So You Want to Treat a Patient Under a Single Patient IND: Here's What you Need to Know

Before you start:

- You'll need Adobe Pro to complete the FDA forms for Single Patient INDs/IDEs. If you don't have Adobe Pro, contact your department head to request it.
- The IND/IDE Office, FDA, and COMIRB all respond very quickly, within hours to a day or two. However, other timelines vary greatly depending on manufacturer requirements and how quickly paperwork and signoffs are completed. Allow about 4 weeks from your initial request. It is important to help your patient understand this.

Understanding your responsibilities:

As the IND/IDE holder, you will be responsible for:

- Executing documents (FDA forms, etc.) and responding to information requests from the IND/IDE Office staff, FDA, and COMIRB
- Tracking Adverse Events
- Completing required safety and annual reporting in accordance with FDA, IRB, and manufacturer requirements
- Coordinating treatment, patient scheduling, care plan signoffs, and clinical processes
- Submitting a final report and withdrawal/closure request to FDA and COMIRB at the end of treatment

How the IND/IDE Office can help:

- Facilitate contact with the manufacturer, and help get your S-IND/IDE up and running as efficiently and smoothly as possible
- Assist with completing required forms and submitting applications and reports to FDA and IRB
- Provide templates and instructions for required documents and processes
- Track your protocol in OnCore and remind you of upcoming reporting deadlines
- Answer your questions and help guide you through the Single Patient IND/IDE lifecycle

What you need to do to get started:

1. **Contact the manufacture**r and confirm that they will provide the investigational product for your patient.
2. Complete any manufacturer customer documentation, eligibility assessments, etc. If they ask for an agreement, send it to IND.IDE.office@cuanschutz.edu to facilitate further processing.
3. Contact IND.IDE.office@cuanschutz.edu to start the application process, and complete the documents we send you as soon as you can to speed the applications along. We'll need your input on the treatment plan, the informed consent, and the monitoring procedures.