



ETSU IRB REVIEW

The Office for the Protection for Human Subject Research (OPHS)

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Who is AAHRPP?

After a long and difficult process, East Tennessee State University was awarded full accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in December 2005. This organization looks to ensure compliance by helping institutions reach performance standards that surpass the inception of state and federal requirements. It works to protect the rights and welfare of research participants and promote scientifically commendable and ethically sound research by fostering and advancing the ethical and professional conducts of persons and organizations that engage in research with human participants. This accreditation was achieved by using this accreditation process based on self assessment, peer review and education.



Maintaining Accreditation

In order to maintain accreditation, the organization must follow the specified process. The organization must meet the reporting requirements specified. An annual report explaining any major changes or problems must be submitted in a standard form specified in the instructions. In addition, the organization must submit, within 72 hours, inquiries of government oversight (OHRP, FDA) and findings or changes that may affect the ability to continue to meet accreditation. The organization must report within 24 hours any sanctions taken by a government oversight office. This ensures that AAHRPP is informed of compliance-related activities. The organization must also be re-visited every 3 years. **East Tennessee State University is scheduled to be re-visited Wednesday, August 27th and Thursday August 28th of this year.**

Note: NO IRB Submissions will be processed during these two days due to the extensive attention AAHRPP site visitors require from the IRB Staff.

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Benefits of An Accreditation

There are several reasons why an organization would choose the accreditation process. Accreditation provides an indicator of excellence to many different participants in human subject research. For example, for potential participants, accreditation provides an assurance that the program has standards that exceed federal requirements. Potential participants can also be assured that ETSU has chosen to put their well-being first by achieving a human protection program of excellence.

For sponsors, institutions that have achieved accreditation offer a program that has achieved a demonstrated level of excellence. In addition, the government recognizes the value of accreditation. In fact, the Office for Human Research Protections (OHRP) acknowledges that when determining which sites to audit (for not-for-cause audits), accreditation is a factor that is considered.



Who Is Accredited?

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) has accredited a total of 107 institutions as of March 2008. Out of the 107 institutions accredited, only 38 of them are universities. AAHRPP has expanded its accreditation process to Korea, Canada and Singapore.

Site Visit

The site visit for re-accreditation has been scheduled for August 27 and 28, 2008. Aside from reviewing IRB files, the site visitors will be interviewing ETSU administrators from the highest ranking down (Dr. Stanton, President; Dr. Bach, Vice President; Dr. Woodruff, Vice Provost for Research, etc). They will also be interviewing principal investigators (students or non-students), IRB board members, including the Chairs and Vice Chairs, IRB Staff, ETSU Legal Counsel and some Department Chairs.

AAHRPP will choose who is being interviewed and will communicate this list to the IRB Office. Once the selections have been made, the IRB Staff will communicate and provide guidance to those who have been chosen.

The selections made by AHRPP are final. AAHRPP expects those selected to be available for those interviews.



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Subject Research (OPHR)**

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October 2008

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

November 2008

Su	Mo	Tu	We	Th	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26		28	29
30						

- 2- Campus Meeting
- 7-Medical Meeting
- 13- Deadline to submit initial full studies for the November 2008 meeting

- 4- Medical Meeting
- 6-Campus Meeting
- 10- Deadline to submit initial full studies for the December 2008 Meeting
- 27-28 Thanksgiving Holiday

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