



Guidelines for CLSI Delegates and Alternate Delegates

Take Advantage of All CLSI Has
to Offer With This **Helpful Guide**



Engage With Colleagues. Access Valuable Resources. Help Raise the Standards of Patient Care.

Sustaining Memberships and Sponsorships

CLSI offers sustaining memberships for companies and organizations that wish to support CLSI's mission above and beyond membership dues. In addition, member organizations have the opportunity to sponsor specific CLSI events and programs throughout the year.

Many levels of sponsorship are available, and organizations can choose whether they wish to sponsor meetings, educational sessions, webinars, specific document development activities, or CLSI's Global Health Partnerships program. More information is available on [here](#), or by contacting CLSI's Customer and Member Services at membership@clsi.org.

Communicating With CLSI

Please don't hesitate to contact us with any questions you may have, or for any information you may need.

You can reach CLSI by telephone between the hours of 8:30 AM and 5:00 PM Eastern (US) Time at +1.610.688.0100. You may also call CLSI Customer and Member Services toll free at 877.447.1888 within the United States.

For e-mail, please send your correspondence to customerservice@clsi.org, or for membership inquiries, to membership@clsi.org. Technical questions can be directed to standard@clsi.org.

CLSI Address:

Clinical and Laboratory Standards Institute
PO Box 633
Annapolis Junction, MD 20701
USA

Send payments to:

Clinical and Laboratory Standards Institute
PO Box 645766
PITTSBURGH, PA 15264-5255





Dear Delegate,

Welcome to the Clinical and Laboratory Standards Institute (CLSI)! We thank you and your organization for choosing to join CLSI. As a valued member of our team, we hope to make your experience worthwhile, interesting, and enjoyable. As your organization's Delegate to CLSI, you have been selected to be the primary liaison between your organization and CLSI. These guidelines are intended to help you understand your responsibilities, and to ensure that your organization takes full advantage of all CLSI has to offer.

As a Delegate, you are being asked to represent your organization in several aspects of CLSI's work, including voting and commenting on documents, recruiting and nominating committee members, proposing documents your organization needs, and performing other tasks that will be outlined further in these guidelines.

Your commitment to the consensus process supports quality patient testing and the health care community as a whole. Thank you for doing your part to help CLSI set the standard for quality worldwide.

Sincerely,

A handwritten signature in black ink that reads "Glen Fine". The signature is written in a cursive, flowing style.

Glen Fine, MS, MBA, CAE
Chief Executive Officer
CLSI

Your Responsibilities as a Delegate

You have been selected by your organization to manage its membership benefits and serve as its representative to CLSI.

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In this role, you have certain responsibilities that will ensure your organization maximizes its participation in CLSI. Your biggest responsibility is communication, both with CLSI and within your organization regarding CLSI's activities.

In addition to managing your membership benefits, your other responsibilities include:

- **Voting and commenting on draft documents** – Be sure you are representing your organization's voice on documents that are important to them.
- **Recruiting volunteers to participate in CLSI's consensus process** – Bring your organization's expertise to the table to help create meaningful standards.
- **Proposing standards for development** – Help CLSI brainstorm ideas for new standards applicable to your industry that will make your daily work easier.
- **Nominating candidates for the Board of Directors** – Bring your organization's voice to the highest level within CLSI.
- **Informing your colleagues of the value that CLSI standards bring to your organization** – Make sure you and your team are following CLSI best practices to ensure high quality.
- **Communicating the value of CLSI to the health care community whenever possible** – Help bring the good work of CLSI to all the places where it's needed.
- **Administering any membership benefits within your organization** – Make sure your organization is taking full advantage of the resources CLSI provides.

Your organization can also appoint an **Alternate Delegate** who can assist with the responsibilities associated with the position. He or she will be included in communications about your membership, and be able to vote in your place. We recommend that you work closely with the Alternate Delegate to fit CLSI activities and responsibilities into your respective daily routines.

The following pages describe CLSI and our processes to help you better comprehend how we work so you can fully understand your membership and your role on our team.

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Membership in CLSI

Membership is an effective way to take advantage of all CLSI has to offer, including participating in the consensus process. CLSI offers membership options designed to meet every organization's specific needs.

Membership Categories

CLSI offers organizational membership for Industry and Large Commercial Laboratories, Health Care Professions, Health Systems, and Government and Public Health Agencies. We also offer Individual Membership for professionals associated with the health care professions and/or clinical and laboratory services, as well as full-time students enrolled in academic programs.



Industry and Large Commercial Laboratories

Through CLSI membership, your industry organization or large commercial laboratory has the opportunity to collaborate with regulators, peers, and customers on developing and implementing standards that are widely recognized to facilitate regulatory review for IVD devices, tests, and other diagnostic products.



Health Care Professions

Our Health Care members have access to the documents and resources needed to help them test with greater accuracy, efficiency, and safety.



Health System

CLSI offers a Health System membership option. Administrators and directors can provide their entire staff with system-wide access to our standards and other great benefits at an affordable per-site rate.



Government and Public Health Agencies

Members in our government constituency have the opportunity to participate in our standards development process and directly influence globally applicable standards.



Individuals

An individual CLSI membership allows those not part of a member organization to support and volunteer for CLSI. Benefits include committee participation, networking opportunities, and discounts on CLSI products.

Accessing Your Membership Benefits

As the Delegate for your organization, you have selected a level of membership that fits the needs and budget of your organization. At CLSI, we value your commitment to our organization and would like to make it easy for you to take advantage of the membership level you have selected.

Access to all of the benefits that are included in your membership will help your organization achieve its goals and deliver high-quality results.

Discounts on CLSI Products and Services:

Level I 70%		Level II 60%		Level III 50%
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As an organizational member, all employees at your location are eligible to order documents and products at the same discounted rate. In order to shop online with this benefit, they will need to add the member ID to their online profile. You will find the member ID/account number on your membership invoice and in your welcome e-mail. Please distribute this to others within your organization so they can also order at the membership rate. To have their profile added to the account, please e-mail customerservice@clsi.org.

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Free Shipping: (Level I and Level II Members)

Level I and Level II members receive free shipping on all orders shipped within the United States.

We have extended this membership benefit to subsidiaries for our Level I Industry and Large Commercial Laboratory members. If your organization is a Level I member, all of your locations will receive the same pricing discount, and free shipping within the United States.

Online Access to All Standards: (Level I Members, Health System Members)

eCLIPSE Ultimate Access™ is an online portal that allows you and your colleagues to search our full database of 200+ documents. As the Delegate, you have been made the administrator for your account and can add as many users as you like.

- Industry and Large Commercial Laboratory Level I members receive access for all employees.
- Industry and Large Commercial Laboratory Level II members receive a license for two concurrent member licenses at one location.
- Health Care Professions and Government Level I members receive a license for two concurrent users at one location.
- Health System members receive access for all employees at covered sites.



Continuing Education Credits and Educational Webinars

You and your colleagues can take advantage of CLSI educational programs by registering at the low member rate. Your membership discount extends to CLSI-hosted workshops, webinars, and our eLearning programs, including the Laboratory Quality Management System (LQMS) Certificate Program.

Level I Industry and Large Commercial Laboratory members can register one site for CLSI educational webinars for free.

Membership eNews and Special Offers:

We will send out the members-only eNews quarterly featuring new products, special members-only discounts, and a highlight of ways some of our member organizations are taking advantage of CLSI membership and benefits. Please make sure you add membership@clsi.org to your e-mail list.

Recognition:

CLSI members are listed in the “My CLSI” section of the website. To be listed, your company must be in good standing. All members are listed in the Membership Directory in the “My CLSI” section of the website, and new members are highlighted in the Membership eNews.

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Networking:

As a Delegate, CLSI connects you with a large and diverse network of more than 2,000 organizations and their representatives, all concerned with quality laboratory testing. As a participant in CLSI’s consensus process, you will help to address and mutually resolve important issues.

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Volunteering:

CLSI distributes more than 75,000 documents per year, worldwide. Participation allows you to influence the development of these consensus documents by openly presenting your organization’s views and perspectives on issues, and having this input considered deliberately and fairly within the process. CLSI consensus standards are recognized by the top regulatory and accrediting organizations. By having an active voice, you can ensure that the documents directly affecting your organization and activities are useful to moving your organizational goals forward.

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Voting:

As part of the standards development process, eligible CLSI members* are able to review, comment, and vote on CLSI standards. This vote allows members to have a seat at the table during the document development process and helps CLSI receive valuable feedback. Active members will receive an e-mail notifying them when a document is ready for review and prompting them to review the document and vote.

*Each organization appoints a member delegate and/or alternate delegate as part of the membership. When CLSI sends out a request to vote, this delegate or alternate delegate will have the opportunity to vote. Please note, a full individual member is considered a delegate and can vote on documents.

Interested in voting on a document? Log in and visit the voting area of [CLSI Exchange](#).

Overview of CLSI

For over 50 years, CLSI has been bringing together the global laboratory community for a common cause: fostering excellence in laboratory medicine. Our members, volunteers, and customers have made CLSI a respected, transformative leader in developing and implementing clinical laboratory standards.

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Together, industry, government, and health care professionals work to create and implement standards that drive quality test results, enhance patient care delivery, and improve public health around the world. A not-for-profit organization, CLSI uses a consensus process that respects and includes the voices of laboratory medicine stakeholders.

Our Vision

Setting the standard in laboratory medicine for a healthier world.

Our Mission

Develop clinical and laboratory practices and promote their use worldwide.

Our Values

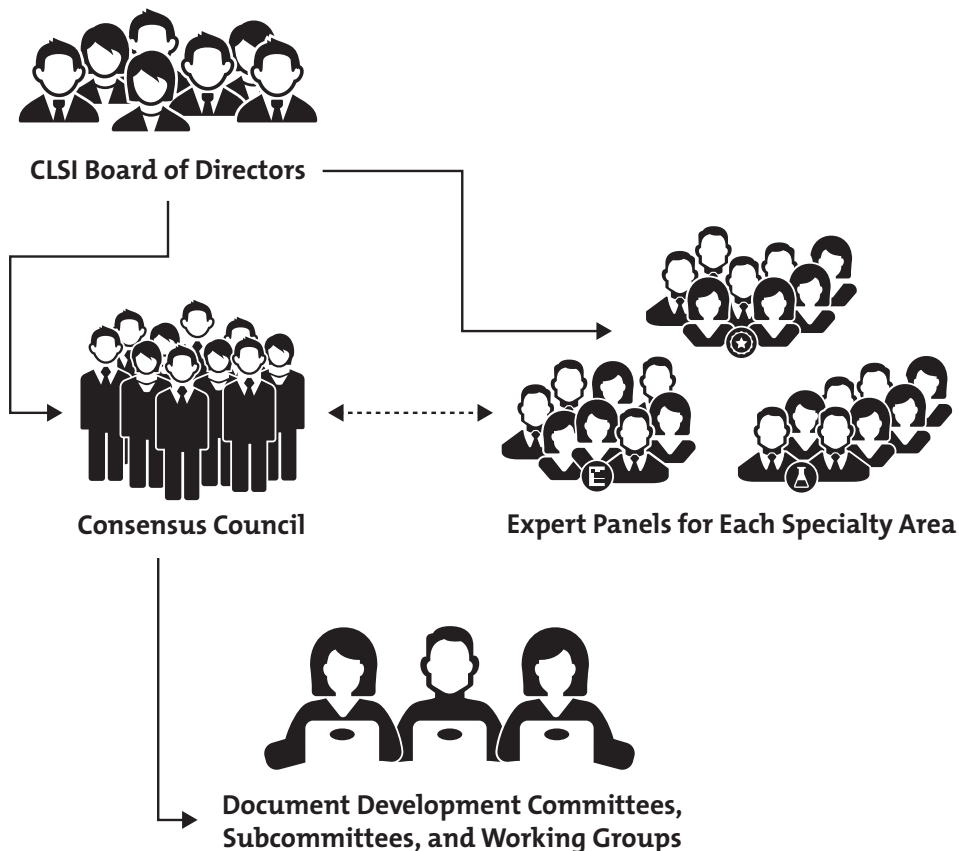
- ▶ **Inclusiveness** – We include the viewpoints of industry, government, and the health care professions in a consensus-driven process.
- ▶ **Excellence** – We continuously improve upon our tradition of technical excellence and superior quality.
- ▶ **Responsiveness** – We proactively identify and respond to the needs of our stakeholders in an open and timely manner.
- ▶ **Integrity** – We act ethically and with fairness, trust, respect, and openness.
- ▶ **Teamwork** – We are committed to effective collaboration among members, volunteers, staff, and other partners.

CLSI's Organizational Structure

CLSI is structured in a cascading series of committees supported by our staff. Each committee includes volunteer representatives from the health care professions, government, and industry.

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Each committee has specific assigned responsibilities and accountabilities. The Board of Directors governs CLSI and advances its voluntary consensus processes and its related programs in communication, education, and global harmonization. See the figure below.



CLSI Committee Structure

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CLSI Committee Descriptions

Committee	Description
Board of Directors	<ul style="list-style-type: none"> Elected officials who establish the policies and procedures that govern CLSI. The Board sets CLSI's vision, mission, values, and strategic direction.
Executive Committee	<ul style="list-style-type: none"> Made up of the President, Immediate Past President, President-Elect, Secretary, Treasurer, and Chief Executive Officer; coordinates CLSI's governance and policy-making activities, and oversees implementation and management of programs.
Finance Committee	<ul style="list-style-type: none"> Chaired by the Treasurer, this committee oversees the development of CLSI's annual budget.
Nominating Committee	<ul style="list-style-type: none"> Chaired by the Immediate Past President, this committee oversees the process of nominating new members for the Board of Directors.
Consensus Council	<ul style="list-style-type: none"> The Consensus Council reviews and approves project proposals, prioritizes projects, oversees project status and expenditures, and gives the final consensus approvals for publication. The Consensus Council serves as CLSI's consensus body, and therefore reviews the consensus process, not the technical content of documents.
Expert Panels	<ul style="list-style-type: none"> The Consensus Council is supported by Expert Panels, which provide discipline-specific expertise as needed to ensure that the standards CLSI develops are of the highest technical and scientific quality. Approximately 10 CLSI-selected volunteers compose each Expert Panel for our key specialty areas. Expert Panels also help fill the pipeline for timely document development by proposing new standards to champion through the process.
Document Development Committees	<ul style="list-style-type: none"> These committees have primary responsibility for drafting individual consensus documents and for evaluating and addressing comments received during the consensus process. They are also responsible for considering scientific accuracy, practicality, and comprehensibility, with the goal of creating documents of overall high quality and utility.
Subcommittees	<ul style="list-style-type: none"> Primarily responsible for drafting individual consensus documents and for evaluating and addressing comments received during the consensus process. Usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental updates of the documents and for continual revision of certain standards. Typically standing committees.
Working Groups	<ul style="list-style-type: none"> Subunits of subcommittees or document development committees. Assignments are limited in scope and the groups are disbanded upon completion of the assignments.

Distribution of CLSI Information

CLSI considers members to be important partners. As a Delegate, you are an important member of CLSI's team. As the primary liaison between CLSI and your organization, you will be asked to communicate your organization's position on issues—from voting and commenting on draft documents to nominating candidates for the Board of Directors, and determining the direction of CLSI.

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Some aspects of your role as Delegate include:

- ▶ **Communicating your organization's needs for standards and program activities.**
This can be done through direct communication with CLSI, responding to surveys, participating in Delegate focus groups, etc.
- ▶ **Voting and commenting on draft documents in the consensus process.**
- ▶ **Helping to promote the value of standards and their positive impact on your organization.**
- ▶ **Encouraging and coordinating participation of experts from your organization in CLSI activities.**
- ▶ **Communicating whenever possible the value of CLSI to your organization and its importance to laboratory medicine worldwide.**

As a Delegate, you are encouraged to circulate CLSI's draft documents within your organization for the purposes of review and comment. For published documents, please respect CLSI's copyright and refrain from posting them on intranet sites or the Internet. Options are available for an organization to have site-wide access to CLSI's published documents. CLSI's full copyright policy can be found [online here](#).

CLSI follows a rigorous process for consensus-based development that is intended to be open, fair, and inclusive of our three constituencies—industry, health care professions, and government. It can be found [online here](#).

Strategies for Optimizing Organizational Participation

1	Uncover interests	Determine which projects in development, as well as published documents, are of interest to your organization. Identify experts within your organization to participate on active committees. Visit the website frequently to investigate opportunities for committee participation https://clsi.org/get-involved/volunteer-opportunities .
2	Submit ideas	Propose a project if there is not a CLSI document that meets a specific need. A form for preparing a proposal can be found on the CLSI website (https://clsi.org/standards-development/propose-a-project/).
3	Get involved	Identify experts in your organization who should be involved in standards development activities. A "Call for Volunteers" is sent to all Delegates by e-mail to solicit for committee participation. As a Delegate, you can act as a facilitator in this process by determining your organization's interest in the topic and identifying and nominating experts. Self-nominations are welcome.
4	Be heard	Review and vote on all documents. At the voting stage, Delegates have the opportunity to review, comment on, and vote for approval on all documents. As your organization's Delegate, you should determine whether the document is pertinent to your organization and circulate it to the appropriate experts for review.
5	Get organized	If your organization is large, you may want to form a standards working group to be sure that all parts of your organization are aware of CLSI activities and participating where needed.

More detailed information on the CLSI Consensus Process is provided in the CLSI [Standards Development Policies and Processes document](#).

Promoting CLSI

As a Delegate, you are in a unique position to communicate your organization's involvement with CLSI. You understand the role that CLSI plays in worldwide laboratory medicine, its strategic direction, and the value that CLSI's standards bring to your organization. Find opportunities to share the value that CLSI brings you with others!

Committee Composition:

Official committee positions are shown below. Each committee has approximately 10 members, as many advisors as needed for expertise, and unlimited numbers of contributors or reviewers. The committee members are balanced among CLSI's three constituencies: government, industry, and health care professions.

	Document Development Committee	Subcommittee	Working Group
Chairholder	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Vice-Chairholder	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Member	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Secretary	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Advisor		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Contributor	<input checked="" type="checkbox"/>		
Reviewer		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

The document development process is dependent on experts' volunteer participation. Ensure that your organization's voice is heard by having your experts take part!

CLSI and ISO

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from 130 countries.

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Its mission is to promote the development of standards to facilitate international exchange of goods and services, and develop cooperation in the spheres of intellectual, scientific, technological, and economic activity. ISO's works are published as international standards.

CLSI has been designated by ANSI as the Secretariat for ISO's Technical Committee 212 (ISO/TC 212), Clinical laboratory testing and *in vitro* diagnostic test systems. As the Secretariat, CLSI manages all of the activities of ISO/TC 212 and acts in an impartial manner to guide the development of ISO/TC 212 standards according to the ISO/International Electrotechnical Commission (IEC) Directives. The ISO standards development process is a different and distinct process from that of CLSI. In ISO, each country gets one vote, no matter how many participants they have.

Currently, there are five working groups for ISO/TC 212:

- ▶ **Working Group 1, Quality and competence in the medical laboratory**
- ▶ **Working Group 2, Reference systems**
- ▶ **Working Group 3, *In vitro* diagnostic products**
- ▶ **Working Group 4, Microbiology and molecular diagnostics**
- ▶ **Working Group 5, Laboratory biorisk management**

Experts from more than 55 countries participate in the development process for ISO/TC 212 documents via each country's mirror group or Technical Advisory Group (TAG) or through liaison organizations such as International Bureau of Weights and Measures (BIPM), International Laboratory Accreditation Cooperation (ILAC), International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and European Diagnostic Manufacturers Association (EDMA). The United States has a TAG that US organizations can join through CLSI. US TAG membership is required if an organization wishes to engage in ISO standards development.

- ▶ **The member organization must exhibit a direct and material interest in the TAG's work.**
- ▶ **The member organization must fulfill relevant obligations including attendance, voting, and correspondence, as well as pay an administrative fee.**

See CLSI's website for more information, or call CLSI Customer Service at +1.610.688.0100.

CLSI FAQ

How long does CLSI membership last?

CLSI offers annual membership only, but this membership can be started on a rolling basis. If you need a calendar year membership, or a specific start and end date, please contact membership@clsi.org or +1.610.688.0100 to discuss options.

How do I update my delegate information?

You can update the information when you receive your annual membership renewal quote or you can use our [online form](#). You may also e-mail the new delegate's name, e-mail address, phone number, and any additional information he or she wishes to provide to membership@clsi.org.

Who can take advantage of my organization's CLSI membership benefits?

All employees from the location that signed up for membership are considered CLSI members. Additional locations are not considered members, but they can sign up for their own membership to receive membership benefits. Level I Industry members and Health System members may share certain benefits with multiple locations in their organization.

Can I renew my membership online?

Yes! Simply log into the My CLSI Member Center and if you are within 90 days of your expiration date you will be able to renew online. Otherwise, please contact our Membership team at membership@clsi.org or use our [online form](#).

Can I share documents with other locations within my hospital's network?

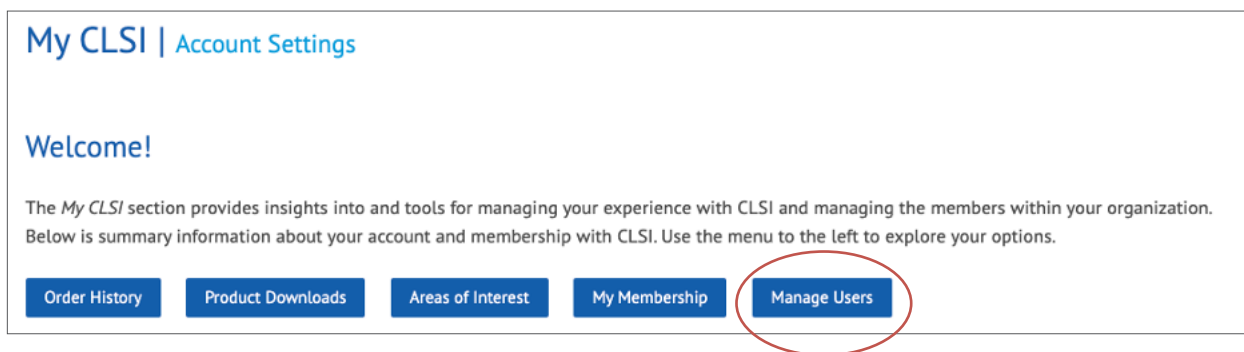
No, that is against our copyright policy; however, if you are interested in expanding your membership to multiple locations, learn more about our Health System Membership [here](#).

How-To Guide for Adding/Managing Users in Your My CLSI Account

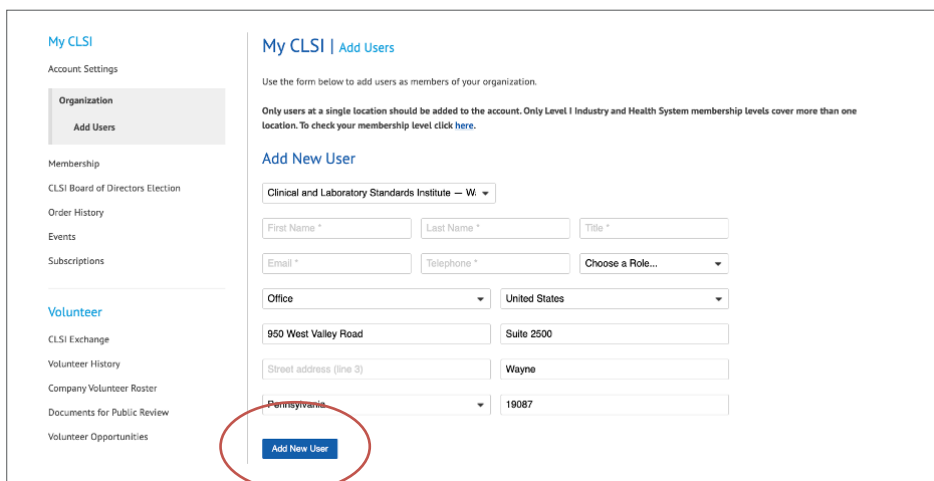
1. Log in to your My CLSI account at www.clsi.org.
2. Go to the My CLSI homepage (dark blue top right button).



3. Click the Manage Users button on the right-hand side.



4. View all Administrators and Employees under your organization.
NOTE: If part of a Health System Membership, you can view the users by site.
5. You can edit an individual's name and role under the organization. All other contact updates must be made by the individual or through a CLSI staff member.
6. You can remove users no longer employed at your organization to terminate their membership access.
7. You can export the list of users to a CSV file. **NOTE:** If part of a Health System Membership, this report will pull all users across all sites for easy review.
8. To add a new user click the Add Users button under Organization on the left-hand side bar. Complete all required fields. **NOTE:** If part of a Health System Membership you can select which site to add the user under.



How-To Guide for Personalizing Your CLSI Account

Setting Up Your Volunteer Profile*

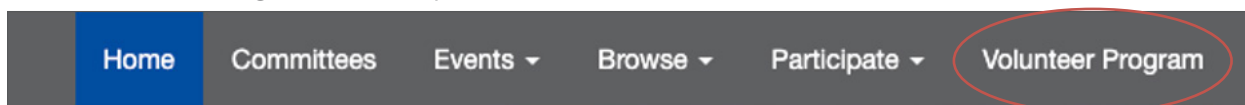
*Complete your Volunteer Profile to be notified directly of future volunteer opportunities in your area of interest.

1. Log in to your My CLSI account at www.clsi.org.

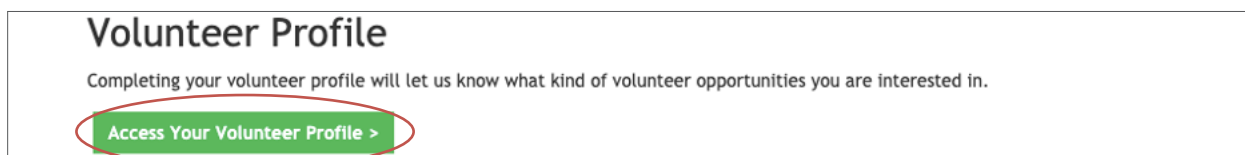
2. Go to CLSI Exchange (green top right button).



3. Go to Volunteer Program in the top menu bar.



4. Click the Access Your Volunteer Profile button under Volunteer Profile.



5. Add/Edit Your Volunteer Experience, Interests, Experience Level, Willingness to Travel, Social Links, and Profile Picture.

Setting Up Your Areas of Interest

1. Log in to your My CLSI account at www.clsi.org.

2. Go to the My CLSI homepage (dark blue top right button).



3. Click the Areas of Interest button on the middle of the homepage dashboard.



4. Check your Areas of Interest.

My CLSI | Areas of Interest

Your Areas of Interest...

- | | | |
|---|---|---|
| <input type="checkbox"/> Antifungal | <input type="checkbox"/> Chemistry and Toxicology | <input type="checkbox"/> Molecular Methods |
| <input type="checkbox"/> Automation and Informatics | <input type="checkbox"/> Documents for Public Review and Co | <input type="checkbox"/> Newborn Screening |
| <input type="checkbox"/> Chemistry and Toxicology | <input type="checkbox"/> General Laboratory | <input type="checkbox"/> Point-of-Care Testing |
| | <input type="checkbox"/> Hematology | <input type="checkbox"/> Quality Management Systems |
| | <input type="checkbox"/> Immunology and Ligand Assay | <input type="checkbox"/> Standards |
| | <input type="checkbox"/> Method Evaluation | <input type="checkbox"/> Veterinary Medicine |
| | <input type="checkbox"/> Microbiology | <input type="checkbox"/> Volunteering |

5. Click Save Selections.

About CLSI

The **Clinical and Laboratory Standards Institute** (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: **to foster excellence in laboratory medicine by developing and implementing clinical standards and guidelines** that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.



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