About Us

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Located in the CTSI Office of Clinical Research, the FDA Affairs team provides FDA support and guidance for investigators submitting or holding an IND or IDE at all stages of an investigation. In addition, the FDA Affairs team has created a virtual clinical research platform called ResearchGO that provides a single portal to a wealth of resources, expertise, and best practices for investigators and research staff to facilitate efficient, compliant and ethical study conduct and management.

What We Do

- Provide consultation to the UCLA community regarding drug, device, and biologic products and technology
- Determination of product classification (e.g., drug, device, combination product, biologic)
- Assist with the determination if an IND or IDE is needed
- Drug, Device, and Biologic Protocol Development
- Assistance with IND or IDE application and subsequent submissions (e.g., amendments, safety reports, annual and final reports) including pre-submissions and Q-submissions
- Preparation, coordination, facilitation, and attendance at FDA meetings
- Preparation for and regulatory support during FDA inspections of investigator-sponsored clinical trials
- Update the UCLA research community regarding new guidance documents, inspection trends, inspection actions and new regulatory actions taken by FDA relating to clinical trials
- ResearchGO updates and maintenance

Who We Are

Marlene Berro, MS, RAC - Director, FDA Affairs

Jenny Ahn, BSN, RN, RAC - FDA Specialist

Amanda Gonzales, MPH, RAC - FDA Specialist

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