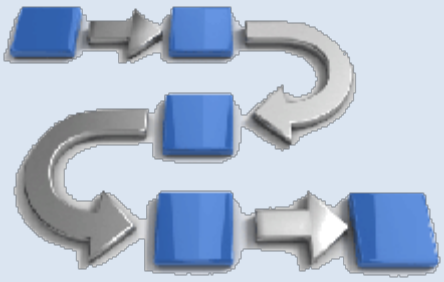
# Site Accreditation and Standards Institute

## Clinical Research Site Accreditation Protocol



Version 5.0
February 5, 2024

SASI CLINICAL RESEARCH ™ SITE ACCREDITATION

## Table of Contents

## 1.0 About the Program

The Site Accreditation and Standards Institute (SASI) Clinical Research Site Accreditation program is an outcome of the vision of the Alliance for Clinical Research Excellence and Safety (ACRES). SASI's creation conforms with ACRES vision to build a global network of accredited world-class Clinical Research Sites that are based on a quality management systems approach. This global network of accredited Clinical Research Sites will model and advocate for research environments that press for continual improvement of quality, performance and safety while reducing the cost and risk of clinical trials. SASI is a fully independent, nonprofit, federally tax-exempt, organization tasked with implementation, oversight, and administration of the Clinical Research Site Accreditation program for certifying conformance to the SASI-QMS:2023-2 Standard for the Quality Management of Clinical Research Sites.

SASI was created as an international collaborative effort to engage stakeholders and experts in clinical research and accreditation from around the world to develop and maintain a uniform, comprehensive standard that can be used globally by organizations to ensure the competence, professionalism, and operational excellence at Clinical Research Sites. The establishment of a worldwide standard is the first step toward building a global system for accrediting clinical research that is modeled after the international air transport system and other similar frameworks.

It is our shared vision that an effective clinical research entity requires all units to operate within a defined set of consensus-based specifications for quality management. The outcomes of this accreditation system are intended to demonstrate a measurable contribution to the overall goals of reducing the failure rate for clinical trials, reducing drug time to market, and lowering drug costs for the betterment of humankind.

A uniform standard applied to Clinical Research Sites supported by an independent accreditation process provides a robust opportunity for enhancing safety, quality, efficacy, and efficiency in clinical trials. This process will enable clinical research leaders to properly evaluate promising therapeutics while enhancing regulatory compliance and permitting regulatory simplification. In addition, the accreditation process provides a structured and objective mechanism for site structure, culture, and performance evaluation, which can form a foundation for ongoing learning and improvement.

Additional information and background on the most current revision of the SASI-QMS:2023-2 Standard can be found at: https://sasi-accreditation.org/PDF/SASI-QMS-2023-2.pdf

## 2.0 General Process Overview

Seeking and maintaining Accreditation is a straightforward process:

1. **Self-Assessment** – Those considering Accreditation should review the publicly available SASI-QMS:2023-2 Standard on the SASI website: https://sasi-accreditation.org/PDF/SASI-QMS-2023-2.pdf Use this document to conduct an internal self-assessment of the Clinical Research Site's readiness to begin the Accreditation process. When the Standard has been reviewed and the Clinical Research Site is ready to start the Accreditation review and preparation process, move on to the next step. See section 8.1 for more detail.

2. **Site Accreditation Candidate Contact Form** - The contact form is available on the SASI website here: https://sasi-accreditation.org/enroll-in-exploratory-program.html The Site Accreditation Candidate Contact Form alerts the SASI Accreditation Services Team of the Clinical Research Site's interest in becoming an Accredited Site. The SASI Accreditation Services Team will reach out for additional information about the Clinical Research Site and to discuss the process. See section 8.2 for more detail.

3. **Accreditation Agreement** - Once the terms of Accreditation have been agreed to by the SASI Accreditation Services Team and the Clinical Research Site, an Accreditation Agreement will be drafted and signed. A non-refundable application and commitment fee will then be required to demonstrate readiness to begin the Accreditation process. See section 8.3 for more detail.

4. **Complete Quality Accelerator Training and Certifications** – Once the Site Accreditation Agreement is finalized, the Clinical Research Site will be placed in Candidate status and receive access to the available SASI Quality Accelerator training curriculum provided through the Quality Management Institute (QMI). Quality Accelerator training is available for those needing training to obtain the required Clinical Research Quality Manager (CRQM) certifications. After obtaining the required CRQM certification, key staff will then be granted access to the SASI Accreditation Management Directory and to the KTP Community.

   The KTP Community is a forum where Accredited Clinical Research Sites and Candidate Clinical Research Sites can have facilitated discussion, receive information, insights, encouragement, and support from the other Community members who have a common framework for discussion.

   Clinical Research Sites may remain in Candidate status for an indefinite period of time. SASI wants to be as certain as possible that each Candidate has had ample opportunity to complete a thorough self-assessment and to mitigate any issues on non-conformance with the Standard before signaling readiness for review. SASI

encourages Candidates to seek advice from fellow Candidates and already Accredited CRSs in how to conform to the Standard. As appropriate, SASI Accreditation Services may also suggest a Candidate consider engaging our Preferred Service Providers to help prepare for Accreditation or mitigate gaps. See section 8.4 and 8.5 for more detail.

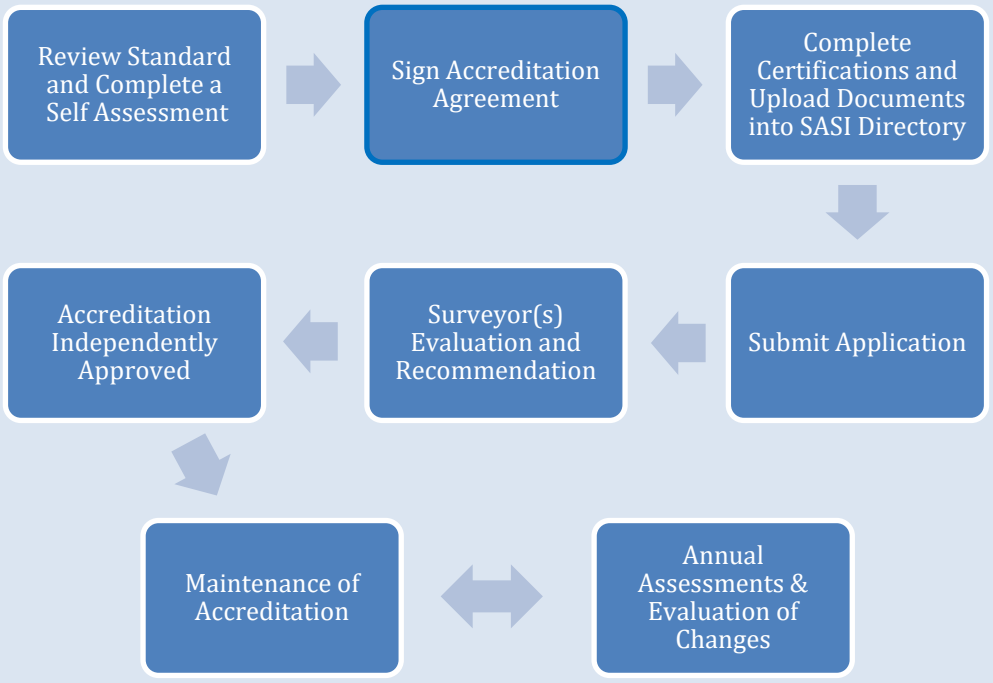
5. **Submit for Assessment** – When self-assessment preparations and required trainings are complete, the Candidate Clinical Research Site should then confirm they are in conformance with the Standard and ready for a formal Assessment by a SASI Surveyor assigned by the SASI College of Surveyors. The Clinical Research Site must complete all sections of the SASI Accreditation Management Directory, upload necessary supporting documentation, and internally consider themselves in full conformance with the standard before submitting their Accreditation application and moving on to the Assessment phase. See section 8.6 and 8.7 for more detail.

6. **Assessment** - A SASI Surveyor, or team of Surveyors, will review your Accreditation materials and complete an assessment to confirm if the Clinical Research Site is in conformance with the Standard. See sections 8.8.2, 8.8.3, and 8.8.4 for more detail. If the Clinical Research Site is found to not be in conformance with the Standard, the Clinical Research Site will be given reasonable opportunity to remedy the non-conformance as part of the Assessment process. The outcome of the Assessment process will be a report from the Surveyor confirming conformance to the standard; or, if the Clinical Research Site is found to not be in conformance with the Standard, details regarding areas of non-conformance. See section 8.8 for more detail.

7. **Accreditation** - The Surveyor's Assessment report will receive peer review by the SASI College of Surveyors and then be independently reviewed by the SASI Site Accreditation Council to confirm the integrity of the process prior to Accreditation being granted. Accreditation is granted to the Clinical Research Site in accordance with the Accreditation Agreement and Categories of the Accreditation. See section 8.7, 8.8, 8.9, and 8.10. for more detail.

8. **Maintain Accreditation** – Clinical Research Sites maintain Accreditation by keeping their quality management system and Clinical Research Site practices in conformance with the Standard and other applicable protocols or contractual requirements. The Surveyor will conduct a Continuation Assessment approximately once per year to confirm the Clinical Research Site remains in conformance with the Standard. Changes in the quality management system, Categories of Accreditation, or other factors may require on-going interactions with the SASI Surveyor between Continuation Assessments. See section 10.0 for more detail.

**General Process Overview:**



## 3.0 Terms & Definitions

**SASI-QMS:2023-2: SASI Standard for the Quality Management of Clinical Research Sites** – The formal name for the Accreditation Standard, sometimes referred to as simply "SASI-QMS:2023-2" or "the Standard".

**Clinical Research Site (CRS)** – Entity seeking Accreditation from SASI. Clinical Research Sites are where clinical research is performed with clinical research participants who are evaluated and/or treated in accordance with specific clinical trial protocol(s), a common system of research operational processes and procedures, and a common quality management system; sometimes referred to in this and other SASI materials as just "CRS". See additional information on defining a CRS in section 4.1.

**Candidate Clinical Research Site** – a CRS in the process of preparing for initial assessment.

**SASI Keeping The Promise Community (KTP Community)** – A forum where Candidate CRSs and already Accredited CRSs can share best practices, collaborate, and help each other prepare for and maintain the highest quality in clinical research.

**Preferred Services Provider** – Organizations vetted by SASI and known to provide consulting and support services to CRSs consistent with SASI ethics and values, and in conformance with the Accreditation standard and contractual obligations.

**Quality Management Institute (QMI)** – Organization providing the Quality Accelerator Program (QAP) and the required Clinical Research Quality Manager (CRQM) certification.

**Site Accreditation Council** - An objective, independent group of senior SASI members, appointed by the Executive Director, who review the work of the College of Surveyors and issue final decisions on Accreditation. Referred to within this document as the "Council".

**Surveyor** – Individual trained on the Standard and in the systems approach to quality management and assigned by SASI College of Surveyors to competently assess a CRS's Accreditation materials and processes to determine if that CRS is in conformance with the Standard and other defined and documented requirements for Accreditation. Depending on a CRS's complexity, SASI College of Surveyors may assign a Survey team to adequately assess a CRS. In this document the term Surveyor should be viewed synonymous with a team of two or more Surveyors.

**College of Surveyors** – A core team comprised of senior SASI leadership who set standards for Surveyors, review and appoint Surveyors, and conduct peer review of Surveyor's Assessments.

**SASI Accreditation Management Directory** – Secure Directory where the CRS provides documentation or other evidence the CRS conforms to the SASI-QMS:2023-2 Standard and where Surveyors review and interact with the CRS regarding documentation.

*For a complete set of additional definitions relating to the Standard, please refer to the SASI-QMS:2023-2: https://sasi-accreditation.org/PDF/SASI-QMS-2023-2.pdf*

# 4.0 Eligible Organizations

Any organization that meets the definition of a Clinical Research Site (CRS) and is actively involved in the conduct of clinical research may seek Accreditation. This includes but is not limited to:

- Private research sites
- Individual physicians, physician groups or other health care professionals
- Hospitals and health systems
- Private research centers
- Academic medical centers
- Government research centers

If the CRS is unclear if the organization would qualify for Accreditation, please review the Accreditation Standard available on the SASI website: https://sasi-accreditation.org/PDF/SASI-QMS-2023-2.pdf. If the organization can reasonably address the Accreditation requirements, we would encourage seeking Accreditation. For questions about eligibility please contact the SASI Accreditation Services Team to discuss the specific situation: https://sasi-accreditation.org/enroll-in-exploratory-program.html

## 4.1 What is a Clinical Research Site (CRS)

SASI Accreditation focuses primarily on the quality management system at the CRS. We understand not all CRSs are organized the same, conduct research on the same scale, or conduct the same type of research. The questions the Surveyor might ask, and the types of evidence provided to support the CRS's conformance with the Standard may be different depending on multiple factors. For instance, a CRS conducting first in human phase 1 research in an inpatient setting will have different ways of conforming to the Standard than a CRS focused on outpatient phase III/IV drug research.

SASI uses standard categorizations to describe the scope of the CRS. These categorizations will appear on the SASI website so others will know not only that the CRS is Accredited, but also know the type and scope of research conducted under the Accreditation. The choices selected for the categories are important and will drive the nature and type of questions you will receive during the initial and continuing Accreditation assessment process.

## 4.2 Determining the Clinical Research Site vs. the Organization

The SASI Accreditation Program and the SASI-QMS:2023-2 Standard are designed to provide a reasonable, robust, and recognized Accreditation to a CRS that is applying a common quality management system that conforms to the Standard using common operational policies, processes, and procedures.

The program has the ability and flexibility to address different types of organizations with varying organizational structures conducting various types of clinical research. Please review the examples below.

If an organization has one or more research units (e.g., university with multiple research programs) that operate independently; or, use different quality management systems, or policies and procedures, then each research unit within the organization will need to be accredited as a separate CRS.

Examples:

1 – **Private research clinic or stand-alone research clinic** – Many research projects are conducted at private research clinics or by the stand-alone research unit of a health care practice. These research practices may have multiple physical offices, but typically follow a common set of research procedures and have a common quality management system for all research conducted at the organization. In this circumstance SASI would consider the organization as one CRS.

2 – **Research Institute with separate research units** – It is not uncommon for hospitals, or larger clinic groups, to have divisions or specialty areas within the organization. If these divisions or specialty areas follow different operating procedures regarding how they conduct research; or, they have different quality management systems within the organization, then each unique division would be assessed and Accredited separately. For instance, hospital X is seeking Accreditation for their overall research program. Within the hospital there are 5 divisions conducting research. Four of the 5 divisions follow the same standardized procedures and quality management system for research; however, the fifth division (e.g., the oncology unit) has its own set of operating procedures specific to the category of trial protocols. In this example, the hospital will have two CRSs for purposes of SASI Accreditation with two distinct practice categorizations that would be assessed and Accredited separately.

3 – **Multi-faceted institution** – Some health systems operate multiple hospitals, physician clinics, surgery centers, and other types of locations with decentralized research operations by location. If an organization's research units have their own operating procedures or quality management system, then each unit will be considered a separate CRS for purposes of Accreditation. For instance, health system Y is seeking Accreditation for their overall research program. Their system consists of 5 main hospital facilities, 30 associated community health clinics, and 2 inpatient surgery centers. All the locations may be conducting research. The overall system has a centralized research administration office that sets overall policy for research as well as conducting global feasibility review of projects. However, each hospital maintains its own research program to carry out the protocols agreed to by

the central research administration office and each hospital has its own procedures for conducting research at the respective facility.

Research at the 30 associated health clinics is overseen by the central office, however each individual facility has its own set of procedures at the clinics, and they are not subject to the quality management system of the tertiary hospitals, and they operate semi-autonomously. The two inpatient rehab centers are closely associated with their closest hospital and research staff from the hospital also cover the rehab centers following the hospital's research procedure. In this example there will be 35 separate CRSs to accredit. Five hospitals and 30 single site clinics. Note that each hospital in turn might have multiple research units within their facility (see example 2). The health system can economize the Accreditation engagement by standardizing procedures and quality management systems throughout the organization.

4 – **Academic medical centers** – Large medical centers may have multiple combinations of example 2 and 3 with separate sites, teams, or labs each having their own unique research operational procedures and/or quality management system and thus requiring separate Accreditation of each CRS.

The final scope of the Accreditation will be outlined in the Accreditation Agreement and include details of the organizational divisions and units of an organization which are being accredited. The SASI team will work with your organization to determine how best to structure the Accreditation approach in conformance with the Standards.

## 5.0 SASI Accreditation Management Directory

The SASI Accreditation Program is supported by the SASI Accreditation Management Directory, a secure cloud-based technology solution that CRSs will use to manage their preparations for Accreditation and support them through collecting, organizing, and presenting all the supporting information that is needed to become an Accredited CRS. The platform is used to upload supporting documentation and evidence to address each clause of the Standard, and as the collaboration tool to interact with the assigned Surveyor. The system provides approved information and links to supporting educational materials regarding how to conform to the Standard. Finally, the information in the SASI Accreditation Management Directory is securely stored using industry standard encryption and security protocols so CRSs can be confident that only those who they designate will have access to their data.

Access to the SASI Accreditation Management Directory is granted to CRSs who have signed the Site Accreditation Agreement, submitted the required payments, and have the required number of Staff holding the CRQM Certification required under the Agreement. (See section 6.0).

## 6.0 Quality Management Institute (QMI)

> In furtherance of their shared mission to enhance medicines development and clinical research performance and through an integrated systems approach, two independent corporate entities, the Site Accreditation and Standards Institute (SASI) and the Quality Management Institute (QMI) have committed to working together in the public interest.
>
> SASI Guiding Principles Document, August 8, 2020

SASI has partnered with QMI to provide the required training and certifications for CRSs seeking Accreditation. The SASI-QMS:2023-2 Standard is designed to verify the CRS's quality management system, and to provide reasonable assurance of the generation and delivery of quality data within clinical trials. For a CRS to be granted accreditation SASI requires certain CRS to have a specific number of staff with a Clinical Research Quality Manager (CRQM) Certification through QMI. The QMI curriculum and the CRQM Certification is recognized by SASI as both a standard for performance and a standard for training that creates a reliable "Keeping the Promise" work culture, one in which the production of accurate and detailed data is supported by the competencies of a high-performing, cohesive team and also one which conforms to Standard Section 4.1.2.1c and Section 5 for the CRS to maintain "a commitment to quality management and a sustaining "Keeping The Promise work culture".

The Accreditation Candidate will be required to have a minimum of two staff members per CRS complete the CRQM certification prior to beginning the Accreditation process and maintain the minimum level of two certifications per CRS during the term of the Accreditation. Each person's QMI certificate of CRQM completion and official transcript must be uploaded to the Accreditation Candidate's SASI Accreditation Management Directory as proof of CRQM Certification.

Depending on the size and scope of the CRS additional CRS personnel, beyond the two minimum, may be required to be credentialed with the Clinical Research Quality Manager (CRQM) certification. Any additional certification requirements will be determined in collaboration between the CRS and the SASI Accreditation Services Team and will be defined in the Accreditation Agreement.

A CRS may be subject to staffing changes through turnover, corporate growth, or merger and the credentialing minimums required in the Accreditation Agreement will be monitored during annual continuing assessments. It is the responsibility of the Accredited entity and/or each CRS to remain in conformance to the CRQM credentialing requirements.

SASI has arranged discounts and special registration pricing with QMI for training and for those seeking CRQM Certification for purposes of SASI Accreditation. More information on obtaining the required CRQM certification can be found at https://qualitymanagementinstitute.com

## 7.0 Language Support

The QMI Training and the SASI Accreditation Program are currently available in English.

If other language support is needed, please contact SASI to discuss options: https://sasi-accreditation.org/contact.html

# 8.0 Initial Accreditation Process

## 8.1 Conduct a Self-Assessment

The first step in Accreditation is to download the Standard from the SASI website and conduct an internal assessment of the CRS against the Standard. CRSs should work their way through each clause of the Standard asking themselves 'how does my CRS conform to the requirements of the Standard and what types of documentation are available at the CRS to provide evidence that the Standard is met. Documentation could be in the form of standard operating procedures, policy manuals, employee handbooks, or any number of items. The goal in this initial self-assessment is to make sure the CRS is generally ready to begin the Accreditation process.

The Standard is publicly available on our website: https://sasi-accreditation.org/PDF/SASI-QMS-2023-2.pdf

## 8.2 Submit Site Accreditation Candidate Contact Form

After conducting a self-assessment, the CRS should then submit a Site Accreditation Candidate Contact Form: https://sasi-accreditation.org/exploratory-program.html. On the form the CRS will be asked to specify the organizational structure of the CRS and categorize the CRS to describe the CRS's scope of practice for which the CRS is seeking Accreditation. The SASI Accreditation Services Team will contact the CRS contact person to confirm the defined parameters of the Accreditation Process, establish training and certification requirements, and verify the description of the CRS for which Accreditation will be sought. CRS's submitting this form are also supported with up to four hours of consultation with the SASI Accreditations Services Team. These discussions are intended primarily to assist the CRS in refining their specific scope of Accreditation but can include other topics. Both SASI and the Clinical Research Site have a vested interest in ensuring that the proposed scope of Accreditation is realistic and achievable given the organization's size, location(s), personnel structure, resources, and timeline. The SASI Accreditation Services Team will use this information to draft an Accreditation Agreement outlining the terms and conditions associated with Accreditation.

## 8.3 Sign Accreditation Agreement

When the Accreditation Agreement terms have been agreed to by the SASI Accreditation Services Team and the CRS leadership, the agreement is signed, and a non-refundable application and commitment fee tendered to demonstrate the CRS's readiness and intent to begin the Accreditation process. The CRS will then be placed in Candidate status and granted access to the QMI training and other support services associated with Accreditation.

### 8.4 Complete Required Quality Accelerator Training and Certifications

Once the Accreditation Agreement has been signed, designated staff at the CRS will receive access to the SASI Quality Accelerator Program training provided through QMI. The CRS will be required to continuously maintain a minimum level of staff holding the CRQM credential (See Section 6.0) to sustain a quality work culture and continued conformance to the Standard. The number of staff at the CRS who are required to hold the CRQM certification will be outlined in your Accreditation Agreement. Training and certification may be completed at any time while the CRS is in Candidate status; there is no time limit.

### 8.5 Get Support in the KTP Community

CRQM Certified staff will be given access to the KTP Community. The Community contains a host of support tools to further help prepare CRSs for Accreditation. The KTP Community is a facilitated community where other Candidate and Accredited CRSs can share best practices and other support materials to help the overall Community prepare for and maintain SASI Accreditation.

It is expected the CRS will repeat this process of self-assessment, evaluation, internal review, and remediation until the key staff at the CRS determine the CRS is in conformance with the Standard and are ready to begin the formal Assessment process. Some issues may be easy to address; for instance, creating an extra log to document a process already in place, but not currently documented. Some issues may be more difficult; for instance, developing procedures and programs to create a culture of quality and prepare adequate objective evidence of effective implementation of the program.

There is no time limit associated with how long a CRS can remain in Candidate status. Access to the KTP Community is designed for and open to all Candidate CRSs and remains open to Accredited CRSs that maintain their Accredited status.

### 8.6 Upload Supporting Documents

To satisfy the Standard, the CRS will be required to provide evidence to the Surveyor demonstrating how the CRS conforms to the Standard. These documents, procedures, explanations, records, or other materials are uploaded to the SASI Accreditation Management Directory during the Candidate phase. When the CRS is ready to declare it is in conformance with the Standard and move on to formal Assessment, the CRS then notifies SASI of its readiness for review.

### 8.7 Requesting an Accreditation Review

By notifying SASI of its readiness for Accreditation Review, the CRS is confirming they have completed all internal assessments, remediation, and documentation; and, that the CRS leadership believes they are in full conformance with the Standard. Upon notification, and per the terms of the Accreditation Agreement, the SASI Accreditation Services Team will alert the SASI College of Surveyors that the CRS is ready to begin the formal Assessment process to confirm the CRS is in conformance with the Standard.

## 8.8 Assessment of Clinical Research Site

### 8.8.1 Selection and Assignment of Surveyor

Upon requesting Accreditation Review, and its acceptance by the SASI Accreditation Services Team, the SASI College of Surveyors will assign one or more qualified Surveyor(s) to assess the CRS's conformance with the Standard. Assignment of Surveyors is based on several criteria including, but not limited to, the Surveyor's expertise with the category of research conducted at the CRS; geographic proximity; and potential conflicts of interest. The College of Surveyors may determine that a team of two or more Surveyors is necessary to assess the CRS. Throughout this document, and other SASI materials, where the term Surveyor appears, it may refer to one or more persons. Please note that when the SASI College of Surveyors assigns a Surveyor team, collectively the team will possess the competence to undertake the Assessment process. Some members of a Survey team may have specialized competencies and not all members of a team may have identical competencies.

The SASI College of Surveyors will notify the primary contact at the CRS know which Surveyor has been assigned to conduct the Assessment. CRSs will have the opportunity to request a different Surveyor if they provide sufficient and reasonable justification to the College regarding why a different Surveyor is being requested.

### 8.8.2 Written Materials Assessment

The Surveyor will review the CRS's written materials in SASIware and may follow-up with the CRS as needed to provide initial feedback on documents provided through the SASI Accreditation Management Directory or any areas where the Surveyor has questions or determines the supporting materials do not provide sufficient evidence that the CRS is in conformance with the Standard. CRSs will have ninety days to address and respond to review of the written materials.

After the first round of any needed revisions are complete, the Surveyor will review the CRS's updated written materials and notify the CRS via the SASI Accreditation Management Directory if there are any remaining areas where the updated documents do not provide sufficient evidence that the CRS is in conformance with the Standard. CRSs will be given another ninety days after this second round of assessment to again address any issues of non-conformance with the Standard. If the CRS is unable to address the non-conformance issues within the ninety additional days, they should contact the SASI Accredited Services Team who may be able to provide other options. If no option is available, the CRS may be asked to voluntarily withdraw their Candidacy and submit again later.

### 8.8.3 On-line Assessment

At the conclusion of the evaluation of written materials the Surveyor will continue with the assessment through a series of remote video interviews between CRS personnel and

Surveyors to assess if and how the written materials are carried out in practice. These interviews will be recorded. Length and number of interviews will depend on the nature and complexity of the CRS. If the Surveyor determines the interviews are more appropriately completed in person during the On-Site Assessment this step may be combined with the On-site Assessment.

### 8.8.4 On-Site Assessment

At the conclusion of the written material evaluation and completion of any on-line video recorded interviews, the Surveyor will continue to the on-site portion of the Assessment. During on-site portion of the Assessment, the CRS's designated Surveyor will complete a physical on-premises assessment of the CRS's facilities. The Surveyor may also conduct additional interviews of key staff. The primary purpose of the interviews and on-premises visit is to confirm the facilities, staff's description of processes, quality management culture, etc. observed through video-conferencing and other interactions with the CRS staff matches the written documentation so the Surveyor can assess if the CRS is in conformance with the Standard in action as well as represented through documentation.

Timing of the on-site portion of the Assessment will be mutually agreed to between the Surveyor, the SASI College of Surveyors, and the CRS.

During the on-site portion of the assessment the Surveyor may request and review additional support records to assess if the CRS and staff are in conformance with the Standard. At the end of the on-site portion of the Assessment and before the Surveyor leaves the CRS, the Surveyor will verbally provide a list of areas where they may have observed the CRS is not in conformance with the Standard. The CRS should take this opportunity to clarify any issues with the Surveyor.

### 8.8.5 Peer Review

The Surveyor will furnish a written report regarding their Assessment findings to the SASI College of Surveyors for peer review. The purpose of the peer review is for transparency and consistency of the Assessment process across CRSs. A panel of reviewers from the College of Surveyors will review the Surveyor's Assessment of the CRS's conformance or non-conformance with the Standard and may pose additional questions or potentially alter some of the findings communicated verbally to the CRS at the end of the on-site Assessment.

### 8.8.6 Findings Report

Within 20 business days after the completion of the on-site Assessment the CRS will receive a written Findings Report detailing any areas where the Surveyor determined, and the peer review process concurred, that the CRS is not in conformance with the Standard.

The CRS will have 10 business days to respond to areas of non-conformance by providing a comprehensive response, and corrective action plan, for each noted area of

nonconformance. The CRS's corrective action plan must include details on the nature of remediation actions and timelines for implementation, along with any other details as requested in the Surveyor's report. As soon as possible upon receipt, the Surveyor will confirm to the CRS if their proposed corrective actions will bring the CRS into conformance with the Standard or if additional corrective actions are necessary. For complicated issues, the Surveyor may confer with members of the College of Surveyors to determine if the proposed corrective actions are appropriate to bring the CRS into conformance with the Standard.

### 8.8.7 Corrective Actions

The CRS will have a maximum of 9 months to implement any corrective actions to address the non-conformances observed during the on-site portion of the Assessment; and, to provide evidence the remediations are implemented and complete. The Surveyor will review the results of the corrective actions to confirm the corrective actions are indeed complete to the Surveyor's satisfaction and that the corrective actions bring the CRS into conformance with the Standard. If the CRS is unable to correct non-conformance issues to the Surveyor's satisfaction as agreed to in the corrective action plan within the nine-month period, the CRS may be asked to voluntarily withdraw their Candidacy and submit an Application again when they have completed the corrective actions.

### 8.8.8 Surveyor Final Assessment

At the completion of the Assessment process, after the Surveyor has confirmed all corrective actions have been completed, the Surveyor will promptly issue a Final Assessment to the Site Accreditation Council either confirming the CRS is in full conformance with the Standard; or that, in the Surveyor's opinion, the CRS is not in conformance with the standard along with a description of the areas of remaining nonconformance. Following a peer review by the College of Surveyors, the CRS will receive a copy of the Final Assessment.

## 8.9 Review by the Site Accreditation Council

Within 10 business days of receipt, the Final Assessment will be reviewed by a three-member review panel of the Site Accreditation Council. The panel will consist of the President of the College of Surveyors and two additional Council members appointed by the Council Chair. Panel members will be selected to avoid any conflict of interest.

If the panel unanimously concurs with the Surveyor's Assessment that the CRS is in conformance with the Standard the panel can grant Accreditation.

If the Final Assessment indicates the Surveyor was unable to confirm the CRS is in conformance with the standard; or, the three-member panel reviewing a Final Assessment indicating conformance does not unanimously agree with the Surveyor's Assessment, the issue will be reviewed at a convened meeting of a quorum of the Site Accreditation Council. The Council, at a convened meeting, can either agree with the Surveyor's assessment that

the CRS is not in conformance and determine that Accreditation should be withheld; or, after thoughtful deliberation and review of the CRS's conformance to the Standard, grant Accreditation. The CRS will be informed of the reasons for the determination and the decision documented in SASIware.

Final authority to grant Accreditation rests with the Site Accreditation Council through a convened meeting or by unanimous determination of the three-member review panel. Authority to withhold or withdraw Accreditation rests with the Site Accreditation Council through determination at a convened meeting of a quorum of the Council.

Any decision to not grant Accreditation can be appealed (see Section 13.0 on Appeals).

### 8.10 Accreditation Granted!

After the Site Accreditation Council determines, based on the Assessment conducted by the Surveyor, with peer review by the College of Surveyors that the CRS is in conformance with the Standard, the CRS will be issued an Accreditation Certificate from SASI and added to the list of Accredited CRSs on the SASI website.

Accreditation is granted to the CRS for a period not to exceed 3 years from the date of the Council's determination.

CRSs who are not granted Accreditation may request to be returned to Candidate status and are encouraged to address the issues of non-conformance to the Standard and upload new materials to the SASI Accreditation Management Directory. After remitting another application and commitment and/or assessment fee, the CRS may re-initiate the Application for Accreditation and matriculate through the process again.

# 9.0 Accreditation Status Classifications

## 9.1 Accredited

A CRS where the Site Accreditation Council affirms that all the Accreditation Standard's requirements have been met and the CRS is in conformance with the Standard. Only CRSs in Accredited status will be displayed on the SASI website with their CRS name and associated practice categories describing the scope of research covered by the Accreditation.

## 9.2 Qualified

If an Accredited CRS experiences a non-conformance event or has a change in quality management procedures, practices, staffing, or similar event which leads to the Surveyor determining the CRS is no longer in conformance with the Standard and has not remedied the issue in a satisfactory time, the CRS's Accreditation will be placed in a Qualified status (see section 10.1). The Surveyor will inform the CRS of those sections of the Standard for which the CRS is out of conformance. They will also inform the CRS regarding the period of time the CRS has to rectify the situation, not to exceed 120 calendar days. Any recommendation from the Surveyor to place a CRS in Qualified status will be reviewed and concurred by a three-member panel of the Site Accreditation Council before going into effect.

The CRS will be notified of Qualified status in writing by the SASI Accreditation Services team. The CRS will need to work with their assigned Surveyor to address the issue(s) through a corrective action plan(s) that brings the quality management system back into conformance with the Standard so that a determination can be made to remove the Qualified status within a timeframe identified in the notice, not to exceed 120 calendar days.

In accordance with the Accreditation Agreement and its requirement for transparency with stakeholders, CRSs placed in Qualified status must alert any person or sponsor inquiring about Accreditation status to the CRS's Qualified status (e.g., on-site feasibility questionnaires).

Qualified status is a step prior to Accreditation being withdrawn.

If the CRS remediates the non-conformance issue within the specified period, the Surveyor can confirm to the Site Accreditation Council the CRS is again in conformance with the standard and Qualified status will be removed.

If the CRS has a valid reason for not addressing the non-conforming issue within the timeframe stipulated, the Surveyor in consultation with the College of Surveyors may recommend a reduction in the scope of the Accreditation (e.g., updating the categories describing the type of research under Accreditation) so that with a reduced scope the CRS

is again in conformance with the Standard; or, confirm the CRS has not remedied the issue and is no longer in conformance with the Standard. Uncorrected nonconformance will lead to Accreditation being Withdrawn.

Qualified status does not appear on the SASI public website. The CRS will continue to be listed as "Accredited" during the review and remediation of the issue(s) leading to a Qualified status.

### 9.3 Withdrawn

Accredited CRSs who do not address the non-conformance with the Standard that led to Qualified status in a timely manner may have their Accreditation formally Withdrawn.

Action to Withdraw Accreditation from a CRS will be determined by a convened meeting of the Site Accreditation Council.

A CRS whose Accreditation is withdrawn will be removed from the SASI list of accredited CRSs.

If a CRS whose Accreditation has been withdrawn seeks to be considered for reinstatement of its Accreditation status, the executive officer of the CRS must submit a signed statement confirming the issue(s) that resulted in the reason for the withdrawal has been rectified and the CRS is ready to be subjected to the full rigor of the Accreditation process. A quorum of the Accreditation Council, along with input from the Executive Director, will consider the reinstatement request and make appropriate determinations regarding next steps.

The CRS may also voluntarily request SASI to withdraw their Accreditation status at any time.

# 10.0 Maintaining Accreditation

After initial Accreditation is granted, in order to maintain Accreditation, the CRS needs to be continuously operated in conformance with operating procedures and quality management system determined through the Assessment process to be in conformance with the Standard. SASI understands CRSs are dynamic places where changes are common. The SASI Accreditation Program focuses on the Surveyor promptly reviewing incremental policy and process changes as they occur, so CRSs remain continually in conformance with the Standard.

## 10.1 Changes to the Clinical Research Site

After initial Accreditation is achieved, the CRS staff are expected to promptly update the CRS's information in the SASI Accreditation Management Directory as changes occur at the CRS. When changes are implemented that impact documents or other responses provided in SASIware to demonstrate conformance with the Standard, the information previously uploaded into the SASI Accreditation Management Directory must be updated within 10 business days of the occurrence of the change and include any other relevant documentation to describe the change. The Surveyor will then promptly review the changes to confirm the CRS remains in conformance with the Standard. All updated information and review by the Surveyor are logged and tracked in the SASI Accreditation Management Directory.

If the magnitude of the change is substantive; for instance, substantive changes to the quality management program, changes to key staff, or adding a new type of research not previously conducted (e.g., the CRS is adding inpatient research as a scope of practice category where previously only outpatient was conducted), the Surveyor will work with the CRS to determine where the CRS may no longer be in conformance with the Standard. The CRS may also turn to the KTP Community (see section 8.5) for support. The Surveyor, with input from the College of Surveyors if needed, will review additional documents to confirm the CRS is in conformance with the Standard given the expanded scope of practice. Document review could potentially also require the Surveyor to conduct additional interviews and, as necessary, review the CRS facilities either through an on-site visit, video-conferencing, or other measures necessary to confirm the CRS continues to conform with the Standard given the change. Additional charges for re-verification or addition to the Accreditation may be required.

If the Surveyor determines that changes have resulted in the CRS no longer being in conformance with the Standard, they will promptly alert the CRS through notice in the SASI Accreditation Management Directory and identify in what areas the CRS is no longer in conformance. The CRS will be required to address the non-conformance issue in a timely manner. Typically, CRSs are given 120 days to address the non-conformance unless there is an immediate safety issue where the Surveyor, in consultation with the College of Surveyors, determines a more accelerated timeline is warranted. If the non-conformance

issue is not addressed within the allotted timeframe the Surveyor will notify the Site Accreditation Council and the CRS will proceed to the process for Qualified status (see Section 9.0 Accreditation Status Classifications).

### 10.2 Continuation Assessments

To maintain confidence in the CRS's continual conformance with the Standard, the Surveyor will conduct a Continuation Assessment on approximately an annual basis. The exact timing of the Continuation Assessment may fluctuate from year to year given scheduling constraints of the Surveyor or CRS; however, the intent is to have a Continuation Assessment as close to every calendar year as possible. During Continuation Assessments the Surveyor will conduct a focused review of current CRS documentation in the SASI Accreditation Management Directory with a specific focus on changes in the CRS from the prior Assessment. The Surveyor will conduct an appropriately focused number of recorded interviews with key staff to confirm the CRS is continuing to operate in accordance with its written documentation. The number of interviews necessary will be determined by the Surveyor but will likely be much fewer than the number completed at initial Assessment. Continuation Assessments may also involve an on-premises Assessment to confirm the CRS continues to be operating in conformance with the Standard.

Continuation Assessments may result in a determination by the Surveyor that the CRS is no longer in conformance with the Standard and corrective action plans or other actions are necessary. If the Continuation Assessment reveals areas where the CRS may not be in conformance with the standard the CRS will be required to address the non-conformance issue in a timely manner. Typically, CRSs are given 120 days to address the non-conformance unless there is an immediate safety issue where the Surveyor, in consultation with the College of Surveyors, determines a more accelerated timeline is warranted. If the non-conformance issue is not addressed in the allotted timeframe the Surveyor will notify the Accreditation Council and the CRS will proceed to the process for Qualified status (see Section 9.0 Accreditation Status Classifications).

Upon completion of the Continuation Assessment, the Surveyor will send a Continuation Assessment Report to the College of Surveyors for peer review and then on to the Site Accreditation Council confirming the CRS continues to be in conformance with the Standard.

If the Surveyor has recently completed review of a significant change (see section 10.1) the Surveyor can rely on all or part of that Assessment to confirm the CRS remains in conformance with the Standard at the time of Continuation Assessment.

The Continuation Assessment Report confirming the CRS remains in conformance with the Standard will be reviewed by a three-member panel of the Site Accreditation Council. If the panel unanimously concurs with the confirmation from the Surveyor, the CRS will be

awarded a new Accreditation Certificate. Similar to the initial Assessment, if the panel disagrees with the Surveyor's report, or cannot unanimously agree, the issue will be addressed by a convened meeting of the Council.

At the completion of the Continuation Assessment process the Council will issue a new Accreditation Certificate to the CRS reflecting a new period of Accreditation for three years from the date of the panel or Council's most recent determination.

The cycle of yearly Continuation Assessments and the resulting issuance of new Certificates of Accreditation reflecting a three-year accreditation period from the date of the last determination will continue indefinitely as long as the CRS remains in conformance with the Standard and abides by the terms of their Accreditation Agreement.

### 10.3 Surveyor Re-Assignment

A different Surveyor may be assigned by the College of Surveyors at any time due to changes in the Surveyor's status as a Surveyor, changes in the categories of research at the CRS requiring different expertise on the part of the Surveyor, or for other reasons. If a different Surveyor is assigned, the CRS will be given the opportunity to review the assignment and request a different Surveyor. The CRS must provide sufficient and reasonable justification to the College regarding why a different Surveyor is being requested.

### 10.4 On-site Assessments

In accordance with the Accreditation Agreement, and in support of the SASI Quality Management System, the Surveyor will visit on-site periodically to assess and confirm the CRS's continued conformance with the Standard through a physical Assessment. The College will try to coordinate any on-site Assessment to coincide with a Continuation Assessment. However, if determined necessary by the Surveyor, and with concurrence from the College of Surveyors, or as directed by the Council, an on-site Assessment can occur at any time.

At a minimum, CRSs will not go longer than four years without a Surveyor conducting an on-site Assessment. An on-site Assessment may occur before the four-year mark, but a CRS will not go longer than four years without a Surveyor visiting on-site.

### 10.5 Changes to the Accreditation Standard

SASI, as the owner and publisher of the Standard, reserves the right to withdraw or amend the Standard at any time. The Standard will be subject to a periodic review process for updates and improvements at intervals not exceeding two years, and any amendments arising from the review will be incorporated into a new edition.

SASI has sole responsibility for authorizing amendments, updates or improvements being made to the Standard.

CRSs will be given early notification regarding new or updated Standards. Any change to the Standard will be accompanied with a realistic timeline and documented process for CRSs to transition to the new or updated Standard so that conformance with the updated Standard and continuation of Accreditation will not be jeopardized. The needs and expectations of all Candidate or Accredited CRSs shall be taken into consideration with an emphasis on minimally disrupting the routines of the CRS's operations and not imposing unrealistic timelines.

### 10.6 Acquiring or Expanding Locations

If an Accredited CRS acquires additional research facilities, or substantively expands alters or merges facilities or operations, Accreditation does not automatically extend to the additional facilities(s) or merged facilities. Adding an additional physical location which is following the same quality management program as the already Accredited CRS would still be considered a change that would need to be added in the SASI Accreditation Management Directory and the change evaluated by the Surveyor as described above.

### 10.7 Mergers or Acquisitions

Mergers or acquisitions will necessitate a review of the CRS's Accreditation and Accreditation Agreement to determine if the merged organization can be incorporated into your Accreditation or it needs to be considered as a new CRS with a new Accreditation Agreement.

Please contact the SASI Accreditation Services office at the earliest opportunity to discuss the merger or acquisition activity and how it will impact your Accreditation status.

# 11.0 Surveyors

To have an Accreditation process that has the full confidence of all stakeholders requires a robust performance-based evaluation and certification system for Surveyors. To ensure that both SASI and all its stakeholders have high confidence in the survey process, it is essential that Surveyor observations are based on factual evidence that stated needs, expectations, and objectives are being met and continually improved. The SASI College of Surveyors oversees the process of selection, training, and on-going evaluation of the SASI Surveyors.

## 11.1 Competence and Qualification

SASI Surveyor competence assessment is based on ISO 19011 definition: 'ability to apply knowledge and skills to achieve intended results.'

The College of Surveyors evaluate each Surveyor's competence based on clearly defined qualifications and the demonstration of key interpersonal skills. Critical to the evaluation are personal behavior characteristics, such as being ethical, open-minded, diplomatic, observant, perceptive, versatile, decisive, self-reliant, open to improvement, culturally sensitive, collaborative, and acting with fortitude. Surveyors must have the required experience, understand the business needs of both the Sponsors and CRSs, and be dependable, with effective communications skills, technical skills (computer and web), decision-making ability, leadership, and be supportive of a zero defects attitude.

All Surveyors will be qualified through experience and certification as appropriate to conduct their assigned survey, or portion of survey, either individually or as part of a Survey Team. All Surveyors must complete the QMI training, be CRQM certified and complete other training as applicable.

## 11.2 Selection and Appointment

The SASI College of Surveyors leadership team will review prospective Surveyor qualifications and competencies and has authority to appoint all Surveyors.

## 11.3 Assignment of Surveyors to CRSs

Each Surveyor will be required to apprentice with a Lead Surveyor, and other Surveyors or members of SASI, to complete a minimum of at least two assessments. They will then conduct a minimum of one Assessment under the oversight of a Lead Surveyor prior to being determined as competent to be assigned as the primary Surveyor for a CRS. After completing the apprenticeship, the SASI College of Surveyors will assign Surveyors to CRSs as described in Section 8.7.

### 11.4 Impartiality and Conflict of Interests

All Surveyors will be required to sign an *Impartiality and Conflict of Interest* agreement. Surveyors with an appearance of a Conflict will not be assigned to the CRS for which they have a potential conflict.

### 11.5 Authority

Surveyors are responsible for assessing if a CRS is in conformance with the Standard given the practice categories of the CRS and the categories of research conducted at the CRS. The Surveyor has the authority through the Assessment Reports to confirm, or not confirm, to the Site Accreditation Council the CRS is in conformance with the Standard. The Surveyor also has the authority to alert the Council when a CRS is no longer in conformance with the Standard and the Council may consider placing the CRS into Qualified status. Surveyors do not have unilateral authority to grant or revoke accreditation.

### 11.6 Compensation

Surveyors are provided a stipend for their time and reimbursement for travel.

### 11.7 Consultations

A Surveyor's impartiality is key to maintaining the integrity of the process. As such, the CRS's assigned Surveyor will determine if the CRS is in conformance with the Standard, or not, and will provide sufficient explanation regarding the areas of non-conformance so the CRS can make changes they deem appropriate for their environment to be in conformance to the Standard. However, the CRS's assigned Surveyor will not provide consultation on specifically what a CRS should do to conform to the Standard. The Surveyor's role is to assess if a given process or program designed by the CRS is in conformance with the Standard, and to provide a clear understanding of the "intent" of the specific clauses of the Standard, not to consult with the CRS on how their processes should be constructed.

Help and advice on how to conform to the Standard is available in the KTP Community. Or CRSs can engage one of SASI Preferred Service Providers to obtain consultative support appropriately separate from the Surveyor role. SASI has an approved list of Preferred Service Providers who are available to help CRSs build their quality management programs to conform with the Standards. If you need consultative help, please contact the SASI office or visit the website: https://sasi-accreditation.org/contact.html

# 12.0 Site Accreditation and Standards Institute (SASI)

## 12.1 Role of the Institute

To maintain the independence and integrity of the Accreditation program, SASI has been established as a separate nonprofit institute to oversee the Standard and the Accreditation process. Led by the Executive Director, SASI members are responsible for maintaining and updating the Standard; through the College of Surveyors establishing criteria for and appointing Surveyors; through the Site Accreditation Council granting or withholding Accreditation; overseeing the SASI Accreditation Quality Management Program, maintaining the Accreditation Protocol and associated supporting processes; and overseeing the grievance and appeals processes.

## 12.2 Membership

All SASI members are committed to the conduct of quality clinical research. Members must complete the QMI training and achieve Clinical Research Quality Manager (CRQM) certification.

SASI operates in accordance with its unique and separate bylaws.

## 12.3 Appointment

The Executive Director has authority to appoint individuals and assign operational roles including the President of the College of Surveyors and the Site Accreditation Council Chair. The Executive Director is appointed by the Board of Directors of SASI.

## 12.4 Term

Members of SASI serve for a four-year term which can be renewed for three consecutive terms.

## 12.5 Impartiality and Conflict of Interests

If a member of SASI has a real or perceived conflict of interest relating to a CRS, that member will recuse themselves from discussion and determinations relating to that CRS.

## 12.6 Site Accreditation Council

The Site Accreditation Council consists of a Non-voting Chair who is appointed by the Executive Director; the President of the College of Surveyors; and other members of SASI as designated by the Executive Director who have the vocational certainty to review the results of the Surveyor's Assessments. The Chair will from time-to-time designate certain members of the Council to serve on review panels as described elsewhere in this document. Convened meetings of the Council will generally follow the principles of Roberts Rules of Order when conducting business at a convened meeting.

When the Chair designates a sub-set of council members to serve on a review panel, the panel only has authority to grant Accreditation upon unanimous agreement of the panel members. Authority to determine that Accreditation is to be withheld, or to put a CRS's Accreditation in Qualified status, resides only with a convened meeting the Council with quorum present.

### 12.7 College of Surveyors

The College of Surveyors is comprised of SASI members and has authority to appoint Surveyors as outlined in section 11, conduct peer review of Survey Assessments, and oversee the Surveyor operations and process.

The President of the College of Surveyors is appointed by the Executive Director. The President of the College of Surveyors in turn designates members of SASI with appropriate vocational certainty to serve in the College of Surveyors. Members of the College of Surveyors may also be designated to serve on the Site Accreditation Council.

### 12.8 Quality Management Program Oversight

SASI maintains a department of Systems Integrity to continuously evaluate and assure that SASI's practice values are consistent with its stated values. The Chair of Systems Integrity will convene sub-committees and oversee continuous activities to monitor the quality of the Accreditation process. Program components include evaluation of Surveyor consistency, survey results, and other components typical to a quality management program. SASI is committed to ensuring the Accreditation process keeps the promise of promoting quality clinical research.

## 13.0 Appeals

All Surveyors are experienced clinical research professionals who can effectively assess a CRS's conformance with the Standards. SASI acknowledges there are many ways CRSs can develop processes to conform with the Standard and differences of opinion may arise on how a CRS meets or does not meet the entirety of the Standards. Any actions or determinations can be appealed. SASI leadership follows a defined process for handling complaints and appeals that conforms to ISO/PAS 17003:2004.

The appeals process begins by filling out an Appeals form through the SASI Accreditation Management Directory.

Any appeal will be reviewed by a three-member panel of the SASI Leadership Team consisting of the Chair of the Systems Integrity Domain, and two members not involved with the Accreditation of the CRS who will review the information provided and any supporting documentation as part of the appeals process. Depending on the nature of the appeal, appropriate and thoughtful action will be taken.

## 14.0 Suggestions

If at any time a CRS would like to suggest improvements to the program, we welcome your feedback. Send an e-mail to Admin@sasi-accreditation.org outlining the nature of the suggestion. The SASI team will review the information. Suggestions will always be taken into consideration and will be used to inform changes to both the Standard and the Accreditation program, whenever practicable.

Grievances are also welcome and will be treated in the strictest confidence. The person submitting the grievance will be informed of the outcome of any ensuing investigation. SASI follows a rigorous process for evaluating and responding to grievances. If you have a grievance, please request a confidential conference with the SASI Executive Director by emailing: Admin@sasi-accreditation.org

## 15.0 Confidentiality

SASI is dedicated to maintaining the confidentiality of the CRS's information. Our SASI Accreditation Management Directory conforms to industry Standard encryption and privacy practices and all Surveyors and other team members are appropriately bound by confidentiality and nondisclosure agreements. In addition to the contractually defined fundamentals of confidentiality, SASI will also operate on a "need to know" basis. Details about the activities or progress of any Candidate or Accredited CRS is restricted to those who have a "need to know" to fulfill their obligations under the Accreditation Agreement. Information will not be shared with third parties without the prior written request and/or agreement by the CRS.

For more information, and to see a copy of our privacy policy visit: https://sasi-accreditation.org/privacy-policy.html

## 16.0 Publicly Available Information

By signing the Accreditation Agreement, the CRS is agreeing that once the CRS achieves Accreditation that SASI is allowed to make public certain information about the CRS on the https://sasi-accreditation.org website (see section 18). The CRS is also agreeing to allow SASI to use the CRS's name and logo in its own marketing and promotional material.

SASI will not initiate public disseminations of any additional or specific data regarding a Candidate CRS or its progress through Accreditation and/or any other information about a Candidate and/or an Accredited CRS without the prior written agreement of the CRS.

Further, SASI generally will not initiate press releases when a CRS achieves Accreditation. SASI will cooperate with and provide quotable material to Candidate or Accredited CRSs who choose to release information to the public on their own.

Candidate or Accredited CRSs may not release any notes, perspectives or quotes related to SASI without SASI's prior written agreement.

## 17.0 Public Listing of Accredited Clinical Research Sites

SASI will display a list of Accredited CRSs on our website. Candidate CRSs in the process of seeking initial Accreditation will not be displayed, nor will a CRS whose Accreditation has been withdrawn. The CRS's name will be displayed as it was entered in the SASIware system. Certain information about the CRS will also be displayed. This information includes the CRS name, primary location, primary contact information, website address, logo as applicable, and the CRS's responses to the Accreditation practice categories questions describing the CRS's scope of practice.

Consistent with the Accreditation Agreement the CRS may not portray or represent itself as Accredited beyond the Accreditation practice categories displayed on the SASI website. For instance, if the CRS is not Accredited as conducting inpatient research, then representatives of the CRS may not portray the CRS in that manner.

## 18.0 Use of SASI Accreditation Logo

Obtaining Accreditation is a major achievement and demonstrates to others the CRS's unwavering commitment to conducting quality clinical research. Once accredited the CRS will receive a special "SASI Accredited Clinical Research Site" seal.

This seal is only allowed to be used by accredited CRSs. It is designed for the CRS's unrestricted use on organizational websites, marketing materials, and similar publications while the CRS maintains Accredited status. SASI encourages Accredited CRSs to incorporate the Accreditation seal on multiple materials to distinguish the CRS as conducting the highest quality clinical research. Use of the seal must follow the Logo Usage Guidelines in the Accreditation Agreement.

## 19.0 Fees

SASI is a non-profit organization. Accreditation fees support our expert Surveyors, the Quality Accelerator Program training, KTP Community, and the continued advancement of quality clinical research.

Access to the Accreditation Standard is provided to the worldwide community free of charge to allow CRSs to conduct their own self-assessment against the Standard as well as see the high Standards and advanced quality programs Accredited CRSs have achieved.

If after completing the self-assessment the CRS is ready to seek Accreditation, a non-refundable application and commitment fee applies. The application and commitment fee allows access to the QMI training and the SASI Accreditation Management Directory to start the CRS's application. SASI's Accreditation process is continuous and on-going, so to lower the costs associated with the review process and the impact to the CRS's budget, there is a monthly maintenance fee which spreads the initial expenses over twenty-four months and then continues as payment to support the CRS's on-going and continuous reviews and Accreditation status.

When the SASI Surveyors have determined that the Accreditation Applicant is in conformance to the Standard, a Site visit will be scheduled to fulfill the requirement for on-site verification. Assuming that the Site visit easily confirms the online review and additional discussions are not required, the Site visit should only require one-day. **Site Visit Travel Expenses (Air, Hotel, Meals, Auto) are NOT included**. Expenses for two Surveyors will be negotiated with the Site for economy travel and are due 30 days prior to a scheduled visit. All other costs to the Site are included in the monthly payments.

## 20.0 Terms

All terms of the SASI Accreditation Program are described and defined in the Accreditation Agreement.