project approval.

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Room 1018 East Building Phone: 772-4200

## **MINUTES**

### Meeting of the Hunter College Senate 6 December 2006

1 2		The 474 <sup>th</sup> meeting of the Hunter College Senate was convened at 3:45 PM in Room W714.
3 4	Presiding:	Richard Stapleford, Chair
5	Attendance:	The elected members of the Senate with the exception of those listed in Appendix I.
7 8 9		Alternate Senators were formally seated in accordance with the procedures approved by the Senate, and clickers were distributed to them.
10 11	Agenda:	The agenda was adopted as distributed.
12 13	Report by the Administrative	The Chair presented the report as follows:
14 15 16 17	Committee:	<u>Special Election to fill vacant seats on the Senate</u> In accordance with Article IV.2.H.i & ii of the <i>Charter for a Governance of Hunter College</i> the Administrative Committee presented the names of all nominees received to date:
18 19 20		Faculty: Anthony Picciano (Curriculum & Teaching)
21 22		It was moved that nominations be closed. The motion carried by voice vote without dissent.
23 24 25		It was moved that the Secretary be instructed to cast a single ballot in favor of the nominee. The motion carried by voice vote without dissent.
26 27 28 29 30		Approved Curriculum Changes: The following curriculum changes as listed in the Report dated 6 December 2006 were approved as per Senate resolution and were submitted for the Senate's information: Items GR-693 (Economics), UR-1480 (Romance Languages), GS-675 and GS0676 (Curriculum & Teaching), US-1476 (Library), US-1477 (Biological Sciences, (and US-1478 (Psychology).
31 32 33 34 35	Reports:	<u>Institutional Review Board (IRB)</u> Professor Sherryl Graves, Chair of the Gold Committee, Professor Andreas Savage, Chair of the Amethyst Committee, and Carolynn Julien, IRB Coordinator briefed the Senate about the IRB. A summary statement, as distributed, is attached as Appendix II.
36 37 38		The floor was then open for discussion.
39 40 41		Among the concerns raised by Senators were the following:  a) A lack of transparency partly due to the secrecy surrounding the membership of the IRB committees, creates a negative impression.
42 43 44		<ul><li>b) A failure to meet normal expectations of due process, also a result of the secrecy of the committee discussions, has led to the appearance of arbitrariness in decisions.</li><li>c) These and other functional problems have led to a chilling effect on those who would apply for</li></ul>

47	Minutes Page 5340
48	Meeting of the Hunter College Senate
49	6 December 2006
50	
51	
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54	d) For students, as well as some faculty, the amount of time which is required for approval (aver-
55	age 38 days) is too long to accommodate semester projects or other time sensitive proposals.
56	e) IRB decisions in relation to oral history projects have been generally misguided leading to
57	serious impairment of scholarly research among those who employ this methodology
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59	After extensive discussion it was moved that the meeting be adjourned. The motion carried and the
60	meeting adjourned at 5:10 PM.
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65	Respectfully submitted,
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69	Jill Gross,
70	Secretary

## Meeting of the Hunter College Senate 6 December 2006

SEEK

APPENDIX I  The following members were noted as absent from the meeting:				
Faculty	The following members were noted	School of Social Work	Carmen Moreno (A) Bernadette Hadden	
Africana & P.R./Latino	Anthony Browne "E" Pedro Lopez-Adorno (A) "E"		Annette Mahoney	
Biological Sciences	Thomas Schmidt-Glenwinkel (A)	Special Education	Dona Matthews (A)	
Chemistry	Pamela Mills "E"	Urban Affairs	Stanley Moses (A)	
	Dixie Goss (A)	Lecturers and		
Computer Science	William Sakas (A) Virginia Teller "E"	Part-Time Faculty		
Curriculum & Teaching	Laurance Splitter	Claus Mueller (Sociology) "E Joshua Grumet (Film&Media		
Economics	Jonathan Conning (A)	Robert Koehl (Classics) "E" Barbara Sproul (Religion)		
English	Marlene Hennessy "E"	Ex-Officio Ahmed Tigani, USG Presiden	t	
Film & Media Studies	Tim Portlock (A) Michael Gitlin	Sarit Levy, GSA President Sarah Jenincky, HEO Forum President Jason Ares, CLT Council President		
Geography	Hongmian Gong (A)	Jason Ales, CL1 Council Fles	adem	
Health Sciences	Jack Caravanis (A) Phil Alcabes	Students		
History	Angelo Angelis (A)	Anthony McRae (Music) Sivia Naimer (Economics) Christophor Vanny (Poli Sai)		
Library	Clay Williams	Christopher Kenny (Poli.Sci.) Channel Mellish Tithi Ghosh (Math)		
Mathematics & Statistics	William Williams (A)	Sharlene Hamlet James Wagstaff (Graduate) Marina Matatov (BA/MA)		
Music	Barbara L. Hampton (A)	Sonia Parrales (Psychology) Emily Bell Dinam		
Nursing	Kunsook Bernstein (A)	Tin Thu (Sociology) Ezra Serrar		
Physics/Astronomy	Ying-Chih Chen (A)	Nicole Odom Jenny Alcaide (undeclared)		
Psychology	Jeffrey Parsons (A) Tracy Dennis Peter Moller "E"	Oluwatobi Jaiyesimi (undeclar Sean Kivlehan (THHP) Danilda Abreu (Sociology)		
Romance Languages	Virginia Santos "E" Michael Perna (A)	George Ra'cz (Film & Media Siobhan Cawley Laurie Dionne (Grad./Theatre Gary Henkle (undeclared)		
CEEV	Maria Padriguaz "E"			

Maria Rodriguez "E"

Page 5342

# APPENDIX II: IRB Briefing

#### Fundamentals

6 December 2006

- The federal body that oversees the IRB is the U.S. Office for Human Research Protections. Institutions are required to sign an agreement with this agency stating that they will comply with the requirements regarding the protection of human subjects. This agreement is called a Federalwide Assurance. Our Federalwide Assurance number is FWA00003623. All of the CUNY schools share the same Federalwide Assurance. The assurance covers both funded and un-funded research. The regulations which the IRBs follow are set by OHRP and FDA. They can be found in the federal regulations 45 CFR 46 and 21 CFR Part 56. There are substantial federal requirements which govern the guidelines, review process and recording and communication of IRB decisions.
- The IRB Committees consist of twenty-six members and one alternate member. These individuals are faculty and research staff members with representation from all Schools of Hunter College, and community members from various institutions not affiliated with CUNY. These members are divided into two Committees the Amethyst and Gold Committees. The Committees are static. The members cannot be interchanged between the two Committees. Once a protocol is assigned to either Committee, it remains with that Committee throughout the review process, except in very rare instances. The workload is evenly distributed between these two Committees. Hunter is the only CUNY school with 2 functioning IRBs. In addition to monthly meetings, these Committees meet together twice a year to review practice and policy.
  - o The Gold Committee is led by Dr. Sherryl Browne Graves <a href="mailto:sqraves@hunter.cuny.edu">sqraves@hunter.cuny.edu</a> .
  - o The Amethyst Committee is led by Dr. Andrea Savage. <u>asavage@hunter.cuny.edu</u>. The Amethyst Committee is designated as a medical IRB (required to include 2 physician members) which means it can review medical protocols.
- The IRB Office separated from the Office of Research Administration in March 2005. The separation is required to minimize the conflict of interest between the goals of Research Administration and the requirements of human subject protection. The IRB Office has separate telephone (212) 650-3053 and fax (212) 650-3055 lines and is staffed by:
  - o Carolynn Julien IRB Coordinator (Carolynn Julien is the only person at CUNY to hold the Certified IRB Professional (CIP) certification. This certification is granted by Applied Research Ethics National Association/ Public Responsibility in Medical and Research, PRIMR/ARENA. Certification for IRB professionals plays a crucial role in protecting subjects within the research system. The certification process evaluates and validates individuals' knowledge of ethical principles, historical events, regulatory requirements, and operational and functional issues relating to IRBs and human subjects protection programs.)
  - Malini Lall Assistant IRB Coordinator
  - o Tara Smith Administrative Assistant for Regulatory Affairs
  - o Sarah Leon Student Research Assistant

#### IRB Member and Staff Training

• Training is an important component in keeping abreast of IRB developments and guidelines.

• IRB Members are required to complete the CITI training. This computer-based training has additional training modules that are designed specifically for IRB members.

#### Appendix II (continued): Page 5343

- IRB Members and Staff attend an annual CUNY sponsored IRB workshop.
- The Chairs and IRB Staff attend continuing education opportunities including national conferences like the annual Human Research Protections Conference sponsored by PRIMR/ARENA, and the annual conference sponsored by the National Association of IRB Managers (NAIM) and local conferences, like Columbia University's annual IRB conference.
- Hunter is represented on the CUNY-wide IRB Committee by the IRB chairs. The CUNY-wide IRB Committee reviews protocols involving multiple campuses. This committee also discusses IRB issues at the CUNY level.

#### Statistics

	7/1/03 – 6/30/04	7/1/04 – 6/30/05	7/1/05-6/30/06
TOTAL NUMBER OF ALL PROTOCOLS RECEIVED AND REVIEWED	363	438	364
NUMBER OF STUDENT PROTOCOLS	176	267	148
NUMBER OF PROTOCOLS REVIEWED VIA FULL REVIEW PROCESS	190	265	283
MEAN DAYS TO APPROVAL	57	46	38

#### New Initiatives

- In November 2005 the IRB rolled out its Protocol Review Information Review System (PRIS). This is a regularly updated, online document to keep researchers abreast of the review of their protocol.
- The first issue of the IRB Newsletter was published in Summer 2005. This publication has been issued 3-4 times a year.
- IRB has updated its coversheet to help Pls better address human subjects protection issues.
- CUNY implemented the CITI training program as the new requirement to meet the OHRP requirement for training of all key personnel in a research project. This program was developed by individuals in the IRB field and is used by several other institutions to meet the federal training requirement. The value of the CITI training program is the presence of a module focused on social and behavioral science research.
- The IRB has placed selected model protocols on the website to assist researchers.
- The IRB launched its new website in November 2005. Our web address is: www.hunter.cuny.edu/irb.
- The Hunter IRB has developed a Policy & Procedures Manual which was implemented in August 2005. The CUNY Office of Research Conduct is in the process of developing CUNY-Wide policies and procedures.
- All CUNY schools use the same IRB application. CUNY is in the process of revising the application.
- CUNY will require that we shift to an on-line IRB management system. This will require that IRB
  protocols be submitted online. It will allow for both researcher and the staff to look online to see
  the status of a protocol for example. Researchers will have a dedicated online space for their
  protocols and related materials.

Appendix II (continued):

### Department/School Training Sessions

o Fall 2004

Sociology, Social Work, School of Education

o Spring 2005

Schools of the Health Professions, Anthropology, School of Education

#### IRB Offerings

Cookies & Comments

An opportunity for researchers (faculty and students) to drop in and ask questions, have the IRB Office pre-review the IRB application, assist in the formulation of a response to the IRB's review and navigate the IRB forms began in October 2005. Cookies & Comments are offered several times each semester.

- Workshop For Faculty Members on Research Methods
   Workshop led by faculty member Dr. Darrell Wheeler to aid faculty in navigating the IRB process,
   helping students formulate a research plan, classroom practica, research methodology and pitfalls.
   Held August 31, 2005
- Video Conference with OHRP "Straight from the Horse's Mouth"
   Presentation and Question and Answer session with Freda Yoder from OHRP.
   Held April 26, 2006
- IRB Faculty/Staff Development Seminar co-sponsored with the Provost Office
   Half-day seminar with sessions on Research Outside the Laboratory, Involving Students in Research
   and Classroom Practica and Life Cycle of an IRB Application
   Held October 5, 2006

#### Planned Offerings

- Roundtable Discussion with the NYC Department of Education on research in the public schools Re-scheduled for February 2007
- Development of Departmental Subject Pools

#### Issues

- The climate of human research protections regulation is a shifting one. One of the newest changes in the requirement that international research be approved by a designated IRB in the country in which the research will be conducted.
- There have been significant changes in the regulations governing research in schools.
- The passage of the HIPAA regulations for health-related information affects research involving this type of data.