Facility Inspection | | |
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| FACT Renewal Inspection  Cord Blood Bank  Washington DC, USA | | |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE | | |
| 08:00 CT | Introductory Meeting  Location:  Zoom 1 | All inspectors,  CBB Director  CBB Medical Director  CBB Collection Director(s)  CBB Processing Facility Director  Quality Unit Manager, Managers, Supervisors  Other leadership  Interpreter |
| O8:45 CT | Collection Site #1/Non-fixed Collection Processes at the Bank  Review Tour / Facility issues Environmental / maintenance records  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:30 CT | BREAK | |
| 10:45 CT | Mock procedure: discussion, clarification | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Personnel records, training records  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 13:45 CT | Collector Interviews  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Collector(s) [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:40 CT | BREAK |  |
| 15:00 CT | Collection Site #2  Review Tour / Facility issues Environmental / maintenance records  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspection  Zoom 5 | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; 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, 2022 TIME ZONE | | |
| 08:00 CT | Introduction to Day 2  Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review labeling and shipping; complete checklist  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | Break | |
| 10:30 CT | Zoom 3 | TBD |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Review of relevant standards in Part B/C/E  Zoom 3 | Collection inspector  Collection coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit Interview  Zoom 5 | All inspectors |
| 16:00 CT | EXIT Interview.  Zoom 1 | All inspectors, applicant participants and invited guests |

| AGENDA: Virtual Processing Facility Inspection | | |
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| FACT Renewal Inspection  Cord Blood Bank  Washington DC, USA | | |
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| DAY/TIME TIME ZONE | Meeting Topic and Zoom Link | Attendees (name and role) |
| DAY 1 January 1, 2022 TIME ZONE | | |
| 08:00 CT | Introductory Meeting  Zoom 1 | All inspectors,  CBB Director  CBB Medical Director  CBB Collection Director(s)  CBB Processing Facility Director  Quality Unit Manager, Managers, Supervisors  Other leadership  Interpreter |
| O8:45 CT | 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: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10;30 CT | BREAK | |
| 10:45 CT | Mock processing and cryopreservation procedure: discussion, clarification  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | Lunch Break | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Operations  Zoom 4 | Interview operations staff [NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 13:30 CT | Document Review Part D  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 14:40 CT | BREAK | |
| 15:00 CT | Review processing records  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 16:30 CT | Adjourn inspection  Zoom 5 | Inspection Team meeting |
| 16:40 CT | Inspectors meet with Bank; 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, 2022 TIME ZONE | | |
| 08:00 CT | Introduction to Day 2  Zoom 1 | Inspectors and applicant participants |
| 08:30 CT | Review records/labeling  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 10:00 CT | BREAK | |
| 10:30 CT | Finish records/labeling  Zoom 4 | Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 12:00 CT | LUNCH BREAK | Everyone |
| 12:30 CT | Inspectors’ closed meeting  Zoom 5 | All inspectors |
| 13:00 CT | Off-site storage checklist or review of relevant standards in Part B/D/E  Zoom 4 | Off-site storage staff – if applicable [NAME: \_\_\_\_]  Processing inspector  Processing coordinator for inspection [NAME:\_\_\_\_\_\_\_\_]  Technical support person, assistant [NAME: \_\_\_\_\_\_\_\_\_]  Interpreter, if applicable [NAME: \_\_\_\_\_\_] |
| 15:00 CT | Inspectors’ meeting; plan Exit Interview  Zoom 5 | All inspectors |
| 16:00 CT | EXIT Interview.  Zoom 1 | All inspectors, applicant participants and invited guests |

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| Persons Interviewed During the Inspection | |
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| Cord Blood Bank | |
| **NAME** | **POSITION / ROLE IN BANK** |
|  | CBB Director |
|  | CBB Medical Director |
|  | CBB Collection Director(s) |
|  | CBB Processing Facility Director |
|  | Quality Unit Manager |
|  | Bank staff |
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|  |  |
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|  |  |
| CB Unit Collection | |
|  | CBB Collection Director(s) |
|  | Quality Unit Manager |
|  | Collection Staff |
|  | Collection Staff |
|  |  |
|  |  |
|  |  |
| CBB Processing Facility | |
|  | CBB Processing Facility Director |
|  | Quality Unit Manager |
|  | Processing Staff |
|  | Processing Staff |
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