



**Policy Title: Clinical Trial Agreements**

**Category: Office of Sponsored Research**

**Policy Number: 100**

**Sponsor: Vice President for Research**

**Effective Date: October 19, 2006**

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**INTRODUCTION AND PURPOSE.** This policy describes the required provisions to be in written Clinical Trial Agreements (CTAs) sponsored by industry.

**SCOPE AND APPLICABILITY.** This policy applies to all CTAs sponsored by industry.

**POLICY STATEMENTS.**

The University will ensure a written CTA exists for all human research conducted under the auspices of the University that has an industry sponsor.

The CTA will contain provisions that are consistent with University policies and guidelines; applicable laws and government guidance; ethical principles regarding research; and applicable accreditation standards and elements.

**DEFINITIONS.**

*Clinical Trial Agreement (CTA)* means a type of sponsored research agreement where the research involves human participants and is sponsored by industry (e.g. pharmaceutical or device company).

**PROCEDURES.**

1. The Director of the Office of Sponsored Research is delegated authority to negotiate and sign CTAs on behalf of the Vice President for Research so long as the CTA contains provisions are consistent with University policies and guidelines; applicable laws and government guidance; ethical principles regarding research; and applicable accreditation standards and elements.
2. The Director of the Office of Sponsored Research will use written CTA guidelines and a CTA template that have been approved by the Vice President for Research to assist in the negotiation process.

**POINTS OF CONTACT.**

Office of Sponsored Research (847) 578-8524.