

Acceptance of CLSI Policies

Instructions: Please complete this form and return promptly. This information will be kept on file at the CLSI Offices.

Name: _____

Credentials: _____

Title or position: _____

Employer: _____

Address: _____

Telephone: _____

Fax: _____

E-mail: _____

In accordance with CLSI's "Standards Development Policies and Processes" document, and in order to participate on a CLSI committee, all CLSI volunteers are asked to review and to indicate that they understand and accept the attached CLSI policies. Volunteers will not be eligible to participate in any CLSI committee until this acceptance is completed, signed, and returned to CLSI. This acceptance is an integral part of the official records of consensus document development and governance committees' meetings and addresses the following core CLSI principles and practices:

- Code of Ethics
- Constituency Selection
- Standards Development Participation
- Conflicts of Interest Disclosure
- Permission to Use
- Attestation

Take note that Volunteers will be asked to sign and return a new "Acceptance of CLSI Policies" form at least every four years, and upon each new committee appointment and/or election to any new governance, standards development, or other volunteer activity on behalf of CLSI. Eligibility to assume such new or different roles in CLSI activities and/or to participate on any CLSI committee shall depend, in part, upon the return of such signed Acceptance.

I. CLSI's Code of Ethics

CLSI Values. I will abide by the fundamental values that guide the way CLSI operates; specifically, these are Inclusiveness, Excellence, Responsiveness, Integrity, and Teamwork.

I agree I do not agree

Antitrust. I will adhere to CLSI's established policy and procedures to help ensure that the activities of CLSI will proceed without violation of antitrust laws.

I agree I do not agree

Confidentiality. I will maintain the confidentiality, privacy, and security of information entrusted to me in accordance with legal and ethical obligations. I will not, without appropriate written authorization, disclose to any third party any confidential information or document to which I obtain access by virtue of my volunteer board or committee service to CLSI. If I have any doubt about whether particular information or a particular document is confidential, I will not make disclosure unless I have first clarified the situation with appropriate CLSI officials or staff and obtained written authorization.

I agree I do not agree

Intellectual Property. I will respect CLSI's copyright and other rights and interests in the works it publishes.

I agree I do not agree

Standards Development Policies and Processes Document, and Laws Adherence. I will abide by CLSI's standards development policies and processes. I will not knowingly violate any applicable laws or regulations.

I agree I do not agree

CLSI's Interest. I will not promote my personal interests at the expense of CLSI's interests and/or the work being performed by CLSI when serving on any CLSI committee or board or contributing to any CLSI effort.

I agree I do not agree

II. Constituency Selection

All volunteers must self-select into one of three applicable constituency category interest groups: health care **professions**, **government**, or **industry**. In determining constituency categories, the following guidelines apply:

- Individuals employed in the field of healthcare by an academic institution, a health care delivery organization, a professional society or association, or an accreditation or certification organization are considered members of the health care **professions** constituency.
- Individuals employed by a publicly-funded organization, institution or agency that receives all or most of its funding from the government are considered members of the **government** constituency.

II. Constituency Selection (Continued)

- Individuals employed by a predominantly for-profit manufacturing or distribution company, or a trade association or other organization comprised substantially of such companies, and individuals whose primary work is consulting for entities in the for-profit sector, are considered members of the **industry** constituency.

Exceptions to the constituency descriptions above are noted as follows:

- An individual officially designated to represent a CLSI member organization in a particular constituency will be deemed in that constituency regardless of his/her primary employment; and
- Individual members, not otherwise affiliated with a CLSI member organization, will self-declare a constituency based on their primary role consistent with the guidelines for organizational members.

I declare that my constituency, based upon the definitions above, and specific for the CLSI work for which I am volunteering, is:

Professions Government Industry

III. Conflict of Interest Disclosure

Conflict of interest (hereafter “conflict”) disclosure is intended to help ensure transparency and unbiased decision-making by CLSI. The existence of an actual or potential conflict does not necessarily preclude board or committee service to CLSI. However, if an individual has an actual or potential conflict relating to a topic that is under discussion, the individual shall promptly identify such actual or potential conflict and explain the nature thereof. The presiding individual for the specific CLSI activity shall then determine, in his or her discretion, whether the individual’s actual or potential conflict should preclude participation in the activity, the discussion, and/or in voting on a given topic and the individual agrees to abide by that determination.

Information on disclosed actual and potential conflicts will be kept on file at the CLSI office.

In the spaces that follow (or on additional pages, if necessary), please provide the requested information when it is relevant to the field(s) of work in which you will be involved with CLSI. In determining your actual or potential conflicts, you should consider your relationships as well as those of your spouse/domestic partner, business partner, parent, child, and/or sibling (“related person(s)”) that give rise, or could give rise, to a conflict.

III. Conflicts of Interest Disclosure (Continued)

Describe the activity(ies)
and/or relationship(s) that
may give rise to a conflict
of interest:

Any other relevant facts or
considerations:

Part A: Financial Interests

In this section, please disclose each financial relationship that might reasonably be seen as a conflict of interest or potential conflict of interest. Disclosure does not necessarily mean that there is a conflict or that you will not be able to participate in specific projects. So, if in doubt, please err on the side of disclosure.

Do you, or any related person, currently have, or have had within the last 12 months, a consultancy, advisory board (or similar) position, or any other relationship from which you or the related person has received more than \$5,000? (Money received from an employer for salary, travel, or other costs associated with business responsibilities does not need to be included.)

Yes

If yes, please list the name(s) of the entity(ies) with which you or the related person held such position(s).

No

Have you, or any related person, received any honoraria or fees (eg, lecture, speaker's bureau, travel reimbursement) of more than \$5,000 in the last 12 months?

Yes

If yes, please list the name of the entity(ies) from which such payment was received.

No

Part A: Financial Interests (Continued)

In the last twelve months, have you, or any related person, served as an expert witness for any individual or organization?

Yes

If yes, please list the name of the entity(ies) served.

No

Have you, or any related person, received in the last 12 months, or expect to receive in the next 12 months, any patents, including pending patent applications?

Yes

If yes, please list the item or method which is covered by such patent(s).

No

Have you, or any related person, received in the last 12 months, or expect to receive in the next 12 months, any royalties?

Yes

If yes, please list the source of the royalty and describe the reason for such royalty payment.

No

In the last 12 months, have you, or any related person, owned or been a beneficiary of stock (including options, but excluding mutual funds) valued at more than \$5,000, or other equity interest of more than one percent (1%) of the shares of a corporation.

Yes

If yes, please list the name of the entity(ies).

No

Part A: Financial Interests (Continued)

In the last 12 months, have you, or any related person, received any items, gifts, or benefits of substantial value (eg, free trips, accommodations, sports tickets, appliances, electronic devices) valued at \$5,000 or more, in the aggregate, from any one commercial or noncommercial entity or related entities?

Yes

If yes, please list the name of the entity(ies).

No

Do you, or any related person, have any other relevant financial interests or other relationships that could pose an actual or potential conflict of interest with your work at CLSI that are not listed above?

Yes

If yes, please list the name of the entity(ies).

No

Part B: Leadership in Other Associations

At present, or within the past 12 months, have you, or any related person, held a leadership position (eg, officer, director, and/or chair of a committee or other subdivision) with another clinical laboratory, medical, or pharmaceutical-related association, OR do you know that you, or any related person, will hold such a position in the next 12 months?

Yes

If yes, please list the name of the entity(ies) and the applicable position(s).

No

Part C: Disclosure of Conflicts

If a matter arises during a topic discussion with respect to which you, or any related person, may have (or reasonably be perceived to have) an actual or potential conflict of interest, you will disclose the nature of the conflict when the matter arises. Unless permitted to do so by the presiding individual (or other CLSI official), you agree not to participate in any discussion or vote relating to such matter and topic.

I agree

I do not agree

IV. Permission to Use

- By voluntarily joining, or by accepting an appointment to, a CLSI committee or board, and by participating in that committee's or board's programs, sessions, collaborations, and/or meetings (individually and collectively "Program(s)"), and/or other Programs arranged or conducted by CLSI, I grant CLSI permission to use the data and information (individually and collectively, "Information") that I contribute to CLSI as a participant in such Program(s), along with Information provided by other Program participants, for the purpose of discussing, analyzing, and evaluating such Information as part of CLSI's Standards Development Process (the "Process").
- I understand that CLSI may create works (the "Work(s)") that are the result of the Process in which I and others may voluntarily participate, that such Works are based upon the Process and Information derived from multiple sources, and that such Works belong exclusively to CLSI. I understand and agree that participants in the Process do not own or control any rights in or to the Works by virtue of participating in the Process or the Programs or by virtue of CLSI synthesizing the Information into the Works.
- I reserve those rights and interests, if any, belonging to me (or my employer, if applicable) to Information contributed by me to the Process subject to CLSI's right to use and synthesize such Information as set out above.
- Without limiting the generality of the above, CLSI agrees that it will not reproduce any specific expression of Information furnished by me in the form submitted by me (eg, a chart, graph, illustration, or text) in a Work without my approval, which approval will not be unreasonably withheld by me so as to frustrate the Process or the purpose of the Process.
- I represent that I have the right and authority to grant this permission and to participate in the CLSI Program(s) and the Process and that the Information provided by me is, to the best of my knowledge, accurate and does not infringe upon the rights of any other party.
- I understand and agree that CLSI has the exclusive right to publish, reproduce, and distribute, the Works throughout the world in all media and platforms whether known now or hereafter developed and I will not copy, adapt, translate, or otherwise reproduce by any means (eg, electronic, file sharing, mechanical, photocopying, recording, or otherwise), any Work without prior written permission from CLSI.

Initials: _____ Date: _____

V. Standards Development Participation

I affirm that I have reviewed the *Essential Job Duties and Skills and Abilities for CLSI Committee Participants* (see attachment), and I agree to perform the duties and to fulfill the responsibilities which correspond to the role, if any, that is assigned to me by CLSI as part of the Process. I acknowledge the time commitment associated with Process participation and I represent that I have adequate time available to participate in the Process.

I agree

I do not agree

Attestation

I attest that I have read and I understand this Acceptance of CLSI Policies, and each of its components. I further attest that I have made the required disclosures to the best of my knowledge, and recognize that I have a continuing responsibility to disclose all actual or potential conflicts of interest that might bias, or that might reasonably be perceived as biasing, any action that I might take or any statement that I might make in connection with my board or committee service to CLSI. I attest that I will promptly inform CLSI of any changes in actual or potential conflicts of interest while I serve on a CLSI committee or other leadership body or otherwise participate in any CLSI Program or the Standards Development Process.

I recognize that if I fail to make the disclosures set forth above or to honor my ethical and other commitments as set forth herein, I shall be subject to removal from the body of CLSI on which I serve without any further proceedings, and I will forfeit any eligibility for indemnification pursuant to the bylaws of CLSI or otherwise.

If I have any questions about this form or its component parts, I will raise those questions with the Chief Executive Officer of CLSI.

Typing your name and the date below will serve as your electronic signature.

Name: _____ Date: _____

Essential Job Duties and Skills and Abilities for CLSI Committee Participants

The essential job duties and skills and abilities for participation in CLSI committees are listed in the tables below.

Essential Job Duty, Skill, or Ability	Expert Panel	Document Development Committee	Subcommittee	Working Group
Liaise with the Consensus Council to represent the expert panel for the technical quality review of documents	C			
Liaise with SC, DDC, or WG chairholders regarding technical and/or quality considerations	C			
Facilitates and ensures consensus throughout all development phases	C	C	C	C
Lead committee activities, ensuring all responsibilities are met	C	C	C	C
Coordinate all activities with the project manager	C	C	C	C
Prepare agendas for meetings	C	C	C	C
Facilitate all committee meetings	C	C	C	C
Review and approve meeting records	C	C	C	C
Adhere to provided budget		C	C	C
Establishes project schedule in collaboration with the project manager		C	C	C
Perform (or delegate) "one voice" edit in preparation for Proposed Draft vote		C	C	C
Ensure draft document conforms with <i>Essential Instructions for Writing CLSI Documents</i>		C	C	C
Prepare call-outs for final document as applicable		C	C	C
Serve as liaison to the relevant expert panel as needed		C	C	C
Appoint <i>ad hoc</i> WGs as needed to complete approved project tasks			C	
After project approval, select DDC or WG participants' roles		C, V	C, V	C, V
Communicate with committee members as needed		C, V	C, V	C, V
Keep projects on schedule		C, V	C, V	C, V
Provide coaching and writing assistance as needed		C, V	C, V	C, V
Review final document layout as applicable		C, V	C, V	C, V
Assume all duties of the chairholder when that person is not available	V	V	V	V
Prepare project proposals	C, V, M		C, V, M	
Serves a one-year term for a maximum of four years	C, V, M	C, V, M, CN	C, V, M, A, R	C, V, M, A
Actively participate in committee activities	C, V, M	C, V, M, CN	C, V, M, A, R	C, V, M, A
Review and comment on document drafts as requested	C, V, M	C, V, M, CN	C, V, M, A, R	C, V, M, A
Author document content, as desired or requested		C, V, M, CN	C, V, M, A, R	C, V, M, A
Contribute data or examples needed for the documents		C, V, M, CN	C, V, M, A, R	C, V, M, A
Provide writing or review assignments on time to meet timeline projections		C, V, M, CN	C, V, M, A, R	C, V, M, A
Assist with comment resolution		C, V, M, CN	C, V, M, A, R	C, V, M, A
Vote on Proposed Draft document		C, V, M	M	
Perform the responsibilities of assigned role (member, advisor, contributor)		S	S	S
With the project manager, complete meeting reports, including documenting decisions made		S	S	S
Ability to lead a group of peers to an effective outcome	C	C	C	C
Lead document and product development processes in conformance with requirements	C	C	C	C
Knowledge of CLSI and the clinical laboratory field	C, V, M	C, V, M, CN	C, V, M, A	C, V, M, A
In-depth knowledge in a technical field	C, V, M	C, V, M, CN	C, V, M, A	C, V, M, A
Serve in a fair, impartial manner	C, V, M	C, V, M, CN	C, V, M, A	C, V, M, A
Conduct activities in a professional demeanour	C, V, M	C, V, M, CN	C, V, M, A, R	C, V, M, A
Reads, writes, and communicates effectively in English	C, V, M	C, V, M, CN	C, V, M, A, R	C, V, M, A

Abbreviations: A, advisor; C, chairholder; CN, contributor; M, member; R, reviewer; S, secretary; V, vice-chairholder.