

# Accessing and Responding to Stipulations (1)

IRB Number (00-0000):  Reference ID:

**WELCOME TO IRBIS, THE IRB INFORMATION SYSTEM**  
The system is designed to be used for all of your interactions with the IRB. Here you can create new applications, modify or update approved studies and view the status of pending submissions. After you select the relevant action from the left hand column, you will be prompted to provide the information needed to complete your submission, including consent forms, as relevant. Your application will be customized to fit the circumstances of your research, depending on your responses as you proceed. The questions are designed to be answered in a sequential order; however, you may use the links in the left column to revisit any portion of the application. Once you have provided the necessary information, your submission will be electronically certified by the principal investigator, routed for department level approvals (when indicated) and then received by the IRB.

- For technical assistance in completing/submitting the online application, call the IRBIS Help Desk (919) 966-3685.
- For substantive questions about IRB reviewer comments, call the IRB Office at (919) 966-3113 and ask to speak with the reviewing IRB coordinator.

[View Sample Application](#)  
Click above to view a sample application with most questions available for review. Your application will differ based on your answers.

Reference ID	IRB Number	Submission Type	Date Submitted	Title	Principal Investigator	IRB Action	View Letters
<a href="#">131397</a>	13-2113	Renewal (Data Analysis)	12/18/2013	CIDRZ-1307 - Antenatal Corticosteroids Trial in Pr...	Albert Manasyan	Letter to PI	
<a href="#">131979</a>	04-1802	Renewal (Data Analysis)	12/18/2013	Genetic Basis of Pain Perception and the Developme...	Luda Diatchenko	Letter to PI	

At your **Home** screen, submissions deferred or returned with minor stipulations are listed as **IRB Correspondence Awaiting PI Response**:

- Click **View Letters** icon to see pdf copy of your contingency letter (not interactive).
- Click [Reference ID](#) to access the **Stipulations** window, listing all IRB stipulations (interactive).

**Note:** Click [View Stipulations](#) link to re-open window, after navigating away.

>> Stipulations Reference ID: 131979

Current Application: [View Stipulations](#)

**INSTRUCTIONS:** Please review and respond to the stipulations found below.

- Click the Go to Question button below each stipulation to navigate to the associated application question; make any requested changes to the application, consent forms or attachments; and click Save and Continue to return to the View Stipulations screen.
- At View Stipulations, below each stipulation, click the Respond button to open a textbox. Briefly describe your response to each stipulation, even if only stating "changes made," or explain why you cannot comply with the IRB's request.
- Only when all changes AND responses are complete, will you be permitted to resubmit. Please click the yellow Proceed to Resubmit button, at bottom of left navigation bar.

**Number of Stipulations: 1**

**General Information**

**2. Project Personnel**  
List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible, do NOT include collaborators who will remain under the oversight of another IRB for this study.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.  
Created by IRB Admin on 12/19/2013 06:58 AM

The application cannot be approved until:

- All Conflict of Interest (COI) filing requirements have been satisfied, AND
- Any potential conflicts have been resolved.

Because this study cannot be approved until these requirements are met, please do not resubmit to the IRB until both requirements are satisfied for all study personnel.

All personnel listed on this study (for whom we have correct email addresses) should have received separate instructions about COI disclosures. The status of COI disclosures can be viewed on the "Personnel" tab on the "Application Status" screen. For anyone not having completed the COI filing requirements be sure the contact information in the online IRB application is correct. If there are questions about COI disclosures already submitted, contact the COI Office at (919) 843-9953 or [coi@unc.edu](mailto:coi@unc.edu).

## Accessing and Responding to Stipulations (2)

Part A. Questions Common to All Studies

Part B. Direct Interaction

Part C. Existing Data, Records, Specimens

Part D. The Consent Process

Number of Stipulations: 2

Part A. Questions Common to All Studies

A.4.A. Biomedical methods and procedures

IDE # (if available)

Created by IRB Admin on 12/16/2013 10:41 PM

Please change this response to "K113455 (510k)"

Respond Go to Question

Responding to each stipulation requires two steps:

- 1) Revise the application:  
\*From **Stipulations**, click *Go to Question*, by stipulation, to access the application.  
\*Revise each response and click *Save and Continue* to return to **Stipulations**.
- 2) Describe the change, or justify why you cannot comply with the IRB's request:  
\*At **Stipulations**, click *Respond* to open each stipulation text box,  
\*Describe/justify, and  
\*Click the *Save Response* button.

Number of Stipulations: 2

Part A. Questions Common to All Studies

A.4.A. Biomedical methods and procedures

IDE # (if available)

Created by IRB Admin on 12/16/2013 10:41 PM

Please change this response to "K113455 (510k)"

Go to Question

Add/Edit Response below

Source

Done

Save Response Cancel Clear Response

Required document(s): IDE Verification or Waiver from FDA

→ K113455.pdf Uploaded by Jonathan Hunter

IDE # (if available)

Stipulation:

Please change this response to "K113455 (510k)"

21 CFR 870.1250

Name of the party holding the IDE (sponsor, investigator or other)

Micro Therapeutics, inc. d/b/a ev3 Neurovascular

Are you requesting a determination from the IRB that this is a non-significant risk (NSR) device study? \*

Yes  No

**Note:** Once you have responded to all stipulations, the *Proceed to Resubmit* button at the bottom of the **Item List** will appear in **red** text, highlighted in yellow, indicating that you may now resubmit.