

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. If you don't have Adobe Pro, contact your department head to request it.
- The CRSC, 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 holder, you will be responsible for:

- Executing documents (FDA forms, etc) and responding to information requests from the CRSC 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 Clinical Research Support Center can help:

- Facilitate contact with the manufacturer, and help get your S-IND 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 lifecycle

What you need to do to get started:

1. **Contact the manufacturer** 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 ClinicalResearchSupportCenter@ucdenver.edu to review.
3. Contact ClinicalResearchSupportCenter@ucdenver.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.
4. Forward any approvals or documentation you receive to the CRSC and copy us on related emails.