RESEARCH COMPLIANCE:

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS (IRB)

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

QUALITY ASSESSMENT & IMPROVEMENT PROGRAM (QAIP)



Institutional Review Board for the Protection of Human Subjects (IRB)

- The Upstate IRB reviews and approves <u>ALL</u> research involving human subjects, human tissue, surveys of human subjects, or medical records prior to the initiation of the research.
- This requirement applies to all human subject research conducted by faculty, on- and off-campus, whatever the funding source for the project.
- The Principal investigator (must have faculty status) is responsible for the conduct of the research study including the conduct of other study team members.
- All persons involved in human subject research must successfully complete 2 web based education programs, through **CITI** (citiprogram.org): "The Protection of Human Subjects" & "The Responsible Conduct of Research."



IRB Electronic Management System IRBNet.org

IRBNet is the electronic system used for all IRB submissions, determinations & decisions

- New users need to register at IRBNet.org
- Features include: electronic document management, web-based protocol sharing and collaboration, automatic notifications, electronic submissions and reviews, and audit capabilities including electronic revision histories, electronic signatures and event tracking.
- All forms, instructions, & deadline dates are within the "Forms & Templates" section in IRBNet.

IRB CONTACTS (4-4317):

Marti Benedict, Chief Compliance Officer for Research Jean Cardillo, IRB Coordinator Michele O' Brien, Administrative asst. for research compliance & CITI Coordinator Stephen Graziano, MD, IRB Chair



Institutional Biosafety Committee (IBC):

The Institutional Biosafety Committee (IBC) is charged with ensuring that research is performed in a safe environment and in accordance with guidelines promulgated by the National Institutes of Health.

Research which involves the use of infectious agents, human blood/ fresh tissue/body fluids and recombinant DNA must be submitted to the IBC for review. Work with recombinant DNA must be conducted in accordance with NIH Guidelines.

Contacts: Marti Benedict, Michele O' Brien (4-4317)

Robert Quinn DVM, IBC Chair- Quinnr@upstate.edu

IBC Website: http://www.upstate.edu/researchadmin/compliance/ibc/



Quality Assessment & Improvement Program (QAIP):

- •Provides **post (IRB) approval monitoring** (routine & directed) of active studies involving human subjects
- •Provides assistance and ongoing education to investigators and their staff with regard to human subject research and compliance
- •QAIP Study Initiation Visits are available for new studies that have received IRB approval:
 - Provides assistance with set-up & organization of study records and required documents
 - Instruction concerning local IRB reporting requirements
 - Link to Study Initiation Visit flyer

Contact info: Robin Cerro, NP (Phone: 4-4328) Email: cerror@upstate.edu

