Job Description – Research Compliance Manager

Department: Provost’s Office
Reports to: Provost

Position Summary
This position is responsible for overseeing research compliance activities regarding research involving human subjects and animal subjects at NYU Shanghai. This function includes administering the Institutional Review Board (IRB) for human subjects research and the Institutional Animal Care and Use Committee (IACUC) for animal subjects research.

Responsibilities

- Processing of human subjects and animal subjects research protocols;

<table>
<thead>
<tr>
<th>IRB</th>
<th>IACUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducts pre-reviews of submissions (initial, continuing review requests, amendments, unanticipated problems, deviations, etc.)</td>
<td>Office is initial point of contact for proposed use of animals in research. Assures that the resources are available to support the specific animal use. Oversees pre-reviews of submissions for completeness of required information. Coordinates submission to other committees that may have oversight such as a Institutional Biosafety Committee, or other safety committees that review use of recognized hazards (initial, annual/de-novo reviews or tri-annual continuing review, unanticipated problems, deviations, etc.)</td>
</tr>
<tr>
<td>Forwards submissions to the appropriate IRB member for review</td>
<td>Ensures protocol is reviewed by veterinarian, review/clearance from animal facility/vivarium manager (best practice), clearance from occupational health program, and assigns a member of the committee to conduct a pre-review of the submitted protocol before full committee review or oversees a designated review process</td>
</tr>
<tr>
<td>Acts as liaison between the IRB and researchers, serving as a regulatory matter expert and primary point of contact</td>
<td>Acts as liaison between the IACUC, Director of Veterinary Resources, facility staff and researchers, serving as a</td>
</tr>
</tbody>
</table>

Page 1 of 3
Coordinates IRB meetings
Coordinates IACUC meetings and facility and lab inspections.

Creates IRB Meeting Agendas
Creates IACUC Meeting Agendas

Attends IRB meetings and drafts meeting minutes
Attends IACUC meetings and drafts meeting minutes

Prepares correspondence to researchers in response to an IRB review
Prepares correspondence to researchers in response to an IACUC review and when there are concerns in post approval monitoring of studies involving animals or animal welfare concerns in general.

Maintains and retains all documentation, including protocols, meeting minutes and correspondence related to the activity, as required by the regulations
Maintains and retains all documentation, including protocols, meeting minutes and correspondence related to the activity, as required by the regulations

Makes exempt and/or not human subjects determinations

- Coordination of IRB and IACUC with other review committee’s (for example: Scientific Review, Bio-Safety, etc.) (see first row of above table)

- Administering or verifying Conflict of Interest

- Working with the IRB/IACUC to ensure compliance with China governmental regulations, US federal regulations, state laws and local policies and procedures

- Administering and verification of training in human subjects and animal subjects protections, as well as assisting in the training and education of IRB and assisting Animal Resource Veterinarian in training and education IACUC members and researchers

- Assisting in the development of reports, as needed

- Provide user input in the relevant management system design, build and implementation. Assisting in the development of policies and procedures

- Assisting in the development and periodic evaluation of animal facility emergency plan

- May serve as an IRB/IACUC member or alternate

- Other Duties as assigned

Qualification

- Required Education

Bachelor’s Degree (or equivalent) required, advanced degree preferred.
• **Required Experience**

Prior experience in research, research administration, and/or regulatory affairs is highly desirable, with preference given to those candidates possessing IRB/IACUC experience with certification or its equivalence.

• **Required Knowledge, Skills, and Abilities**

Candidate must be bi-lingual (Chinese and English).

Should have understanding and knowledge of international standards (to include American, European, Asian, and Chinese) on use of Human and animal subjects in research.