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Institutional Review Board (IRB)  
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TO: Faculty, Students and Administrators  
FR: Gil Brookins, IRB Chair  
DT: December 5, 2011  
RE: Human Subject Review Changes – Effective Spring 2012

Dear Colleagues,

As many of you know, any research project involving human subjects must undergo review by the Institutional Review Board (IRB), an independent group of faculty and administrators appointed by the Vice President for Academic Affairs. In keeping with Federal law as prescribed in [DHHS Title 45 PART 46, Protection of Human Subjects](#), an “IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.”

The IRB has seen an exponential increase in the number of human subject applications submitted by faculty and students, particularly student-initiated projects under the supervision of a faculty member. This increase is attributed to the College’s commitment to increasing student engagement and affording students an undergraduate research experience beyond the classroom. In the past the IRB averaged 20 protocols under expedited review during the fall semester. For fall 2011, the IRB received, screened and reviewed 68 protocols to date (and still counting). That is close to a three-fold increase and we expect that the average of 75 protocols during spring 2012 will increase as well. Overall, this is a positive indication of Siena’s commitment to academic excellence.

With that said, the IRB is responsible for compliance with Federal regulations to protect the rights and safety of those who are involved in research projects undertaken by faculty and students at Siena. In order to uphold these responsibilities, the IRB is proposing the following changes to begin in the Spring 2012 term:

1. **Revised IRB Application:** due to recent changes in Federal regulations and the addition of Exemption Review (see below for further information), we have revised the IRB Application. To obtain the revised application, please visit <https://www.siena.edu/pages/741.asp>. Faculty and students should begin using the revised IRB Application immediately.
2. **Exemption Review:** Under Federal policy, there are six (6) categories that require faculty or student to receive an exemption from the IRB. For information about the new policy and the six exemption categories, please visit [www.siena.edu/pages/735.asp](http://www.siena.edu/pages/735.asp). The revised IRB application provides directions

for applying under Exemption Review. Even if a research project involving human subjects falls under exempt status, it still must be reviewed by the IRB and an approval must be granted under one of the six Federally recognized criteria.

3. **Online Training Certification:** Also under Federal law and in compliance with Siena College's Federal-wide Assurance (FWA) registration, anyone engaged in human subject research is required to complete adequate training on responsible conduct of research. Therefore, to fulfill this federal mandate the IRB will be requiring all PI(s), Co-PI(s), and the faculty supervising the project to complete the NIH Office of Extramural Research, *Protecting Human Research Participants* training module (<http://phrp.nihtraining.com/users/login.php>). This free web-based training software consists of 7 modules, 4 of which are followed by quizzes. The entire course will take approximately 3 hours to complete. The IRB will be unable to approve any IRB project without providing a NIH computer-printed *Certificate of Completion* along with the IRB application. Upon completion of the training, the certificate is valid for two years.
4. **IRB Review Time:** In order to continue to effectively ensure that the rights and safety of those involved in the growing number of human subjects research projects are being adequately considered, more time will be necessary to complete a thorough review of each application. For the past decade, the Siena IRB has averaged a 5 business day review process for fully completed IRB applications. Due to the increase in applications, the IRB will extend the review process to ten business days for expedited and exempt reviews only. Again, this is an average time of the review process for fully completed IRB applications under these two review categories. Full board review applications typically take between one and three months and will be handled on a case-by-case basis.

The policies described above go into full effect January 17, 2012. To help communicate these changes, Alfredo Medina, designated Human Subjects Compliance Officer, and I are available to speak with you and your classes about these changes. If you believe it would be helpful, we can make ourselves available to discuss these changes in person and answer questions before the end of the fall semester.

Please feel free to contact Alfredo Medina at (518) 783-2307 or via email at [amedina@siena.edu](mailto:amedina@siena.edu) about scheduling a meeting time to discuss these changes and how we can be of assistance. Thank you.

Sincerely,

Gil Brookins  
Chair, Siena College Institutional Review Board

cc: Linda Richardson, VPAA

IRB Committee

Josh Alexander

Max Levine

Salvatore Lombardo

Oscar J. Mayorga

Alfredo Medina, Jr.

Carol Sandoval

Carla Sofka

Russell Moore, External Member