Five Content Areas and Percent of Scored Test Items (Range) in Each Area
This table shows the percent of scored test questions that are included in each major content area.

<table>
<thead>
<tr>
<th>Five Content Areas</th>
<th>Percent of Scored Test Items (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical Principles / Informed Consent / Safety</td>
<td>20% - 25%</td>
</tr>
<tr>
<td>Institutional Review Board / Independent Ethics Committee (IRB/IEC) Roles and Responsibilities</td>
<td>7% - 11%</td>
</tr>
<tr>
<td>Clinical Trial Protocol and Protocol Amendments</td>
<td>4% - 8%</td>
</tr>
<tr>
<td>Investigator Roles and Responsibilities</td>
<td>28% - 32%</td>
</tr>
<tr>
<td>Sponsor Roles and Responsibilities</td>
<td>31% - 35%</td>
</tr>
</tbody>
</table>

![Pie chart showing the distribution of content areas and their percent of scored test items]
# Detailed CCRP® Examination Outline

The CCRP certification examination content is arranged into five major content areas (listed below). The examination outline has been expanded to be more descriptive of the topics that are included within the major content areas of the exam. It is our hope that these descriptions will further assist you in your study process.

<table>
<thead>
<tr>
<th>Five Content Areas</th>
<th>Topic Areas</th>
</tr>
</thead>
</table>
| Ethical Principles/Informed Consent/Safety | • Nuremberg Code  
• Belmont Report  
• Declaration of Helsinki  
• Informed consent including development, content, review, approval, discussion, documentation and ongoing updates.  
• Maintenance of informed consent documents (paper/electronic)  
• Abstracting/verification of information from medical records related to informed consent and safety reporting  
• Vulnerable subjects  
• Safety Reporting (adverse events, serious adverse drug experiences, unanticipated adverse device effects)  
• Financial disclosure |
| Knowledge Of:                    | • Ethical principles described in the Nuremberg Code, Belmont Report and Declaration of Helsinki  
• Regulatory Requirements:  
  - Informed consent/assent process including development, content, review, approval, discussion, documentation and ongoing updates  
  - Submission (obtain approval) of informed consent documents to reviewing IRB/IEC- original and updates  
  - Essential elements/information to be provided to subjects  
  - Safeguards for children in clinical trials  
  - Exemption for informed consent for emergency research  
  - Permission by parents or guardians and for assent by children  
  - Protection of vulnerable subjects  
  - Obtaining consent with use of a short form written consent  
  - Informing subjects of safety concerns and any relevant changes to the study  
  - Subject safety issues – definitions, documentation, and reporting of adverse events, serious adverse events/serious adverse drug reaction, and unanticipated adverse device effects including the following:  
    - Documentation  
    - Expected or unexpected results associated with investigational products  
    - Investigator’s plan/protocol of action for management of adverse event (e.g., stop investigational product; call, retest, treat subject)  
    - Follow-up to determine resolution of adverse event  
    - Definition / classification of: adverse event, adverse drug reaction, serious adverse event, and unanticipated adverse device effects  
    - Documentation of serious adverse events/serious adverse drug reaction, and unanticipated adverse device effects and relevant information on source documents and CRFs  
    - Regulatory requirements for reporting serious adverse event/serious adverse drug reaction, and unanticipated adverse device effects to Sponsor/CRO and IRB/IEC  
    - Regulatory requirements for documenting reasons for subject discontinuation/termination  
    - Regulatory requirements for documenting follow-up medical care for study subjects  
    - Safety monitoring/reporting activities  
    - Un-blinding  
  - Requirements for documentation and reporting financial disclosure for clinical investigators including:  
    - Form FDA 3454 and 3455  
    - Definition of significant equity interest and significant payments in clinical trial  
    - Definition of covered clinical trial  
    - Record maintenance |
### Institutional Review Board/Independent Ethics Committee (IRB/IEC) Roles and Responsibilities

- Roles and Responsibilities etc. of IRB/IEC
- Determination that the rights, welfare and safety of study subjects including vulnerable populations are protected
- Development and implementation of Standard Operating Procedures (SOPs)
- Membership
- Protocol review
- Significant Risk/Non Significant Medical Device study determination
- Documentation
- Development, maintenance of IRB/IEC related documents (paper/electronic)
- Record retention IRB/IEC

### Knowledge Of:

- Regulatory Requirements Related to:
  - Responsibilities and obligations of the IRB/IEC
  - Development and review of informed consent documents, recruitment materials, safety reports, continuing review of investigational device exemptions (IDEs) (significant risk, non-significant risk, and exempt studies)
  - Standard operating procedure development and implementation for the IRB/IEC
  - IRB / IEC membership
  - IRB / IEC protocol review
  - IRB / IEC protocol amendment review
  - IRB / IEC expedited protocol review
  - Significant risk/non significant medical device study determination
  - Documentation of IRB/IEC meeting minutes, reviews and decisions
  - Communication of IRB/IEC decisions
  - Record retention for IRB/IEC

### Clinical Trial Protocol and Protocol Amendments

- Protocol development including:
  - Clinical trial phases
  - Study design characteristics (e.g., double-blind, crossover, randomized)
  - Study objectives and purpose
  - Inclusion/exclusion criteria
  - Description of procedures
  - Statistical plan
  - Development, review protocol amendments
  - Submission of protocol amendment(s) to applicable authorities, IRB/IEC
  - Investigational New Drug (IND) and Investigational Device Exemption (IDE) Amendment submission to applicable authorities and approval

### Knowledge Of:

- Development of protocols (including study design with consideration of methods to reduce bias, objectives, endpoints, data safety monitoring)
- Clinical trial phases (e.g. drug trials- phase 1, 2, 3 and medical devices- feasibility, pivotal)
- Randomization and blinding
- Development and review of protocol amendment(s)
- Regulatory requirements for submission of protocol amendment(s) to applicable authorities, IRB/IEC
### Investigator's Roles and Responsibilities

- Roles, responsibilities and obligations of the investigator
- Study conduct in accordance with investigational plan, investigator agreement and applicable regulations
- Protocol(s) and protocol related document(s) (i.e., informed consent documents, recruitment materials, safety reports, continuing reviews) development, review, and submission for reviewing authorities
- Recruitment, screening, enrollment, and retention of subjects
- Investigational site Investigational product accountability including training of subjects
- Study visits and follow up care
- Investigational site source documentation
- Documentation/Reporting discontinuation of study subjects
- Investigational site study related reports (i.e. progress reports, protocol changes, protocol deviations, final reports source documentation/case report forms
- Maintenance of essential study related documents (paper/electronic)
- Abstracting/verification of information from medical records
- Record retention requirements for clinical sites
- Quality control, quality assurance and corrective and preventive action plans (CAPA) at investigational site

### Knowledge Of:

- Roles, responsibilities and obligations of the clinical investigator
- Regulatory requirements for compliance to conduct study in accordance with investigational plan, investigator agreement, and applicable regulations
- Regulatory requirement for protocol(s) and protocol related document(s) (i.e., informed consent documents, recruitment materials, continuing reviews) development, review, and submission for reviewing authorities
- Subject Scheduling, Screening, Recruitment, and Retention including:
  - Recruitment plan/strategies (including regulatory requirements for recruitment materials)
  - Subject compliance
  - Subject visits
  - Subject retention
  - Subject discontinuation
- Regulatory requirements related to receipt and distribution of investigational product and other supplies at study site:
  - Documentation of randomization of subjects and investigational product
  - Packaging and labeling of investigational products
  - Evaluation and documentation of Investigational product compliance (e.g., according to protocol)
  - Documentation of Investigational Product Accountability
  - Subject training for study agents
- Regulatory requirements related to source documentation (paper/electronic) - completion/review of source documentation and case report forms of subject participation in a study including:
  - Subject eligibility
  - Informed consent
  - Safety- adverse events, adverse drug reaction, serious adverse effect, unanticipated adverse device effect
  - Study related visits, procedures, and assessments
  - Discontinuation/termination of study subject
- Regulatory requirements for Investigational site study reports development and submission to reviewing authorities (i.e. progress reports, safety reports, final reports protocol changes, protocol deviations)
- Regulatory requirements for essential documents
- Regulatory requirements for record retention
- Quality control, quality assurance and corrective and preventive action plans (CAPA)
<table>
<thead>
<tr>
<th>Sponsor's Roles and Responsibilities</th>
<th>Knowledge Of:</th>
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<tbody>
<tr>
<td>• Roles, responsibilities and obligations of the sponsor</td>
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</tr>
<tr>
<td>• Investigator/site qualifications</td>
<td>• Evaluating clinical site and personnel for qualification to conduct the clinical study</td>
</tr>
<tr>
<td>• Investigator Brochure</td>
<td>• Investigator meetings</td>
</tr>
<tr>
<td>• Investigational site training, management, oversight and investigator compliance</td>
<td>• Development and review of investigational product brochure</td>
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<tr>
<td>• Protocol(s) and protocol related document(s) (i.e., informed consent documents, recruitment materials, safety reports, continuing reviews) development, review, and submission for reviewing authorities</td>
<td>• Regulatory requirement for protocol(s) and protocol related document(s) (i.e., informed consent documents, recruitment materials, safety reports, continuing reviews) development, review, and submission to reviewing authorities</td>
</tr>
<tr>
<td>• Site/investigator training (GCP, investigational product, study, reporting requirements)</td>
<td>• Site/investigator training (GCP, investigational product, study, reporting requirements, compliance with protocol)</td>
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<tr>
<td>• Sponsor Investigational product accountability</td>
<td>• Regulatory requirements related to shipment and disposition of investigational products including:</td>
</tr>
<tr>
<td>• Standard Operating Procedures</td>
<td>• Investigational product (e.g., package insert, report of prior investigations, Investigator's Brochure)</td>
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<tr>
<td></td>
<td>• Documentation of randomization of investigational product</td>
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<td>• Packaging and labeling of investigational products</td>
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<td></td>
<td>• Evaluation and documentation of investigational product compliance (e.g., protocol, standard operating procedures, local governance)</td>
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<td>• Documentation of investigational product accountability</td>
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<tr>
<td></td>
<td>• Standard operating procedure (SOP) development and implementation</td>
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<td>• Regulatory requirements related to the development, submission and review of regulatory documents (i.e., FDA Forms 1572, 3454, 3455, Medwatch 3500 and 3500A, annual reports, safety reports, final reports)</td>
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<tr>
<td></td>
<td>• Data Safety Monitoring Boards (DSMB)</td>
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<td>• Regulatory requirements related to electronic record systems</td>
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<td></td>
<td>• Review of accuracy and completeness of site records including monitoring source documentation/case report forms: eligibility, product dosing and accountability, adverse events, study related visits and follow up care, and informed consent</td>
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<td></td>
<td>• Regulatory requirements related to essential documents for clinical studies (sponsor)</td>
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<td></td>
<td>• Preparation and follow-up for study site and sponsor regulatory agency inspections (including FDA forms 482 and 483)</td>
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<tr>
<td></td>
<td>• Knowledge of principles of Quality Assurance and Corrective and Preventive Action Plans (CAPA)</td>
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