ACCF Accreditation Services Program Requirements Posted 11/04/2022

Contents

1.0	American College of Cardiology Foundation Accreditation Services	2
2.0	Accreditation Program Requirements	
2.1	Accreditation Facility Responsibilities and Obligations	2
2.2	Accreditation Program-Specific Requirements	5
3.0 Accreditation Program Benefits		12
4.0 National Cardiovascular Data Registry (NCDR)		12
5.0 Hospital Recognition Kit		12
6.0 Research Opportunities		12
6.1	Research Responsibilities and Obligations	12
6.2	Research Benefits	12

ACCF Accreditation Services Program Requirements Posted 11/04/2022

1.0 American College of Cardiology Foundation Accreditation Services

The American College of Cardiology Foundation ("ACCF") offers a variety of Accreditation and Certification products, and in this document, Accreditation, Certification, Designation, and Distinction will be referred to collectively as "Accreditation." Current ACCF Accreditation Program offerings include the programs listed below, and the Program Requirements within this document apply to each of these programs.

- Cardiac Cath Lab (CCL)
- Cardiac Cath Lab with External Review (CCL with XR)
- Chest Pain Center (CPC)
- Chest Pain Center Certification Critical Access Hospital (CAH)
- Chest Pain Center Certification Free Standing Emergency Department (FSED)
- Chest Pain with Primary PCI (CPC PCI)
- Chest Pain with PCI and Resuscitation
- Electrophysiology (EP)
- HeartCARE Center: National Distinction of Excellence (HCC)
- Heart Failure (HF)
- Heart Failure with Outpatient Services
- Transcatheter Valve Certification (TCV)
- Partner in Care Designation

2.0 Accreditation Program Requirements

ACCF's Pledge of Support.

ACCF recognizes the importance of Accreditation to the facility seeking Accreditation ("Facility") and is committed to providing a broad range of resources, tools, and personnel to assist with improving patient outcomes and financial performance in the cardiovascular areas for which ACCF has developed an Accreditation designation. ACCF strives to make the Accreditation process as collegial and collaborative as possible and provides Accreditation Review Specialists (ARS) who are specifically trained and educated to conduct a comprehensive review of the facility's processes.

By signing the Accreditation/Certification Services Agreement and indicating the Accreditation Program(s) your Facility wishes to participate in, your Facility agrees to comply with the Agreement and this Program Requirement document. ACCF may update the requirements outlined in this Program Requirements document and will notify you when the Program Requirements have been modified. The Facility is required to comply with any such modifications to the Program Requirements following notification from ACCF.

2.1 Accreditation Facility Responsibilities and Obligations

Accreditation Program Management:

• Each participating Facility must designate and provide contact information for the following roles for each Accreditation Program:

Posted 11/04/2022

- Key Contact—The Key Contact is the primary point of contact for an assigned Accreditation Program and will coordinate the Accreditation activities and receive updates on behalf of the Facility. The Key Contact will be given access to the purchased Accreditation tool(s) upon receipt of the Agreement and payment.
- Executive Sponsor—The Executive Sponsor will ensure adequate resources are in place to support Accreditation activities.
- o **Billing Contact**—The Billing Contact is the point of contact for annual Accreditation fees and modifications to the Agreement.
- o Marketing Contact- The Marketing Contact is the point of contact for all marketing needs.
- Accreditation User- The Accreditation User is an identified individual with access to the specific Accreditation Program. A minimum of one (1) user is required per Accreditation Program. Additional Users may be added upon written request from the Key Contact.
- The Facility is required to provide a valid and unique email address for all designated contacts at the participating Facility. The email addresses will be used to communicate relevant Accreditation Program information.
- The Facility is responsible for contacting ACCF upon any changes in name, address, or phone number of any designated contacts. If there is a change in the physical location of the Facility, ACCF may require an additional site review to determine continued compliance with Accreditation Program requirements and standards, and the Facility will be responsible for any associated costs of the site review.
- Any Facility found deficient in any Accreditation criteria at the time of the site review will be
 provided with detailed instructions for becoming compliant and removing the status of criteria
 deficient.

Training and Orientation:

- The Facility data collection staff are expected to complete applicable training programs and adhere to the Accreditation Data Dictionary and Essential Component requirements.
- The Facility is expected to stay current with all instructions published by ACCF and posted within each Accreditation Tool on the private side of the Accreditation website.

Publication of Data:

- The Facility may use the information provided by ACCF for internal purposes only.
- The Facility must seek approval from ACCF before sharing Accreditation-produced reports to any external party. Contact ACCF for review and approval if you desire to share Accreditation-produced reports.
- The Facility agrees that ACCF will publicly recognize the Facility's Accreditation achievement through media outlets.
- ACCF may use Facility data provided by Facility or accessed by ACCF via the National Cardiovascular Data Registry pursuant to Section 4.0 of these Program Requirements to provide aggregate summary data to its wholly owned subsidiaries for the purpose of providing the Facility with the opportunity to participate in value-added quality improvement services. ACCF will aggregate all Facility data and reports at the facility level, and no patient information will be shared. All such reports shall be provided through a secure login and shall not be used for any purpose other than as described.

Annual Fees:

The Facility is required to pay an annual fee for each Accreditation Program.

Posted 11/04/2022

- ACCF will provide the Facility with a yearly invoice via email no later than ninety (90) days before
 the Accreditation Program Purchase anniversary date. Yearly invoices will be sent to the Billing
 Contact and the Key Contact.
- Program Purchase dates may vary depending on the Accreditation Program and the initial timing of participation.
- The annual fee is non-refundable even if your participation in the Accreditation Program(s) is terminated for any reason.

Additional Fees Per Accreditation Program:

- The Facility is responsible for all travel costs for up to two (2) ACCF staff members for a site review to be conducted onsite at the Facility. ACCF's Accreditation Site Review travel policy shall govern the way travel costs are reimbursed.
- A Loss of Productivity (LOP) fee may be applied if a site review (video conference or onsite) does not take place within fourteen (14) months of the Facility's receipt of access to the Accreditation Tool (this LOP fee does not apply to HeartCARE Center Designation). The fee will be \$500 per month for each month beyond the fourteen (14)-month period to a maximum of \$5000 and will be invoiced at the time of the site review (if applicable). The LOP fee, including noncancelable items (hotel, airfare), may be applied if ACCF cancels the site review due to any unauthorized third-party agent, representative, consultant, or invitee present in the site review.
- A Criteria Deficient fee of \$5,000 may be assessed if the Facility fails to meet the Accreditation requirements at the time of the site review.
 - The Facility is responsible for all travel costs associated with Criteria Deficiency status for one
 - (1) ACCF staff member to conduct a follow-up site review(s).
- A fee may apply to the Facility that requests to change its Accreditation designation from the one
 originally granted, to the extent such changes are permissible, or if the Facility moves from one
 physical location to another and wants to transfer the Accreditation designation to the new
 location.
 - o Examples of designation change include but are not limited to:
 - A Facility Accredited as Chest Pain with PCI loses 24/7 coverage; the Facility would need to adhere to the requirements of Chest Pain Accreditation without PCI.
 - A Facility Accredited as Chest Pain with PCI wants to add Resuscitation.
 - A Facility Accredited as Cardiac Catheterization Lab Base has added 24/7 coverage and wants to become Accredited with PCI.
 - The Facility is responsible for all travel costs associated with an onsite review, if needed, for up to one (1) staff member.

Termination of Program:

• If a Facility terminates the Agreement at any point in the Accreditation cycle, the Facility is required to stop using the Accreditation designation marks and must remove the Accreditation designation marks from all external and internal Facility materials, websites, signage, as outlined in the Agreement.

ACCF Accreditation Services Program Requirements Posted 11/04/2022

2.2 Accreditation Program-Specific Requirements

For Cardiac Catheterization Lab Accreditation:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Facility must demonstrate active participation in the NCDR CathPCI Registry®
 - If the Facility stops entering data into the CathPCI Registry® or does not renew the annual CathPCI Registry® enrollment, the Facility is at risk of having the Cardiac Catheterization Lab Accreditation designation revoked.
- The Facility understands Accreditation is granted for three (3) years.
- The Facility understands that the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Cardiac Catheterization Lab Accreditation designation is initially granted.
- The Accreditation expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- The annual fee must be paid in full.
- Any Facility that achieves Accreditation may apply for re-accreditation. To preserve the Anniversary Date, it is strongly recommended that the Facility submit its application for re-accreditation no later than six (6) months before its Anniversary Date. If the re-accreditation process is completed before the Facility's Anniversary Date, the re-accreditation will be for a full three (3) year term from the current Anniversary Date. If not, the re-accreditation will begin from the Facility's new anniversary date determined by the new Accreditation date.
- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within 60 days of receiving access to the Accreditation tool.
- Confirmation of an onsite review date is expected within 60 days of receiving access to the Accreditation tool.
- Submission of the Application is expected within 12 months of receiving access to the Accreditation online tool. Early submission of the application is encouraged.

For Chest Pain Accreditation:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

The Facility must demonstrate active participation in the NCDR Chest Pain-MI Registry™

OR

Posted 11/04/2022

- Active data entry into the Chest Pain Accreditation Conformance Database (ACD) as outlined in the ACD User Guide
 - o If the Facility stops entering data into the Chest Pain-MI Registry™ or ACD or does not renew the annual Chest Pain-MI Registry™ enrollment, the Facility is at risk of having the Chest Pain Accreditation designation revoked.
- Defense Health Agency Military Treatment Facilities will utilize internally developed reports to demonstrate compliance with required data elements.
- The Facility understands Accreditation is granted for three (3) years.
- The Facility understands that the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Chest Pain Accreditation designation is initially granted.
- The Accreditation expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- Any Facility that achieves Accreditation may apply for re-accreditation. To preserve the
 Anniversary Date, it is strongly recommended that the Facility submit its application for
 re-accreditation no later than six (6) months before its Anniversary Date. If the re-accreditation
 process is completed before the Facility's Anniversary Date, the re-accreditation will be for a full
 three (3) year term from the current Anniversary Date. If not, the re-accreditation will begin from
 the Facility's new anniversary date determined by the new Accreditation date.
- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within 60 days of receiving access to the Accreditation tool.
- Confirmation of the onsite review date is expected within 60 days of receiving access to the Accreditation tool.
- Submission of the Application is expected within 12 months of receiving access to the Accreditation online tool. Early submission of the application is encouraged.

For Chest Pain Center Certification- Critical Access Hospital - Equal to or less than 25 Acute Care Beds:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Facility must demonstrate active participation in the NCDR Chest Pain-MI Registry™
 - o If the Facility stops entering data into the Chest Pain-MI Registry™ or does not renew the annual Chest Pain-MI Registry™ enrollment, the Facility is at risk of having the Chest Pain Accreditation designation revoked.
- The Facility understands that Certification is granted for three (3) years.
- The Facility understands that the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Chest Pain Certification designation is initially granted.
- The Certification expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- Any Facility that achieves Certification may apply for re-certification. To preserve the

Posted 11/04/2022

Anniversary Date, it is strongly recommended that the Facility submit its application for re-accreditation no later than six (6) months before its Anniversary Date. If the re-certification process is completed before the Facility's Anniversary Date, the re-accreditation will be for a full three (3) year term from the current Anniversary Date. If not, the re-accreditation will begin from the Facility's new anniversary date determined by the new Accreditation date.

- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis
- Submission of Baseline Gap Analysis is expected within sixty (60) days of receiving access to the Accreditation tool.
- Confirmation of an onsite review date is expected within sixty (60) days of receiving access to the Accreditation tool.
- Submission of the Application is expected within twelve (12) months of receiving access to the Accreditation online tool. Early submission of the application is encouraged.

For Chest Pain Center Certification- Free Standing Emergency Department:

- The Facility must demonstrate active participation in the NCDR Chest Pain-MI Registry™
 - o If the Facility stops entering data into the Chest Pain-MI Registry™ or does not renew the annual Chest Pain-MI Registry™ enrollment, the Facility is at risk of having the Chest Pain Accreditation designation revoked.
- The Facility understands that Certification is granted for three (3) years.
- The Facility understands that the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Chest Pain Certification designation is initially granted.
- The Certification expires on the Anniversary Date unless:
 - Appropriate application documentation for re-certification is received before the Anniversary Date.
- Any Facility that achieves Certification may apply for re-certification. To preserve the
 Anniversary Date, it is strongly recommended that the Facility submit its application for
 re-certification no later than (six) 6 months before its Anniversary Date. If the re-certification
 process is completed before the Facility's Anniversary Date, the term of the re-certification will
 be for a full three (3) year term from the current Anniversary Date. If not, the re-certification will
 begin from the Facility's new anniversary date determined by the new Certification date.
- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within sixty (60) days of receiving access to the Certification tool.
- Confirmation of an onsite review date is expected within sixty (60) days of receiving access to the Certification tool.
- Submission of the Application is expected within twelve (12) months of receiving access to the Certification online tool. Early submission of the application is encouraged.

Posted 11/04/2022

For Electrophysiology Accreditation:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Facility must demonstrate active participation in the NCDR EP Device Implant Registry™, the NCDR LAAO Registry™, or the NCDR AFib Ablation Registry™,
 - o If the Facility stops entering data into the EP Device Implant Registry™, the LAAO Registry™, and/or the AFib Ablation Registry™ or does not renew the EP Device Implant Registry™, the LAAO Registry™, and/or the AFib Ablation Registry™ annual enrollment, the Facility is at risk of having the Electrophysiology Accreditation designation revoked
- The Facility understands Accreditation is granted for three (3) years.
- The Facility understands that the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Electrophysiology Accreditation designation is initially granted.
- The Accreditation expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- Annual fees must be paid in full.
- Any Facility that achieves Accreditation may apply for re-accreditation. To preserve the
 Anniversary Date, it is strongly recommended that the Facility submit its application for
 re-accreditation no later than (six) 6 months before its Anniversary Date. If the re-accreditation
 process is completed before the Facility's Anniversary Date, the re-accreditation will be for a full
 three (3) year term from the current Anniversary Date. If not, the re-accreditation will begin from
 the Facility's new anniversary date determined by the new Accreditation date.
- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within sixty (60) days of receiving access to the Accreditation tool.
- Confirmation of an onsite review date is expected within sixty (60) days of receiving access to the Accreditation tool.
- Submission of the Application is expected within twelve (12) months of receiving access to the Accreditation online tool. Early submission of the application is encouraged.

For HeartCARE Center™ -National Distinction of Excellence:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Facility must maintain the current Accreditation Program(s)
 - At the time of application submission, the Facility must have at least (1) current accreditation; (must not be expired, i.e., can't be in the process of renewal).
 - At the time of application submission, if any Accreditation Program(s) being utilized for one of the mandatory requirements is set to expire within six (6) months of the application date, the Facility must be in the process of renewing that Accreditation Program.

Posted 11/04/2022

- o If the Accreditation Program utilized to achieve HeartCARE Center™ distinction expires during the term of the HeartCARE Center™ Accreditation, the Facility is at risk of having the HeartCARE Center designation revoked.
- The Facility must demonstrate active participation in an NCDR registry if the registry requirement has been selected:
 - If the Facility stops entering data into the registry selected for the HeartCARE Center designation or does not renew the annual registry enrollment, the Facility is at risk of having the HeartCARE Center™ designation revoked.
- The Facility must actively participate in the selected QII toolkit if this is selected for use.
- The Facility must actively participate in the selected QII Campaign if this is selected for use.
- The Facility must maintain NCDR Public Reporting if this is selected for use
- The Facility understands Accreditation is granted for one (1) year.
- The Facility understands that the "Anniversary Date" refers to the date HeartCARE Center designation is initially granted.
- The Accreditation expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- Annual fees must be paid in full.
- Any Facility that achieves Accreditation may apply for re-accreditation. To preserve the Anniversary Date, it is strongly recommended that the Facility submit its application for re-Accreditation no later than sixty (60) days before its Anniversary Date. If the re-accreditation process is completed before the Facility's Anniversary Date, the term of the re-accreditation will be for a full one (1) year term from the current Anniversary Date. If not, the re-accreditation will begin from the Facility's new anniversary date determined by the new Accreditation date.
- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.

HeartCARE Center Public Recognition

The ACCF will publicly recognize those hospitals that achieve the HeartCARE Center designation through media outlets and public reporting. The form and location(s) of such public recognition will be determined by ACCF and include the use of the hospital's name and logo, as well as the names of the MACC or FACC and the AACC serving as ACCF Member CV champions. By applying for the HeartCARE Center designation and continuing to maintain the designation, the hospital consents to the use of the hospital's name and/or logo in connection with the public recognition and further consents to the use of the names of the ACCF Member CV champions on behalf of the ACCF Member CV champions.

For Heart Failure Accreditation:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Facility must demonstrate active data entry into the Heart Failure Accreditation Conformance Database (ACD) as outlined in the ACD User Guide.
 - The Facility may also utilize internally developed reports to demonstrate compliance with required data elements.
 - o The Facility may also provide reports from a Nationally Recognized Database to

Posted 11/04/2022

- demonstrate compliance with required data elements.
- If the Facility stops entering data into the ACD, providing internal reports, or reports from a Nationally Recognized Database, the Facility is at risk of having the Heart Failure Accreditation designation revoked.
- The Facility understands Accreditation is granted for three (3) years.
- The Facility understands the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Heart Failure Accreditation designation is initially granted.
- The Accreditation expires on the Anniversary Date unless:
 - Appropriate application documentation for re-accreditation is received before the Anniversary Date.
- Annual fees must be paid in full.
- Any Facility that achieves Accreditation may apply for re-accreditation. To preserve the Anniversary Date, it is strongly recommended that the Facility submit its application for re-accreditation no later than six (6) months before its Anniversary Date. If the re-accreditation process is completed before the Facility's Anniversary Date, the re-accreditation will be for a full three (3) year term from the current Anniversary Date. If not, the re-accreditation will begin from the Facility's new anniversary date determined by the new Accreditation date.
 - The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within sixty (60) days of receiving access to the Accreditation tool.
- Confirmation of an onsite review date is expected within sixty (60) days of receiving access to the Accreditation tool.
- Submission of the Application is expected within twelve (12) months of receiving access to the Accreditation online tool. Early submission of the application is encouraged.

For Transcatheter Valve Certification:

The Facility must adhere to mandatory Accreditation requirements outlined in the application, the Agreement, and this document.

- The Facility must demonstrate active participation in the STS/ACC TVT Registry™.
 - If the Facility stops entering data into the STS/ACC TVT Registry or does not renew the annual STS/ACC TVT Registry enrollment, the Facility is at risk of having the Transcatheter Valve Certification designation revoked.
- The Facility must participate in the STS National Database for Cardiac Surgery.
- The Facility understands that Certification is granted for three (3) years.
- The Facility understands the "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Transcatheter Valve Certification designation is initially granted.
- The Certification expires on the Anniversary Date unless:
 - Appropriate application documentation for re-certification is received before the Anniversary Date.
- Annual fees must be paid in full.
- Any Facility that achieves Certification may apply for re-certification. To preserve the
 Anniversary Date, it is strongly recommended that the Facility submit its application for

Posted 11/04/2022

re-certification no later than (six) 6 months before its Anniversary Date. If the re-accreditation process is completed before the Facility's Anniversary Date, the term of the re-certification will be for a full three (3) year term from the current Anniversary Date. If not, the re-certification will begin from the Facility's new anniversary date determined by the new Certification date.

- The ACCF reserves the right to modify anniversary dates to create exceptions on a case-by-case basis.
- Submission of Baseline Gap Analysis is expected within sixty (60) days of receiving access to the Certification tool.
- Confirmation of a Video (remote) site review date is expected within sixty (60) days of receiving access to the Certification tool.
- Submission of the Application is expected within twelve (12) months of receiving access to the Certification online tool. Early submission of the application is encouraged.

For Partner in Care Program:

The Provider (EMS or HF Outpatient Clinic) must adhere to mandatory Partner in Care requirements outlined in the application, the Agreement, and this Program Requirements document.

- The Provider must demonstrate active engagement with the corresponding Accredited Facility.
 Documents submitted by the Facility into the Accreditation tool are expected to support active and ongoing engagement.
- The Provider understands the Partner in Care designation is only active during the Facility Accreditation period of three (3) years.
- The Provider understands the Facility "Anniversary Date" refers to the date that is the three (3) year anniversary of the date Accreditation designation is initially granted.
- The Partner in Care expires on the Accredited Facility Anniversary Date unless:
 - The Facility must submit the renewal application for re-accreditation prior to the Anniversary Date.
 - o If not, the re-accreditation will begin from the Facility's new anniversary date determined by the new Accreditation date.

3.0 Accreditation Program Benefits

ACCF provides support via telephone and email during ACCF's business hours which are posted on the Accreditation Services website https://cvquality.acc.org/accreditation

- For optimal functionality, the following are required:
 - Operating System Microsoft Windows 2007 or higher.
 - Browser Google Chrome is the preferred browser to utilize for Accreditation Tools.
 (Recommend that pop-up blockers are disabled)
 - Adobe PDF Reader.

4.0 National Cardiovascular Data Registry (NCDR)

Posted 11/04/2022

ACCF Accreditation Services allows hospitals who are accredited or who have purchased the accreditation service to use their registry data to meet specific Accreditation requirements. Therefore, the Facility, by participating in one or more Accreditation Programs, hereby consents and authorizes ACCF to use the appropriate registry data for the applicable Accreditation Program(s)

5.0 Hospital Recognition Kit

ACCF Accreditation Services has developed a recognition kit to support hospitals in communicating their Accreditation achievement. The recognition kit includes a sample press release, sample articles, social media messages, a digital seal for use on the Facility webpage, and other tips and ideas the Facility can use to promote the Facility's quality improvement efforts to the Facility's patients and community. By signing the Agreement and indicating the Facility's commitment to the ACCF Accreditation program, the Facility agrees to comply with the appropriate use of the recognition kit.

6.0 Research Opportunities

From time to time, ACCF leads projects or collaborates with outside research organizations to explore cardiovascular science and care delivery questions. ACCF will present key research opportunities to hospitals. Each research opportunity will be a voluntary, optional item for the Facility's consideration.

6.1 Research Responsibilities and Obligations

There is no obligation to participate in any research project with ACCF. If the Facility chooses to opt into a research project, the responsibilities and obligations (including research protocols) will be clearly outlined in the enrollment materials.

6.2 Research Benefits

In addition to furthering cardiovascular science to improve patient outcomes, some research opportunities may involve financial compensation for the Facility's role in the study, similar to clinical trials run by clinical or academic research organizations. If the Facility chooses to pursue a research project, the enrollment materials will clearly outline the financial and non-financial benefits.