

Panel Discussion 2:
Empowering Investigators for Ethical Health Research

Certification for Ethics in Research Proficiency

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CERTIFICATION
EXAMINATION
FOR
IRB
PROFESSIONALS

Handbook for Candidates

SPRING 2008 TESTING PERIOD

Application Deadline: January 15, 2008

First Day of Testing: Saturday, March 1, 2008

Last Day of Testing: Saturday, March 15, 2008

FALL 2008 TESTING PERIOD

Application Deadline: August 1, 2008

First Day of Testing: Saturday, September 13, 2008

Last Day of Testing: Saturday, September 27, 2008



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*Council for
Certification
IRB
Professionals*

US



Application for Certification Examination for IRB Professionals

Please read the directions in the Handbook for Candidates carefully before completing this Application.

MARKING INSTRUCTIONS: This form will be scanned by computer, so please make your marks heavy and dark, filling the circles completely. Please print uppercase letters and avoid contact with the edge of the box. See example provided. →

A	B	C	D	E	F	1	2	3	4	5	6
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Candidate Information

Last Name and Suffix (Jr., Sr., etc.)

First Name Middle Initial

Number and Street Apartment Number

City State/Province Zip/Postal Code

Daytime Phone - - Evening Phone - -

E-mail Address

Examination Date Spring Fall

Eligibility and Background Information

Darken only one choice for each question unless otherwise directed.

- A. PERCENT OF WORKING TIME CURRENTLY SPENT IN IRB ACTIVITIES:**
 Less than half-time Full-time
 More than half-time
- B. PRIMARY ROLE IN IRB ACTIVITIES: (Darken only one response.)**
 IRB Staff/Administrator/Manager
 IRB Chair with IRB administrative responsibility
 Organizational Official with direct IRB admin. responsibility
 Other (explain) _____
- C. EXPERIENCE IN IRB ACTIVITIES:**
 2 years 5 years More than 10 years
 3 to 4 years 6 to 10 years
- D. PRIMARY EMPLOYER: (Darken only one response.)**
 Academic Nonmedical Clinic
 Academic Medical Independent IRB
 Industrial/Corporate VA or Military Medical
 Government Health Maint./Managed Care
 Medical Center Research Institute/Foundation
 Community Hospital Other
- E. HIGHEST ACADEMIC LEVEL:**
 High School Graduate Master's Degree
 Some College Doctoral Degree
 Associate Degree Other (specify below) _____
 Bachelor's Degree
- F. NUMBER OF FULL-TIME OR EQUIVALENT PEOPLE IN YOUR OFFICE SUPPORTING IRB ACTIVITIES:**
 Less than 1.0 5.0 to 9.9
 1.0 to 2.9 More than 10
 3.0 to 4.9
- G. SCOPE OF IRB REVIEW: (Darken only one response.)**
 Biomedical only
 Behavioral/Social only
 Both Biomedical and Behavioral/Social
- H. HAVE YOU TAKEN THIS EXAMINATION BEFORE?**
 No Yes
If yes, indicate month, year and name under which the examination was taken.
 Date (month/year): _____
 Name: _____

(Complete Page 2)

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CERP vs. CIP

Organization	Initials	Full Title
FERCAP	CERP	Certification for Ethics in Research Proficiency
CCIP US	CIP	Certification of IRB Professionals

Objectives of CERP

- ❑ To protect the human subjects' safety and welfare in research through continuing education and certification in research ethics of IRB/EC members and investigators
- ❑ To validate qualifications of IRB/EC members/staff and investigators related to ethical standards in research
- ❑ To provide international recognition for professionals qualified in research ethics
- ❑ To improve knowledge and practice in research ethics

Certification

- is one part of a process called credentialing
- focuses specifically on the individual and is an indication of current knowledge in an international and a specialized area of practice
- is highly valued and provides formal recognition of knowledge of IRB functions and human research protection programs

Duties and Responsibilities (1/3)

Refer to Code of Ethics for CIP, 2007

- ❑ Conduct myself personally and professionally with honesty and integrity at all times to inspire trust and confidence in my actions
- ❑ Give prime consideration to protection of the rights and welfare of human research subjects
- ❑ Apply the principles of the Belmont Report and other ethical standards pertaining to the conduct of research involving human subjects
- ❑ Adhere to international and local laws and regulations

Duties and Responsibilities (2/3)

Refer to Code of Ethics for CIP, 2007

- ❑ Respect the rights, dignity and worth of all people and be sensitive to cultural and individual differences
- ❑ Fully disclose or avoid all potential conflicts of interest when rendering professional services, judgments and assessments
- ❑ Avoid using proprietary knowledge or private information for personal gain
- ❑ Ensure that all confidential and private information that comes into my possession is protected

Duties and Responsibilities (3/3)

Refer to Code of Ethics for CIP, 2007

- ❑ Pursue education, network with colleagues and consult with others to develop and maintain the highest possible level of knowledge and understanding
- ❑ Facilitate and encourage open communication among all parties, recognizing the shared responsibility for the ethical conduct of human subject research
- ❑ Protect the integrity and content of the Certification Examination for Ethics in Research Proficiency

CERP: Intended Outcome

Eligible candidates who pass the Certification for Ethics in Research Proficiency are eligible to use the registered designation CERP after their names and will receive certificates from the FERCAP

ELIGIBILITY REQUIREMENTS

CIP	CERP
A Bachelor's degree plus two (2) years of relevant IRB experience within the past seven years	
Four (4) years of relevant IRB experience within the past ten years	
Currently certified as a CIP	
Completion and filing of an Application for the Certification Examination for IRB Professionals.	Completion and filing of an Application for the Certification Examination for IRB Professionals.
Payment of required fee.	Payment of required fee.
Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for experience.	PI/Board member/Staff

Content of CERP Exam

Content	%	# of Qs
International guidelines	10	15
Informed consent	20	30
Ethical issues/consideration (confidentiality, vulnerable)	30	45
Research design and methodology	20	30
IRB procedures/operation	20	30
Total	100	150

Content of CIP

Content	%	# of Qs
Foundations and Concepts of IRB Practice	25	62
Organizational and Personnel Knowledge	15	38
IRB Functions and Operations	45	112
Records and Reports	15	38
Total	100	250

Contrast of Content

CERP	CIP
International guidelines	Organizational and Personnel Knowledge
informed decision making consent	Foundations and Concepts of IRB Practice
Ethical issues/consideration (confidentiality, vulnerable)	
Research design and methodology	Records and Reports
IRB procedures/operation	IRB Functions and Operations

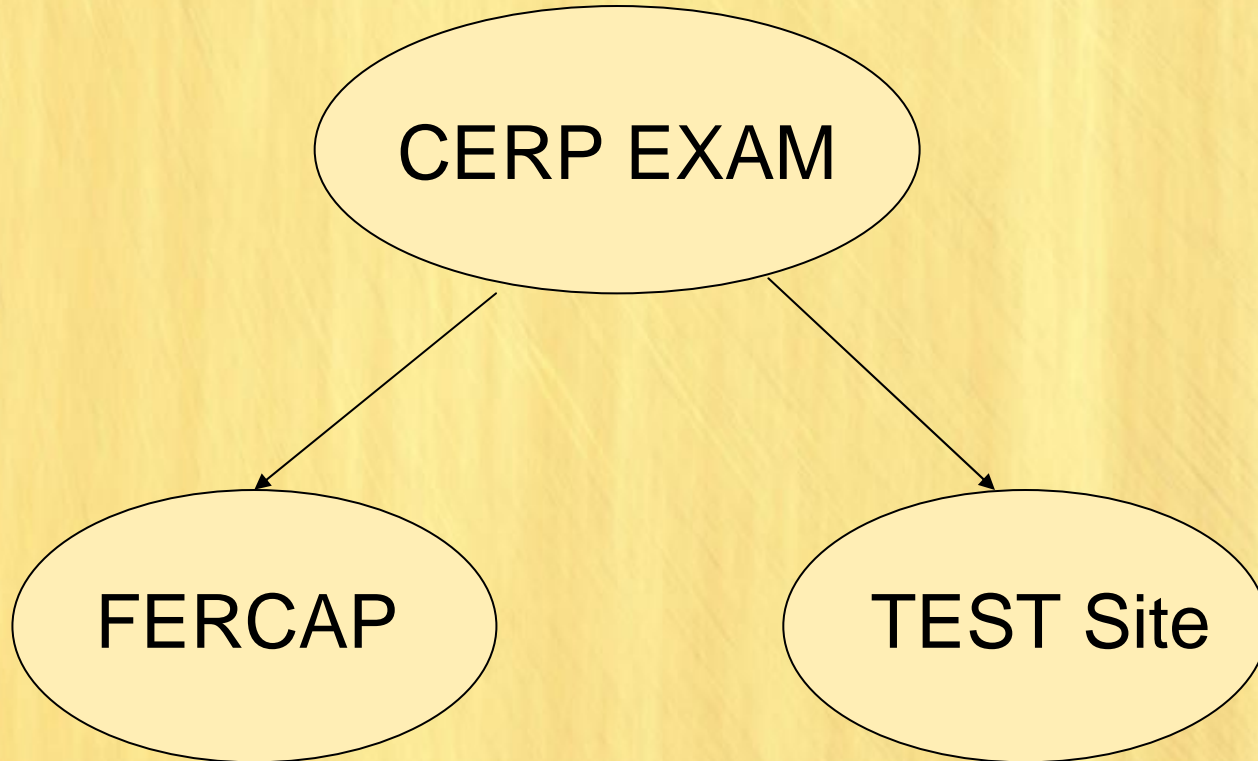
60% corrected answer to pass the exam

Content of CERP	#of correct	# of Qs
International guidelines	9	15
informed consent	18	30
Ethical issues/consideration (confidentiality, vulnerable)	27	45
Research design and methodology	18	30
IRB procedures/operation	18	30
Total	90	150

Contrast of CERP vs. CIP

	CERP	CIP
Time	120->140mins	240 minutes
# of Qs	150 questions	250 questions
Exam Fee	\$100	\$335(PRIM&R Members) \$435(Non-PRIM&R Members)
Pass Line	60% for each item	66% for each item
Language	English Or local Language	English

Division of Work Load



FECAP

- Registration to FERCAP directly by e-mail or FAX
- Examination sheets prepared by FERCAP and sent to test site
- The test result will be send to examinee from FERCAP by e-mail
- Passing list will be posted on FERCAP website
- Budget

$$\frac{100USD}{2(= FERCAP + TEST Site)} = 50USD$$

TEST Site- Coordinator

- Test site is responsible for related expense: Proctor fee, test site rental poster, etc.
- Budget

$$\frac{100USD}{2(= FERCAP + TEST Site)} = 50USD$$

References for exam(1)

- Ethical Principles and Guidelines for the Protection of Human Subjects of Research (*Belmont Report*)
- Declaration of Helsinki
- Nuremberg Code
- Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice

References for exam(2)

- Operational Guidelines for Ethics Committees That Review Biomedical Research
- Operational Guidelines for Surveying & Evaluating Ethical Review Practice
- SIDCER Self assessment tool
- Standard Operating Procedures (SOPs) templates for IEC/IRB

Thank You

Dialogue

	CCIP		CERP
I	<i>I. Foundations and Concepts of IRB Practice</i>		
	A. Historical Background		
	B. Research Ethics		
	1. Belmont Principles	I	Belmont Report
	2. International Codes/Standards		
	a. Nuremberg Code		Nuremberg Code
	b. Declaration of Helsinki		Declaration of Helsinki
	c. Council for International Organizations of Medical Sciences		Council for International Organizations of Medical Sciences
	d. International Conference on Harmonization		International Conference on Harmonization
	3. Professional Codes		
	a. CIP Code of Ethics		
	b. Professional Association Codes		
	4. Conflict of Interest	I V	Conflict of Interest

	C. Research Design Issues	III	Research Design Issues
	1. Types of Study Designs		1. Types of Study Designs
	2. Minimizing Risks		2. Minimizing Risks
	3. Study Monitoring(DMC, Plans, etc.)		3. Study Monitoring(DMC, Plans, etc.)
	4. Sample Size/Statistics		4. Sample Size/Statistics
	5. Privacy, Confidentiality, and Data Security		5. Privacy, Confidentiality, and Data Security
	6. Deception		6. Deception

	D. Regulatory Application		
	1. HHS Regulations		
	2. Common Rule		
	3. FDA Regulations(Human Subjects)		
	4. FDA Regulations(Drugs/Biologics/Devices)		
	5. State/Local Regulation	IV	Local law and legislation
	6. Regulatory Audits		
	7. Health Insurance Portability and Accountability Act(HIPAA)		

	E. Definitions	III	Definitions
	1. Research		1. Research
	2. Human Subjects		2. Human Subjects
	3. Minimal Risk		3. Minimal Risk
	4. Vulnerable Populations		4. Vulnerable Populations
	5. Engaged in Research		

	CCIP		CERP
II	<i>II. Organizational and Personnel Knowledge</i>		
	<p>A. IRB Committee Organization Authority</p> <ol style="list-style-type: none"> 1. Authority 2. Membership Requirements 3. Quorum Requirements 4. Reporting Lines 5. Leadership Issues 	<p>V</p> <p>V</p> <p>V</p>	<p>Structure and compositions of EC</p> <p>Membership Requirements</p> <p>Meeting requirements</p>
	<p>B. IRB Office Organization</p> <ol style="list-style-type: none"> 1. Staff Responsibilities and Authorities 2. Reporting Lines 3. Management(Personnel, Budget, and Billing) 	<p>IV</p> <p>IV</p> <p>V</p>	<p>Staff Qualifications</p> <p>GCP Reporting Standards</p> <p>EC management</p>

<p>C. Institutional Considerations</p> <ol style="list-style-type: none"> 1. Scientific Review 2. Grants and Contracts Review 3. Other Committee Review(RDRC, Biosafety) 4. Institutional Review 	<p>V</p>	<p>Elements of review</p>
<p>D. Education Programs Design/Implementation</p> <ol style="list-style-type: none"> 1. Education Programs for IRB Staff 2. Education Programs for IRB Members 3. Education Programs for Investigators/Research Sites 4. Education Programs for Institutional Officials 	<p>IV</p>	<p>GCP Conduct Standards</p>

	CCIP		CERP
III	<i>III. IRB Functions and Operations</i>		
	<p>A. IRB Review</p> <p>1. Levels of Review</p> <p>a. Exempt Procedures</p> <p>b. Expedited Review</p> <p>c. Convened Meeting Review</p>	V	Completeness of its review process
	<p>2. Types of review</p> <p>a. Initial Review</p> <p>b. Continuing Review</p> <p>c. Amendment Review</p> <p>d. Adverse Event/Unanticipated Problems Review</p> <p>e. Final Reports/Study Closure</p>	V	Completeness of its review process

3. Criteria for Approval of Research

a. Risk Determination and Minimization of Risks

1. Minimal/Minor Increase/Greater than Minimal
2. Significant/Non-significant Risk Devices
3. Procedure Review

b. Risk-Benefit Analysis

c. Equitable Subject Selection

1. Inclusion/Exclusion of Children, Minorities and Women
2. Inclusion/Exclusion of Other Vulnerable Populations

III Criteria for Approval of Research

a. Risk Determination and Minimization of Risks

1. Minimal/Minor Increase/Greater than Minimal
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c. Equitable Subject Selection

1. Inclusion/Exclusion of Children, Minorities and Women
2. Inclusion/Exclusion of Other Vulnerable Populations

d. Informed Consent

1. General Conditions
2. Elements
3. Waiver of Consent
4. Documentation
5. Waiver of Documentation

6. HIPAA

e. Monitoring Plans

f. Protection of Privacy and Maintenance of Confidentiality

g. Additional Safeguards for Vulnerable Subjects

d. Informed Consent

1. General Conditions
2. Elements
3. Waiver of Consent
4. Documentation
5. Waiver of Documentation

III Monitoring system

1. Monitoring team from sponsor
2. DSMB
3. IRB/IEC

IV Protecting privacy and confidentiality on health information

IV Vulnerable Subjects

	<p data-bbox="216 159 788 211">C. Post Approval Monitoring</p> <ol data-bbox="266 425 637 782" style="list-style-type: none"><li data-bbox="266 425 637 468">1. Consent Process<li data-bbox="266 582 498 625">2. Research<li data-bbox="266 739 703 782">3. Protocol Deviations	IV	GCP Conduct Standards