GENERAL ASPECTS:
1. FACT virtual inspections will be conducted for renewal accreditation. New applicants will require an on-site in-person inspection and are not eligible for this process.
2. The virtual inspection will mimic an actual on-site inspection to the extent possible.
3. Processes for scheduling, choice of dates, inspection team selection will remain unchanged. Inspector responsibilities, including the Team Leader, will remain unchanged.
4. In general, the inspections will be scheduled in the applicant's time zone.
5. The inspection will be conducted via a series of Zoom meetings. The meetings will be set up in advance by the FACT Office with appropriate Zoom settings.
6. The full program inspection is expected to require most of two days. If personnel limitations necessitate (e.g., one quality manager for two areas), the areas may be inspected on sequential days rather than on the same day. Opening and closing meetings will be adjusted accordingly.
7. FACT Coordinators will work with the Inspection Team Leader and Program Director to establish the agenda. Interviews with personnel will be scheduled for discrete times on the agenda.
8. The inspector should treat the inspection days as time away from work in the same manner as if the inspection were in-person, on-site.
9. Resources required for the inspector:
    a. A quiet and private room to conduct inspection. Do not use an office where you will be interrupted or where confidentiality could be breached by other employees entering.
    b. Computer with microphone and camera.
    c. Two screens might be helpful.
    d. Headphones with microphone are optional but may be desirable to minimize background noise.
    e. Zoom should be updated to latest version. Do not use virtual background. Do not record.

PRIOR TO THE INSPECTION
1. Refer to the Timeline for Virtual Inspections: http://www.factwebsite.org/TimelineForVirtualInspections/.
2. The inspectors should review the Zoom How-To Guide for Virtual Inspections: Inspectors: http://www.factwebsite.org/ZoomHTGVirtualInspections-Inspectors/.
3. The inspection team will meet with the Accreditation Coordinator approximately 4 weeks prior to the inspection to train the team as needed in technology issues and answer any questions.
4. The current list of documents required to be submitted in advance by the applicant program is unchanged; available at http://www.factwebsite.org/CTDocumentSubmissionRequirements7-0/. Applicants will update documents that have changed since submission due to the extended accreditation cycle. A *Virtual Inspection Tab* has been added in the Portal for all new documents.
5. If there are additional specific documents that you want to request or questions about the videos, address these to the FACT Accreditation Coordinator at the initial meeting 4 weeks in advance of the inspection.
6. The Team Leader, inspection team, and Program Director are responsible for creating the Inspection Agenda. Refer to additional information below. This should be complete at least two weeks prior to the inspection.

7. Within a few days of the inspection, the inspector should test his/her technology in the room that will be used for the inspection. Update to the latest version of Zoom prior to the inspection.

THE INSPECTION

1. The Team Leader for the inspection will host the main Zoom meeting where the introduction, private inspection team meetings ("lunch"), and closing meeting will occur.
   a. Each inspector will have a separate meeting for the area to be inspected.
   b. All meetings will be set up in advance by FACT Staff, who will not be present at the inspection but will be available for technical assistance throughout the inspection.
2. There will be an agenda that includes the Zoom links for each part, identification of the inspector for that part, expected participants from the applicant facility, and cell phone contact information for each person. Refer to FACT Virtual Inspection Agenda Examples.
3. Interviews will be scheduled (and listed on agenda) for various people who may be interviewed during the tour. These people should call in to designated Zoom meeting from a quiet private place. (e.g., not the nurses' station). These people should be prepared to show their environment (e.g., clinical unit, apheresis, ICU) or someone from the applicant team could go there to assist. This will include:
   a. Nursing – inpatient, outpatient, ambulatory
   b. Advanced Practice Provider
   c. ICU nurse and physician
   d. ER nurse / physician
   e. Pharmacist
   f. Data Manager
   g. Apheresis collection staff
   h. Processing staff
   i. Quality Managers, if not already part of team
4. Interviews may be longer or shorter than indicated on the sample agenda at the discretion of the inspector.
5. The inspector should document the name and position of each person interviewed. The final report should include a log of all interviewees. See attached example.
6. Applicants will provide evidence of compliance during the virtual inspection by one of these general methods:
   a. Shared screen: electronic documents, electronic medical record, or documents scanned into the computer. This would include SOPs, meeting minutes, potentially incident/occurrence reporting, corrective actions, audits, other quality documents. Scanned documents could be training logs, cleaning logs, consents, product processing records. The inspector can request remote control from the applicant who is sharing a screen, allowing the inspector the ability to scroll through a shared document. See also Zoom instructions.
   b. Document camera or cell phone camera. Cell phone camera is adequate for smaller documents, specific pieces of information such as a sign on a freezer or calibration sticker.
      i. Refer to http://bestreviews.com/best-document-cameras for information about document cameras. Various models are available and reasonably priced. Many come with built-in software and can be connected to the computer via USB port.

      ii.   The document camera will be most useful for the Processing Facility inspection due to the likelihood that many documents to be reviewed [such as a product processing record] may be maintained as paper records.

      iii.   A single document camera could be shared as needed by the various areas throughout the days of the inspection.

   c. Upload into FACT Portal. A document may be uploaded during the inspection to the Virtual Inspection Tab in the FACT Portal. The inspector can view it there or download and print for review.

   d. A document can be uploaded into the *Chat* function to be viewed by everyone or selected participants.

7. Virtual tours are to be shared through Zoom at the beginning of the first section of the inspection for each area, after the Introductory Meeting.

8. Since the inspection will span two days, there will be several opportunities for the inspection team to meet, compare notes, determine if someone needs assistance, and ensure a complete inspection. These meetings should be held through Zoom 1 account, and include lunch break each day and at least a short meeting at the end of the first day. There should also be the usual time before the exit interview for the team to plan that interview.

9. Inspectors should also keep a record of which documents were reviewed that were not submitted to the Portal: e.g., minutes of which meetings, which dates; which patient records; which audits and validations.

AGENDA – refer also to FACT Virtual Inspection Agenda
Example: http://www.factwebsite.org/VirtualInspectionAgendas/. The inspection team will work with the Accreditation Coordinator and Program Director at least 2 weeks prior to the scheduled inspection to finalize the agenda.

1. Introductory Meeting – Zoom 1 - Attended by all inspectors, applicant facility personnel from clinical, apheresis, and processing facilities – about 30-45 minutes.
   a. Begin with Introductions:
      i.   Everyone introduces self; have camera on and name displayed correctly. It is possible to change the name if necessary. Include short description of yourself, your role for the day.
   b. Inspectors introduce themselves
   c. Inspectors review some housekeeping guidelines for the inspection
      i.   Role of host and co-host
      ii.   Applicants will let appropriate people into meeting from waiting room
      iii.   Keep yourself on mute when not speaking, etc.
   d. Applicant will present overview of the program using power point and shared screen.
   e. Review schedule for the inspection, confirm it is still appropriate.
   f. Inspectors will present list of specific documents they will want prepared for each area – which medical records, procedure records, minutes, training records, etc.

2. All persons leave this Zoom 1 meeting and go to assigned Zoom meeting to conduct inspections:
   a. Clinical – "Zoom 2"
   b. Apheresis – "Zoom 3"
   c. Cell Processing – "Zoom 4"

3. Lunch break – take an actual break; then inspectors meet in Zoom 1 for closed meetings

4. Resume inspections in afternoon in separate Zoom meetings.
5. Designated individuals will call into assigned Zoom meeting for interview at designated times. Inspectors will document the name and job title for each person interviewed.
6. Inspectors meet in Zoom 1 at end of day.
7. DAY 2:
    a. Begin with joint meeting in Zoom 1 to review plan for the day, estimate time for exit interview.
    b. Divide group into respective areas.
    c. One hour before exit interview, inspectors meet in Zoom 1 to prepare.
    d. EXIT INTERVIEW: Zoom 1 – all call in at designated time.

GENERAL ZOOM Guidelines [Refer also to the Zoom How-To Guide for Virtual Inspections: Inspectors: http://www.factwebsite.org/ZoomHTGVirtualInspections-Inspectors/ for technical details]

1. Within a few days of the inspection, update to newest version of Zoom on all computers, cell phones, and tablets that will be used for the inspection.
2. Test technical capabilities in the rooms that will be used.
3. Retest connectivity and functionality the night before the inspection.
4. When using a laptop for a Zoom meeting, place the laptop on a firm foundation such as a desk. Do not hold the laptop in your lap during a Zoom meeting.
5. Do not use virtual backgrounds.
6. Do not allow other persons in the room during the inspection. No observers are permitted unless prior authorization has been documented.
7. Zoom Meetings will have settings determined in advance by the FACT Office so that functionality will be ensured as described.
    1. Chat function will be enabled.
    2. Doorbell will not be active, but this function can be selected by the applicant if desired.
8. You can only be in one Zoom Meeting at a time. Sign out of one before signing into another.
9. You can enter a Zoom Meeting with more than one device.
10. The inspector will be the HOST. The applicant coordinator will be designated as Co-Host.
11. As the HOST, the inspectors must sign into the Zoom account before entering the meeting. Everyone else can sign in by clicking the link in the agenda.
12. Waiting Room option will be available if applicant prefers. Default setting will not have a waiting room.
13. Host and Co-host have the ability to share screen.
14. Do not save confidential information.
15. Do not share screen during the introductions so that everyone can be seen. Only share screen when there is actually a document to view.
16. Be sure that everyone who calls in has a private and quiet location. Camera and microphone are optional but preferred for those listening to and viewing the meeting only.

Persons Interviewed During the Inspection

Cellular Therapy Clinical Program

NAME	POSITION / ROLE IN PROGRAM
	Program Director
	Clinical Program 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

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