# Certified in Healthcare Research Compliance Handbook

Enhances your credibility

Develops professional standards

Demonstrates knowledge and dedication





The Certified in Healthcare Research Compliance (CHRC)® exam is certified by the Compliance Certification Board (CCB)®. CCB was established in 1999 to develop and manage its seven professional compliance certification programs.

CCB is governed by a Board of Directors who are appointed by the the Society of Corporate Compliance and Ethics & Health Care Compliance Association (SCCE & HCCA) Board of Directors.

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The material in this printed handbook is current as of January 2024 and is subject to change without notice. Please visit *hcca-info.org/certification* for the most up-to-date **CHRC Candidate Handbook** and program details.

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# **Contents**

Manage your CCB certifications online	1
What it means to become CHRC certified	2
Five steps to CHRC certification	3
Gain work experience Earn and submit the required CEUs	
Apply to take the examSchedule your exam	7
Review your score report	10
Renew your certification in three steps	11
Keep track of your renewal date Earn and submit the required CEUs Submit the renewal fee	11
Candidates' frequently asked questions	13
Proper logo and title usage	15
Certification policies and legal disclaimers	16
Exam and renewal fees	18
Join a candidate group	19
Exam resources	20
Exam sample questions	21
Detailed Content Outline	22
Certification made easy	25
Code of Ethics for Health Care Compliance Professionals	26
Individual Accreditation Application	31
Renewal Extension Request	33
Request for Special Exam Accommodations	35
Documentation of Disability-Related Needs	37

# Manage your CCB certifications online

Your CCB certification information is accessible anytime online. It's easy, convenient, and free.

### Online at hcca-info.org/certification you can:

- ▶ Manage your CCB CEU account
- ▶ Add CEUs from CCB-hosted and accredited activities
- ▶ Submit CEUs from outside organizations for CCB approval
- Apply to sit for a certification exam
- Renew your certification

### **Login now**

Any individual who has previously participated in an SCCE or HCCA activity has a free password-protected online account already set up at *corporatecompliance.org* or *hcca-info.org*.



Under the "Certification" section, you can apply for a CCB certification exam, view and add CEUs, and renew your CCB certification.

It's possible you may not remember the username or password associated with the account. If this is the case, then select the "Forgot your password?" option and an email will be sent with your login credentials.

To help you remember your username and password going forward, write them here:

Username			
Password			

If you experience difficulty logging into your free online account, or have a question, please contact HCCA at +1 952.988.0141 or 888.580.8373.

### No membership required

Candidates are not required to become SCCE or HCCA members in order to apply for any basic CCB (CHC, CHPC, CHPC, CCEP, or CCEP-I) certification exam.

# What it means to become CHRC certified

The healthcare world can be a high-risk and challenging environment that demands a proactive compliance approach. Being certified in this dynamic, changing profession can help mitigate compliance-related risks.

An individual who actively holds the Certified in Healthcare Research Compliance (CHRC)® certification is someone with knowledge of relevant regulations and expertise in compliance processes sufficient to assist the healthcare industry in understanding and addressing legal obligations, and promote organizational integrity through the operation of effective compliance programs.

The CHRC exam was developed through a combined effort of qualified content experts and testing professionals. It tests a well-defined body of knowledge representative of professional practice in the discipline. Content experts and testing professionals review test items to ensure they are accurate in content, relevant to practice, and representative of good testing procedures.

The CHRC certification program is managed by the Compliance Certification Board (CCB)®, established in 1999. CCB certifies compliance professionals through its seven compliance certification programs. CCB's mission is to develop criteria for the determination of competence in the practice of compliance at a variety of levels, and to recognize individuals meeting these criteria.

CCB has contracted with PSI Services, Inc. (PSI), to assist in the development, administration, scoring, and analysis of its exams. Additionally, PSI reports exam scores to individuals who take the exam.

CCB and PSI do not discriminate among candidates on the basis of age, gender, race, color, religion, national origin, disability, marital status, sexual orientation, physical or mental disability, veteran status, or any other protected characteristics. PSI testing centers are wheelchair accessible and equipped with Telecommunications Devices for deaf or hearing impaired candidates.

# Benefits of becoming CHRC certified -

The rigorous standards and professional conduct required for certification demonstrate a diligent effort on the part of the compliance practitioner, and verifies broad-based knowledge in the discipline being tested.

Becoming CHRC certified can:

Enhance your credibility within your organization, among peers, and strengthen the credibility of the compliance programs you develop, implement, and maintain within your organization.

- Arm you with the broad-based knowledge necessary to perform compliance functions.
- ► Help establish professional standards and status for healthcare compliance professionals.
- ► Give you and your compliance-related work an advantage when interacting with other professionals in the healthcare industry.
- ► Recognize your hard work and dedication necessary to perform the compliance task.

### **About this handbook**

This handbook provides information you will need to apply, prepare for, and take the CHRC exam. It includes eligibility requirements, frequently asked questions, exam content and outline, exam policies

and procedures, and Exam Application information. The handbook also includes information on how to renew this two-year certification.

# Five steps to CHRC certification

Individuals who meet the eligibility requirements and who successfully pass the exam attain the two-year CHRC designation. The CHRC is an actively held certification in which maintenance within an individual's renewal period is required in order to be eligible for renewal and to ultimately maintain the certification beyond this initial two-year renewal period. Failure to comply with CHRC exam eligibility

requirements and/or renewal policies and procedures is grounds for prohibition from testing and revocation of this certification.

SCCE and HCCA members and non-members alike can become CHRC certified. Membership with SCCE or HCCA is not necessary to attain, maintain, or renew a CHRC certification.

# 1. Gain work experience

In order to apply to sit for a CCB exam, you must meet one of these classifications in order to fulfill the professional experience requirement for certification. CCB staff is unable to determine this for you.

### **Compliance Professional**

(All must apply):

- ➤ You have at least one year in a full-time compliance position or 1,500 hours of direct compliance job duties earned in the two years preceding your application date; and
- ▶ Your job duties directly relate to the tasks reflected in the "Detailed Content Outline" on pages 22–24.

### Student:

▶ You have successfully completed a certificate program from a CCB-accredited university within the last two years and can apply to sit for a CCB certification exam, provided the exam is taken within 12 months of successfully completing the CCB-accredited university program.

 See a list of approved programs at hcca-info.org/certification → External Accreditation → University Accreditation.

### TO SIT FOR THE EXAM

Total CEUs needed: 20 CEUs

Needed from live training: 10 CEUs

Content: One or more of the 10 subject areas

Time-frame: Earned within 12 months prior to the scheduled exam date

# 2. Earn and submit the required CEUs -

You must earn and submit 20 CCB approved Continuing Education Units (CEUs) in order to apply to sit for a CCB exam. CEUs must:

- Include a minimum of 10 earned from "live" trainings or events, which include face-to-face training events or real-time virtual events and webinars; and
- ▶ Be earned within the 12-month period preceding the date of the exam.

# How to request and submit your CCB CEUs

You have participated in compliance trainings or events and now want to have those events added to your CCB CEU account. Whether you participate in a CCB pre-approved activity or one sponsored by another organization that is not pre-approved, you will need to submit your CEUs to CCB so they are available to be used toward initial certification and/or

renewal. Here's how to request and submit CEUs to CCB if you participated:

▶ In an SCCE or HCCA in-person event you need to request and complete the Application for Continuing Education Units (CEUs) and submit to CCB for processing. Within four weeks of your submission the CEUs, along with a certificate of attendance, will be placed into your SCCE or HCCA online account.

This step is especially important if you plan on taking the exam following an SCCE or HCCA event and intend to use the CEUs earned at the event to be eligible to sit for the exam. The completed event CEU application serves as your attestation that you attended the event and should be awarded CEUs. Be sure to give your completed CEU application to SCCE, HCCA or CCB staff prior to taking the exam.

- ► In an SCCE or HCCA webinar you can easily log your CEUs online at hcca-info.org/certification → Continuing Education Units (CEUs). Then select "Add CEUs."
- In a CCB pre approved event or activity hosted by another organization you need to request a CCB certificate directly from that event sponsor. You will need the program code at the bottom of the official CCB certificate. This certificate will list the total amount of CCB CEUs awarded for the event. Certificates distributed by event sponsors are done so according to their organization's timeline. You can use the information on the certificate itself to easily log your CEUs online at hcca-info.org/certification → Continuing Education Units (CEUs). Then select "Add CEUs."
- In an event that was not CCB pre-approved you may still submit those CEUs to CCB for review using an Individual Accreditation Application found on page 37 and online. CCB certification staff will review the application and program information to determine whether the content meets CCB requirements for CEUs. For more information on this topic, see page 14.

It is up to you as the submitter to review and verify any and all of your CEU submissions sent to CCB for the purposes of seeking initial certification and/or renewal. View and track your CEU submissions in your SCCE or HCCA online account.



Add your CCB CEUs through the easy-to-use online portal at hcca-info.org/add-ceus

Content submitted for CCB CEUs must meet at least one of the 10 subject areas identified by CCB as relevant to compliance certification. Those subject areas include: Application of management practices for the compliance professional, application of personal and business ethics in compliance, written compliance policies and procedures,

designation of compliance officers and committees, compliance training and education, communication and reporting mechanisms in compliance, enforcement of compliance standards and discipline, auditing and monitoring for compliance, response to compliance violations and corrective actions, and complying with government regulators.

METHOD	DETAILS	NO. OF CEUs EARNED	CONSIDERED "LIVE" TRAINING
Attend SCCE & HCCA events	SCCE & HCCA hosts more than 90 events annually.	1 per 50-minute hour	Yes
Attend events hosted by	Submit CEUs for any outside event that, at least in part, relates to compliance.	1 per 50-minute hour	Yes
other organizations	Submit university courses that, at least in part, relate to compliance	3 per 1 academic credit	Yes**
*Participate in a live webinar hosted by SCCE	Participate in SCCE & HCCA's live webinars. SCCE & HCCA hosts numerous webinars annually.	1 per	
& HCCA or another organization	Participate in any organization's webinar that, at least in part, relates to compliance.	50-minute hour	Yes
*Participate in a recorded webinar by SCCE & HCCA or another organization	Listen to an SCCE & HCCA, or other organization's recorded webinar.	1 per 50-minute hour	No
	The Complete Compliance and Ethics Manual	10	No
Pass quizzes	Compliance 101 book	2	No
	Monthly Compliance Today or Compliance & Ethics Professional magazine (quizzes expire 12 months after issue date)	1 per issue	No
Present or teach on a	Present at an SCCE & HCCA event or one hosted by another organization.	2 per presentation	Yes
compliance-related topic	Teach a university course that, at least in part, relates to compliance	10 per university course	Yes
Publish an article or Blog post or Guest commentate on SCCE & HCCA's social networks	Publish an article in SCCE's Compliance & Ethics Professional or HCCA's Compliance Today magazine or in any organization's educational publication. Publish a compliance related educational blog post (minimum 400 words).	2 per article per day	No
Read approved articles	The Report on Medicare Compliance, The Report on Research Compliance, or The Report on Patient Privacy.	1 per issue	No
*Self-study	Complete any self-study activity such as online training modules that relate to compliance. Self-study submissions require proof of duration from sponsor.	1 per 50-minute hour	No

<sup>\*</sup>CCB CEUs cannot be awarded for networking, social activities, breaks, meals, or time spent in non-instructional activities like standalone question-and-answer sessions.

<sup>\*\*</sup>This list is a guideline, and may change at any time. CEU values or type may be adjusted once CCB certification staff has viewed submissions.

<sup>\*\*\*</sup>Individuals cannot submit direct job related duties or functions for the purpose of continuing education.

# 3. Apply to take the exam

Once you have satisfied candidacy requirements, complete and submit the Exam Application and the appropriate testing fee. There are two formats to choose from when applying for the exam: applying to take the test Paper and Pencil following an SCCE or HCCA event, or taking the exam via one of the Computer Based Test (CBT) options.

For the CBT options, candidates can test at a local PSI Testing Center or choose to take their exam from a location of their choosing via the Remote Proctored Test option.

You can complete the Exam Application found on pages 31–36 and online.

Only complete and legible Exam Applications will be accepted. Be sure to include documentation of 20 CCB CEUs, if not already on file with CCB, and include the Exam Application fee.

If applying online, go to your free, password-protected SCCE or HCCA account, log in and click on "Become Certified" listed under the "Certification" tab. Scroll down and select "Apply to take the exam." Any individual who has previously participated in an SCCE or HCCA activity has a free password-protected online account already set up. If you don't remember your login information, click "Forgot your password?"

CCB and PSI comply with the Americans with Disabilities Act and strive to ensure that no individual with a disability is deprived of the opportunity to take the exam solely by reason of that disability. An individual with a disability is defined by the ADA as a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such impairment, or a person who is perceived by others as having such impairment.

PSI will provide reasonable accommodations for candidates with disabilities. Candidates requesting special accommodations must call PSI at 888.519.9901 to schedule their exam.

Wheelchair access is available at all established Test Centers. Candidates must advise PSI at the time of scheduling that wheelchair access is necessary.

Candidates with visual, sensory, physical, or learning disabilities that would prevent them from taking the exam under standard conditions may request special accommodations and arrangements.

Verification of the disability and a statement of the specific type of assistance needed must be made in writing to CCB at least 45 calendar days prior to your desired exam date by completing the Request for Special Exam Accommodations and the Documentation of Disability-Related Needs forms on pages 41 & 43. CCB will review the submitted forms and will contact you regarding the decision for accommodations.

### If your application is accepted

If your Exam Application is accepted, you will receive an email confirmation from CCB within five business days. If you do not receive a confirmation notice, contact CCB at +1 952.988.0141 or 888.580.8373.

If CCB has accepted your Exam Application to later find you did not meet the necessary eligibility requirements, you forfeit all submitted fees and, if applicable, will have your exam score voided. To reapply you must submit a new Exam Application with full fees.

### If your application is not accepted

If your Exam Application is not accepted because it is incomplete or illegible, you will receive a call or an email within five business days from CCB certification staff in an attempt to obtain the required information.

If the information is not obtained within five business days, the Exam Application will be discarded.

You can reapply for the exam by submitting a new Exam Application with full fees—ensuring that it is complete, accurate, and legible.

# 4. Schedule your exam

Once your application has been accepted, you will receive an exam eligibility confirmation from CCB which includes your eligibility end date. If you are taking the Paper and Pencil exam offered at an SCCE or HCCA event, your confirmation will include the location, date, and time of your testing. Please print and bring this confirmation with you on the day of your exam administration.

If you are taking the CBT exam at a local PSI testing center or via the Remote Proctored Test option, your confirmation includes the information needed to schedule an exam appointment with PSI. PSI will reach out separately to confirm your exam eligibility status and to request that you contact them for scheduling. PSI administers the two-hour computer-based exam by appointment only.

Please make note of your PSI appointment time; you will only receive a confirmation of the appointment if you provided an email address.

Be sure to submit the Exam Application, as well as sit for the exam, within your current exam eligibility end date as determined by your CEUs on file with CCB. (Please note: Allow five business days to process Exam Applications.)

# PSI exam appointments at testing centers in the United States are:

- Scheduled as early as five business days after receiving PSI's confirmation, depending on site availability, or can be scheduled weeks ahead to accommodate your schedule.
- ► Made Monday through Saturday. You can only take the exam at the time it was scheduled.
- Not offered on most federally-recognized U.S. holidays, as well as Christmas Eve and New Year's Eve.
- ► Located at PSI testing centers. Go to schedule.psiexams.com to find a testing location nearest you.

# PSI exam appointments at international testing centers are:

 Coordinated through email at AMPIntlExamServices@goAMP.com.
 Contact information, preferred testing center location, and requested test dates are required approximately 2-4 weeks prior

- to your requested test dates to begin the scheduling process.
- ► Located at PSI testing centers. Go to schedule.psiexams.com to find a testing location nearest you.

### **Remote Proctored Test appointments are:**

- Scheduled as early as two business days after receiving PSI's confirmation, depending on availability, or can be scheduled weeks ahead to accommodate your schedule.
- Scheduled any day of the week at any time noted as available in PSI's scheduling system. You can only take the exam at the time it was scheduled.
- Available to all candidates who have confirmed they meet the minimum system requirement as well as reviewed the recommendations, limitations, policies and procedures related to this testing option, including but not limited to having:
  - Minimum system compatibility requirements and internet connection speed; we recommend 5 Mbps or higher upload and download
  - Location must support Voice over Internet (VoIP) in order to complete the exam
  - Current version of Google Chrome
  - Administrative access to disable firewalls; corporate firewalls and VPNs may restrict user access, and a personal device is recommended for this reason
  - Ability to download and install small program: PSI's secure web browser

Visit our website at hcca-info.org/exam-information for further details regarding system requirements and testing to ensure this testing option is right for you.

### 5. Take the exam

Exam day has arrived! You will have two hours to complete the 120-question exam. Only 100 questions will be scored. Be sure to answer each question before ending the exam. The exam is only given in English.

### **Exam entrance rules**

Whether taking the CBT exam at a PSI testing center, via the Remote Proctored Test option, or the Paper and Pencil exam at an SCCE or HCCA event, you must:

- ▶ Leave all personal belongings, including beverages, digital watches, phones, books, papers and electronic devices in a vehicle if testing at a PSI testing center, outside of the room in which you are testing if opting to take the Remote Proctored Test, or in the designated area of the testing room at an SCCE or HCCA event.
- ▶ If you are taking the CBT exam at a PSI testing center or the Paper and Pencil exam at an SCCE or HCCA event, present two forms of current identification to gain admission. Both forms must be current and include your current name and signature. Any type of temporary identification is not acceptable as the primary form of identification.

One form of identification MUST include a current photograph such as a driver's license with photograph; state identification card with photograph; passport; military identification card with photograph. No forms of temporary identification will be accepted.

The second form of identification must display your name and signature for signature verification (e.g., credit card with signature, social security card with signature, employment/student ID card with signature).

If your name on these documents is different than it appears on your identification, you must bring proof of your name change (e.g., marriage license, divorce decree, or court order).

▶ If you are testing via the Remote Proctored Test option, present one form of current identification to gain admission. Identification MUST include a current photograph such as a driver's license with photograph; state identification card with photograph; passport;

military identification card with photograph. No forms of temporary identification will be accepted.

Arrive up to 30 minutes early before your scheduled exam start time. You will be required to download the secured browser and perform a System Compatibility Check to ensure that all your computer system items are satisfactory to be able to proceed with your exam. If you do not start your exam within 15 minutes after your scheduled exam start time, you will not be admitted.

- ▶ If you are taking the CBT exam at a PSI testing center, arrive no later than your scheduled testing time. If you arrive more than 15 minutes after the scheduled exam start time, you will not be admitted.
- ▶ If you are taking a Paper and Pencil exam at an SCCE or HCCA event, you will receive an email notification from CCB regarding your approval to sit for the exam. Print and bring a copy of this email notification with you. Note you must arrive by the specified check-in time in the email notification. If you arrive late, you will not be admitted.

You are prohibited from misrepresenting your identity or falsifying information to obtain admission to the exam. If there is any doubt surrounding your identity, you will be turned away from the exam and will forfeit your exam fees. If you are taking the exam at a PSI testing center or at an SCCE or HCCA event, you will be required to sign a roster for verification of identity to gain admission to the exam.

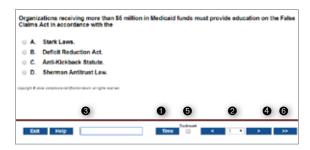
### **Exam rules**

After you have provided sufficient identification and completed all other Proctored required documents and checks you will be directed to your exam and begin upon further proctor instruction. All CCB exam candidates are closely monitored by the onsite proctors and/or remotely via computer/audio/video surveillance.

For those taking the Paper and Pencil exam at an SCCE or HCCA event, the proctor will begin the exam session with a reading of the exam rules.

For those taking a CBT exam through PSI, you will have your photo taken. This photo will print on your Score Report.

PSI testing center locations may also use metal detector wanding as one of several security measures you may encounter. Metal detector wanding procedures maintain comfort and dignity for candidates while scanning for hidden devices candidates may not have surrendered prior to entering the testing room. Candidates wishing not to be wanded will be allowed to test, but will be closely monitored by both the on-site proctor and remotely via video surveillance. Candidates with hidden devices that are uncovered during wanding must lock their devices away during testing, but will also be allowed to test.



A practice exam is offered prior to attempting the actual computerized exam.

- 1. Use the "Time" button to view the time remaining to complete the exam. The program will terminate if you exceed the two-hour time limit.
- **2.** Only one exam question and its four options appear on each screen. The question number appears in the lower right portion of the screen.
- **3.** Indicate your choice by entering the letter of the option in the bar at the bottom of the screen, or by selecting the option with your mouse.
- **4.** Click on the forward arrow (>) in the lower right portion of the screen to move to the next question.
- **5.** An exam question may be left unanswered to return later in the testing session. Questions may also be bookmarked for later review by clicking the blank box to the right of the "Time" button.
- **6.** Repeatedly click on the double arrows (>>) to identify all unanswered and bookmarked questions.

When you are comfortable with the CBT process, you may quit the practice exam and begin the timed exam. The time used for the practice exam is not counted as part of your exam time.

Be sure to abide by all exam rules:

- Personal pens, pencils, or other writing instruments are not allowed in the testing center. Pencils will be provided during check-in.
- Electronic devices of any kind are not allowed in the testing center.
- Questions concerning the content of the exam may not be asked during the test.
- ► Eating, drinking, or smoking are not permitted in the testing center.
- ▶ You will be given scratch paper to use during the exam. This paper must be returned to the proctor at the exam completion or you will not receive a Score Report. No documents or notes of any kind may be removed from the testing room. All computer screens, questions, papers, and written materials are the property of PSI and may not be reproduced in any form.
- ► The proctor may dismiss you from the exam at any time and at their discretion. See the full list of reasons on page 17.

At the conclusion of the exam, you will be asked to complete a short evaluation of your testing experience.

# Review your score report

Review your Score Report to determine whether you passed the exam.

Your Score Report will indicate a "pass" or "fail." Additionally, it includes raw scores by major content categories. A raw score, which determines your pass/fail status, is the number of questions you answered correctly. Your score is based on 100 of the 120 question exam.

- ▶ If you took the Remote Proctored Test exam, in most instances, you will receive your pass/fail results immediately after completing the exam. Following, you will receive your detailed Score Report from PSI by postal mail to the address on record within ten business days.
- ▶ If you took the CBT exam at a PSI testing center in the United States, in most instances, you will receive your Score Report with your results immediately after completing the exam. If you do not receive your Score Report immediately following completion of the exam, it will be mailed to you from PSI.
- ▶ If you took the CBT exam at a PSI international testing center, you will receive your Score Report from PSI by postal mail to the address on record within ten business days.
- ▶ If you took the Paper and Pencil exam, you will receive your Score Report with your results from PSI within four weeks.

The methodology used to set the minimum passing score is the Angoff method, where expert psychometricians estimate the passing probability of each item on the exam. These ratings are averaged to determine the minimum passing score.

The scores by content area on the Score Report are not used to determine pass-fail decision outcomes. They are only provided to offer a general indication regarding your performance in each content area. The exam is designed to provide a consistent and precise determination of your overall performance and is not designed to provide complete information regarding your performance in each content area. You should remember that areas with a larger number of questions will affect the overall score

more than areas with a fewer number of questions. The precision and consistency of scores diminishes with fewer questions, and therefore, scores by content area should be interpreted with caution, especially those that correspond to content areas with very few questions.

### If you pass the exam

Congratulations! Your certification is valid for two years. You may now can use the Certified in Healthcare Research Compliance (CHRC)® designation.

You may want to use it in professional communication items such as business cards, letters, or in your email signature, among others. CCB will separately send you instructions for how to access your digital badge so you can verify, share, and use your certification logo. See page 15 for more information on proper logo usage.

Additionally, CCB will mail you an official certificate and other documents within four weeks of your exam.

CCB reserves the right to publicly recognize anyone who has successfully completed a CHRC certification exam.

### If you did not pass the exam

If you do not pass the exam, apply to retest by submitting the re-exam application section included in your Score Report along with the exam application fee. In order to retest, you will need 20 CCB CEUs that have been earned within 12 months of the anticipated retesting date.

If you fail two exam attempts within a 180-day period, you must wait 180 days from your most recent exam date before applying to retake the exam. The application fee to retake the exam is based on your submitted CEUs. Keeping your CEUs current and submitting additional CEUs as needed to maintain 20 CEUs prior to your eligibility expiration will prevent you from having to pay the full exam application fee .

# Renew your certification in three steps

Attaining a certification is a verification of broadbased knowledge in the discipline being tested at that point in time. Therefore, certification renewal is required every two years. Attendance at SCCE or HCCA events or renewing your SCCE or HCCA membership is not the same as renewing your CCB certification. See page 13 for more information about the differences.

# 1. Keep track of your renewal date

It is your responsibility to keep track of your renewal date. Be sure to submit the CEUs and renewal fee prior to your certification expiration — which is every two years from the month you originally passed the certification exam.

You may receive courtesy reminders from CCB certification staff; however, failure to receive these reminders does not constitute a right to petition CCB's Board of Directors for an extension.

As a CHRC certification holder, you have a one month grace period beyond your renewal date to earn and submit CEUs. If you need additional time, you may extend the period by one and/or two months by completing the Renewal Extension Request form on page 39 and paying the monthly extension fee.

If you need to use the grace or extension periods, you should note that your next renewal period will be fewer than 24 months. Within this reduced time, you will still be required to accumulate 40 CCB CEUs.

# 2. Earn and submit the required CEUs

As a certification holder, you must earn AND submit 40 CCB CEUs within your renewal/extension period in order to renew your certification. CEUs must:

- ► Include a minimum of 20 CEUs earned from "live" trainings or events, which include face-toface training events or real-time virtual events and webinars; and
- ▶ Be earned within the two-year renewal period preceding the date of certification renewal.

CCB accepts relevant CEUs from any organization or event sponsor as long as the education is compliance related. Certification holders are not required to attend SCCE or HCCA events to accrue CCB CEUs. Content submitted for CCB CEUs must meet at least one of the 10 subject areas identified by CCB as relevant to compliance. For more information on those areas and ways to accumulate CCB CEUs, see page 5.

CEUs used to qualify for the initial certification cannot be used to qualify for renewal. You will need to obtain 40 CCB CEUs <u>after</u> passing the CHRC exam and becoming a certification holder.

### **CERTIFICATION RENEWAL**

Total CEUs needed:	40 CEUs
Needed from live training:	20 CEUs
Content:	One or more of the 10 subject areas
Time-frame:	Within 24 months of renewal date

### 3. Submit the renewal fee

Once CCB has documentation of your 40 CCB CEUs, submit the renewal fee to complete the renewal process. See page 18 for exam and renewal fees.

You will receive a letter within four weeks confirming your renewal. The certification is valid for another two years.

If the 40 CEU requirement is met and documented by CCB, but payment for the renewal fee has not yet been submitted by your renewal date, your certification will become inactive. However, you will have a duration, not to exceed two consecutive renewal periods (or four years of inactivity), to submit payment to "activate" your certification. After two consecutive renewal periods (or four years of inactivity), retesting will be your only option to regain the certification and you will not receive renewal reminders.

Please note that CCB will not be able to verify credentials if your certification is "inactive."

If the 40 CEU requirement is met, but not properly submitted to CCB for review and assessment by your renewal date, your certification will become inactive. However, you will have until what would have been the end of your next renewal period (two years) to submit the required CEUs to again "activate" your certification without having to retest. The CEUs must have been earned within the renewal period and given grace and extension periods in question. The applicable renewal, extension and reactivation fees will apply. After two years, your certification will officially expire, and retesting will be your only option to regain your certification.

### Retesting to renew certification

Actively certified individuals can choose to renew their certification by opting to retake the current form of the exam, and passing. If you are retaking the exam to renew your certification, you must:

- ► Earn 20 CCB CEUs within your current two year renewal period; a minimum of 10 CEUs must be live. Renewal extension fees may apply;
- Submit the Exam Application along with the application fee online at hcca-info.org/apply-exam; and
- ▶ Pass the current form of the exam.

### Retake the CHRC exam

The CHRC is an actively held certification wherein the earning AND submitting of compliance related education must be done within an individual's current renewal period and given extension periods.

If you have missed the renewal date and have exhausted the grace and extension periods and still do not have the required CEUs for renewal, your CHRC certification will lapse. There are no appeals for individuals unable to demonstrate they earned and submitted all required CEUs by their renewal end date and its given grace and extension periods.

To re-obtain the credential, you must meet the eligibility requirements to take the CHRC exam, apply for and pay the full application fee, and take the exam just as you did to originally obtain the certification.

You will have a new certification renewal date based on the month that you sit for and pass this exam.

For more information on eligibility requirements, see page 3.

### Failure to renew certification

If you fail to renew your certification, you are no longer considered CHRC certified and may not use the credential in professional communications such as on letterhead, stationary, business cards, in directory listings, or in your signature.

# Candidates' frequently asked questions

# Do I need to be an SCCE or HCCA member to become CHRC certified?

Membership with SCCE or HCCA is not necessary to attain, maintain or renew a CHRC certification.

# Do my SCCE or HCCA membership dues include the exam or renewal cost?

SCCE or HCCA membership dues do not include the cost of becoming CHRC certified or renewing a certification.

SCCE or HCCA membership and CHRC certification are two separate renewal processes.

CHRC certification fees are paid prior to the initial certification and every two years for certification renewal. See page 18 for exam and renewal fees.

# Does my event fee also apply toward the exam or renewal fee?

The cost of attending an SCCE or HCCA Academy or other event does not apply toward the cost of initial certification or certification renewal. Certification costs are in addition to the event fees, even when you are planning to take the optional certification exam at the end of the event, such as at an Academy or national conference.

See event fees at *hcca-info.org* or *corporatecompliance.org*. See page 18 for exam and renewal fees.

# What is the cost to take the exam and to renew my certification?

See page 18 for current exam and renewal fees.

### Should I become CHC, CHRC or CHPC certified?

CCB offers three similar healthcare compliance certifications:

- ► Certified in Healthcare Compliance (CHC)®
- ► Certified in Healthcare Research Compliance (CHRC)®
- Certified in Healthcare Privacy Compliance (CHPC®)

CHRC certification is geared toward general healthcare compliance while CHRC is geared toward compliance

professionals in the research realm. Likewise, the CHPC is best suited for compliance professionals in the healthcare privacy arena.

# Can my professional experience waive the continuing education requirement?

No, there are no exceptions to the continuing education requirements. All candidates and certification holders must fulfill the CEU requirements.

# How can I earn CCB-accredited Continuing Education Units (CEUs)?

CCB accreditation is based on the content of the activity. The content must be relevant to compliance by meeting at least one of the 10 major subject areas set forth by the CCB, see page 5.

CCB accepts relevant CEUs from any organization or event sponsor as long as the education is compliance related. You are not required to attend SCCE or HCCA trainings or events to accrue CCB CEUs. SCCE or HCCA trainings or events provide an avenue to accrue CCB CEUs.

The list of CCB CEU values on page 5 is a guideline for you to use in helping to determine your annual training needs for certification or renewal. However, actual values of submitted CEUs may be adjusted once CCB certification staff has reviewed your application. If you have a specific question, contact CCB certification staff for guidance.

### What is a CCB pre-approved event or activity

It is any activity that has been pre-approved by CCB to offer CCB CEUs to participants. The event's sponsor submitted the content to CCB prior to the event for CCB CEU consideration, and the CCB certification staff determined that CCB CEUs should be awarded for the activity.

Activities may include conferences, workshops, webinars, and presentations, among others.

At the end of the event, the event sponsor will distribute a certificate of attendance to all participants. The certificate lists the number of CCB CEUs earned for that activity.

hcca-info.org/certification

### Are CEUs awarded for an activity that wasn't CCB pre-approved?

You still can submit CEUs for activities and events that were not pre-approved for CCB CEUs but are, at least in part, relevant to compliance.

After the event, submit an Individual Accreditation Application either online or use the form on page 37. See page 4 for more information.

To receive CEUs for speaking, instructing, or facilitating at an event, or for publishing an article, you must submit an Individual Accreditation Application and a copy of your presentation or article. Please allow up to six weeks for review.

### Does SCCE or HCCA apply to other organizations for CEU qualification?

SCCE and HCCA regularly apply to outside organizations for pre-approval of continuing education for its events. In addition to being CCB pre-approved, SCCE and HCCA events are often pre-approved for Continuing Legal Education, RN, and NASBA/CPE credits. Continuing education details are listed in the event brochure and on the "Continuing Education" tab of the event page on the SCCE and HCCA website. Go to hcca-info.org/conferences or corporatecompliance. org/conferences.

### I'm in a master's program and some of my classes are compliance related. Do these qualify for CCB CEUs?

CCB partners with several colleges, universities, and law schools across the United States to offer CCB CEUs for compliance accredited courses and certification programs.

There are some nuances associated with these offerings, though, so it would be best to speak with CCB certification staff.

### What is "live" training?

For purposes of continuing education, the term "live" training is any training that is being conducted by the speaker with attendee participation in real-time.. Examples of "live" training include a face-to-face training events, real-time virtual events and webinars.

### Where can I find how many CCB CEUs I have?

You can view and easily track your CEUs online at hcca-info.org/certification → Continuing Education Units (CEUs) → My CEUs.

If you do not have internet access, call CCB at +1 952.988.0141 or 888.580.8373 to find out how many CEUs you have.

### Can I use the CEUs I earned to sit for the exam toward my CHRC renewal?

No. The CEUs that you accumulate in order to qualify for the exam do not carry forward toward the 40 CEUs needed for renewal.

You will need to accrue 40 CEUs within the twoyear renewal period in order to maintain your CHRC certification. See page 11 for more information.

### Can I carry extra CEUs over to the next renewal date?

No. CEUs earned in excess of the requirement are not carried into the next renewal cycle. CEUs submitted for renewal must be earned within your current twoyear renewal period.

### Is there a study guide for the exam?

The exam is largely based on compliance work experience; an official study guide is not available for this exam.

However, CCB recommends you review the "Exam resources" on page 20, the "Detailed Content Outline" on pages 22-24, and review the reference materials online at hcca-info.org/certification → Become Certified → CHRC.

### How soon after an activity should I submit my **CEUs to the CCB?**

CEU credits should be submitted to CCB as soon as possible, preferably within 30 days of the activity.

### Can I obtain an extension on my renewal period?

You have a one month grace period beyond your renewal date to earn and submit CEUs. If you need additional time, you may extend the period by one and/or two months by completing the Renewal Extension Request form on page 39 and paying the monthly extension fee.

### What if I cannot take the exam at an SCCE or HCCA event or the event is too far away from my location?

It is not required for you to test at an SCCE or HCCA event. You can take a computerized exam through PSI at one of their testing centers or remotely. For more information about how to schedule these computerized exams or find a PSI testing center near you, see page 7.

For more Frequently Asked Questions, go to hcca-info.org/certification → Frequently Asked Questions (FAQs).

# Proper logo and title usage

If you passed the exam or recently renewed your CHRC certification, you may now use the Certified in Healthcare Research Compliance (CHRC)® designation for as long as your certification remains in "active" standing. You may use this logo in professional communication items such as business cards, letters, or in your email signature, among others.

CCB will separately send you instructions for how to access your logo and digital badge so you can verify, share, and use your certification logo. If you have not received access to your logo, email ccb@compliancecertification.org to request access.

The CHRC is an actively held certification. Only those individuals who meet the eligibility requirements and successfully pass the exam attain the two-year CHRC designation. Only these individuals may use the logo and gain access to the digital badging offerings as long as their certifications are maintained and kept in "active" standing.

See image of proper logo and title usage below:

### Proper logo and title usage



Certified in Healthcare Research Compliance (CHRC)®

# Certification policies and legal disclaimers

Please read and understand CCB's policies regarding applying for, attaining, and renewing a CHRC certification.

### **Auditing CEU submissions**

CCB reserves the right to audit continuing education submissions at any time. The scope of these audits will be limited to verification of attendance and compliance with content area requirements. Fraudulent submission of continuing education for certification, or certification renewal, is grounds for prohibition from testing and/or revocation of certification.

### **Confidentiality policy**

Information about candidates for testing or renewal of certification and their exam results are considered confidential. However, CCB, SCCE, and HCCA reserve the right to use information supplied by or on behalf of a candidate for research and publicity. Studies and reports concerning candidates will not contain information identifiable with any candidate, unless authorized by the candidate.

### **Exam appointment changes**

No refunds will be issued to eligible candidates who need to cancel an exam or fail to schedule their exam by their eligibility end date. You must notify CCB at least five business days prior to the scheduled test date, if you are unable to attend the scheduled exam on that date.

If you fail to give five business days notice, or if you need to reschedule the exam more than once, a rescheduling fee will be imposed.

You have until your eligibility end date to contact CCB to reschedule a cancelled exam or your initial Exam Application and fee(s) will be forfeited.

If you fail to contact CCB within your eligibility end date to reschedule the exam, you will need to complete a new Exam Application and submit a new exam fee to re-apply for the exam.

### Late arrival for exam

If you arrive after the scheduled exam check-in time for a Paper and Pencil administration, you may not be admitted, per onsite proctor instruction. After proctor instructions have begun, you will not be admitted and will forfeit your exam fees.

If you arrive to a PSI testing center more than 15 minutes past your scheduled start time, or start/access your Remote Proctored Test more than 15 minutes past your scheduled start time, you will not be admitted and will forfeit your exam fees.

Those individuals not admitted due to late arrival have the remainder of their exam eligibility period to remit the rescheduling fee and contact CCB to schedule a new exam appointment.

### Inclement weather or emergency

Every attempt is made to administer exams as scheduled; however, inclement weather or an unforeseen emergency may require CCB or PSI to cancel an exam.

- ▶ If an exam is cancelled, all scheduled candidates will receive notification after the cancelled exam and information on how to reschedule or re-apply for the exam.
- ► You are encouraged to contact PSI's "Weather Hotline" at 800.380.5416 prior to the exam to inquire about a testing center closing.
- ▶ If you experience a personal or medical emergency on exam day, you may request consideration of rescheduling the exam without an additional fee. The request must be sent to CCB in writing within 30 days of the scheduled exam session. The request must include a description of the emergency and supporting documentation. Considerations for rescheduling without additional fees are made on a case-by-case basis.

### **Medical extensions**

Medical extensions are reviewed on a case by case basis.

This extension type is for individuals with medical circumstances substantial enough that the earning and submitting of the required CEUs is not possible within their allotted 24-month renewal periods or given extension periods.

Requests must be sent in writing to CCB for consideration. Medical extensions allow for up to six additional months, post-renewal date, for individuals to earn and submit their required CEUs. Approval of medical extension for one renewal period does not mean approval for future renewal periods, as well as shortens future renewal periods.

### PSI exam security

CCB and PSI maintain exam administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their ability. The testing center is continuously monitored by audio and video surveillance equipment for security purposes.

### Proctor dismissals from the exam

Testing proctors may dismiss you from the exam if you:

- Are unauthorized to be admitted into the exam.
- ► Create a disturbance or are abusive or otherwise uncooperative.
- Give or receive help on the exam or are suspected of doing so.
- Attempt to take the exam materials or notes from the testing room.
- Attempt to take the exam for someone else.
- Are observed with notes.
- ► Fail to follow exam rules.

Violation of any of the above provisions results in dismissal from the exam session. Your exam score will be voided and the exam fees are forfeited.

Evidence of misconduct is reviewed by the CCB Ethics Review Committee to determine whether you will be allowed to re-apply for the exam. If re-exam is granted, a complete application and exam fee are required to re-apply.

### Scores cancelled by PSI or CCB

CCB and PSI are responsible for the integrity of scores they report. On occasion, occurrences such as computer malfunction or misconduct by a candidate may cause a score to be suspect. CCB and PSI are committed to rectifying such discrepancies as quickly as possible.

CCB may void exam results if, upon investigation, violation of its regulations or exam ineligibility is discovered.

### **Grievance policy and process**

Persons wishing to file a complaint regarding an individual actively certified by the Compliance Certification Board (CCB)® may do so within two years of the date of the circumstances giving rise to the complaint. A complaint may be warranted by, for example, a violation of the Code of Ethics for Health Care Compliance Professionals found in the CHRC Candidate Handbook.

The complaint must be submitted by email or mail to ccb@compliancecertification.org or to:

Compliance Certification Board (CCB)<sup>®</sup> Attn: Certification Chief 6462 City West Parkway Eden Prairie, MN 55344 USA

The submitter should include a full explanation as to the reason for the complaint, along with supporting documentation explaining the complaint.

### **Revocation of certification**

Grounds for prohibition from exam or revocation of certification may include:

- ► Intentional misrepresentation of information provided on a CHRC application.
- ▶ Fraudulent submission of CEUs.
- ▶ Failure to disclose a conviction of any felony directly related to the candidate or certification holder's role as a compliance and ethics professional.

# **Exam and renewal fees**

### FEES THAT MAY APPLY

Exam application fee:	
SCCE or HCCA member	\$350
Non-member	\$450
Re-exam/rescheduling fee	\$75*
Duplicate Score Report fee	\$25
Score verification fee	\$25
Certification renewal fee:	
SCCE or HCCA member	\$125
Non-member	\$245
Monthly renewal extension fee (two-month maximum)	\$50

\*Re-exam/rescheduling fees are based on a candidate's submitted and approved CEUs on file. Please contact a CCB representative to verify your exam application fee.

### Acceptable payment methods

You may provide payment via check or by credit card from the following creditors: AmericanExpress, MasterCard, Visa, or Discover.

Please make checks payable to "Compliance Certification Board."

If you are concerned about sending credit card information via fax or mail, please write "call me" on the paper application and provide a phone number where you can be reached.

### **Cancellations and refunds**

No refunds will be issued to eligible candidates who need to cancel an exam or fail to schedule their exam by their eligibility end date. You must notify CCB at least five business days prior to the scheduled test date, if you are unable to attend the scheduled exam on that date.

### **Duplicate Score Report requests**

You may purchase additional copies of your Score Reports. Requests must be submitted in writing to PSI within 12 months of the exam. The request must include your full name, mailing address, telephone number, date of exam, name of the exam taken, and the duplicate Score Report fee. A duplicate Score Report will be mailed within two weeks after receipt of the request.

PSI Corporate Headquarters 18000 W. 105th Street Olathe, KS 66061-7543 USA

### **Score verification requests**

You may request a "Score Verification." Requests must be submitted in writing to PSI (address listed above) within 12 months of the exam. The request must include your full name, mailing address, telephone number, date of exam, name of the exam taken, and the score verification fee. A Score Verification is mailed within two weeks after receipt of the request.

# For peer support, join a candidate group

Join one of HCCAnet's new candidate groups. Post questions, share your insights, and network with other compliance professionals who have taken or are preparing for an exam.

- ▶ CHC Candidate Group for healthcare compliance and ethics
- ► CHRC Candidate Group for healthcare research
- ► CHPC Candidate Group for healthcare privacy

HCCAnet is the official social network of the Health Care Compliance Association and is free to join.



# Go to hcca-info.org/hccanet to get started

- 1. Login to your account via the "Login" button in the upper right corner of the page.
- 2. Click on "Communities," select "All Communities" then scroll down to locate the study groups.
- 3. Select your desired study group, then click "Join."
- 4. You will then be prompted to specify your desired method for receiving messages from the eGroup. Make your selection then click "Yes, join the community."

Post questions · Share your insights · Network with others



## Exam resources

The exam is largely based on compliance, an individual's work experience and knowledge areas as it relates to the "Detailed Content Outline" on pages 22–24. An official study guide is not available for this exam.

To help prepare for the CHRC exam, CCB recommends you:

- ▶ Review the CHRC Candidate Handbook, and the Detailed Content Outline on pages 22–24.
- Review reference materials and programs that are the basis for the Detailed Content Outline, such as the Federal Sentencing Guidelines. These programs and reference materials are created by government agencies and groups that establish policies and guidelines related to compliance, and groups that regulate healthcare compliance and ethics issues. A full list of these references and web links can be found online at hcca-info.org/certification → Become Certified → CHRC.
- ▶ Attend healthcare compliance events that provide current education in the areas you need, and as they relate to the Detailed Content Outline, which indicates the subject areas you will be tested on.
- Learn from healthcare compliance industry experts and agencies about current regulations, best practices, and current government guidance.

The CHRC practice exam: It is only intended to help you become familiar with how the computerized testing program functions. Those taking the Paper and Pencil exam do not need to use this resource. Additionally, you may take a similar practice exam at the PSI testing center.

### **Detailed Content Outline**

The "Detailed Content Outline" contains:

- ► The areas and tasks that will be tested in the CHRC exam.
- ► The number of questions on the exam from each of the three cognitive levels and subject areas

The exam will be scored on participants' responses to 100 of the 120 multiple-choice questions spread across all subject areas.

The numbers on the right side of each section of the outline indicate:

- ▶ **Recall:** the number of questions that require recollection of specific knowledge related to the subject area. This number is part of the total
- ▶ **Application:** the number of questions that require application of recalled knowledge to discern the final answer. This number is part of the total.
- ▶ **Analysis:** the number of questions that require the analysis of a situation to determine a proper action listed among several choices. This number is part of the total.
- ► **Total:** the total number of questions from the subject area that will appear on the exam.

# **Exam sample questions**

The sample questions are only intended to help familiarize you with the format of the exam. Questions presented here are not indicative of the actual exam nor are they meant to infer actual exam results

- 1. Whom may the FDA sanction in response to a failure to report adverse events to the IRB and study sponsor?
  - A. research coordinator
  - B. clinical department
  - C. other research sites
  - D. principal investigator
- 2. The three basic principles of The Belmont Report are respect for persons, justice, and
  - A. societal benefit.
  - B. beneficence.
  - C. public welfare.
  - D. ethics.
- 3. Before an organization accepts HHS funds for human subjects research, a research compliance professional should verify that the organization has submitted
  - A. a Federalwide Assurance.
  - B. a research informed consent.
  - C. an NIH grant application.
  - D. a clinical trial budget.

- 4. In a risk assessment process, after identifying an initial list of risk areas, which of the following steps should a research compliance professional take NEXT?
  - A. Prioritize risk areas into high, medium, or low categories.
  - B. Discuss risk areas selected for review with legal counsel.
  - C. Review previous internal and external audit consulting reports.
  - D. Interview senior management throughout the organization.
- 5. A hospital is currently conducting a clinical trial on knee surgery. If a PI offers to waive the co-pay for a Medicare patient, the institution should evaluate for a violation of
  - A. the False Claims Act.
  - B. The Common Rule.
  - C. Anti-Kickback Statutes.
  - D. CLIA.

Find the answer key at the bottom of page 24.

Exam questions on this page are shown in the font and size as presented on the actual exam (Arial 12, Bold).

		gnit Level		
Detailed Content Outline	Recall	Application	Analysis	TOTAL
1. Standards, Policies, and Procedures	3	11	3	17
A. Conduct a review of policies and procedures				
B. Consult with legal resources				
C. Coding/billing policies and procedures				
1. Evaluate policies and procedures that address overpayments				
2. Confirm internal control procedures for billing accuracy				
<b>D.</b> Code of conduct				
1. Integrate mission, vision and values				
2. Maintain a code of conduct				
3. Ensure code of conduct includes research activities				
E. Maintain compliance program including plan documents				
F. Ensure that a non-retaliation policy exists				
G. Oversee internal and external compliance audit policies and procedures				
H. Ensure maintenance of policies and procedures, including but not limited to the following:				
1. record retention/destruction				
2. conflict of interest				
3. confidentiality, privacy and security				
4. research misconduct				
5. biosafety				
6. human/animal subject protections				
<ul><li>7. other</li><li>I. Ensure maintenance of policies and procedures to address regulatory requirements of agencies including but not limited to the following:</li></ul>	5,			
1. FDA				
2. USDA				
<b>3.</b> ORI				
4. OCR				
5. OHRP				
6. other				
<b>J.</b> Ensure maintenance of policies on interactions with other research collaborators (e.g., sponsors, physicians, collaborating institutions, pharmaceutical industry)				
<b>K.</b> Recommend governance policies related to research compliance activities				
2. Compliance Program Administration	3	9	3	15
A. Administer a research compliance program (e.g., budget, staffing, risk assessment, internal controls	5)			
<b>B.</b> Inform governance board/oversight committee of research compliance activities				
C. Collaborate with others to identify best practices				
<b>D.</b> Define the scope of the compliance program consistent with current industry standards				
<b>E.</b> Evaluate the effectiveness of the compliance program on an ongoing basis				
F. Maintain knowledge of current regulatory changes and interpretation of laws				
<b>G.</b> Identify the need for outside expertise				

		gnit Level		
<b>Detailed Content Outline</b>	Recall	Application	Analysis	TOTAL
<b>H.</b> Ensure that the organization has defined the responsibilities, purpose, function and authority of the compliance officer	of		***************************************	
I. Verify that the role of counsel in the compliance process has been defined				
J. Delineate the responsibilities, purpose and function for all compliance staff				
<b>K.</b> Incorporate regulatory agencies' guidance/priorities into compliance operations				
L. Integrate the compliance program into operations				
M. Develop an annual compliance work plan				
N. Conduct organizational risk assessments				
3. Screening and Evaluation of Researchers, Employees, Physicians, Sponsors, Vendors, Contractors, and Others	3	5	0	8
A. Ensure the organization has processes in place to identify and disclose conflicts of interest				
B. Include compliance in all job descriptions				
C. Include compliance as an element of job evaluation				
<b>D.</b> Assure background checks are conducted on personnel in accordance with applicable responsibilities, rules and laws				
<b>E.</b> Assure monitoring of government lists for excluded individuals/entities				
4. Communication, Education, and Training	3	11	4	18
A. Disseminate regulatory guidance material				
B. Communicate compliance information throughout the organization				
C. Develop a communication plan				
<b>D.</b> Provide resources to respond to research compliance questions				
E. Translate complex laws and regulations into a format employees can understand				
F. Provide initial and ongoing training to workforce on the following:				
1. their obligation to accurately document activities				
2. the compliance aspects of their job responsibilities				
3. research compliance requirements				
<ol><li>risk specific training for targeted employees</li></ol>				
<b>G.</b> Promote a culture of compliance throughout the organization				
H. Encourage employees to seek guidance and clarification				
I. Track participation in ongoing compliance training programs				
J. Validate third parties have received compliance training				
<b>K.</b> Provide training to the governing board on its compliance program oversight responsibilities				
5. Monitoring, Auditing, and Internal Reporting Systems	4	6	10	20
A. Protect anonymity and confidentiality within legal and practical limits				
<b>B.</b> Monitor for violations of applicable laws and regulations				
C. Confirm auditors are independent				
<b>D.</b> Develop action plans based on risk assessments				
<b>E.</b> Ensure system(s) exist(s) to report noncompliance (e.g., hotline, helpline, confidential message line, suggestion box)				
F. Respond to compliance concerns in a timely manner				
<b>G.</b> Monitor elements of the compliance program				

			gniti _evel:		
D	etailed Content Outline	Recall	Application	Analysis	TOTAL
н.	Conduct compliance audits including but not limited to the following:				
	1. records management				
	2. conflict of interest				
	3. confidentiality, privacy and security				
	4. biosafety				
	5. human/animal subject protections				
	6. grants management				
	7. research billing				
	8. researchers' time and effort				
	9. protocol review and approval				
	10. other				
I.	Engage in routine monitoring of compliance related activities				
	Monitor compliance audit results (e.g., track, trend, evaluate, benchmark)				
	Develop annual compliance auditing and monitoring plans				
L.	Coordinate response to audits conducted by external entities				
М.	Ensure audit tools exist				
N.	Monitor implementation of mandated corrective action plans from external parties				
6.	Enforcement, Discipline, and Incentives	1	5	2	8
A.	Recommend response when noncompliance is substantiated				
В.	Recommend action be proportionate to violation and fair and consistent				
C.	Assure action is consistent with policies and procedures				
D.	Assure actions are documented				
	Verify management has taken action(s) when individuals and third parties have been excluded				
	Verify corrective action is implemented				
	Assure incentives promote and reward compliant and ethical behavior				
•	Recommend enforcement action to ensure compliance	_			
•	Investigations and Remedial Measures	2	7	5	14
	Communicate noncompliance through required channels				
	Assure mandated reporting is completed in a timely manner				
	Identify root cause of noncompliance				
	Collaborate with management to develop corrective action plans for risk mitigation  Monitor corrective action plans				
	Respond to inquiries promptly, thoroughly and discreetly				
	Assure fair, objective, timely and discreet investigations are conducted and documented in				
	compliance with applicable standards				
	Recommend remedial action in response to identified problems or vulnerabilities				
	Cooperate with government inquiries and investigations in a timely manner				
J.	Recognize when legal counsel should be involved in investigations and reporting (e.g., legal privilege, voluntary disclosure)				
	Totals	19	54	27	100

Answer key for page 21						
1.D	2.B	3.A	4.A	5.C		

# **Certification made easy**

# 1. Talk to a CCB certification specialist

CCB's certification staff are happy to help with application, certification or continuing education questions. Call +1 952.944.0141 or 888.580.8373,

Monday through Friday, between 8 am and 5 pm (CT), to speak with certification staff.

# 2. Order compliance resources

Review reference materials and compliance resources that are the basis for the Detailed Content Outline. A full list of these references and web links can be found online at *hcca-info.org/certification* → Become Certified → CHRC.

After you have identified your needed areas of study as it relates to the Detailed Content Outline you can look to organizations like HCCA who provide several compliance related resources produced by industry experts. You can order books, training videos, and past webinars on CD. Order online at hcca-info.org.

# 3. Attend compliance conferences

Attend compliance events that provide current education in the areas you need, and as they relate to the Detailed Content Outline, which indicates the subject areas you will be tested.

CCB accepts relevant CEUs from any organization or event sponsor as long as the education is compliance related. HCCA for example hosts face-to-face training events, real-time virtual events

and webinars, all of which are submitted to CCB for the purposes of CEU pre-approval. HCCA offers national conferences concentrated on specific areas of healthcare compliance, one-day regional conferences, Academies and 90-minute webinars. Each event offers insights from professionals in the compliance community across the United States and internationally. View and register online at hcca-info.org → Conferences.

# 4. Receive peer guidance and support @HCCAnet -

HCCA's social network, HCCAnet, is the premier healthcare compliance and ethics social network. With compliance peers and experts alike at your fingertips, it is the place to go when you have a question.

Go to hcca-info.org/hccanet today. An HCCA membership is not required to view most of this content; however, a free password-protected account is necessary to post discussions, subscribe to groups, and access most library content.

# Code of Ethics for Health Care Compliance Professionals

### Preamble -

Health care compliance programs are ultimately judged by how they affect, directly or indirectly, the delivery of health care to the patients, residents and clients served by the healthcare industry and, thus, by how they contribute to the well-being of the communities we serve. Those served by the healthcare industry are particularly vulnerable, and therefore health care compliance professionals (HCCPs) understand that the services we provide require the highest standards of professionalism, integrity and competence. The following Code of Ethics expresses the profession's recognition of its responsibilities to the general public, to employers and clients, and to the legacy of the profession.

The Code of Ethics consists of two kinds of standards: Principles and Rules of Conduct. The principles are broad standards of an aspirational and inspirational nature, and as such express ideals of exemplary professional conduct. The rules of conduct are specific standards that prescribe the minimum level of conduct expected of each HCCP. Compliance

with the code is a function both of the individual professional and of the professional community. It depends primarily on the HCCP's own understanding and voluntary actions, and secondarily on reinforcement by peers and the general public.

A Commentary is provided for some rules of conduct, which is intended to clarify or elaborate the meaning and application of the rule. The following conventions are used throughout the code: "Employing organization" includes the employing organization and clients; "Law" or "laws" includes all federal, state and local laws and regulations, court orders and consent agreements, and all foreign laws and regulations that are consistent with those of the United States; Misconduct" includes both illegal acts and unethical conduct; and "Highest governing body" of the employing organization refers to the highest policy and decision-making authority in an organization, such as the board of directors or trustees of an organization.

# Principle I -

### **Obligations to the Public**

Healthcare compliance professionals should embrace the spirit and the letter of the law governing their employing organization's conduct and exemplify the highest ethical standards in their conduct in order to contribute to the public good.

**R1.1** HCCPs shall not aid, abet or participate in misconduct.

**R1.2** HCCPs shall take such steps as are necessary to prevent misconduct by

their employing organizations.

**R1.3** HCCPs shall exercise sound judgement in cooperating with all official and

legitimate government investigations of or inquiries concerning their employing organization.

**Commentary:** While the role of the HCCP in a government investigation may vary, the HCCP shall never obstruct or lie in an investigation

R1.4 If, in the course of their work, HCCPs become aware of any decision bytheir employing organization which, if implemented, would constitute misconduct, adversely affect the health of patients, residents or clients, or defraud the system, the professional shall: (a) refuse to consent to the decision; (b) escalate to the highest governing authority, as appropriate; (c) if serious issues remain unresolved after exercising "a" and "b", consider resignation; and (d) report the decision to public officials when required by law.

**Commentary:** The duty of a compliance professional goes beyond other professionals in an organizational context, inasmuch as his/her duty to the public includes prevention of organizational misconduct.

The compliance professional should exhaust all internal means available to deter his/her employing organization, its employees and agents from engaging in misconduct. HCCPs should consider resignation only as a last resort, since compliance professionals may be the only remaining barrier to misconduct. In the event that resignation becomes necessary, however, the duty to the public takes priority over any duty of confidentiality to the employing organization. A letter of resignation should set forth to senior management and the highest governing body of the employing organization the precise conditions that necessitate his/her action. In complex organizations, the highest governing

body may be the highest governing body of a parent corporation.

The steps of resignation and government notification are typically only appropriate if: (1) the compliance officer has detected a course of action that is a certain, serious, and material violation of the law; (2) the health care compliance professional has made the most energetic of efforts internally to surface and resolve the matter; and (3) the management of the organization, including at the highest levels, declines to take any remedial action and does so in apparent recognition that the course of action which the compliance officer seeks to correct is in violation of the law.

# Principle II -

# Obligations to the Employing Organization

Health care compliance professionals should serve their employing organizations with the highest sense of integrity, exercise unprejudiced and unbiased judgment on their behalf, and promote effective compliance programs.

**R2.1** HCCPs shall serve their employing organizations in a timely, competent and professional manner.

Commentary: HCCPs are not expected to be experts in every field of knowledge that may contribute to an effective compliance practice in the healthcare industry. HCCPs venturing into areas that require additional expertise shall obtain that expertise by additional education, training or through the retention of others with such expertise. HCCPs shall also have current and general knowledge of all relevant fields of knowledge that reasonably might be expected of a health care compliance professional, and shall takes steps to ensure that they remain current by pursuing opportunities for continuing education and professional development.

**R2.2** HCCPs shall ensure to the best of their abilities that employing organizations comply with all relevant laws.

**Commentary:** While HCCPs should exercise a leadership role in compliance assurance, all employees have the responsibility to ensure compliance.

**R2.3** HCCPs shall investigate with appropriate due diligence all issues, information, reports and/or conduct that relate to actual or suspected misconduct, whether past, current or prospective.

**R2.4** HCCPs shall keep senior management and the highest governing body informed of the status of the compliance program, both as to the implementation of the program, and about areas of compliance risk.

Commentary: The HCCP's ethical duty under this rule complements the duty of senior management and the highest governing body to assure themselves "that information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to reach informed judgments concerning both the corporation's compliance with law and its business performance." In re Caremark International Inc., Derivative Litigation,1996 WL 549894, at 8 (Del. Ch. Sept. 25, 1996).

**R2.5** HCCPs shall not aid or abet retaliation against any employee who reports actual, potential or suspected misconduct, and they shall strive to implement procedures that ensure the protection from retaliation of any employee who reports actual, potential or suspected misconduct.

**Commentary:** HCCPs should preserve to the best of their ability, consistent with other duties imposed on them by this Code of Ethics, the anonymity of

reporting employees, if such employees request anonymity. Further, they shall conduct the investigation of any actual, potential or suspected misconduct with utmost discretion, being careful to protect the reputations and identities of those being investigated.

**R2.6** HCCPs shall not reveal confidential information obtained in the course of their professional activities, recognizing that under certain circumstances confidentiality must yield to other values or concerns, e.g., to stop an act which creates appreciable risk to health and safety, or to reveal a confidence when necessary to comply with a subpoena or other legal process.

**Commentary:** It is not necessary to reveal confidential information to comply with a subpoena or legal process if the communications are protected by a legally recognized privilege (eg attorney client privilege).

**R2.7** HCCPs shall take care to avoid any actual, potential or perceived conflict of interest; to disclose them when they cannot be avoided; and to remove them where possible. Conflicts of interest can also create divided loyalties. HCCPs shall not permit loyalty to individuals in the employing organization with whom they

have developed a professional or a personal relationship to interfere with or supersede the duty of loyalty to the employing organization and/or the superior responsibility of upholding the law, ethical business conduct and this Code of Ethics.

**Commentary:** If HCCPs have any business association, direct or indirect financial interest, or other interest which could be substantial enough to influence their judgment in connection with their performance as a professional, the HCCPs shall fully disclose to their employing organizations the nature of the business association, financial interest, or other interest. If a report, investigation or inquiry into misconduct relates directly or indirectly to activity in which the HCCP was involved in any manner, the HCCP must disclose in writing the precise nature of that involvement to the senior management of the employing organization before responding to a report or beginning an investigation or inquiry into such matter. Despite this requirement, such involvement in a matter subject to a report, investigation or inquiry will not necessarily prejudice the HCCP's ability to fulfill his/her responsibilities in that regard.

**R2.8** HCCPs shall not mislead employing organizations about the results that can be achieved through the use of their services.

# Principle III -

### **Obligations to the Profession**

Compliance professionals should strive, through their actions, to uphold the integrity and dignity of the profession, to advance the effectiveness of compliance programs and to promote professionalism in health care compliance.

**R3.1** HCCPs shall pursue their professional activities, including investigations of misconduct, with honesty, fairness and diligence.

**Commentary:** HCCPs shall not agree to unreasonable limits that would interfere with their professional ethical and legal responsibilities. Reasonable limits include those that are imposed by the employing organization's resources. If management of the employing organization requests an investigation but limits access to relevant information, HCCPs shall decline the assignment and provide an explanation to the highest governing authority of the employing

organization. The compliance professional should with diligence strive to promote the most effective means to achieve compliance.

**R3.2** Consistent with paragraph R2.6, HCCPs shall not disclose without consent confidential information about the business affairs or technical processes of any present or former employing organization that would erode trust in the profession or impair the ability of compliance professionals to obtain such information from others in the future.

**Commentary:** Compliance professionals need free access to information to function effectively, as well as the ability to communicate openly with any employee or agent of an employing organization. Open communication depends upon trust. Misuse and abuse of the work product of compliance professionals poses the greatest threat to compliance programs. When adversaries in litigation use an organization's own self-policing work against it,

this can undermine the credibility of compliance professionals. HCCPs are encouraged to work with legal counsel to protect confidentiality and to minimize litigation risks.

**R3.3** HCCPs shall not make misleading, deceptive or false statements or claims about their professional qualifications, experience or performance.

**R3.4** HCCPs shall not attempt to damage, maliciously or falsely, directly or indirectly, the professional reputation, prospects, practice or employment opportunities of other compliance professionals.

**R3.5** HCCPs shall maintain their competence with respect to developments within the profession, including knowledge of and familiarity with current theories, industry practices, and laws.

**Commentary:** HCCPs shall pursue a reasonable and appropriate course of continuing education, including

but not limited to review of relevant professional and healthcare industry journals and publications, communication with professional colleagues and participation in open professional dialogues and exchanges through attendance at conferences and membership in professional associations.

### Health Care Compliance Association's Code of Ethics Development Committee (Adopted in 1999)

- ▶ Jan Heller, PhD
- ▶ Mark Meaney, PhD, CCEP
- ▶ Joseph E. Murphy, JD, CCEP, CCEP-I
- ▶ Jeffrey Oak, PhD

For copies of the Code of Ethics for Health Care Compliance Professionals, please visit http://bit.ly/hcca-code-of-ethics.

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### Compliance Certification Board (CCB)®

\*Signature

# **Individual Accreditation Application**



Complete this form if you participated in an event that was not pre-approved for CCB Continuing Education Units. If approved, CCB CEUs may be used toward Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Compliance–Fellow (CHC-F)®, Certified in Healthcare Privacy Compliance (CHPC®), Certified in Healthcare Research Compliance (CHRC)®, Certified Compliance & Ethics Professional (CCEP)®, Certified Compliance & Ethics Professional–Fellow (CCEP-F)®, Certified Compliance & Ethics Professional–International (CCEP-I)® certifications. See the appropriate Candidate Handbook for more information. Following application review and approval, credits will be logged in your account and available to view online. Allow up to six weeks for CCB certification staff to review.

One application must be completed and submitted for each event. Complete the online Individual Accreditation Application at *corporatecompliance.org/add-ceus* or *hcca-info.org/add-ceus*, send this completed Individual Accreditation Application with the required documentation to:

mail: Compliance Certification Board, 6462 City West Parkway, Eden Prairie, MN 55344 USA fax: +1 952.988.0146 | email: ccb@compliancecertification.org | phone: +1 952.933.4977 or 888.580.8373

# PERSONAL INFORMATION \*First Name Middle Name \*Last Name \*Telephone SCCE/HCCA ID number \*Email (confirmations will be sent to this address) **EVENT INFORMATION** \*Event Title \*Sponsoring Organization \*Start Date \*End Date \*Location \*DENOTES REQUIRED FIELD **EVENT FORMAT** ☐ Live ☐ Non-Live/Self Study ☐ Speaker ☐ Other (Note: CEUs from "Live" events must constitute at least 50 percent of CCB CEUs toward certification and renewal. See the certification's Candidate Handbook for a list of suggested activities and their CEU values.) **TOTAL HOURS** Total hours (60 minutes/hour) spent in instructional activity in program above: (Note: Only half-credits are granted for participating in a presentation during a meal. Speakers may earn a maximum of 2.0 live CCB CEUs per presentation.) SUPPLEMENTAL MATERIALS Attach a complete agenda that outlines session times, a sample of handouts that does not exceed ten pages, and/or a certificate of attendance with total hours of participation included. Documentation must be provided by the sponsoring organization. ATTENDANCE VERIFICATION Sign and date below certifying that you were in attendance during the hours indicated above.

\*Date

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### Compliance Certification Board (CCB)®

# **Renewal Extension Request**



All CCB certification holders are given a 1 month grace period to submit their renewal documentation and fees. However, if additional time is needed, certification holders can apply for an additional 1 or 2-month extension using this form. CCB will process extension requests within five business days. Ensure the form is completed accurately and completely to avoid delays.

Return completed form and fees to:

\*Signature

mail: Compliance Certification Board, 6462 City West Parkway, Eden Prairie, MN 55344 USA

*First Name	*Last Name	Middle Name				
*Telephone	*SCCE/HCCA ID number	*Email (confirmations will be sent to this address				
*DENOTES REQUIRED FIELD						
CERTIFICATION						
	requesting an extension for:  GCEP-F GCHC GCHRC  more than one certification listed above, you must sub	☐ CHPC ☐ CHC-F bmit one form for each certification.)				
EXTENSION						
I would like to request a 1-mc	onth $\square$ 2-month extension beyond my re	enewal date and 1 month grace period.				
FEES						
Extensions will not be processed until payment has been received.	<b>EXTENSION FEE</b> ☐ \$50 (1-month) ☐ \$100 (2-month)					
All checks should be made	PAYMENT					
payable to "Compliance Certification Board." Funds from international countries should be submitted in U.S.	<b>Email</b> to ccb@compliancecertification.org — Due to PCI compliance, do not provide credit card information via email. You may email this form (without credit card information) and CCB will contact you for payment using the telephone number you provided within this form.					
dollars. For wire transfer	Fax to: +1 952.988.0146   Mail to CCB, 6462 City West Parkway, Eden Prairie, MN 55344 USA					
details, email ap@corporatecompliance.org.	O Check enclosed					
No refunds will be issued for	O Credit card: I authorize CCB to charg					
	○ Visa ○ MasterCard ○ Discover ○	) American Express				
paid extension fees even if the requested time is not used.		•				
paid extension fees even if the requested time is not used.	Credit Card Account Number	· 				
•	Credit Card Account Number  Credit Card Expiration Date	Credit Card Billing Zip Code				
•						

that their next renewal period will be shorter than 24 months. Within this reduced time, you will still be required to accumulate 40 CCB CEUs.

\*Date

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### Compliance Certification Board (CCB)®

# **Request for Special Exam Accommodations**



CCB and PSI comply with the Americans with Disabilities Act (ADA) and strive to ensure that no individual with a disability is deprived of the opportunity to take the exam solely by reason of that disability. Individuals with disabilities covered by the ADA may request special exam accommodations and arrangements.

Your request for accommodations should be submitted as early as possible. Requests are reviewed and considered on a case by case basis. Once your completed forms have been received, allow at least 45 days for review. Do not schedule your exam appointment until CCB confirms status of your request for accommodations. The information you provide and any documentation regarding your disability and need for accommodations will be treated with strict confidentiality. Do not provide any medical records to CCB as medical records are not required for evaluation.

To request special exam accommodations, complete and return this form with your Exam Application and the Documentation of Disability-Related Needs form to:

mail: Compliance Certification Board, 6462 City West Parkway, Eden Prairie, MN 55344 USA fax: +1 952.988.0146 | email: ccb@compliancecertification.org | phone: +1 952.933.4977 or 888.580.8373

*First Name	*L	ast Name			Middle	Name		
*Street Address								
*City/Town		*State/Provin		*Country			*7in/Dos	ital Code
City/ 10WI1		State/FIOVIII		Country				tar code
*Telephone	SC	CCE/HCCA ID num	ber	*Er	nail (confi	rmations	will be sent	to this addres
 *DENOTES REQUIRED FIELD								
SPECIAL ACCOM	MODATION	S						
*Select the certification yo			ommodati	ons for:				
□CCEP-I	☐ CCEP-F	□снс	□ CHR		CHPC	□CH	HC-F	
*Select the accommodati	on(s) you would like	e to request (che	eck all that	apply):				
Reader								ctual test time
☐ Reduced-distraction e	nvironment			Specify ar	nount in	increme	nts of 30 m	ninutes:
Other special accomm	odations (specify k	pelow)						
By signing below, I attest that all of the information supplied is sho may disclose and transfer my infowill be treated with strict confider	vn to be incorrect, I may rmation to PSI only as re	be subject to prohibi	tion from the	exam in accord	dance with	CCB policy.	Further, I unde	erstand that CCE
					*Date			

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### Compliance Certification Board (CCB)®

# **Documentation of Disability-Related Needs**



This form must be completed by a qualified, licensed professional (educator, physician, psychologist, or psychiatrist) authorized to assess, diagnose and treat the stated disability to ensure that CCB and PSI are able to provide the appropriate exam accommodations.

To request special exam accommodations, return this completed form with your Exam Application and Request for Special Exam Accommodations to:

mail: Compliance Certification Board, 6462 City West Parkway, Eden Prairie, MN 55344 USA fax: +1 952.988.0146 | email: ccb@compliancecertification.org | phone: +1 952.933.4977 or 888.580.8373

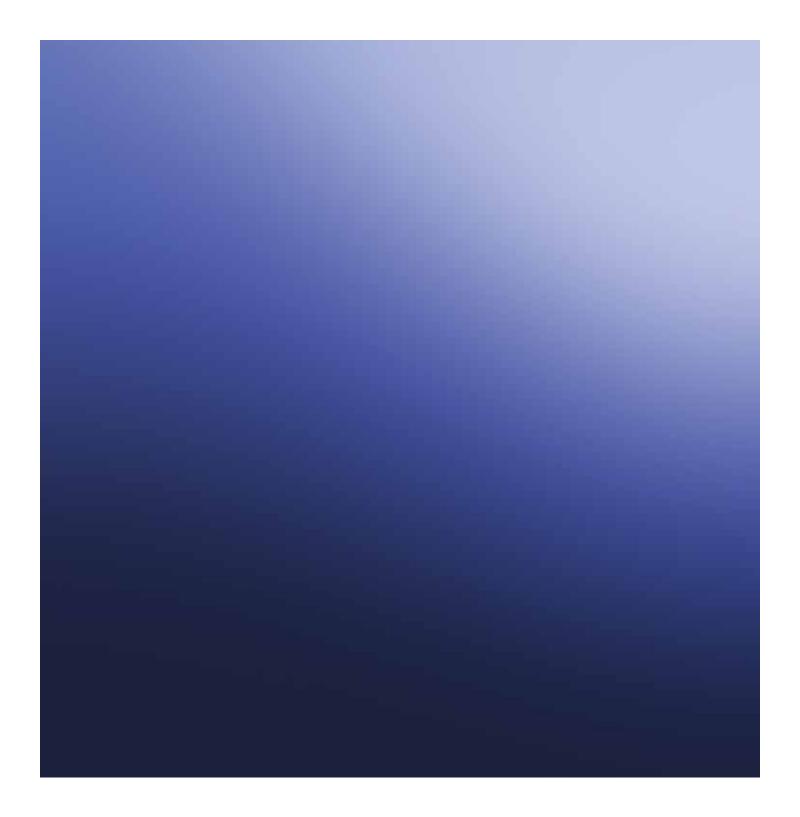
### PROFESSIONAL DOCUMENTATION

It is my professional opinion that because of the candidate's disability described below, the candidate should receive the accommodations noted on their Request for Special Exam Accommodations form, based on the nature of the exam, as discussed with the candidate.

	*Candidate N	Name		*Date of initial treatment
I have treated			since	
*Professional Title				
in my capacity as a				
*DENOTES REQUIRED FIELD				
*Is treatment for the candidate in	progress?	Month Year		
☐ No - When was treatment cor	npleted for the candidate	e?/		
Yes - How long do you anticipate continuance of treatment for the candidate (in the event the candidate may require the requested accommodations for a future exam)?				
*Provide a description of the candidate's disability. Attach a separate document if more space is needed.				
*How does the disability describe if more space is needed.	d above affect the candid	date's ability to take th	e exam? Attach a sep	parate document
PROFESSIONAL'S CONTACT INFORMATION				
*Printed Name *Title			*Occupation	
*Mailing Address				
*City/Town	*State/Pro	vince *Countr	у	*Zip/Postal Code
*License Number	*License Expiration Date	*Daytime phone numb	er *Email	
By signing below, I attest that all information included on this form is true and accurate to the best of my knowledge.				
*Professional's Signature			*Date	

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# **Notes**



### **Compliance Certification Board**

6462 City West Parkway Eden Prairie, MN 55344 USA

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