

**Site Accreditation and Standards Institute,
the Quality Management Institute and Preferred Service Providers:
Shared Commitments and Guiding Principles (200829 v4)**

Preamble

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.

The Site Accreditation and Standards Institute, Inc. (SASI) is a fully independent Delaware nonprofit corporation operating as a "fee for service" (IRS 509 (a) (2)) organization. Our singular mission is to continue to update the SASI-QMS:2020-1 Standard for the Quality Management of Clinical Research Sites and to deploy and operate a system of Accreditation with a global span.

While SASI maintains its independent management, governance and focused agenda, we recognize the contribution of Dr. Greg Koski, the Founder and CEO of ACRES, who envisioned a global association of professionals and organizations that would reach across the clinical research enterprise with practical, systems-based solutions and the influence to affect meaningful change.

In recognition of this legacy and in furtherance of its mission, SASI, a separate, fully-independent, nonprofit, federally tax exempt, successor organization will assume the activities of, and by grant, the relevant assets and in furtherance thereof has or will:

- A) Assumed the ownership of the ACRES Intellectual Property: ACRES-QC S001: 2019, and subsequently rebranded it as the SASI-QMS:2020-1 (Standard), and
- B) Preserve, protect and manage with appropriate fiduciary responsibility the value and credibility of the Standard including the necessary updates and edits required to maintain its global relevance, and
- C) Deploy and maintain a regimen for certifying conformance to the Standard and award a "SASI Accredited" registration for Clinical Research Sites in compliance with the Standard, and
- D) Initiate all necessary and relevant business activities, processes, or philanthropic initiatives to support, expand and maintain its mission within the constraints of its federally tax exempt status.

This document is intended to delineate and memorialize the alignment and relationships among SASI, QMI and its Preferred Service Providers so that they can be easily shared and understood by all parties both within and outside of the organizations. Important and strategic confluences of interests among these organizations' relationships can be lasting and helpful to the field of clinical research, provided they are properly vetted and are fairly and transparently organized.

Briggs Morrison, SASI Chair
Larry Kennedy, SASI Executive Director,
and QMI Founder and CEO

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Section 1.0 Transitioning from SASI "the Initiative" to SASI "the Institute"

1.1 Simply stated, this has been an evolution from an "initiative" within ACRES to write and develop the Standard to a separate, independent, nonprofit "Institute." SASI is tasked to nurture, protect and implement the Standard and its accrediting processes. The Institute will continually review and update the Standard, with independent multi-stakeholder input and oversight, to keep it relevant and effective in the changing international, regulatory, and business climate. It will strive to maintain its credibility as a recognizable certification of a CRS's reliability and commitment to maintain high levels of quality and performance.

1.2 In the spirit of the Initiative, the SASI Team has voluntarily and without remuneration "bootstrapped" the deployment of the Standard in order to avoid any payment, granting or contributing to our operating funds by any person or organization that might benefit from a Site Accreditation. As revenues from Accreditation Services increase to appropriate levels, we have budgeted for FTE's, etc. Surveyors that review Candidate Sites will be paid accordingly by salary or per diem and for expenses.

1.3 As SASI elaborates and codifies its protocols and methodologies, it may then optionally recognize, delegate, or license "certifying bodies" around the world to act as Surveyors to expand the capacity of the Accreditation process while maintaining its quality and integrity as the overall Accreditor.

1.4 During the development of this Standard, its pressure-testing, development of accreditation protocols, and discussions with possible early adopters, SASI discovered essential operating requirements that must be considered to properly control the effective deployment of the Standard and ensure integrity of the Accreditation process. They are:

A) The requirement for a fully independent Accrediting Organization; and thus, the SASI volunteers created the successor organization SASI.

B) The requirement for comprehensive training in quality management and reasonable measures of a Candidate Site's sustaining QM culture; and thus, the partnership with QMI.

C) The requirement to recognize competent service providers to help organizations prepare for Accreditation; and thus, we will recognize Preferred Service Providers (PSP).

Section 2.0 SASI and the Quality Management Institute (QMI)

2.1 The SASI deliverables, the SASI-QMS:2020-1 Standard and its accreditation regimen have been developed by volunteers and organized by a volunteer Chair, Larry Kennedy who is also the CEO of QMI. Larry's expertise in Quality Management influenced the continued involvement of British Standards Institution (BSI) and in its participation by BSI Americas Group to fund fifty

percent of the costs of writing the Standard. The leadership and QM bona fides provided by QMI and the application of its curriculum for developing high-performing QM work cultures and systems also became a defining factor in the Standard's maturity.

2.2 The QMI Curriculum, of which QMI is the sole provider, was thoroughly vetted and adopted into the Standard by the SASI Team and it has been proven internally and through pressure-testing to be an essential element of the Standard. The QMI Curriculum validates the values, skills and competencies required to successfully write and implement a plan for conformance to the Standard and to maintain conformance. In other words, it helps create a culture of conscience and competence that readily attains compliance and the effective and efficient management of the clinical trial environment that leads to improved data collection. It provides a methodology for both training and performance, and it can shorten the timeline and reduce internal expenses related to a Candidate Site's preparation for accreditation.

2.3 QMI has created a specialized certification "Clinical Research Quality Manager" (CRQM) to facilitate the SASI vision. All SASI Team Members are CRQM's and all Candidate Surveyors will be required to be CRQM's before matriculating into their Surveyor training by the College of Surveyors. The Accreditation Protocols also call for minimum of two CRQM's within each Accreditation Candidate to facilitate their conformance to the Standard and two CRQM trainings will be included in the Accreditation Application Fees.

2.4 The validity of the CRQM requirement has been confirmed by Reg Blake, SVP Knowledge Transfer of BSI Group America Inc., who noted that some organizations, especially many in the clinical research field, are "inspection" oriented and lacking the knowledge to create effective process-based Quality Management Systems. He also noted the communications and time-to-market efficiencies achieved by the SASI Team after having their QM skills and values validated through the CRQM and that it enabled them to write and publish a Private Standard in only six months whereas a National or International standard can typically take several years. Likewise, Candidate Sites will be enabled to more accurately and quickly complete self-assessments and prepare the systems and documentation required for Accreditation to SASI-QMS:2020-1.

2.5 The highly respected Association of Clinical Research Professionals (ACRP), has independently affirmed the confluence of interests between the Standard and the QMI CRQM. Bridget Gonzales, the ACRP Director of Training and Professional Development is a Member of SASI and a CRQM. She has reported to Jim Kremidas, Executive Director at ACRP, that there is *no other training program of its kind and that it provides a much-needed curriculum for QM that reciprocates nicely with the certifications provided by ACRP.*

2.6 SASI has had extensive discussions with ACRP regarding how SASI, ACRP and QMI could collaborate and the Parties have agreed to a Memorandum of Understanding (MOU) to facilitate those collaborations. The MOU notes that ACRP is very supportive of the Standard and has agreed to an arrangement where SASI and ACRP create beneficial reciprocations including the sale of the CRQM training by ACRP and with special discounts for ACRP Members. ACRP will emphasize that the CRQM Certification will provide their constituents with a recognized professional credential in Quality Management and thus qualify persons to lead QM self-assessments and systems development processes within a Clinical Research Site as well as gain eligibility to become an SASI Surveyor. QMI will provide turnkey fulfillment via a resale agreement between SASI, QMI and ACRP with direct revenue shares for SASI and ACRP to support the essential elements of their shared vision.

SASI will not directly sell training to the public and thus compete with ACRP but will follow this model of collaborating with other organizations and associations, etc. This alignment among non-profit professional certifying and accrediting entities is envisioned as part of an integrated systems, development, achieving synergies that are not otherwise possible.

2.7 Larry Kennedy, SASI Executive Director and QMI CEO, will not participate in any direct decision-making capacity over any organization's Accreditation. His responsibilities will be to develop and deploy the QM Systems and ethical working culture described throughout this document. In certain special circumstances, he could be reasonably made available to PSP's - without fee or remuneration - as a higher-level coach/consultant in organizational development, QM education and/or teambuilding. All other Accreditation readiness services will be performed by PSP clinical research professionals as hereinafter described and with the proper caveats for avoiding a conflict of interest.

Section 3.0 SASI and Preferred Service Providers

3.1 SASI must take responsibility for enabling the availability of sufficient consulting capacity to help all early adopters prepare for Accreditation, whether it be a small, one-site Candidate or a large, complex clinical research system. While it would be easier from a purely ethical/possible-conflict-of-interest viewpoint to allow the marketplace to provide these services randomly and be driven by each vendor organization's commercial motivation, it could also place the entire vision for Accreditation at risk. Because the Standard is an "open" document, third parties providing "implementation" services do not require any licensing or authorization from SASI. And although they would not be able to provide an "accredited" status, their success or failure would directly impinge upon the credibility of the Standard.

To meet this challenge, we have established collaborative relationships with independent but carefully aligned "Preferred Service Providers (PSP)" that are SASI trained and properly oriented to the ethic and ethos of the SASI culture. PSP's will deliver practical solutions that extend the competencies and capacity of SASI while promoting and facilitating the accreditation process. PSP's will provide candidate sites preparing for accreditation with education, training, tools and resources of the highest quality to assist them in their self-assessment and preparatory efforts--with the caveat that there will be absolutely no promise or link to any formal Accreditation decisions. To do so, we have envisioned and detailed herein necessary protections, firewalls and ethical restraints that would protect the credibility of the Standard and allow for the reasonable and stable development of the enterprise.

3.2 PSP's will function independently of SASI and will have no contractual obligations or financial interests in its Accreditation processes or Standards. A PSP will have no exclusive rights or privileges to provide services on behalf of SASI but will instead be arms-length facilitators of the consulting, training and implementation services required by early-adopters and complex systems that need well-planned and developed ramp-ups for SASI to recognize Sites as "SASI Accredited."

Our intent is to declare openly what might be considered "conflicts of interest," to deploy resources transparently and to create modalities' of accountability so that any reasonable party will see the preferable benefits and confluence of interests of our structure and operations.

3.3 We anticipate that most initial discussions with Candidate Sites will begin with SASI and that we will most probably discover their need for ramping up to readiness during our initial discussions. However, in congruence with the Standard's described goal of providing an

educational, collaborative and supportive process of Accreditation, and after providing an initial application fee, all Candidate Sites will be given access to the SASIware user interface (Provided by Acesis, an SASI Preferred Service Provider) to begin the process of defining their “scope of practice.” They will also be required to matriculate at least two of their Site personnel through the Clinical Research Quality Manager Certification (CRQM) which will include a comprehensive exam on the Standard.

Candidate Sites will then be invited to participate in the SASI Candidate Community that will have regularly scheduled online meetings to be facilitated by the College of Surveyors. The Candidate Community will provide Site Candidates with a broad range of information and opportunities to discuss their needs that will supplement their own self-assessment and gap analysis. As it is appropriate and as Candidates participate in the Community, we may describe and suggest our PSP’s as a possible solution to help close existing gaps and will disclose the nature and reasoning for the reciprocating configuration of SASI and these organizations.

3.4 A PSP may engage, as appropriate, any organization seeking Accreditation. Its primary purpose will be to help current or potential Candidates attain readiness for Accreditation. Candidate Sites who are interested in Accreditation but self-determine their need for consultative assistance to prepare the QM Systems required to conform to the Standard may want to engage a PSP.

3.5 A PSP may, at its discretion, offer a range of consultative services and offerings or a coordinated suite that includes training and capacity building and that results in measurable improvements in those research sites’ ability to conform to the Standard. However, it must clearly and specifically declare in writing to the Site Accreditation Candidates that there will be no advantage or linkage of any kind between a PSP’s provision of services and any accreditation decision by SASI.

3.6 A PSP must use only SASI trained and approved consultants, teachers or trainers who have achieved CRQM Certification, have completed Surveyor training and have been vetted by the College of Surveyors. Highly competent and knowledgeable Surveyors from SASI, including many volunteers who participated in writing and/or testing the Standard, and who may engage in routinely certifying conformance to the Standard as part of the Accreditation process, will be available to Candidates, as PSP’s, or in support of PSP’s on a personal contractual basis to assist in providing readiness services. However, no Surveyor who has provided services of any kind, either personally or through a PSP to an organization seeking Accreditation will be allowed to serve as a Surveyor for that organization's review or in any other capacity within SASI regarding that organization. An SASI Systems Integrity Group will be responsible for preventing any such conflict of interest and will routinely audit the performance of PSP’s, SASI Surveyors and Candidate Accreditation processes.

3.7 QMI will license the PSP’s to use its Quality Accelerator Program™ for the development of high-performing work cultures and teambuilding. This will not be available through SASI. QMI will also license PSP’s to include in its consulting and services packages the relevant QMI training materials, including the Clinical Research Quality Manager Certification course required by the Accreditation Protocols for Clinical Research Site (CRS) Leaders and the QM-KTP Associates Certification course for use by CRS Leaders in conforming to the training and KTP “Keeping-the-Promise” Culture requirements of the Standard. In recognition of the essential nature of this collaborative and cooperative effort, QMI will share revenues with SASI to support the essential elements of their shared vision.

Section 4.0 SASI Governance and Oversight - Roles and Duties

4.1 SASI is an autonomous organization and it will develop its own bylaws and protocols for maintaining the credibility of its Accreditation Service, the College of Surveyors, and all persons acting on its behalf.

LinkedIn for Board of Directors:

[Briggs Morrison](#), Chair
[Larry Kennedy](#), Executive Director
[Terry Stubbs](#), Director and Treasurer
[Steven Hirschfeld](#), Director and Secretary
[Dennis LaCroix](#), Director
[Michael Brown](#), Director

4.2 SASI will function as a distinct and separate organization. Its mission includes the charter to establish a reliable, competent and self-sustaining organization that can manage and maintain the transition from the single initiative of writing the original Standard to the multi-layered responsibilities involved with an accreditation standards organization including:

4.2.1 Preserving, protecting, updating and maintaining the integrity of the SASI-QMS:2020-1 Standard for the Quality Management of Clinical Research Sites.

4.2.2 Creating an organizational and operational framework and protocols for the deployment of the Standard through a globally recognized formal accreditation process; including establishing the economic schema for gaining its acceptance in the clinical research ecosystem.

4.2.3 Establishing a “College of Surveyors” within SASI to recruit and train Accreditation “Surveyors” and provide initial and continuing certification of the credentials and capacity of the Surveyors and all persons associated with the Accreditation processes.

4.2.4 Collaborating with other organizations to develop a continuum of products, services and economic schemas to support and extend the effectiveness of the Standard, including the development of site performance metrics.

4.2.5. Initiating discussions within the clinical research ecosystem to define and develop operational Standards for technologies such as imaging or that reflect interventions that can be classified based on modalities such as: mechanical, electrical, chemical, biological, behavioral, etc. These additional Accreditations will be based upon the technical capacity to consistently deliver high-quality interpretable data based on the expertise to capture and record signals with precision.

4.3 With authority extending from the SASI Board of Directors, the SASI Executive Director will design and deploy specifically structured and separate management functions within SASI comprised of a combination of volunteers, paid staff and task-specific, contracted, professional Surveyor and/or certification services.

4.4 On at least an annual basis, the Executive Director of SASI will present an amended business plan to the SASI Board of Directors that includes budget projections. The SASI Board of Directors will regularly review and approve the budget as part of its oversight function. The Executive Director will then be required to manage the SASI budget so that the expenses of its operations are never greater than its revenue (unless explicitly approved by the SASI Board).

The SASI Board of Directors will review annual revenues and decide on adequate operating reserves. Any surplus that is generated above operating reserves will be made available for grants and other collaborative arrangements as the SASI Board decides is appropriate.

4.5 The SASI Executive Director will be recused from making any judgement for or against an Accreditation decision or to attempt in any way to influence an outcome and will remain in the objective position of maintaining the credible functionality, ethics and reliability of the organizational processes.

4.6 Any and all new initiatives or additions to or extensions of our stated vision will be subject to the review of the SASI Board of Directors. The initiator will be required to demonstrate the merits of the idea and its financial sustainability through a well-developed business plan.

Section 5.0 SASI Operations Organizational Structure

5.1 All SASI participants, whether volunteers, paid staff or contracted vendors and suppliers, will be Certified Clinical Research Quality Managers (CRQM) and/or credentialed Surveyors and the growth modality of SASI will be based upon the indigenous development of Surveyors and Leaders from within the College of Surveyors who are committed to preserving the integrity of the Standard and its Accreditation processes.

5.2 The SASI Executive Director will complete the design of the required organizational responsibilities and boundaries in consultation with the appropriate leaders and volunteers within SASI and under the oversight of the SASI Board of Directors and including collaborations with those Stakeholders relevant to the conceptualization of effective operations.

5.3 The Site Accreditation Council (SAC) is a separate division within SASI and will be staffed by volunteers that have been credentialed by the College of Surveyors. All functions will be fulfilled by recognized conformity assessment and clinical research professionals. The SAC is responsible for reviewing the Site conformity assessment reports provided by the College of Surveyors and to approve the initial granting or extending of the Accreditation certificate.

The Chair of the SAC will act as a non-voting facilitator; will schedule and guide review meetings and will oversee a three-member review panel. The three-member review panel will be comprised of the College of Surveyors (COS) President and two others appointed by the SAC Chair from a list of available participants pre-approved by the SAC Chair and the President of the COS. Every effort will be made to avoid all conflicts of interest and to impanel vocationally certain participants.

The President of the COS (or designate) will present and overview the results of each conformity assessment, answer questions and recommend initial accreditation or extension by the SAC. The SAC Chair will require a unanimous vote of approval by the three-member panel assigned to each Site conformity assessment review before issuing Certificates of initial Accreditation or extension of an existing Accreditation.

5.4 Site Accreditation Council - Accreditation Protocols Domain. The Chair will recruit members from the College to support its Domain activities. The Accreditation Protocols Domain will maintain and update the Protocols to be used by the College of Surveyors for the review and conformity assessment of Candidate Sites.

LinkedIn for Accreditation Protocols Domain Chair, [James Riddle](#)

5.5 The College of Surveyors (COS) is the “springhead” from which will flow a continuous supply of competently prepared Surveyors who will conscientiously assess conformance to the Standard. Initial acceptance of the Standard is dependent upon its adoption by significant stakeholders within the clinical research community. But the credibility of the Standard must be sustained by the culture at the heart of the Accreditation process; those who wrote the Standard, those who pressure-tested it, those who will certify conformance to its requirements within clinical research sites and those acting as the Gatekeepers of continuous quality – the SASI College of Surveyors.

The COS will be a cultural force for social and political influence, professional resourcing and for conformity assessment within SASI. It will continue the ethos, ethics and best practices of SASI and it will be guided by a President appointed by the SASI Executive Director for a renewable two-year term upon the vote of the members of the College.

The COS President will oversee the planning and development of the COS Domains; and will convene regular online and open meetings of the College of Surveyors Members and Domain Chairs to discuss the College business, etc. The President of the College of Surveyors will also coalesce with the membership and its constituencies as needed. Members of the College of Surveyors may fulfill one or more roles in the various Domains but will be limited to only one Chair or Co-Chair role.

LinkedIn for College of Surveyors President, [Mary Westrick](#)

5.5.1 The COS is responsible for the deployment of Surveyors to certify the conformance of a Clinical Research Site’s operations to the Standard, including the development and improvement of all relevant and ethically viable supporting procedures. This will be described in more detail in the Executive Director’s Business Plan and Budget and other documents that will provide further explanations of SASI and its operating functions. In brief, we will strive to effectively deploy the Standard and its Accreditation and to prevent drifting into ethical conflicts by putting in place logical, rational, fair, and transparent QM processes.

5.5.2 The COS will develop and improve the appropriate protocols until there is a clearly defined and tested system of conformity assessment that can be effectively licensed to external Certifying Bodies. All activities within the COS will be paid either by contract, per diem or salary depending upon the job description and duties required.

5.5.3 The Surveyor(s) who cite conformance to the Standard will submit a properly formatted recommendation to the COS who will convene a sub-committee of Surveyors to peer review their findings, approve for referral to the Site Accreditation Council or return for remediation in the manner specifically directed by the Accreditation Protocols. The President of the COS will then act on behalf of the COS to meet with the SAC to finally approve the Clinical Research Site’s conformance.

5.5.4 Clinical Research Sites that are certified in conformance to the Standard will be authorized to display the “SASI Accredited™” logo in appropriate forms and documentation.

5.6 The College of Surveyors - Surveyor Credentialing and Training Domain. The Chair will recruit members from the College to support its Domain tasks and activities as well as provide training and certification for PSP Surveyor Candidates. It will keep an official list of qualified Senior Surveyors that have the authority to peer review assessments completed by a Surveyor and recommend Accreditation to the COS President and the Site Accreditation Council. The Surveyor Certification Domain will provide subject matter expert referrals to the Systems Integrity Domain and Site Accreditation Council as requested.

The Surveyor Certification Domain will define and implement the protocols for validating and verifying the competencies and cultural congruence of all Surveyor Candidates. Candidates will first complete the CRQM and then a comprehensive exam on the Standard. Then each Surveyor Candidate will complete a series of Accreditation-Observer and Supervised-Accreditation assignments. The Candidate's work will be materially reviewed and will culminate in oral reviews before a sub-committee of the College of Surveyors who will make a recommendation for certification as a Surveyor or indicate the remedial action required.

Link to Surveyor Certification Domain Chair, [Penelope Jester](#)

5.7 The College of Surveyors - Standard(s) Review Domain. The Chair will recruit members from the College to support its Domain tasks and activities. The Standard(s) Review Domain will be responsible for preserving the integrity of the Standard and updating it as required. It will also consider additional or supplemental Standards and organize to review, evaluate, or write them.

LinkedIn for Standards Review Domain Chair, [Beth DiGiulian](#)

5.8 College of Surveyors – Information Technologies Domain. The Chair will interact with all relevant parties to the accreditation process to identify and update the requirements for the “SASiware” Accreditation Candidate user interface.

LinkedIn for Information Technologies Domain Chair, [Michael Brown](#)

5.9 The College of Surveyors – Candidate Community Domain. The SASI Accreditation process is intentionally educational, collaborative and supportive; and the Leadership of Candidate Sites and their staff who have completed the required Quality Accelerator Program training and the relevant CRQM or QM-KTP Certifications will be invited to participate in the SASI Candidate Community and its regularly scheduled online meetings, blogs and supporting helps.

By its nature, the Candidate Community will be openly interactive so that the participants can take full advantage of the opportunity to network with one another and develop their unique plans for conforming to the SASI-QMS:2020-1 Standard and its Accreditation process. The participants will describe their own experiences in completing their gap analysis and the steps to mitigate those gaps, etc. And, there will be expert commentary by SASI Surveyors and other specialists. The Chair will recruit members from the College to support its Domain activities.

LinkedIn for Candidate Community Domain Chair, [Michael Ellis](#)

6.0 The Systems Integrity Domain (SID) reports directly to the SASI Executive Director to provide an independent and reliable source of recourse and redress for any of the actions of SASI or its Surveyors or representatives. Its purpose is to assure the quality, integrity, and ethical compliance of all SASI activities and to develop, in cooperation with the Site Accreditation Council and the College of Surveyors, the relevant policies and procedures to support its mission.

6.0.1 The SID is responsible for organizing the random and forensic review of Surveyor activities and for convening panels to preside over the review of appeals submitted by Candidate Sites or from within any part of SASI.

6.0.2 The SID is also responsible to assure that all SASI conformity assessment and Accreditation processes and personnel, their policies and procedures and supporting documentation, all training activities, and all internal and external communications consistently teach, represent and apply the values, principles and constructs of the Eight Attributes of a Quality Manager described in the CRQM Certification.

6.0.3 The SID is responsible to assure the harmonization of the content of all SASI public and internal documentation including websites.

LinkedIn for Systems Integrity Domain: Chair, [Ruth NeMire](#); Co-Chair: [Ben Albensi](#)

6.1 The Systems Integrity Domain will convene three-person panels comprised of two persons recommended by the COS and the legal representative of SASI to preside over all appeals submitted by Candidate Sites or from within any part of SASI. Subject Matter Expertise required for the review of appeals will be supported by referrals from and consultations with the COS.

6.1.1 The Systems Integrity Domain will assure that All SASI Team Members sign comprehensive CDA/NDA's that will apply to all SASI activities, clients, vendors, etc. Members will also sign a declaration of their known conflicts of interest and/or perceived or potential conflicts of interest, and will agree to voluntarily advise Systems Integrity of any perceived or potential conflicts of interest that might arise in the conduct of their duties with SASI and will promise to adhere to the highest standards of confidentiality.

6.1.2 The Systems Integrity Domain will assure that All SASI Team Members acknowledge in writing any Conflicts of Interest they may have and that the value of Accreditation and the potential risks and exposure in the process of accrediting Candidate Sites will be respected and that no public or private discussions will take place revealing the results or processes involved with a Candidate Site. All knowledge of a Candidate Site's participation in either preliminary inquiry, self-assessment or the Accreditation regimen will remain confidential and shared only on a "need to know" basis between Surveyors and the Site Accreditation Council. All public acknowledgments of a Candidate Site's interests, and/or its activities will be subject to approval and release by the SASI Executive Director.

6.1.3 The Systems Integrity Domain will organize occasional, random and forensic-level internal audits of all Accreditation Processes including the verification and documentation that no Surveyor participating at any level with the certification of the conformance to the Standard by a Candidate Site, will have any other contact with the Candidate Site either as an individual, independent contractor or in service to any third-party or PSP regarding consulting, implementation or training services. The Systems Integrity Domain will be responsible for preventing any such conflict of interest and will routinely audit the performance of PSP's, SASI Surveyors and Candidate Accreditation processes.

6.1.4 While SASI Team Members, Surveyors and College of Surveyors participants may correctly fulfill multiple roles in their vocation, volunteer service and/or other contractual arrangements, we will protect the integrity of the Accreditation by vigilantly separating these activities.

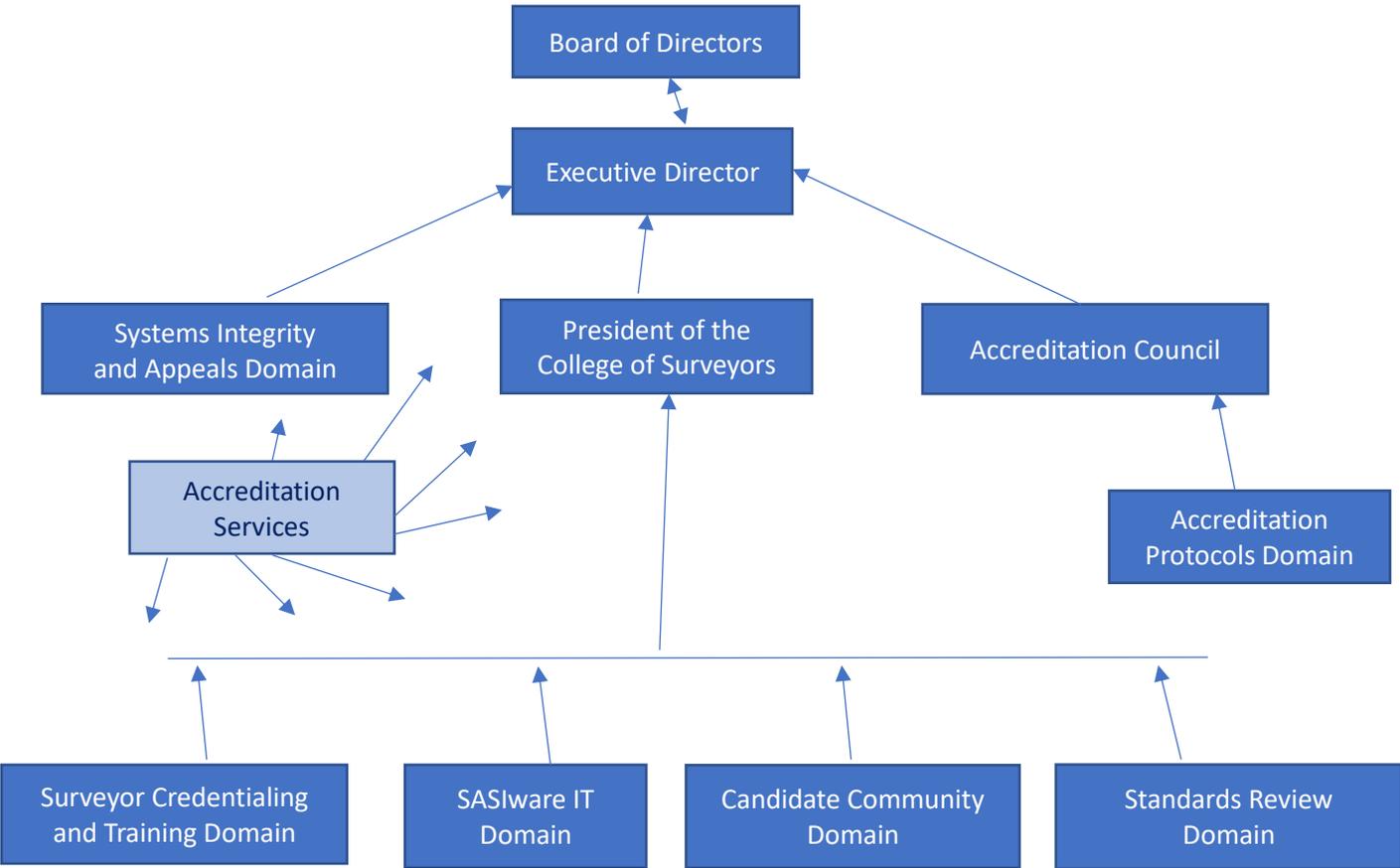
An SASI Certified Surveyor or Member of the College of Surveyors may perform only one of the following activities connected to a specific Accreditation Candidate:

- a. Act as a compensated Surveyor of a Specific Candidate's conformance,
- b. Sit on an appeals or review committee for that Same Candidate's Accreditation,
- c. Act as a paid or volunteer consultant to evaluate and assist the Candidate's Self-Assessment,
- d. Act as a paid or volunteer consultant for implementation or training service for the

Candidate via a PSP or any personal business or third-party provider, or

- e. Serve on an Ethics Board or be employed or act as a paid or volunteer consultant for a Sponsor or CRO or be employed within or acting as a paid or volunteer consultant for a government or regulatory agency with direct knowledge or ties to the Candidate.

SASI ORGANIZATIONAL STRUCTURE (200630 V3)



Additional details regarding all described items and duties remain in development under the leadership of the Executive Director.