Overview of FACT Accreditation Process

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FACT Chief Medical Officer
FACT Voluntary Accreditation Process

- Overview
- Timeline
- Guidelines for success
Accreditation Overview

Accreditation is based on documented compliance with current Standards
- Submitted documents
- On-site inspection
- Accreditation Committee review

Eligibility (initial) and Renewal Applications
- Demographics; services
- Length of time in operation; presence of required personnel; number of procedures

Compliance Application – “checklist”
- Includes each Standard
- Customized to each specific program or bank
- Requires uploaded documents
International Inspections

Immune effector cell inspections will likely all be in North America for the time being

• Still important to understand that FACT is an international organization and has processes for situations in which a program does not primarily do business in English

If applicant’s primary language is not English, pre-inspection documentation submitted to FACT must be translated or summarized in English

• A document checklist will be created to list what must be submitted in advance of the inspection
• These are documents that are reviewed before the inspection
• FACT does NOT require all documents to be in English for the inspection

Applicants must provide an interpreter to translate/interpret documents for inspector throughout the inspection if English is not the primary language

• NOT necessarily an independent person
• Staff member(s) who are fluent in English can serve as interpreter(s)
Overall Timeline & Steps

- **Renewal Application**: 3 months to submit checklist
- **Initial Eligibility Application**: 12 months to submit checklist
- **Month**: 1 2 3 4 5 6 7 8 9 10 11 12

Steps:
- **Submit Compliance Application**
- **Schedule and Conduct Inspection**
- **Determine Outcome and Notify Applicant**
- **Correct Deficiencies and Award Accreditation**

Note: A delay in any of these steps will require shortened timeframe for subsequent steps.
Eligibility Application

- Used to apply for initial accreditation
- Includes a nonrefundable registration fee
- Apply after self determination of eligibility and confirmed organizational commitment
- FACT uses answers to Eligibility Application to:
  - Determine eligibility for accreditation
  - Define accreditation goals based on services
  - Generate the compliance application
Renewal Application

- Renewal Application - similar to Eligibility Application
- Accredited programs notified when to complete as part of annual reporting process after second year of accreditation cycle
- FACT uses renewal application to:
  - Determine continued eligibility for all services
  - Define renewal accreditation goals
  - Note critical changes since last application
  - Generate the Compliance Application
Submission of Compliance Application

Renewal Application

3 months to submit Compliance Application

Submit Compliance Application

Initial Eligibility Application

12 months to submit

Month

1  2  3  4  5  6  7  8  9  10  11  12
Compliance Application

- Describes the applicant’s organization and accreditation goals
  - “Goals” = services performed

- Includes customized checklists created by FACT
  - Customized to applicant’s services
  - Minimizes use of “not applicable”
  - Not completely perfect

- Documents applicant’s self-assessment of compliance with the Standards
- Requires document uploads for some standards
Submit Online Compliance Checklist By Assigned Deadline

- Initial applicants have 12 months from initial application
  - Expected that more time is necessary to bring documents and processes into compliance
- Renewal applicants have 3 months from notice
  - Should already be in compliance with Standards
  - Be sure to complete gap analysis when new edition of Standards is published
  - Can start renewal preparation early by reviewing Standards requirements, gathering in-date documents, updating organizational chart
# Coordination: FACT Office, Applicant, and Inspectors

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- **Compliance Application Submitted**
- **Coordinate the Inspection**
Accreditation Coordinators

• FACT staff members with specific expertise in standards and accreditation
  • Review applications, inspection reports; summarize reports for Accreditation Committee
• One coordinator assigned to each application to provide consistency
  • Useful resource for inspectors and applicants
  • Can be reached by phone or email
  • Also available after accreditation has been awarded and throughout the accreditation cycle
FACT Accreditation Coordinator confirms applicant’s readiness for on-site inspection:

• Reviews compliance application
• Confirms presence, but not adequacy, of required pre-inspection documents, including:
  ✓ Current medical licenses, board certification
  ✓ A clear and complete QM Plan that includes all elements
  ✓ SOP for SOPs
  ✓ Required informed consent elements
  ✓ Complete and appropriate label content
  ✓ Appropriate steps/number of observations in validation plans
Applicant: Choosing the Best Date

- Applicant provides potential inspection dates to FACT
- Key personnel available
- Designated personnel available – tours, translators, transportation
- All sites selected for inspection available
- Not later than six months before expiration date
- Suggest more than one potential date!
Applicant Preparation

**Inspection Schedule**
- Staff: Knowledgeable personnel accompany each inspector; answer questions; retrieve info
- Tours: All personnel aware of expectations
- Especially important for multiple sites
- Exit interview: Invite other key persons

**Room Reservations**
- Inspector Work Room
- Initial meeting and Exit Interview room(s)
- Internet Connection (ideally for each inspector)
  - Wireless/wired
  - Conference room computer

**Lunch Arrangements**
- Often used as working lunch
- Light fare
- Remember the off-site inspectors (if applicable)
- Applicant may wish to offer separate lunch for staff
Logistics

**HOTEL**
- Recommend for inspectors:
- Convenient
- Reasonable
- Meeting Room available

**Transportation**
- Arrangements or directions
- Be specific
- Allow for transit time; applicants should inform inspectors
Selecting the Inspection Team

**Team Selection**
- Qualifications and experience
- Facility size and complexity
- Type of products
- Facility geography

**Assignment Acceptance**
- Area of expertise
- Necessary time commitment
- Arrive day before inspection for evening team meetings
- Conduct complete inspection with 7 pm or later flight
- Complete reports immediately following inspection

**Applicant Acceptance**
- Applicant approves team
- Organization can object to team within 5 business days

*Common Complaint*
Inspector Conflicts of Interest

• Recuse yourself from inspection

• Potential conflicts
  • Close working/collaborative relationship
  • Competition for referrals, contracts, etc.
  • Non-financial incentives
  • Unfavorable history – employment; grants

• Potential legal implications
  • Applicant and accredited facilities
  • Patients, insurance companies, etc.
  • FACT
On-Site Inspection

- Compliance Application Submitted
- Inspection Coordinated

Conduct the inspection
Typical Inspection

- Initial Interview
  - Inspection Team introductions, overview of organization presented by applicant, questions/clarifications

- Facility(ies) Tour
  - Provides confirmation of compliance with several standards, enhances understanding of general organization workflow
  - Brief interview of staff and/or chance to observe

- Working Lunch

- Document Review
  - Review of documentation not previously submitted

- Exit Interview
  - A brief summary of the inspection, a closure to the day

Repeated on each day as needed (e.g., multiple sites, cord blood banks, etc.)
Initial Interview

• Purpose: To introduce inspectors, applicant personnel, and the applicant organization

• Applicant presents introductory information:
  • History of the organization; power point slides are good idea; provide copies to team
  • Services provided
  • Overview of organizational chart – emphasize unusual
  • Include off-site facilities
  • Overview of Quality Management Plan(s)

• The inspection team introduces themselves, role on the inspection team, and “day job”

• Inspection team reviews schedule for the inspection day; verify appropriateness

• Inspection team may request additional documentation
Tours

• Purposes:
  • Assessment of facilities – Inspectors: be observant!
  • Confirm compliance with many standards and understand the organization’s general workflow
  • Interact with staff; ask questions about policies or procedures
  • Observe procedures. Inspectors may request mock procedure

• May be conducted in the morning or afternoon, depends on scheduled procedures, preferences, availability

• First rule of tours: Every place must be seen; not everyone needs to see everything

• Be careful not to be critical of staff in front of patients or families
What makes a good inspection?  
Preparation!

**Applicant**
- Begin early
- Read Standards carefully
- Thoroughly complete Compliance Application
  - Note *exactly* where inspector can find documentation of compliance for each question
- Schedule inspection on date key personnel will be available

**Inspector**
- Review documentation ahead of time
  - *Before* getting on the plane!
  - Follow-up with applicant regarding questions
  - Mark compliant Standards if possible
  - Make notes to check on site
- Attend pre-inspection team meetings and conference calls
Applicant Preparation: Checklist

Complete Compliance Application
- Mock inspection/self-assessment tool first
- Be honest and compulsive
- Be careful with “Not applicable”

Address Deficiencies
- Are you documenting compliance?
- Revise or add SOPs, forms, and worksheets to include necessary documentation
- Submit Compliance Application

Organize Documents
- Order SOPs by Standards
- Highlight SOP section/attach documentation pertaining to Standard
- Indicate location on the Compliance Application
Applicants: What to Do . . .

- Be courteous, punctual, and helpful
- Have at least one staff member appointed to each inspector
- Be conscious of demands on inspectors
- Promptly gather additional documentation requested
Applicants: What Not to Do ...

- Plan to show inspectors *exclusively* electronic records
- Assume that whatever passed the last inspection will be sufficient
- Expect to know the outcome of the inspection before the inspection team leaves
- Argue with the inspectors
Closing the Inspection

• Inspection team will have a closed session to review findings and prepare for exit interview
  • The inspector may request a private session with the Program Director if needed

• Exit interview:
  • Summation
  • Applicant may invite significant personnel as desired
  • Should be no surprises at interview or in final report

• Exit interview process will be explained later today
Inspection and Accreditation Outcome

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<td>Determine inspection outcome</td>
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Inspection Report

- Each inspector writes report; submits online within three days of on-site inspection.
- Each inspector reviews each standard marked “not compliant” and clearly describes the deficiency.
- Team leader reviews final report and submits online to the FACT office within two weeks of inspection.
- Additional details will be provided later today.
- Sample deficiency:

<table>
<thead>
<tr>
<th>B7.1.1</th>
<th>The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy.</th>
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<tbody>
<tr>
<td>Deficiency:</td>
<td>The informed consent form includes risks and benefits of cellular therapy, but it does not explain what cytokine release syndrome is.</td>
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<td>Required Response:</td>
<td>The program must submit a revised informed consent form that describes, or a process for verbally explaining, cytokine release syndrome.</td>
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Next Steps...

Accreditation Committee

- Reviews and discusses each accreditation report.
- May revise deficiencies, variances, and suggestions.
- Determines accreditation outcome/next steps.
- Includes inspectors in meetings to respond to questions.
  Should be educational for inspectors.
- Refers special issues to the FACT Board of Directors.
Potential Outcomes

- Full Accreditation
- Full Accreditation Pending Corrections and Additional Documentation
- Full Accreditation Pending Accreditation Committee Review and Assessment of Responses
- Partial Focused Re-inspection
- Full Focused Re-inspection
- Complete Re-inspection
Notification of Outcome

• Key personnel identified in accreditation portal receive email notification
• Letter explains overall results
• Accreditation report includes each deficiency, variance, and suggestion
• Accreditation report includes for each deficiency:
  • Applicable standard number
  • Explanation of deficiency
  • Required responses
  • Response timeline
Responding to Deficiencies

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**Month:**
- Month 1: Compliance Application Submitted
- Month 2: Inspection Conducted
- Month 3: Outcome Determined
- Month 4: Applicant Notified
- Month 5: Respond to Deficiencies
Final Report and Response

• Before receipt of final report, applicant should not:
  • Submit responses
  • Make changes they would not otherwise make

• Upon receipt of final report, applicants should:
  • Submit response for each deficiency within the specified period of time
  • Consult with Accreditation Coordinator as needed
Respond to Deficiencies

• For each deficiency:
  • Explain how the deficiency has been corrected
  • Provide documentation of implemented correction
    • If deficiency requires significant change, applicant may be asked to submit a corrective action plan and agree to provide interim data

• Provide explanation for variances

• Deficiencies generally must be corrected within 3 months

• If process is not complete within 12 months:
  • Program may be required to reapply
  • Renewal applicants may be suspended

• Reinspections may be allowed 16 months to complete process
## Example Response to Deficiency

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<tr>
<th>Applicant Response</th>
<th>The informed consent form was revised to explain the symptoms and risks of cytokine release syndrome.</th>
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Re-Inspection

• Return to site to verify significant deficiencies have been corrected
• Opportunity for applicant to show improvement
• May be original or new inspector
  • Depending on preferences of the organization or inspector or determination of the Accreditation Committee
• May be focused
  • Inspect checklist items where issues identified on initial visit
• May be complete reinspection
Accreditation Awarded!

Once all Standards have been met:

- Director will receive a letter and certificate indicating FACT accreditation; which facilities; which services
- FACT accreditation is for a period of three years
- Renewal process begins two years from accreditation date

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On-Site Inspection Evaluation

- Send feedback on inspection process to FACT office
- Goal is to continue to improve process
- Evaluations are kept confidential
- The evaluation does not impact the accreditation outcome
  - Separate committees and staff
Accreditation Suspension or Termination

**Suspension**
- Not accredited
- Removed from website pending resolution of issue
- Accreditation reinstated without change in expiration date when issue is resolved

**Termination**
- Accreditation revoked
- Completion of entire accreditation process required to regain accredited status

**Typical Causes**
- Extensive delays past accreditation timelines caused by the applicant
  - Significant deficiencies that take long periods of time to correct
Resources

• Process Overview
  http://www.factwebsite.org/accreditationprocess/

• Applicant Guidelines
  http://www.factwebsite.org/Accreditation_Process/CB_Applicant_Guidelines.aspx

• Maintaining Accreditation
  http://www.factwebsite.org/Accreditation_Process/Maintaining_Accreditation.aspx
Thank you!