

UMMG: KNOWLEDGE SHARING SESSION

17th FERCAP INDIA

Forum of Ethical Review Committees in Asia-Pacific
(Nov 19-21, 2017)

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January 30, 2018

17th FERCAP: Myanmar Delegates

- **18 Myanmar Delegates**
- **Full funding from Myanmar Research Ethics Program (UMB) USA with the help of the Program Director: Prof Henry Silverman**
- **Myanmar Research Ethics Initiative Program**

www.mm-researchethics.net

hsilverman@som.umaryland.edu

17th FERCAP: Myanmar Delegates

1.	Dr Kyaw Zin Thant	DMR Yangon
2.	Dr Win Pa Pa Naing	
3.	Dr Khin Hnin Pwint	
4.	Dr Thuzar Hla Shwe	
5.	Prof Myo Thaik Oo	UM1 Yangon
6.	Prof Ohnmar	
7.	Dr Yan Htoo Aung	
8.	Daw Mi Tin Tin Soe Aye	
9.	Dr Kalaya	
10.	Dr Min Wun*	FDA Yangon
11.	Dr Zaw Zaw Oo*	UM2 Yangon
12.	Dr Aye Aye Han	UM Mdy
13.	Prof Myat Mon Khine	UM Magway
14.	Dr Latt Latt Win	UoP Ygn
15.	Dr Khin Thet Wai	UPH
16.	Rector Khin Thet Wai	UN Mdy
17.	Rector Sun Sun Win	UDM Mdy
18.	Rector Mya Mya Aye	UMT Mdy

17th FERCAP: Myanmar Delegates



17th FERCAP: India



Myanmar Speakers in 17th FERCAP

1. Dr Min Wun, DD, FDA Yangon

(Research Ethics Fellow, UMB USA)*

Attitudes and Practices of Myanmar Health Researchers towards Research Ethics

2. Dr Zaw Zaw Oo, AP, Dept of Forensic Medicine, UM2

(Research Ethics Fellow, UMB USA)*

Structure and Functions of RECs of Medical Institutions in Myanmar

FERCAP: Official Invitation Letter



Patron:

Randeep Guleria
Director, AIIMS, New Delhi

Advisors:

Balram Airon
Dean, AIIMS, New Delhi
YK Gupta
AIIMS, New Delhi

International Advisors

Kenji Hirayama
President, FERCAP
Juntra Laothavorn,
Coordinator, SIDCER
Cristina Torres
Co-ordinator, FERCAP
Arthur Navarro
Research Fellow, FERCAP

**Organising Committee
Chairman**

Uendra Kaul
Batra Hospital and Medical
Research Centre, New Delhi

Dated: 14th November 2017

To,

Dr Zaw Zaw Oo
Ministry of Health and Sports, Myanmar

Sub: Invitation for the 17th FERCAP International Conference & 5th FERIC National Conference.

Dear Dr Zaw,

We are pleased to announce that the 17th FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific Region) and 5th FERIC (Forum for Ethical Review Committees in India) annual conference to be conducted in the month of November 2017, in collaboration with All India Institute of Medical Sciences, Batra Hospital and Medical Research Centre and Fortis Escorts Heart institute. This is the first time FERCAP is holding its conference in India.

We would like to invite you to be the Speaker for the session **"Structure and Function of RECs in Medical Institutions in Myanmar"** on 20th November 2017, timing will be 16:00-17:30 hrs.

17th FERCAP: Myanmar Delegates



17th FERCAP: India



17th FERCAP: Myanmar Delegates



17th FERCAP: Myanmar Delegates



17th FERCAP: India

Dr Zaw Zaw Oo, Prof Henry Silverman, Dr Min Wun



17th FERCAP: India



17th FERCAP: India



Next FERCAP: 2018 in Taiwan

18th FERCAP Annual Conference Announcement



We are pleased to announce that we will be hosting
The 18th FERCAP Annual Conference in TAIWAN at the
Lincou Chang Gung Memorial Hospital (CGMH), Taoyuan City, Taiwan

【Dates】

18th November, 2018: Pre-Conference

19th - 20th November, 2018: Main Conference

21th November, 2018: General Assembly & Recognition Ceremony

【Welcome to Taiwan-The Heart of Asia】

Self-Assessment of the Structure and Functions of Research Ethics Committees in Myanmar



Zaw Zaw Oo¹, Yin Thet Nu Oo², Min Wun², Myaing M. Nyunt^{3,4}, Henry J. Silverman⁴

¹ University of Medicine 2, Yangon, Ministry of Health and Sports, Myanmar

² Department of Medical Research, Myanmar Ministry of Health and Sports, Myanmar

³ Institute for Global Health, University of Maryland School of Medicine, Baltimore, USA

⁴ Department of Medicine, University of Maryland School of Medicine, Baltimore, USA

Myanmar REC Survey Study

- **Objectives**

1. To assess the organizational structure and functions of RECs in Medical Teaching Institutions in Myanmar
2. To provide the basic information regarding the RECs of Medical Institutions in Myanmar

- **Methodology**

Study Design Cross-sectional survey using the MERETI self-administered SAT tool

Study Area **16 Medical and Allied Institutions in Myanmar**

Study Population REC Chairpersons, Members and Secretaries

Myanmar RECs Survey with MERETI SAT

Questions: 10 Domains focusing on:

- 1. Organization Support**
- 2. Membership and Educational Training**
- 3. Submission Policy**
- 4. Meeting Minutes**
- 5. Protocol Review Policy**
- 6. Informed Consent Review**
- 7. Approval Letter**
- 8. Continuing Review Report**
- 9. Resources**
- 10. Workload**

**With all 134 Questions
Maximum Points = 200**

Myanmar RECs Survey with MERETI SAT

Method

- Visited 16 RECs in different regions of Myanmar
- Distributed self-administered questionnaire
- Informed consent obtained and confidentiality assured
- Responses collected anonymously
- Response Rate: 100 % (16/16)
- Descriptive statistics

Ethics Approval: Approved by

1. Myanmar: DMR REC
2. USA: UMB REC

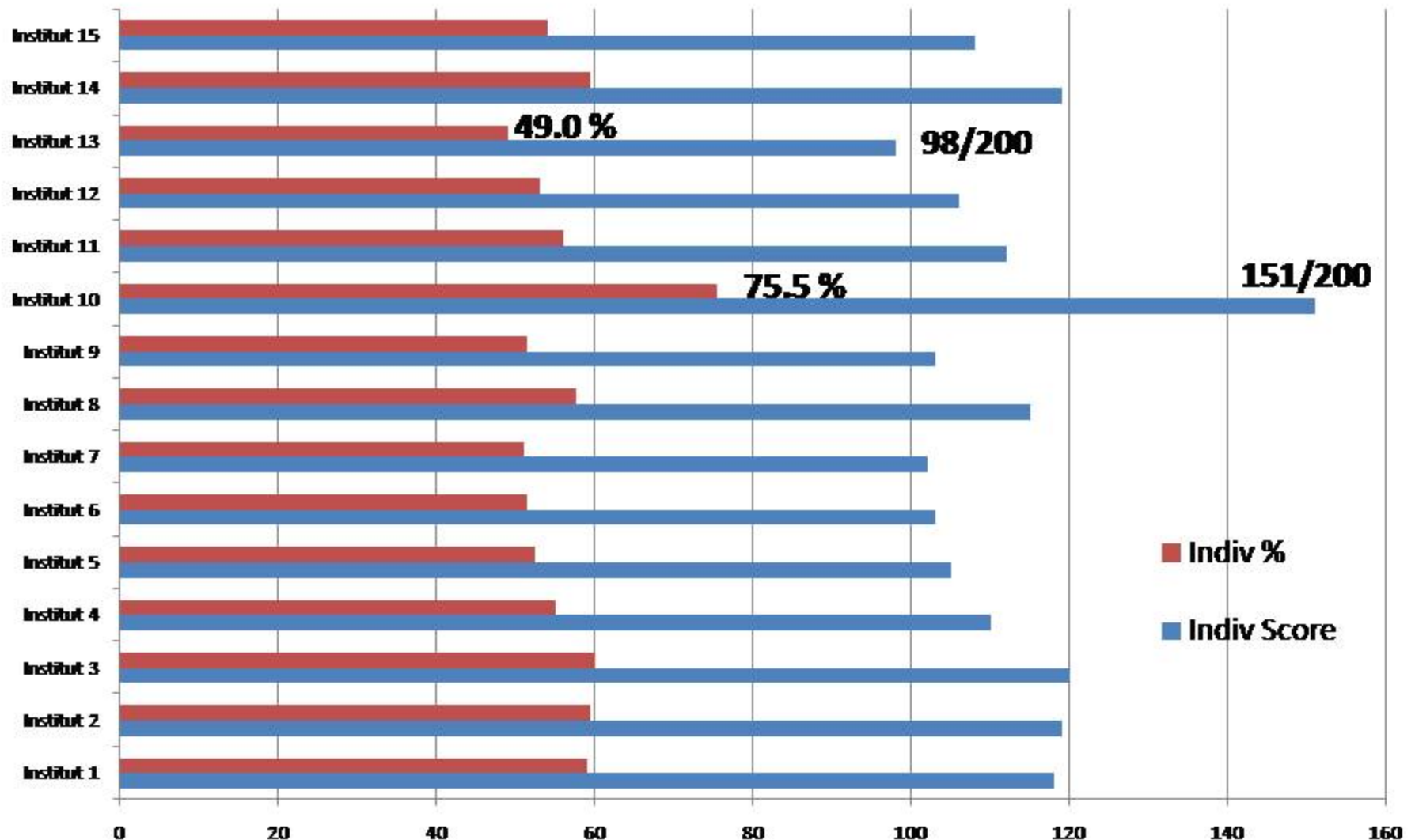
Results - Demographics (n=16)

Item	Response
Year Established	(1998 – 2005) = 6 (2006 – present) = 10
Frequency of Reviews	Less than 6/year = 8 Greater than 6/year = 6 Once a month = 1 No review yet = 1
Time to review a protocol	Average = 50 – 60 minutes
Types of Policy	SOPS = 2 COI = 1 Subjects file a complaint = 3
Type of Chair	Rector (Dean) = 11 Head of Dept = 1 Emeritus Prof = 2 Retired Prof = 2

Results - Demographics (n=16)

Item	Response
Membership	Range of Members (7-19) Average No. = 13.6
Gender Balance	W/M > 1.0 = 12 W/M ≤ 1.0 = 4
Membership Type	with Non-affiliated = 12 with Non-Scientist = 11 with Community = 2
Prior Ethics Training	Chairs = 16/16
Policy Requiring Ethics Training	REC members = 3 Investigators = 5 (course)
Resources	Number with budget = 0 Number with Admin = 16

Individual Total Scores (n=15)



Total Scores (n=15)

Country	Average Score	Average Percentage	Average Median
Myanmar	112.6 ± 12.77	56.3 ± 6.38 % (49.0 – 75.5%)	110
South Africa*	128.7 ± 38.7		
Egypt	133.7 ± 37.8		
India	157.5 ± 16.1		
Average	137.4 ± 35.8		145

* Silverman HJ et.al. Results of a self-assessment tool to assess the operational characteristics of research ethics committees in low- and middle-income countries. [J Med Ethics](#). 2015 Apr;41(4):332-7

Individual Domain Scores (n=15)

Domain Name	Mean Score/Maximum	Mean %
1. Organization Aspect	24.8/52	47.69 %
2. Membership and Training	17.9/32	56.03 %
3. Submission Policy	9.1/12	76.08 %
4. Meeting Minutes	8.5/13	65.13 %
5. Review Policy	5.3/11	47.88 %
6. Review Items *	36.3/43	84.49 %
7. Approval Letter	0.7/5	13.34 %
8. Continuing Review Report *	0/16	00.00 %
9. Resources	10/16	62.50 %

- **Limitation of the survey**

- Self Report**

- **Feedback of the survey participants**

- More than 95 % agreed that the survey questions adequately reflect the structure and functions of REC.
 - Most (14/16) completed the survey in less than 2 hours.
 - Requested 'Research Ethics Training program'.

Conclusion of the Myanmar REC Survey

- Many have sufficient members other than physicians and scientists with excellent gender balance.
- All Chairs have prior ethics training.
- More than 80% of important items are reviewed.
- Many lack important policies (e.g., SOPs, COI, educational requirement)
- Organizational support needs to be enhanced
 - Funding for education

Today Discussion Topics

- 1. Ethics Review Committees in Myanmar**
- 2. Structure and Functions of ERCs in Myanmar**
- 3. International Accreditation of ERCs**
- 4. Networking of ERCs**
- 5. Way Forward for Myanmar ERCs**

1. ERCs in Myanmar



The first ERC in Myanmar,
at DMR in 1980.

The first ERC in Medical University in Myanmar,
at UM1 Yangon in 1998.

At the present, there are 18 ERCs in Myanmar.

Only two ERCs: in DMR & DSMRC are with FWA !!

2. Structure & Functions of ERCs

Structure

1. Chair
2. Vice-chair
3. Members (specialists, consultants, guests)
4. Secretary (usually not more > 15 persons)
5. Staff

CIOMS Guidelines: 2016

GUIDELINE 23:

Requirements for Establishing RECs and for Review of Protocols

All research proposals involving humans must be submitted to a REC to assess their ethical acceptability, unless they qualify for an exemption from ethical review.

The researcher must obtain approval or clearance by such a committee before beginning the research.

The research ethics committee should conduct further reviews as necessary.

CIOMS Guidelines: 2016

GUIDELINE 23: Formation of REC

RECs must be:

- 1. formally established with adequate mandate and support**
- 2. multidisciplinary membership**
- 3. Members - duly qualified and regularly update their knowledge of ethical aspects of research**
- 4. independent**
- 5. should have a clear procedure for researchers or sponsors to make legitimate appeals against the decisions of REC**

**to ensure timely and competent review
according to clear and transparent procedures (REC SOP)**

2. Structure & Functions of ERCs

Functions

1. Ethics Review of PhD/Doctorate Research Protocols
2. Ethics Approval of Research Studies
3. Research Monitoring ??

Main Purposes of ERC

1. To promote the Science
2. To protect the Human Subjects



3. International Accreditation of ERCs

- **SIDCER (WHO)**

Strategic Initiative for Developing Capacity in Ethical Review

- **AAHRPP (USA)**

Association for the Accreditation of Human Research
Protection Programs

- **FERCAP (Thailand)**

Forum of Ethical Review Committees in Asia-Pacific

3. International Accreditation of ERCs

- SIDCER (WHO/Geneva)**

Strategic Initiative for Developing Capacity in Ethical Review
Network of Regional Fora



The image shows a screenshot of the SIDCER website. The top banner features the SIDCER logo on the left, a stethoscope in the center, and a white dove on the right with the URL www.sidcer.org. Below the banner is a navigation menu with links: What's New ?, About SIDCER, Regional Fora, Partner Organizations, Events, Documents, and Photo Gallery. The main content area has a colorful background with a heartbeat line and the word 'Welcome' in a script font. A quote at the bottom describes SIDCER as a network of regional fora for ethical review committees, health researchers, and partner organizations.

SIDCER

www.sidcer.org

- What's New ?
- About SIDCER
- Regional Fora
- Partner Organizations
- Events
- Documents
- Photo Gallery

Welcome

"The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) is a network of independently established regional fora for ethical review committees, health researchers and invited partner organizations with an interest in the development of ethical review. The

3. International Accreditation of ERCs

- **AAHRPP (USA, LA)**

Association for the Accreditation of Human Research Protection Programs



The screenshot shows the AAHRPP website homepage. The header features the AAHRPP logo on the left, a row of international flags in the center, and navigation links for 'Forms', 'Newsletter', 'Contact Us', and a 'LOGIN' button on the right. Below the header is a dark blue navigation bar with links for 'Learn >', 'Apply >', 'Connect >', and 'Grow >', along with a 'Site Search' box. The main content area has a light blue background. On the left, the heading 'The Value of Accreditation' is followed by a paragraph explaining the significance of AAHRPP accreditation and a 'Get Started >' button. On the right, a 'Tip Sheets' section highlights 'Tip Sheet 26 Reviewing Research Involving Adult Participants with Diminished Functional Abilities' with a download icon and a 'View more >' link.

3. International Accreditation of ERCs

- **FERCAP (AP Regional Forum/Thailand)**



The screenshot displays the FERCAP website. The header features the FERCAP logo on the left, a decorative orange and green wave graphic in the center, and the text "Forum for Ethical Review Committees in the Asian & Western Pacific Region" on the right, with the website URL "www.fercap-sidcer.org" below it. A left-hand navigation menu lists links: Home Page, About FERCAP, Membership, SIDCER Recognition, Photo Gallery, Archives, Links, and Contact FERCAP. The main content area, titled "WHAT'S NEW?", is divided into two sections: "Announcements!" and "SURVEYS AND TRAININGS".

Announcements!

ANNUAL INTERNATIONAL CONFERENCE

- [FERCAP Annual International Conference 2018 - Announcement](#)

SURVEYS AND TRAININGS

- [FERCAP Surveys 2017](#)

4. Networking of ERCs



International Networks

Regional Networks

Local Networks

5. Way Forward for Myanmar ERCs

1. Networking of ERCs
2. National Ethics Committee
3. Capacity Strengthening**
4. SOPs & Guidelines for ERCs
5. Accreditation of ERCs

Research Ethics Certificates

1. UMB USA: Research Ethics Intensive Training Course **three weeks course in Aug, 2015**



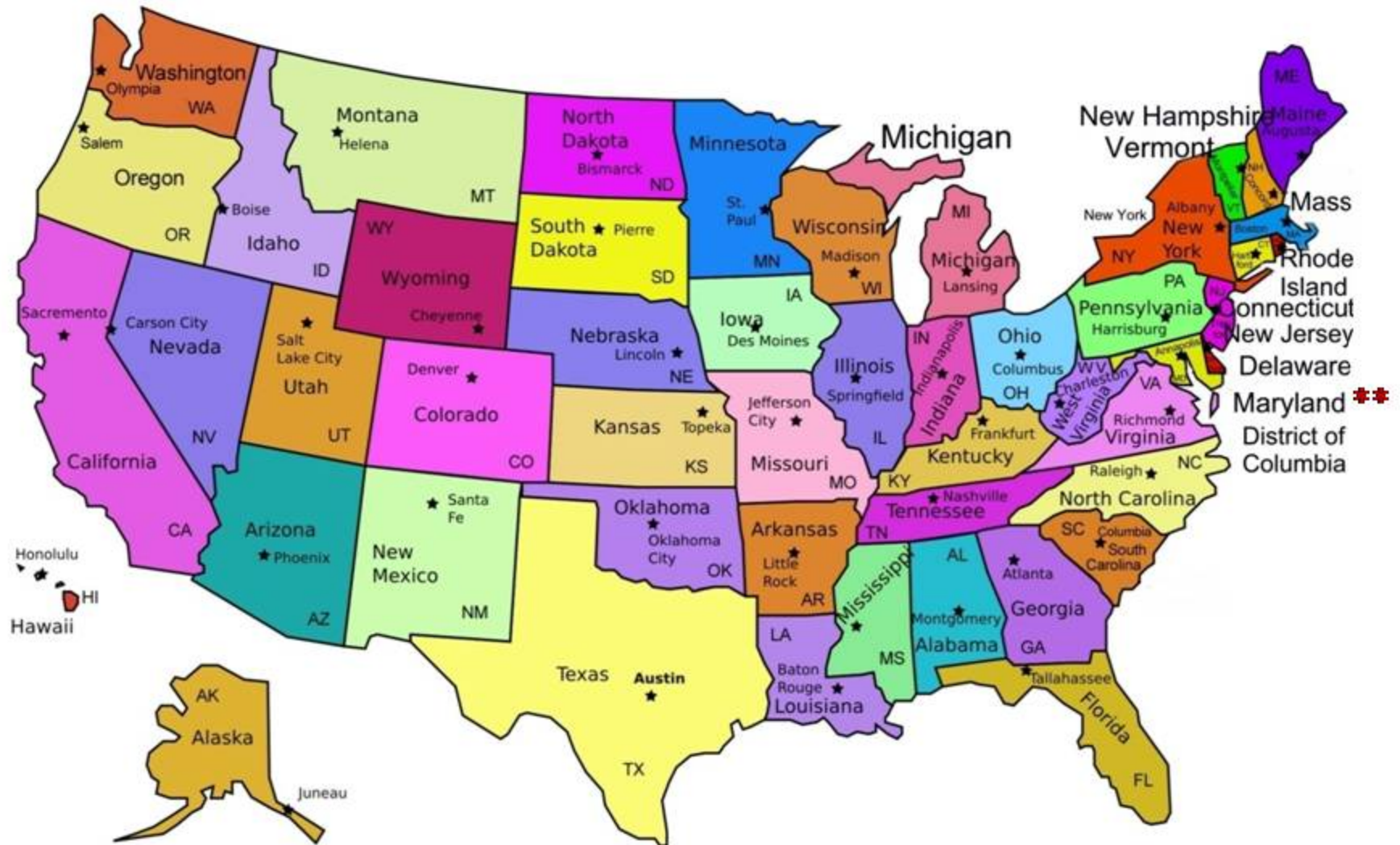
Research Ethics Certificates

2. NIH USA: Protecting Human Research Participants

Online course - phrp.nihtraining.com / gcp.nidatrain.org



2015 UMB USA: Research Ethics Course



2015 UMB USA: Research Ethics Course



2015 UMB USA: Research Ethics Course





2015 UMB USA: Research Ethics Course



with Ms Julie Doherty
Director, Quality Management, UMB
Office for Human Research Protections



With the Director of OHRP, Mr Edward Bartlett





Thank you !!