The Certified IRB Professional—How Do I Get Started?

Lori Roesch, CIM, CIP

Conference Content Copyright

All content included in this session is the property of the presenter(s), and is protected by United States and international copyright laws. Certain materials are used by permission of their respective owners. The course content may not be reproduced, transmitted, or shared in any way without the prior written permission of the presenter(s). Access to this presentation should not be construed as a license or right under any copyright, patent, trademark or other proprietary interest of PRIM&R or third parties.

Disclosure: Lori Roesch

I have relevant personal/professional/financial relationship(s) with respect to this educational activity with the following organization(s)

PRIM&R CIP Council Co-Chair

AAHRPP Site Visitor and Team Leader

Learning Objectives

1. Discuss the CIP credential and the eligibility guidelines
2. Review the types of questions on the CIP exam
3. Share study preparation strategies
4. Share recertification strategies

Revised Common Rule

The CIP exam is reviewed and updated each year to ensure it reflects current regulations and guidance. Therefore, **all questions on the 2020 exam will be consistent with the 2018 Common Rule and any final guidance that has been released as of October 15, 2019.** The 2020 CIP exam will not include questions about pending draft guidance related to the revised Common Rule.

CIP Program At-A-Glance

- Grassroots movement created in 1999 by the leadership of ARENA, PRIM&R's former membership division
- First exam was held in fall 2000
- Since then, over 3,400 people have become certified

The CIP Council

- The CIP Council members are a diverse group of volunteers who oversee the content of the exam, the eligibility guidelines, and the recertification guidelines
- Three-year terms which may be renewed once
- Council subgroups review exam and recertification applications, and review educational programs for continuing education credit
- Certification Committee puts out a call for Council members as they are needed

CIP Eligibility Guidelines

- ✓ Serving as a regulatory/technical resource during IRB meetings
- ✓ Supporting IRB meetings
- ✓ Preparing, reviewing and maintaining IRB correspondence and documentation
- ✓ Providing required ancillary services to the IRB such as conditions of approval, reconciliations, and tracking consent form changes
- ✓ Managing and/or supervising the office that provides support for the operation of the IRB
- ✓ Developing and implementing IRB policies and procedures
- ✓ Performing IRB directed reviews such as exemption determinations and expedited reviews
- ✓ Performing monitoring activities (audits) for/directed by the IRB
- ✓ Ongoing training of, and serving as a resource to staff, investigators, and IRB members on issues pertinent to the protection of human subjects
- ✓ Performing oversight activities of IRBs for or on behalf of a Common Rule agency.

- x Solely serving as an IRB member
- x Solely coordinating studies for PI
- x Interfacing with IRB on behalf of other offices
- x Managing grants and contracts
- x Solely managing COI disclosures

Exam Application

Bachelor's Degree +
24 months of experience
within past seven years

or

No education requirement +
36 months of experience
within past seven years

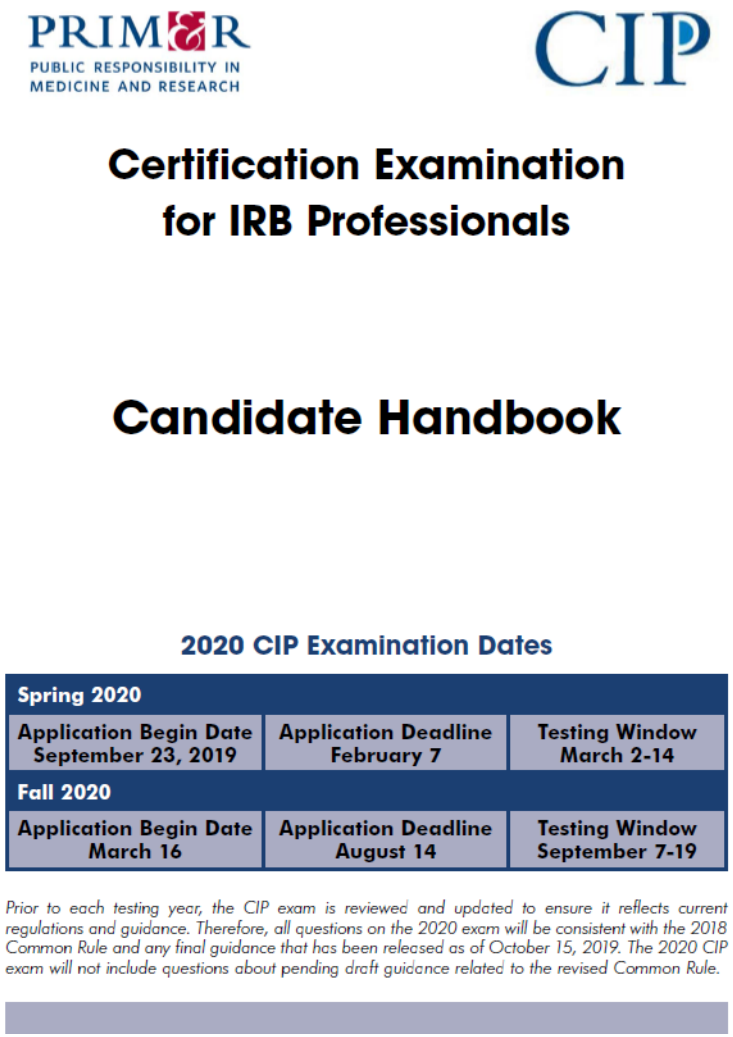
- No exceptions to the experience requirement
- CVs/resumes must demonstrate IRB administration-related functions are required

Exam Application

- **Name:** What appears on your ID
- **Address:** Where you want your results mailed
- **Email:** Where your receipt and exam scheduling instructions will be sent
- **Phone:** The number PSI will call in case of exam cancellation or postponement due to inclement weather or power outage

Exam Delivery

Computer-based exam offered in two week periods each March and September



PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

CIP

Certification Examination for IRB Professionals

Candidate Handbook

2020 CIP Examination Dates

Spring 2020		
Application Begin Date September 23, 2019	**Application Deadline** February 7	**Testing Window** March 2-14
Fall 2020		
Application Begin Date March 16	**Application Deadline** August 14	**Testing Window** September 7-19

Prior to each testing year, the CIP exam is reviewed and updated to ensure it reflects current regulations and guidance. Therefore, all questions on the 2020 exam will be consistent with the 2018 Common Rule and any final guidance that has been released as of October 15, 2019. The 2020 CIP exam will not include questions about pending draft guidance related to the revised Common Rule.

Exam Format

- Computer-based
- Closed-book
- 250 multiple choice questions
- Four hour testing period
- Ability to bookmark questions
- Ability to leave comments

Validation of Exam Questions

- All exam questions are reviewed multiple times each year for:
  - Accuracy and relevance
  - Clarity
  - How well candidates scored
  - Comparison of results from high scorers and low scorers
- Comments received from exam candidates are reviewed

Types of Exam Questions

Direct Questions

- Ethics
- Historical Background
- Regulatory Requirements
- Guidance

Application Questions

- Scenario-based
- Require application of regs and guidance

Exam Question Format

- ✓ Scenarios that require candidates to apply the regulations
- ✓ Four plausible answer options

- × No *all of the above* or *none of the above* answer options
- × No *true/false* questions

A Note on Examination Preparation

The CIP Council is **unable** to sponsor preparatory programs for the exam for conflict-of-interest reasons

Passing Score

- The cut score is set each year by the Council in partnership with PSI
  - Historically, it averages 180/250 questions
- Approximately 2/3 of test-takers pass the exam on their first try
- Exam results are carefully reviewed by PSI and the CIP Council before results are finalized

Reminders

- There are no trick questions
- All the information you need is in the question
  - Don’t make additional assumptions!
  - Some questions require analysis of facts and application of multiple relevant regulations or guidance to reach the best/correct answer

Reminders

- The examination **does not** test on specific institutional/ organizational policies and procedures developed by individual HRPPs
- You may be asked questions based on well established best practices and federal guidance
- Don’t “overthink” a question; any information needed to answer the question is provided
- Choose the correct or best answer when prompted

Body of Knowledge/Content Outline

I. Foundations and Concepts of IRB Practice	25%
II. Organizational and Personnel Knowledge	12%
III. IRB Functions and Operations	45%
IV. Records and Reports	18%

Foundations and Concepts of IRB Practice (25%)

- Historical background
- Research ethics
- Conflicts of interest
- Research design
- Regulatory application and audits, HIPAA
- Regulatory definitions

Foundations and Concepts of IRB Practice (25%)

- This is an important area of the examination and is an area where less successful candidates frequently do poorly
- Know your history and ethical codes
- Understand the basic backgrounds to the historical ethics cases and codes
  - e.g. the Nuremberg Code -- read the code and the history of its development

Organizational and Personnel Knowledge (12%)

- IRB committee organization
- IRB office organization
- Institutional considerations
- Educational programs

IRB Functions and Operations (45%)

- Levels/types of review
- Criteria for approval of research
- Emergency uses/treatment uses
- Human subject private information: data, documents, records, specimens
- Subject recruitment

IRB Functions and Operations (45%)

- Special regulatory requirements (fetuses, pregnant women, IVF, prisoners, children, emergency-setting)
- International research
- Data and specimen repositories
- Staff pre-screening and post-meeting communications/review
- Monitoring

Records and Reports (18%)

- Written policies and procedures
- Assurances and registration
- Regulatory reports (internal/external)
- Audit reports, monitoring, and other communications

Records and Reports (18%)

- Meeting minutes
- Document and file maintenance
- Archiving requirements
- Information management
- Training records

Key References

- Belmont Report
- 21 CFR 50/56
- 21 CFR 312
- 21 CFR 361
- 21 CFR 600
- 21 CFR 812
- 21 CFR 814 Subpart H
- 45 CFR 46 and Subparts A, B, C, D
- 45 CFR 160/164
- 34 CFR 98/99
- CIOMS
- ICH GCP E6
- Declaration of Helsinki
- Nuremberg Code
- FDA GCP, Information Sheets, Guidance for IRBs and Clinical Investigators
- OHRP Guidance

Recertification

- Certification is valid for 3 years
- Always have option of recertifying by exam
- Continuing Education
  - CE may be used for TWO 3-year renewals and then the examination must be taken for the next renewal
  - If there is more than a 6-month lapse you cannot renew by CE and must take the examination to recertify
- Have option to renew early (before the 3 year certification period comes up)
- CIPs continuously certified for 10 years or more without any lapses are eligible to keep recertifying by CEs

Recertification by Continuing Education

- 30 documented hours of CE - at least 15 hours carrying credits from a recognized accrediting body or from an event previously recognized as eligible for CIP CE credits (event reviewed by council in advance)
- Must be within the **Body of Knowledge** and generally beyond initial, basic, fundamental training
- CE must be obtained after the date the examination was passed
- Training that you conduct cannot be used (currently)
- Attending IRB meetings cannot be counted as CE
- There are other CE options beyond attending conferences in person

Recertification by Continuing Education

- Candidates are responsible for ensuring that credits being submitted for accredited CE hours are valid
  - This means that the CE event is eligible as accredited programs (notwithstanding the OHRP and AAHRPP exceptions just described)
  - Some CE providers no longer issue accredited CE hours for their events
- TIP: Start logging your credits early

Recertification by Continuing Education

- Be familiar with the CIP **Body of Knowledge** for eligible CE topics than can be used for recertification
  - The further the topic strays from IRB and human research protection issues, the more scrutiny and review it receives
  - Don’t submit CE events on topics for disease management, CPR training, time spent preparing for accreditation, etc.
  - Just because it meets your profession’s CE requirements does not automatically qualify it for CIP CE credits
  - Document more than 30 hours (i.e., submit more than 30 hours of CE in case some events are not eligible)
  - The Council appreciates well prepared and legible applications

Job Analysis Update

The CIP program is currently undergoing a job analysis, a systematic process in which the exam content and eligibility guidelines are aligned with the core job functions of the target audience for the exam.

The first part of this process was the job analysis survey, which was completed this summer.

We are on target to announce refreshed program specifications for 2021!

Questions?

Thank You

PRIM&R's
2019 Social, Behavioral, and Educational Research Conference
November 17 • Boston, MA

2019 Advancing Ethical Research Conference
November 17-20 • Boston, MA

The Certified IRB Professional (CIP®) Credential—How Do I Get Started?

David Matesanz, JD, CIP

Andrew Hedrick, MPA, CIP

Disclosure: David Matesanz

I have relevant personal/professional/financial relationship(s) with respect to this educational activity with the following organization(s)

PRIM&R CIP Council Member

(beginning Jan 2020)

Disclosure: Andrew Hedrick

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

Thinking about the exam

- Recognize that this is a process and can't be performed overnight…think about training to run a marathon
- Start studying well before you schedule your exam date
- Make a plan. What do you need to have accomplished:
  - In a week, 2 weeks, A month, 3 months
  - Re-evaluate your plan throughout the process
  - Test yourself and evaluate weak spots

Getting started

- Understand your learning style
  - Visual (learn through seeing): written word, reading and note-taking
  - Auditory (learn through listening): lectures, seminars, search for online lectures, tape recording notes
  - Tactile/Kinesthetic (hands on, doing): work experience

- Identify your Learning Style
  - http://www.ldpride.net/learning-style-test.html (fee)
  - http://homeworktips.about.com/od/homeworkhelp/a/lstyleqz.htm (short free quiz)

Getting started

- When are you going to study?
- Can you use work time?
  - Talk to your supervisor
  - See if its ok to form study groups
- Be sure to have realistic dedicated time.

Make a plan

- Use Certification Examination for IRB Professionals Candidate Handbook for Candidates
  - Code of Ethics (know these!!!)
  - Understand the Rules
  - Content of the Examination
    - I. Foundations and Concepts of IRB Practice.... 25%
    - II. Organizational and Personnel Knowledge..... 12%
    - III. IRB Functions and Operations..... 45%
    - IV. Records and Reports 18%
  - Content Outline
    - GREAT study outline
  - Sample Examination Questions

https://www.primr.org/certification/cip/handbook/

Form a study group

- Local colleagues
- Connect here at AER
- Make Facebook friends
- Use study groups to:
  - Quiz each other
  - Discussion
  - Different perspectives
  - Helps to identify institution policy vs. regulation/guidance requirement
  - Added benefit: connect with colleagues

Start with the basics

- OHRP
  - Regulations: 45 CFR 46 (Subparts A, B, C, D, E)
    - Common Rule: Different Agencies http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html
  - OHRP Policy & Guidance Index http://www.hhs.gov/ohrp/policy/index/index.html
  - FWA: Terms of Assurance
  - OHRP Educational Videos www.dhhs.gov/ohrp/education/training/ded_video.html
  - Decision Charts
  - Frequently Asked Questions
- OCR
  - 45 CFR 160/164 (HIPAA)

Start with the basics

- FDA Regulations (http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
  - 21 CFR 50 and 21 CFR 56 (FDA – Informed Consent and Human Subjects)
  - 21 CFR 312 (investigational drugs)
  - 21 CFR 812 (investigational devices)
  - 21 CFR 600 (biologics)
  - 21 CFR 54 (financial disclosure)
  - 21 CFR 361 (radioactive drugs for research purposes)
  - 21 CFR 814 subpart H (HUD)

Start with the basics

- FDA Other Resources
  - Running Clinical Trials www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm
  - Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm

Don’t forget!

- Ethical Principles
  - BELMONT REPORT!! (read and re-read)
  - Declaration of Helsinki
  - Nuremberg Code
- ICH: Good Clinical Practice (E6)
- Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research
- Privacy Rule and Research (NIH)

Great resources

- CIP Facebook CIP Study Group: https://www.facebook.com/home.php?sk=group_182123301822689
- IRB Forum: www.irbforum.org
- PRIM&R:
  - Amp&rsand: https://blog.primr.org/
  - CIP Exam info page: https://www.primr.org/certification/cip/exams/
- Your colleagues!
- Other IRB websites

Hands on learning

- The pre-requisites are there for a reason…take your own experiences into account.
  - Everyday while performing your job…think about the regulations being applied and why
  - Think about what you need to look up or ask someone else about…write them down and make sure you cover these topics when you study

Hands on learning

- Recognize the difference between your local practices/policies and the regulations/guidance documents
  - Example: Stamping consent forms
- Understand when your local policies/procedures impose additional requirements
  - Example: Ancillary reviews that are specific to an institution

Test yourself

- *Study Guide for Institutional Review Board: Management and Function* (Davis, Bankert, Hansen, and Kornetsky)
  - Questions at the end of every chapter
  - Discussion topics
- *Protecting Study Volunteers in Research: A Manual for Investigative Sites* (Dunn &Chadwick)
  - 52 questions in the back of the book

Test yourself

- Throughout the process to reaffirm what you are learning
- Use practice exams (there may be a cost for these)
- Use Facebook questions!

Reminders

- Stick to a schedule
- Read the regulations
- Know the differences between FDA and Common Rule
- Ask questions and talk to colleagues
- Don't underestimate the exam; you will be challenged
- Get plenty of rest the leading up to exam day

CIP Recertification

- Required every three years
- Two options
  - Retaking and passing the exam
  - Continuing education
    - Note: Can only be done twice in a nine year period.

CIP Recertification

- Continuing education (CE)
  - "CIPs must complete **30 documented hours** of CE in topics **within the CIP® Body of Knowledge/Content Outline** that are **beyond the initial, basic, or fundamental level of knowledge**. The Council encourages CIPs to complete CE activities representing a diversity of topics."

Source: https://www.primr.org/certification/cip/recertification/

CIP Recertification

- CE Documentation
  - CIPs are responsible for maintaining source documents that support their CE claims
  - Documentation must include the individuals name printed on the document in addition to:
    - Date
    - Program title
    - Sponsor name
    - Number of hours attended

CIP Recertification

- Must be accomplished prior to certificate expiration to avoid a lapse
- Once certification is maintained consecutively for ten years the individual may recertify solely via CE credit and not have to sit for the exam again.
- If lapse is greater than six months, CIP must take and pass the exam again

Questions?

Thank You

PRIM&R's
2019 Social, Behavioral, and Educational Research Conference
November 17 • Boston, MA

2019 Advancing Ethical Research Conference
November 17-20 • Boston, MA

Conference Content Copyright

All content included in this session is the property of the presenter(s), and is protected by United States and international copyright laws. Certain materials are used by permission of their respective owners. The course content may not be reproduced, transmitted, or shared in any way without the prior written permission of the presenter(s). Access to this presentation should not be construed as a license or right under any copyright, patent, trademark or other proprietary interest of PRIM&R or third parties.