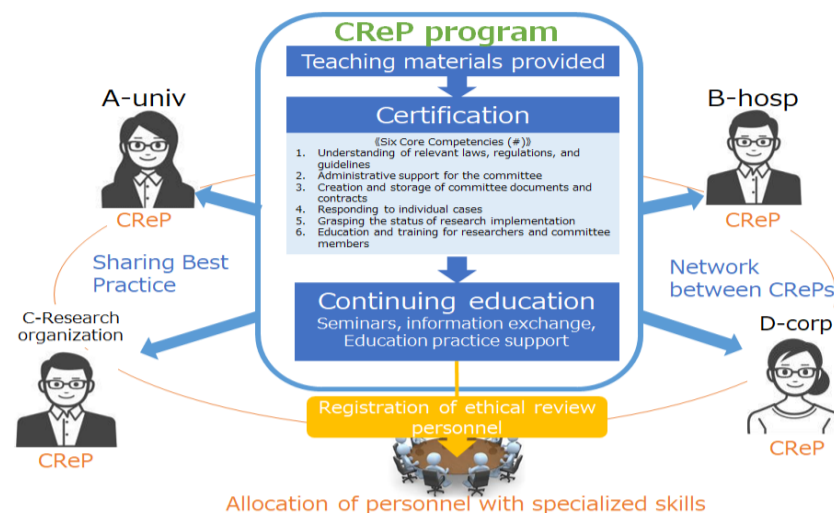


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### Background

- In Japan, three rules for clinical research
  - Clinical trial under ICH-GCP regulations
  - Clinical trial under Clinical Trial Act
  - Medical and Health-related research under ethical guidelines.
- research outside of ICH-GCP regulations is conducted in accordance with ethical guidelines
- Ethical guidelines are frequently updated
- Researchers and committee members are not familiar with the current ethical guidelines
- Both researchers and committee members need the support of research ethics experts
- Japanese funding agencies support the establishment and maintenance of Certified Research Ethics Committee Professionals (CReP)
- Ethical Review of Multi-Institutional Research by single IRB
  - Past: Variety of ethical decisions per institution
  - Present: Conflict among ethical decisions of institutions
- Need to reconcile ethical decisions among institutions

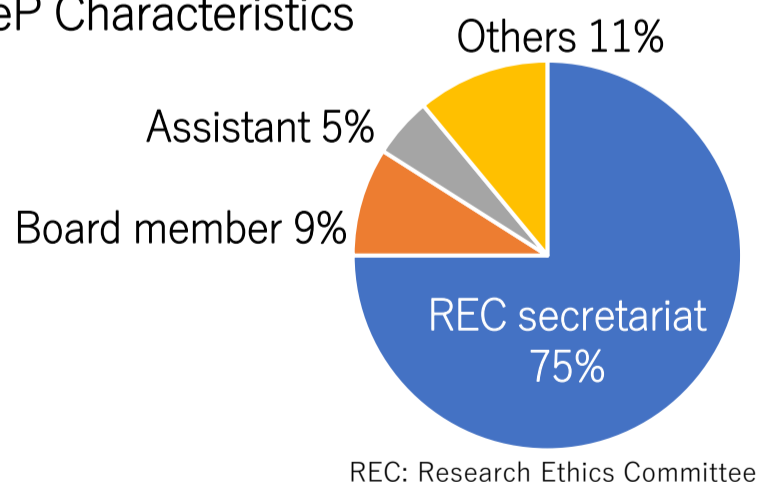
### • What is a CReP?



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- Establishment of qualification renewal requirements and provision of teaching materials and training
  - A program that emphasizes lifelong education after qualification
- Networking
  - CReP spreadsheet
  - CReP Working Group
- Best practices indicate answer percentage of multiple choices, not true/false

### CReP Characteristics



### To know the "Standard of Research Ethics"

- Research ethics should reflect the thinking in the society
- CReP expresses thoughts from a fair perspective that differs from that of the researchers and the participants
- Research ethics issues should not be biased solely towards medical or legal experts' ideas

### Conclusion

- CReP are essential in REC administration
- Sharing the Best Practice through networking using web seminar, spreadsheet, and frequent questionnaire in Japan
- Opinions on research ethics are expressed from a position that differs from that of the researchers and research subjects, and from that of medical and legal experts

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