

出國報告（出國類別：短期進修）

美國人體試驗委員會機構訓練

服務機關：國防醫學院三軍總醫院

姓名職稱：張芳維 主治醫師

派赴國家：美國

報告日期：98年7月17日

出國時間：98年01月04日至07月03日

(美國西方人體試驗委員會機構訓練)

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壹、會議摘要

初期學習人體試驗醫療倫理相關規範，分析國內外人體試驗醫療倫理，進而討論出對於婦女人體試驗醫療倫理模式及婦產科相關人體研究之規定。藉由訓練活動學習人體試驗醫療倫理相關活動，分析國內外人體試驗醫療倫理訓練課程，研究婦產科人體試驗醫療倫理訓練課程。在人體試驗委員會會議中，研討相關婦產科人體試驗醫療倫理議題，藉以改善未來婦產科相關研究與實驗方式。以實際參與醫學人體試驗倫理審核評估，來進一步分享婦產科醫學人體試驗倫理審核評估。此學術集會著重人體試驗研究計畫審核指標。目前國際性人體試驗研究計畫審核以保護受試者的安全與福祉為主題，分析美國與世界的貢獻。人體試驗研究計畫審核之國際交流包括有台灣、韓國及秘魯。研究與學術的交流。透過這會議，讓醫師活躍於國際人體試驗研究計畫審核交流且擁有廣大視野。美國人體試驗委員會揭示嶄新的研究計畫審核之研究與新知，一項令人期待而有前瞻性的人體試驗研究計畫審核。

貳、參加目的

婦產科醫師做爲照護婦女健康福祉重要的守護者，爲了積極提昇醫學研究水準，並落實充分保障受試者之權益，依據「醫療法」及其施行細則、「醫療機構人體試驗委員會組織及作業基準」、衛生署頒布之藥品優良臨床試驗準則、新醫療技術（含新醫療技術合併新醫療器材）臨床試驗計畫作業規範、研究用人體檢體採集與使用注意事項等各項人體試驗相關基準及其他各項法規，與歐美先進國家相關倫理規範，制定婦產科人體試驗委員會之標準作業流程（Standard Operation Procedure，SOP）。

本著落實標準作業流程，以行善、不傷害、公正、尊重自主等醫學倫理四規則；秉持誠實、守密、知情同意、尊重隱私權，以保護「受試者」。遵循國內衛生主管機關對人體試驗之相關規定與法規環境進展，定期檢討改進，創造符合法規的良好研究環境，使婦產科能發揮出最好的研究成果，藉由研究結果造福更多的病患。

提昇三軍總醫院婦產科人體試驗學與醫學教學、研究的創新與視野。與國際接軌，促進交流及學術競爭力。我們可以徹底了解到各個國家文化不同，產科處置上就出現極大的差異，而這也是相當有趣的事情。

了解美國人體試驗委員會的內容，不論是外賓演講，或是研究審查會議，都相當的國際化而多采多姿，在多元文化及多方資訊的匯集之下，也許因此而孕育出更多元的新知識。此行會我增長不少見識，日後也有許多值得我們借鏡之處。深入當地人體試驗委員會情形，比較台灣常看見的人體試驗委員會，發現其他人體試驗審查優點。

參、進修過程

一月份

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
<p>4</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m. except Monday</p> <p>Depart Heritage: 4:30 p.m.</p>	<p>5</p> <p>9:00 – 2:00</p> <p>ORIENTATION DAY</p> <p>2:00 – 4:00</p> <p>Program Overview – Brad Waite</p>	<p>6</p> <p>9:00 – 11:00</p> <p>Regulatory Training –</p> <p>Historical Cases and reading assignments – David Forster</p> <p>2:00 – 4:00</p> <p>Board Member Training – Brad Waite</p>	<p>7</p> <p>9:30 – 11:00</p> <p>Regulatory Training –</p> <p>Nuremberg Code – Bert Wilkins</p> <p>2:00 – 3:00</p> <p>Pre-Board Observation</p> <p>Discussion (Review of Agenda) – Brad Waite</p>	<p>8</p> <p>8:30 – 1:00</p> <p>Panel 4 Observation via Video Conference – Michelle Maxin-Wells</p> <p>2:00 – 3:00</p> <p>Discussion about Board Observation – Brad Waite</p>	<p>9</p> <p>9:00 – 11:00</p> <p>Board Member Training – Brad Waite</p>
<p>11</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m.</p> <p>Depart Heritage: 4:30 p.m.</p>	<p>12</p> <p>9:00 – 11:00</p> <p>Regulatory Training – Belmont Report, Principle Approach to Research Ethics – Doreen Packel</p> <p>1:00 – 2:00</p> <p>E-packet training – Brad Waite</p>	<p>13</p> <p>8:30 – 1:00 C, R, S, P</p> <p>Panel 2 Observation</p> <p>8:30 – 1:00 K</p> <p>Panel 5 Observation</p> <p>2:00 – 4:00</p> <p>Board Member Training – Brad Waite</p>	<p>14</p> <p>9:00 – 10:00</p> <p>US Regulatory Training – Overview of U.S. Regulatory System - Common Rule, NIH, FDA – Doreen Packel</p> <p>2:00 – 3:00 Program Update – Brad Waite</p> <p>3:00 – 3:30 TEA with Board Physicians (Heritage Dining Room)</p>	<p>15</p> <p>9:00 – 11:00</p> <p>Regulatory Training – U.S. NIH Regulations (45 CFR 46, Sub A) – Adam Dubov</p> <p>2:00 – 4:00</p> <p>Board Member Training – Brad Waite</p>	<p>16</p> <p>9:00 – 11:00 Regulatory Training – U.S. NIH Regulations (45 CFR 46, Sub B, C, D) – Claire Brown</p> <p>2:00 – 4:00</p> <p>Regulatory Training – Declaration of Helsinki/Comparison of Versions – Mitchell Parrish</p>
<p>18</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m. except Friday</p> <p>Depart Heritage: 4:30 p.m. except Friday</p>	<p>19</p> <p>9:00 – 11:00</p> <p>Accreditation – Cindy Gates</p> <p>2:00 – 4:00</p> <p>Board Member Training – Brad Waite</p>	<p>20</p> <p>9:00 – 11:00</p> <p>Conflicts of Interest – Claire Brown</p> <p>2:00 - 4:00</p> <p>Presentations by individual Fellows regarding research in their home countries</p>	<p>21</p> <p>9:00 – 12:00</p> <p>Regulatory Training –</p> <p>U.S. FDA Regulations (21 CFR 50, 56, 312, 812) – Jim Baldwin</p> <p>2:00 – 3:00</p> <p>Program Update – Brad Waite</p>	<p>22</p> <p>9:00 – 11:00</p> <p>Regulatory Training –</p> <p>Review U.S. FDA Guidance - Paul Newton</p> <p>2:00 – 4:00</p> <p>Board Member Training – Brad Waite</p>	<p>23</p> <p>10:45 – 5:00</p> <p>Guest Lecturer: Dr. Albert Jonsen</p> <p>(3535 Conference Room, Main Campus)</p>
<p>25</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m. except for Tuesday</p>	<p>26</p> <p>9:00 – 11:00</p> <p>Regulatory Training – Review of OHRP</p>	<p>27</p> <p>9:00 – 10:00</p> <p>Observation of Opening Meeting for External</p>	<p>28</p> <p>9:00 – 11:00</p> <p>Regulatory Training – International Conference</p>	<p>29</p> <p>9:00 – 11:00</p> <p>Regulatory Training – Health Insurance</p>	<p>30</p> <p>8:30 – 1:00 C, R, P, K</p> <p>Panel 6 Observation</p>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Depart Heritage: 4:30 p.m. except for Wednesday	Guidance – Paul Newton 2:00 – 4:00 Board Member Training – Brad Waite	Audit of WIRB – 3535 Conference Room – main campus 2:00 – 3:00 Clinical Equipoise – Steven Byers 3:00 – 4:00 Informed Consent/ Therapeutic Misconception – Steven Byers	on Harmonisation (ICH) – Steven Byers 2:00 – 3:00 Program Update – Brad Waite 3:00 – 4:00 ??? Observation of Exit Meeting for External Audit of WIRB	Portability and Accountability Act (HIPAA) – Bert Wilkins 2:00 – 4:00 Board Member Training – Brad Waite	8:30 – 1:00 S Panel 8 Observation

二月份

-Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
1 VAN SCHEDULE Depart apartment: 7:45 a.m. Depart Heritage: 4:30 p.m. (Training in Heritage Room C unless noted otherwise)	2 9:00 – 11:00 Government Oversight/ Inspections – Adam Dubov 2:00 – 4:00 Board Training – Brad Waite	3 9:00 – 11:00 Data Safety Monitoring – Jim Baldwin 11:00 – 12:00 Practical Training – Pre-Board Workups and Subspecialty Review – Owen Reese 12:30 – 1:30 Lunch with Dr. Stephen Rosenfeld at the main campus Annex 2:00 – 4:00 Regulatory Training – Recent Events – David Forster	4 8:30 – 1:00 C, S, P Panel 3 – Observation 8:30 – 1:00 R, K Panel 11 - Observation 3:00 – 4:00 Program update – Brad Waite	5	6 9:00 – 10:30 Regulatory Training – CIOMS/WHO Guidelines – Mitchell Parrish 1:00 – 2:00 PSV Exam – Brad Waite (Heritage Room C)

-Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
<p>8</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m.</p> <p>Depart Heritage: 4:30 p.m.</p>	<p>9</p> <p>10:00 – 11:00</p> <p>Regulatory Training – WHO/OPS</p> <p>Guidelines for ECs – Mitchell Parrish</p> <p>2:00 – 3:00</p> <p>Guest Lecturer Dr. Marjorie Speers, Executive Director of AAHRPP to talk about accreditation</p>	<p>10</p> <p>10:00 – 12:00</p> <p>Dr. Burke speak on Genetic Research at the University of Washington – David Forster and Brad Waite (confirmed)</p>	<p>11</p> <p>2:00 – 3:00</p> <p>Regulatory Training – Developing Countries – Claire Brown</p>	<p>12</p> <p>2:00 – 4:00</p> <p>Board Member Training - Brad Waite</p>	<p>13</p> <p>9:00 – 12:00</p> <p>MOCK meeting #1 – Jim Baldwin/Kay King</p>
<p>15</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m. except for Monday</p> <p>Depart Heritage: 4:30 p.m. except for Monday and Friday</p>	<p>16</p> <p>Holiday</p> <p>WIRB Closed</p>	<p>17</p> <p>9:00 – 10:00</p> <p>First Regulatory Exam (small conference room at Heritage next to IBC) – David Forster</p> <p>11:00 – 12:00</p> <p>Regulatory Training - Comparison of Different Countries – Denelle Reilly</p> <p>3:00 – 4:00</p> <p>Program Update – Brad Waite</p>	<p>18</p> <p>9:00 – 11:30</p> <p>MOCK Meeting</p> <p>12:30 – 1:30</p> <p>Practical Training – Selection of Board Members – Dr. Stephen Rosenfeld (Executive Conference Room – Main Campus)</p> <p>2:00 – 3:30</p> <p>Practical Training – Public Policy Development/Effect on IRB</p> <p>Visit to Secretary of State Sam Reed’s Office – State Capitol Building – Ted Schultz</p>	<p>19</p> <p>8:30 – 1:00 K, R, C</p> <p>Panel 4 Observation</p> <p>8:30 – 1:00 P, S</p> <p>Panel 12 Observation</p> <p>1:00 – 3:00</p> <p>Individual oral Exam with David Forster and Brad Waite (small conference room next to IBC)</p>	<p>20</p> <p>10:00 – 12:00</p> <p>Individual Interview for Board Appointment – Dr. Stephen Rosenfeld (main campus)</p> <p>1:30 – 3:30</p> <p>Practical Training Lesson #1, 2, 4 Operational Overview, Paperwork Flow, Post-Board Work – Cindy Gates (3535 Conference Room - main campus)</p> <p>3:30 – 4:30</p> <p>SIIDR (Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research) Update with David Forster (Heritage Room A or B)</p>
<p>22</p> <p>VAN SCHEDULE</p> <p>Depart apartment: 7:45 a.m.</p>	<p>23</p> <p>8:30 – 1:00 R, S, P</p> <p>Panel 1 Observation</p>	<p>24</p> <p>2:30 – 4:00</p>	<p>25</p> <p>9:00 – 12:00</p> <p>MOCK Meeting #2 – Ron Gadde/Denelle Reilly</p>	<p>26</p> <p>2:00 – 7:00</p>	<p>27</p> <p>8:30 – 1:00 R, S</p> <p>Panel 8 Observation</p>

-Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Depart Heritage: 4:30 p.m.	8:30 – 1:00 C, K Panel 7 Observation 2:00 – 3:00 Practical Training – Manual Record Keeping – Connie Murphy – small room next to IBC	Practical Training – Expedited – Cathy Coates	3:00 – 4:00 Program Update – Brad Waite	International Bioethics, Social Justice & Health Seminar at the University of Washington – Connie Vasek	8:30 – 1:00 C, P, K Panel 6 Observation

三月份

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
1 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m.	2 8:30 – 1:00 C Panel 1 - Presentation (Gustavo Kaltwasser) 8:30 – 1:00 S Panel 7 - Observation 2:00 – 3:00 Practical Training – Adverse Events (Brad Waite) – Heritage C	3 8:30 – 1:00 R Panel 2 – Presentation (Rosemay Vazeux) 8:30 – 1:00 P Panel 5 – Presentation (Brad Waite) 3:00 – 4:00 NIH Video cast (1) Session 1 (Ezekiel Emanuel and Susan E. Lederer)	4 8:30 – 1:00 S Panel 3 – Presentation (Hala Aghanigian) 8:30 – 1:00 K Panel 11 – Observation 3:00 – 4:00 Program Update – Brad Waite – Heritage C	5 8:30 – 1:00 P Panel 4 - Observation 8:30 – 1:00 C Panel 12 Observation 3:00 – 4:00 Practical Training – Institutional Issues (Elaine Azarenko-Weakley) – Heritage C	6 Dr. Cabrera Out of Office 8:30 – 1:00 K Panel 6 – Presentation (Lucille Broberg) 2:00 – 3:00 IBCS (Institutional Biosafety Committee Services) Overview Training with Dr. Jan Vleck – Heritage C
8 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m. except for Friday	9 Dr. Cabrera Out of Office 8:30 – 1:00 P Panel 1 Observation 8:30 – 1:00 C Panel 7 - Observation	10 Dr. Cabrera Out of Office 8:30 – 1:00 K Panel 2 – Presentation (Hala Aghanigian) 8:30 – 1:00 S Panel 5 – Presentation (Thomas Kaufman) 2:00 – 3:00 Practical Training –	11 Dr. Cabrera Out of Office 8:30 – 1:00 P Panel 11 – Presentation (Gustavo Kaltwasser) 1:00 – 1:30 K, C Orientation to Board Meeting Scheduling with Helen Barr	12 Dr. Cabrera Out of Office 8:30 – 1:00 K Panel 4 Observation 1:00 – 1:30 S, P Orientation to Board Meeting Scheduling with Helen Barr	13 Dr. Cabrera Out of Office 8:30 – 1:00 C Panel 6 - Presentation 8:30 – 1:00 S Panel 8 - Observation 2:00 – 3:30 visit The

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
	1:50 – 3:30 C, S, P, K Observation of IBC Meeting – small room next to IBC at Heritage	Review of Recruitment/ Advertising – Dick Swier 3:00 – 4:00 NIH Video cast (2) Session 1 (Christine Grady) and Session 2 Jerry Menikoff)	3:00 – 4:00 Program Update – Brad Waite		Evergreen State College and meet the college President (Dr. Les Purce) with Board member , Dr. Artee Young (confirmed)
15 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m.	16 Ms. Carceres Out of Office Dr. Cabrera Out of Office 8:30 – 1:00 K Panel 1 – Presentation (Gustavo Kaltwasser) 8:30 – 1:00 P Panel 7 - Presentation	17 Ms. Caceres Out of Office Dr. Cabrera Out of Office 8:30 – 1:00 C Panel 5 - Presentation 3:00 – 4:00 NIH Video cast (3) Session 2 (Dave Wendler and Alan Wertheimer)	18 Ms. Caceres Out of Office 8:30 – 1:00 R Panel 3 - Observation 8:30 – 1:00 P Panel 11 - Observation 1:00 – 2:30 Practical Training – Self-Assessment of IRB Activities and Administration (Loren Ferro) 3:00 – 4:00 Program Update – Brad Waite	19 8:30 – 1:00 K Panel 12 - Observation	20 8:30 – 1:00 C Panel 8 - Observation 1:00 – 2:00 Practical Training – How to Chair a Board – Ted Schultz
22 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m. except for Thursday	23 8:30 – 1:00 K Panel 7 – Presentation (Connie Vasek) 1:30 – 3:30 Guest Lecturer: Dr. Kelly Fryer-Edwards from University of Washington “Responsible Conduct of Research” – Heritage Room C	24 8:30 – 1:00 P Panel 2 – Presentation (Rosemay Vazeux) 8:30 – 1:00 R Panel 5 – Presentation – Robert Taylor 3:00 – 4:00 NIH Video cast (4) Session 3 (Ezekiel Emanuel and Robert Truog)	25 Depart around 9:45 11:30 – 12:30 Brown Bag discussion at the University of Washington – Lucille Broberg 3:30 – 4:00 Program Update – Brad Waite	26 8:30 – 1:00 C Panel 4 - presentation 8:30 – 1:00 R Panel 12 12:30 – 1:30 lunch with Dr. Rosenfeld at the Annex – main campus 2:00 – 4:30 Tour and Visit to Providence St. Peter Hospital in Olympia – Sue Middle	27 1:30 – 3:00 Practical Training – Expedited Review – Cathy Coates – Heritage Room C

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
29 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m.	30 8:30 – 1:00 R Panel 1 2:30 – 3:30 Practical Training – SOP Development -Elizabeth Weisenfeld	31 8:30 – 1:00 C Panel 2 8:30 – 1:00 K Panel 5 3:00 – 4:00 NIH Video cast (5) Session 3 (Cary Gross and Session 4 Frank Miller)			
四月份					
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. except Thursday Depart Heritage: 4:30 p.m. except Thursday			1 8:30 – 1:00 P Panel 3 8:30 – 1:00 R Panel 11 3:00 – 4:30 Visit Capital Medical Center and meet Dr. Carl Ott with Carolyn Fornoff (confirmed)		4
5 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. except Wednesday Depart Heritage: 4:30 p.m. except Wednesday	6 8:30 – 1:00 P Panel 1 - Observation	7 8:30 – 1:00 K Panel 2 - Presentation	8 Leave about 8:30 am Visit PATH in the morning – (confirmed) – Dr. Connie Vasek (lunch at PATH) 1:30 – 3:20 International Bioethics, Social Justice & Health Seminar at the University of Washington – Dr. Connie Vasek		11
12 VAN SCHEDULE	13 8:30 – 1:00 C	14 8:30 – 1:00 P	15 8:30 – 1:00 C		18

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
<p>Depart Apple Park Office: 7:45 a.m. except for Friday</p> <p>Depart Heritage: 4:30 p.m. except for Friday</p>	<p>Panel 1 - Presentation 3:00 – 4:00</p> <p>NIH Video cast (6) Session 4 (Lainie Ross and Session 5 Dave Wendler)</p>	<p>Panel 5 - Presentation</p>	<p>Panel 3 - Observation 3:00 – 4:00</p> <p>Program Update – Brad Waite</p>		
<p>19</p> <p>VAN SCHEDULE</p> <p>Depart Apple Park Office: 7:45 a.m. except for Friday</p> <p>Depart Heritage: 4:30 p.m., except for Wednesday, Thursday and Friday</p>	<p>20</p> <p>8:30 – 1:00 P</p> <p>Panel 7 Presentation (Thomas Kaufman)</p>	<p>21</p> <p>8:30 – 1:00 C</p> <p>Panel 2 – Presentation (Rosemary Vazeux)</p> <p>2:30 – 3:30</p> <p>Guest Lecturer: Dr. Gustavo Kaltwasser – (Research in Latin America and the IRB Process) - Heritage Room C – confirmed</p>	<p>22</p> <p>8:30 – 1:00 K</p> <p>Panel 11 - Presentation</p>	<p>25</p> <p>9:00 – 12:00 Spring Meeting in Redmond, WA</p>	
<p>26</p> <p>VAN SCHEDULE</p> <p>Depart Apple Park Office: 7:45 a.m.</p> <p>Depart Heritage: 4:30 p.m.</p>	<p>27</p> <p>8:30 – 1:00 K</p> <p>Panel 1</p> <p>8:30 – 1:00 C</p> <p>Panel 7</p> <p>2:00 – 3:00</p> <p>Practical Training – Subject Complaints -Barbara Benson</p>	<p>28</p> <p>10:00 – 11:00 Practical Training – Site Visits (Regina Dearborn)</p> <p>2:00 – 3:00 Practical Training – IRB Budgeting -Kevin Traff</p> <p>3:00 – 4:00</p> <p>NIH Video cast (7) Session 5 (Maggie Little and Don Rosenstein)</p>	<p>29</p> <p>8:30 – 1:00 C</p> <p>Panel 3</p> <p>8:30 – 1:00 P</p> <p>Panel 11</p> <p>3:00 – 4:00</p> <p>Program Update – Brad Waite</p>		

五月份

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
<p>3</p> <p>VAN SCHEDULE</p> <p>Depart Apple Park Office: 7:45 a.m. except Friday</p> <p>Depart Heritage: 4:30 p.m.</p>	<p>4</p> <p>8:30 – 1:00 P</p> <p>Panel 1</p> <p>3:00 – 4:00</p> <p>NIH Videocast (8)</p>	<p>5</p> <p>8:30 – 1:00 C</p> <p>Panel 5</p> <p>8:30 – 1:00 K</p> <p>Panel 2</p>	<p>6</p> <p>Lv. Heritage around 11:30 a.m. for 1:30 – 3:20 International Bioethics, Social Justice & Health Seminar at the UW – Connie Vasek</p>	<p>7</p> <p>8:30 – 1:00 P</p> <p>Panel 12</p>	<p>8</p> <p>8:30 – 10:00</p> <p>Watch Video “Quiet Rage: The Stanford Prison Experiment” and discuss</p> <p>2:00 – 3:30 K</p>

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
except for Wednesday and Friday	Session 6 (John Arras and Christine Grady)				IFM Meeting – Observation
10 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m.	11 8:30 – 1:00 K Panel 7  2:00 – 3:30	12 2:00 – 3:00 Fellows Program Update – Brad Waite – Heritage Room C	13 8:30 – 1:00 K Panel 3 8:30 – 1:00 C Panel 11 2:00 – 4:00 Guest Lecturer: Cindy Bouillon-Jensen - Review of Social/Behavioral Research” – confirmed Heritage C	14 Leave about 7:00 for 9:00 – 1:00 Observation of Washington State University IRB Committee G (social and behavioral) meeting in Seattle – David Forster - confirmed	15 8:30 – 1:00 P Panel 6
17 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. except for Wednesday Depart Heritage: 4:30 p.m. except for Wednesday and Thursday	18 12:30 – 1:30 NIH teleconference for Q & A – Heritage Room C – Brad Waite 2:00 – 3:30 Watch Video “Elixir of Death” and discuss (Heritage C) – Tori Lallemond	19 Leave at 9:30 a.m. for 11:30 – 1:30 visit to Bastyr in Kenmore - confirmed 3:00 – 4:00 NIH Videocast (9) Session 7 (Alan Wertheimer and Reidar Lie)	20 Leave at 11:30 for 1:30 – 3:20 International Bioethics, Social Justice & Health Seminar at the UW – Sue Middle	21 leave Heritage at 9:30 a.m. to observe Oregon Health Sciences University (OHSU) IRB meeting in Portland 12:00 – 2:00 – Paul Newton - confirmed (NOTE: bring laptops)	22 8:30 – 1:00 C Panel 6 8:30 – 1:00 P Panel 8 8:30 – 1:00 K Panel 1
24 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. except for Monday Depart Heritage: 4:30 p.m. except for Monday	25 HOLIDAY – WIRB IS CLOSED	26 Dr. Chang out of office 3:00 – 4:00 NIH Videocast Session 7 (Seema Shah) and Session 8 (Ben Wilfond and Sara Chandros Hull)	27 Dr. Chang out of office 8:30 – 1:00 P Panel 3	28 Dr. Kim out of office	29 Dr. Kim out of office Dr. Pacheco out of office 8:30 – 1:00 C Panel 8
六月份					
VAN SCHEDULE	June 1	2 Dr. Kim out office	3 Dr. Kim out of office	4 2:00 – 2:30 P	

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Depart Apple Park Office: 7:45 a.m. Depart Heritage: 4:30 p.m.	Dr. Kim out of Office	8:30 – 1:00 P Panel 2 - observation	8:30 – 1:00 C Panel 11 - observation	Meeting in Regulatory (Paul's Office)	
7 VAN SCHEDULE Depart Apple Park Office: 7:45 a.m. except for Tuesday and Friday Depart Heritage: 4:30 p.m. except for Tuesday, Thursday and Friday	8 8:30 – 1:00 K Panel 7 12:00 – 1:00 Lunch at main campus Annex with Dr. Rosenfeld 2:00 – 4:00 Watch Video "Acres of Skin, and discuss – Adam Dubov – Heritage Room C	9 Approximately 7:30 – 2:30 Visit and Tour of Timberline High School and Lakes Elementary School with Cathy Coates	10	11 10:00 – 10:30 K,P,C meet with Dr. Bowen in her office 2:30 – 3:30 completion ceremony – executive conference room – main campus	

肆、會議心得

1. 訓練簡介(第一至二週)

初期學習人體試驗醫療倫理相關規範，分析國內外人體試驗醫療倫理，進而討論出對於婦女人體試驗醫療倫理模式及婦產科相關人體研究之規定。

2. 訓練活動(第三至六週)

藉由訓練活動學習人體試驗醫療倫理相關活動，分析國內外人體試驗醫療倫理訓練課程，研究婦產科人體試驗醫療倫理訓練課程。

3. 受訓者測驗(第七週)

以測驗評估七週所學，並藉以改善學習內容。

4. 參與人體試驗委員會會議(第八至十二週)

在人體試驗委員會會議中，研討相關婦產科人體試驗醫療倫理議題，藉以改善未來婦產科相關研究與實驗方式。

5. 參與醫學人體試驗倫理審核評估(第十三至十六週)

以實際參與醫學人體試驗倫理審核評估，來進一步分享婦產科醫學人體試驗倫理審核評估。

6. 參與其他臨床醫學人體試驗倫理審核評估(第十七至二十週)

參與其他臨床醫學人體試驗倫理審核評估，可分析各方對婦產科醫學人體試驗倫理審核評估，並研究討論其優缺點，可用來改善醫院婦產科醫學人體試驗倫理審核評估。

7. 回歸訓練委員會評估(第二十一至二十四週)

在所有課程訓練結束後，以學習內容與研究方向來分析，藉以得到研究成果發表。

鑑於國內人體試驗倫理為目前醫學研究必備標準，且婦產科相關研究（如生殖不孕、遺傳染色體及婦癌…等）皆需高標準醫學倫理。本院目前尚無國外人體醫學研究婦產科倫理醫師。本院副院長暨人體試驗委員會主席汪志雄上校評估為合適人選，並予以推薦(詳如推薦書)。

美國西方人體試驗委員會機構訓練主要任務是改善世界開發中國家人體試驗，受試者在醫學研究前或試驗中能夠得到安全與保障。受訓後成為專家能夠有能力改善世界開發中國家的倫理審核評估，依個自文化來發展特有倫理審核評估，進而在醫學

人體試驗中，受試者在醫學研究前或試驗中能夠得到安全與保障。受訓學成歸國後，發揮所學於婦女醫療、生殖不孕及婦女泌尿等相關人體研究之倫理審查、人體試驗之風險利益評估與研究倫理的發展與國際現況研究。

我們可以徹底了解到各個國家人體試驗委員會不同，研究審核處置上就出現極大的差異，而這也是相當有趣的事情。在不同的文化下人體試驗研究計畫處理上差異極大，而這也造就了每個國家在人體試驗委員會的研究上各有強項。

美國人體試驗委員會的內容，不論是外賓演講，或是海報口頭論文，都相當的國際化而多采多姿，在多元文化及多方資訊的匯集之下，我想美國的研究受試者是幸福的，也許因此而孕育出更多元的新知識。此學術集會著重於人體試驗研究計畫審核指標之受試者安全及標準化。且針對目前國際性人體試驗研究計畫審核主題，分析美國與世界的貢獻。透過這訓練，讓年輕的醫師活躍於國際學術交流且擁有廣大視野。人體試驗研究計畫審核的未來，不同的國家會有不同的處境，但是人體試驗研究計畫審核知識的缺乏似乎是全世界共通的問題。全世界都面臨人體試驗研究計畫審核的問題，造成醫療受試者受傷問題卻是最嚴重的，成為整體國家醫療上一個很大的問題。我想美國現在的處境就是我們將來的處境，學會也很積極在為推動人體試驗研究計畫審核而盡心，這是需要我們共同來為自己的權益而努力的。

我們和許多外國的醫師利用這個機會交流，也期待將來能有再聚會的時候。這次的美國行給我們機會認識結交了不少外國友人，瞭解各國人體試驗研究計畫審核面臨的挑戰，也見識到了美國年會的盛況，真是成果豐碩。我衷心感謝醫院給我這個機會，也期盼這類的國際交流能夠繼續延續下去。

想來近幾年來，在台灣的年輕醫師，常常因為工作勞累，負擔過重而失去和其他人互相交流的機會，平常連在台灣本島內院際的交流就很少了，更惶論國際性的學術交流和國際友誼的建立，殊不知我們目前擁有的一切，都是人體試驗研究計畫審核前輩一點一滴的努力所累積得來的。如果不能延續前輩的腳步，我們在國際舞台的空間將越來越小、越來越窄，屆時在醫界而進入一個無法自拔的惡性循環。有些趨勢我們無法改變，但我們仍期盼儘己所能護衛受試者的健康與福祉，這次非常感謝有這樣的一個機會，讓我對自己未來的任務有更深的體悟，期盼未來的後進，也可以藉由這個機會改變未來人體試驗研究計畫審核的命運。為了深入當地美國的人體試驗研究計畫審核情形，

伍、建議事項

1. 積極參與人體試驗相關會議，鼓勵年輕醫師續至國外研究及交流，建立國際性的學術交流和國際友誼的，一點一滴的努力所累積得來的。延續前輩的腳步，擴展我們在國際舞台的空間，而進入一個良性循環。我們仍期盼盡己所能護衛研究受試者的健康與福祉，這次非常感謝有這樣的一個機會，讓我對自己未來的任務有更深的體悟，期盼未來的後進，也可以藉由這個機會改變未來研究計劃的審核。
2. 紮根臨床與基礎研究計劃審核，爭取國內研究經費，爭取發表於國內外研究成果。
3. 爭取加入國際人體試驗相關會議的舞臺，可以讓我們台灣人體試驗研究計劃審核能更保護研究受試者的健康與福祉。
4. 爲了因應人體試驗研究計畫審核訓練不足的問題，人體試驗研究計畫審核訓練是需要。
5. 引進人體試驗研究計畫審核之理念與訓練。
6. 激發部內研究風氣，依專業背景的外國人，認可我們的人體試驗研究計畫審核，以美國國際人體試驗研究計畫審核訓練的激勵下，相信很多人將會增加參與人體試驗研究計畫審核的意願，亦可提高本院人體試驗研究計畫審核的國際能見度。
7. 回饋人體試驗研究計畫審核新知。
8. 發表罕見人體試驗研究計畫審核之處理經驗。
9. 可以引進之人體試驗研究計畫審核理念與心得。
10. 對外國人體試驗研究計畫審核觀摩。
11. 了解到各個國家人體試驗研究計畫審核文化差異，並學習優點。
12. 加強科內人體試驗研究計畫審核，配合國內外醫學倫理，研討完善的人體試驗研究計畫審核方案。

IRB 為學術界專業之項目，本部培養
年輕住院医师等培訓，期望對本院
有所貢獻

三軍總醫院
婦產部部主任 武國璋

07171600

陸、參加此會議對單位之貢獻

1. 對國際與國內婦女醫療人體試驗之法律責任及相關法令認知，研擬醫院人體試驗計畫審議制度及規則。
2. 研究婦女醫療倫理的發展與國際現況研究。
3. 針對婦女醫療人體研究之倫理審查。
4. 針對婦女醫療人體試驗之風險利益評估。
5. 國際人體試驗委員會認證。

柒、附件資料

- 一、訓練證明。
- 二、西方人體試驗委員會訓練計畫。