

CITI 課程時數認證參照表

1. 生物醫學領域：

課程模組名稱	課程代碼	內含章節	認證時數
Basic Course	RBMRB01	Avoiding Group Harms: U.S. Research Perspectives	5
		Avoiding Group Harms: International Research Perspectives	
		Belmont Report and CITI Course Introduction	
		History and Ethical Principles	
		Basic Institutional Review Board (IRB) Regulations and Review Process	
		Informed Consent	
		Social and Behavioral Research for Biomedical Researchers	
		Records-Based Research	
		Genetic Research in Human Populations	
		Research With Protected Populations - Vulnerable Subjects: An Overview	
		Vulnerable Subjects - Research with Prisoners	
	RBMRB02	Vulnerable Subjects - Research Involving Children	5
		Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates	
		FDA-Regulated Research	
		I Have Agreed to be an IRB Community Member. Now What?	
		International Studies	
		Human Subjects Research at the VA	
		Research and HIPAA Privacy Protections	
		Vulnerable Subjects - Research Involving Workers/Employees	
		Hot Topics	
		Conflicts of Interest in Research Involving Human Subjects	
		The IRB Member Module - "What Every New IRB Member Needs to Know"	

2. GCP 課程

課程模組名稱	課程代碼	內含單元	認證時數
GCP Course	OBMRG01	GCP Introduction	4
		Overview of New Drug Development	
		ICH- Overview	
		ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	
		Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	
		Investigator Obligations in FDA-Regulated Clinical Research	
		Managing Investigational Agents According to GCP Requirements	
		Conducting Clinical Trials of Medical Devices	

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2.GCP 課程(續)

課程模組名稱	課程代碼	內含單元	認證時數
GCP Course	OBMRG0 2	Informed Consent	3
		Detection and Evaluation of Adverse Events	
		Reporting Serious Adverse Events	
		Monitoring of Clinical Trials by Industry Sponsors	
		Audits and Inspections in Clinical Trials	
		Completing the CITI GCP Course	

3.社會行為領域

課程模組名稱	課程代碼	內含章節	認證時數
Basic Course	RSBRB01	Belmont Report and CITI Course Introduction	5
		Students in Research – SBR	
		History and Ethical Principles – SBR	
		Defining Research with Human Subjects – SBR	
		The Regulations and The Social and Behavioral Sciences – SBR	
		Assessing Risk in Social and Behavioral Sciences – SBR	
		Informed Consent – SBR	
		Privacy and Confidentiality – SBR	
		Research with Prisoners – SBR	
		Research with Children – SBR	
		Research in Public Elementary and Secondary Schools – SBR	
	RSBRB02	International Research – SBR	4
		Internet Research - SBR Human Subjects Research at the VA	
		International Studies	
		Research and HIPAA Privacy Protections	
		Workers as Research Subjects-A Vulnerable Population	
		Hot Topics	
		Conflicts of Interest in Research Involving Human Subjects	
		The IRB Member Module - "What Every New IRB Member Needs to Know"	