

## Timeline for Virtual Inspections

| TIME BEFORE INSPECTION (MINIMUM)  | ACTIVITY   |
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| <b>6-8 weeks</b>  | <p>Schedule inspection:<br/>INSPECTION Team has access to portal and all documents<br/>APPLICANT</p> <ul style="list-style-type: none"> <li>• Update application</li> <li>• Submit any additional required documents</li> <li>• Prepare video tours</li> </ul>   |
| <b>3-4 weeks</b>  | <p>INSPECTION Team Meeting with FACT coordinator:</p> <ul style="list-style-type: none"> <li>• IT Training; private quiet room, no recording</li> <li>• Review Standard inspection topics, (e.g., data, outcomes)</li> <li>• Ensure inspectors have portal access and have reviewed documents</li> <li>• Develop agenda for inspection days</li> <li>• Identify specific documents inspectors will want to review</li> </ul> <p>APPLICANT meeting with FACT coordinator:</p> <ul style="list-style-type: none"> <li>• Determine technology availability</li> <li>• Verify people available [3 per inspector – runner, subject expert, Applicant Coordinator (Co-Host)]</li> <li>• Train staff on expectations re: technology</li> <li>• Test technology in actual environment; check outlets</li> <li>• Notify program of specific documents to have prepared</li> </ul> |
| <b>2 weeks</b>  | TEAM LEADER / FACT COORDINATOR ensure final inspection agenda is complete and available to program   |
| <b>Day Prior to Inspection</b>  | <p>INSPECTION Team Call:</p> <ul style="list-style-type: none"> <li>• Review agenda</li> <li>• Plans for inspection</li> <li>• Ensure everyone has access to technology and call-in numbers</li> </ul>   |
| <p><b>INSPECTION DAY 1</b></p> <ul style="list-style-type: none"> <li>• <b>Opening Meeting</b></li> <li>• <b>Divide into assigned groups and breaks per agenda</b></li> <li>• <b>4:30 PM</b></li> </ul> | <p>At initial meeting, list of additional (random) documents to prepare<br/>All together on same Zoom meeting</p> <ul style="list-style-type: none"> <li>• Introductions</li> <li>• Program overview</li> </ul> <p>Clinical, Apheresis, Processing (individual Zoom meetings)</p> <p>Inspection Team Meeting to end Day 1<br/>Ensure program has a list of any additional documents to prepare overnight</p>   |
| <p><b>INSPECTION DAY 2</b></p> <ul style="list-style-type: none"> <li>• <b>8 AM or per agenda</b></li> <li>• <b>Team Meeting</b></li> <li>• <b>EXIT Interview</b></li> </ul>                            | <p>Meet in rooms<br/>Review findings<br/>All participate</p>   |
| <b>3 Days Post Inspection</b>   | Submit reports   |