



Section 300: Proposal Development and Submission

OSR Policy 300.4 — Pre-Submission Compliance Requirements

Responsible Officer: Director
Responsible Unit: Proposal Management
Effective date: July 1, 2008
Last revised on: October 17, 2008

Policy Statement

The University and any persons conducting research on behalf of the institution are required by law to comply with established Federal standards regarding sponsored research. In conjunction, the University is responsible for maintaining compliance through training and education, communication between and among researchers, monitoring and auditing systems to detect compliance issues, and preventing non-compliance by proactively accessing and responding to compliance concerns.

The University institutes its compliance policies through the combined efforts of University Administration, the Principal Investigator (PI), the Office of Sponsored Research, the Sponsored Programs Office, and the Office of Clinical Trials (OSR, SPO, and OCT) and those University offices responsible for maintaining compliance.

Prior to the approval of a sponsored research proposal, OSR, SPO and OCT review the proposal to verify compliance information is accurate and complete in the following areas:

<i>Area of Compliance</i>	<i>Proposal Reviewed for:</i>
Human Subjects Protection	Submission of IRB approval, excluding those pending JIT approval.
Animal Care and Use	Submission of IACUC approval, excluding those pending JIT approval.
Research Safety	Identification of research materials requiring DEHS approval.
Export Control	<ul style="list-style-type: none"> • Notification of intentions to transport materials outside the U.S. • Identification of research team members who are of foreign national status. • Identification of select agents for potential licensure or export control management.
Conflict of Interest	Identification by each team member of potential financial interests requiring management by the University.
Intellectual Property	Identification of potential patent agreement requirements.



Reason for Policy

In accordance with all relevant ethical, legal, and regulatory obligations, UNC-Chapel Hill has established this policy demonstrating the University's commitment to have all required compliance-related elements in place prior to expending funds.

Exclusions/Exceptions

None.

Procedures and Related Policies

Procedures, requirements, forms, and questions regarding compliance are addressed at the individual websites responsible for each:

1. [Human Subjects Protection](#)
2. Health Insurance Portability and Accountability Act ([HIPAA](#))
3. Animal Care and Use ([IACUC](#) and [DLAM](#))
4. [Research Safety and Security](#)
5. [Export Control](#)
6. [Conflict of Interest](#)

OSR Research Tool Kits

[Proposal Development and Submission: Developing a Proposal](#)

Contacts

Questions and concerns can be submitted online at [Ask OSR](#) or by using the [OSR staff directory](#). Within [RAMSeS](#), the “*Speak to Someone*” option assists in locating the staff member best suited to address project-specific issues.

References



[Research Administration Glossary at Carolina](#)

1. Responsible Conduct of Research Brochure.
2. Office of Human Research Ethics (OHRE).
3. Division of Laboratory Animal Medicine (DLAM).
4. Office of Animal Care and Use (IACUC).
5. HIPAA Administration.
6. Environment, Health and Safety (EHS) Manuals.
7. Export Control Regulations, OSR.



8. Memorandum from the Vice Chancellor for Research and Economic Development and the Associate Vice Chancellor for Research to Deans, Directors and Department Directors Regarding Export Control.
9. Policy and Procedures on Ethics in Research at UNC-Chapel Hill.
10. Policy for Use of University Resources in Support of Entrepreneurial Activities.
11. Policy on Institutional Conflict of Interest, UNC-Chapel Hill Board of Trustees University Affairs Committee, May 24, 2006.

Revision History

Prior Revisions: The policies in the *Office of Sponsored Research Policies & Procedures Manual* supersede any OSR policies, procedures and appendices previously included in the *University Business Manual*, a publication of UNC Chapel Hill's [Division of Finance](#).

