**Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA**

**Meeting Requests with the FDA**

 **All IDE Meeting Requests must be emailed to the IIS Office for shipment to the FDA. Please provide the IIS office with an eCopy of the meeting request. IIS will format your eCopy to disc, but you are responsible for emailing IIS all PDFs of your submission with proper naming conventions.** Upon receipt of the submission, O3IS will send to the FDA. The IIS should be copied on all correspondence with the FDA.

**Types of Meeting Requests**

1. **The Pre Sub Program –** The main purpose of the Pre-Sub program remains the same as the previously established pre IDE program: to provide the opportunity for a sponsor to obtain FDA feedback prior to an intended submission of an IDE.

The Pre-Sub program is intended to allow sponsors the opportunity to obtain targeted FDA feedback in response to specific questions regarding related to product development, including planned nonclinical evaluations, proposed clinical study protocols, or data requirements prior to making a submission to the Agency.

**When to Submit a Pre-Sub**

Pre-Subs are generally useful for early feedback on specific questions during submission preparation, such as in the following circumstances:

* The new device involves novel technology and it may be helpful to familiarize the FDA review team with the technology in advance of the submission.
* You are proposing a “first of a kind” indication or a new indication for an existing device.
* The new device does not clearly fall within an established regulatory pathway, and you desire informal input on a proposed regulatory strategy.
* The new device is a multiplex device capable of simultaneously testing a large number of analytes.
1. **Informational Meetings –** A sponsor or applicant may request a meeting in which the intent is to share information with FDA without the expectation of feedback. Specifically, an Informational Meeting may be appropriate to:
* Provide an overview of ongoing device development when there are multiple submissions planned within the next 6-12 months, or
* Familiarize the review team about new device(s) with significant differences in technology from currently available devices.

**Format for Requesting Pre-Sub Meeting**

Before submitting any meeting request, the sponsor or applicant should contact the appropriate review division to determine to whom the request should be directed. Be sure to include the following information listed below in the meeting request.

1. **Cover Letter**—The cover letter should clearly state the reason for the submission, for example, Pre Sub for an IDE. In addition, the cover letter should contain complete contact information, as well as clearly identify the name of the device and include the signature of the contact person, or other responsible party.
2. **Table of Contents**
3. **Device Description** – In addition to pictures and a written description, other information about the clinical use of the device, such as a surgical technique guide or video of how the device is used in the clinical setting, may be helpful.
4. **Proposed Intended Use/Indications for Use**
5. **Previous Discussions or Submissions**
6. **Overview of Product Development-** Please provide an overview of the product development,including an outline of nonclinical and clinical testing either planned or completed. However, please note that FDA’s review of a Pre-Sub will not include a review of bench or clinical data that you have already collected.
7. **Specific Questions**
8. **Method for Feedback –**You should specify if you are requesting feedback from the FDA through an in-person meeting, a teleconference, facsimile, or by email. Please note that FDA will ultimately decide the means of communicating the feedback, but will consider the desired method requested in the Pre-Sub.

**If you are requesting a meeting or teleconference as the method for feedback, your submission should include:**

* the meeting format you are requesting (i.e. , in-person or by teleconference);
* three or more preferred dates and times when you are available to meet. Please note that for Pre-submissions the FDA has a 75-90 day window for review.
* the planned attendees, including each attendee’s position, or title, and affiliation. If you have not yet identified all of your attendees, you should indicate the type of subject matter experts you plan to invite so that FDA can ensure that appropriate FDA experts are in attendance.

**Please Note :** You should propose the duration of the meeting you are requesting. One hour is adequate for most meetings. If you believe that more than (1) hour is needed, please provide a rationale for the duration you propose. You should allocate the last 10 minutes of the meeting for summarizing the discussions and any next steps or action actions.

**FDA will aim to schedule a Pre-Sub meeting within 75 days, but no later than 90 days after receipt of the complete Pre-Sub.**

**For more detailed information regarding a Pre-Sub for an SR Device Study Requiring an IDE Application, please select the following link.**

 **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf**

**Format for Requesting an Informational Meeting**

1. A cover letter that clearly identifies the submission type in the reference line.
2. A brief statement describing the purpose, scope, or objectives of the meeting.
3. A proposed agenda describing the devices and/or topics to be presented and the estimated time for each agenda item.
4. The meeting format you are requesting (i.e., in-person or by teleconference).
5. Three or more preferred dates and times when you are available to meet. **Please note that FDA has a 90 day window from receipt of submission to review your request.**
6. The planned attendees, including each attendee’s position, or title, and affiliation.

If you have not yet identified all of your attendees, you should indicate the type of subject matter experts you plan to invite so that FDA can ensure that appropriate FDA experts are in attendance.

**Please Note :** You should propose the duration of the meeting you are requesting. One hour is adequate for most meetings. If you believe more than (1) hour is needed, please provide a rationale for the duration you propose.

**FDA will aim to schedule an Informational Meeting or Teleconference within 90 days of receiving the meeting request.**