

# Suggested IDE Submission Format

The following is a suggested ordered list of components for inclusion in an IDE submission. FDA does not have a standard format for IDE submissions, but does require investigators to supply certain pieces of information. FDA's Device Advice resource lists [required elements](#) for IDE submissions. The following information is adapted from FDA resources as well as Dr. Jelena Berglund's and Dr. David Litwack's presentations at the [NHGRI IDE and Genomics Workshop](#) that took place on June 10<sup>th</sup> 2016.

1. **Cover Letter:** This is the first page of the application[1] and should indicate
  - That the submission is an "Original Investigational Device Exemption Application"
  - IDE application title (i.e. Name of the research group/lab proposing the study)
  - Name of investigator(s) sponsoring the application, their job title(s), and workplace address
  - Test's name and intended use
  - Any previous discussions with the FDA about the application
2. **Table of Contents:** A detailed table of contents describing the contents of the submission.
3. **Name and Address of the Sponsor:** Investigator's name, address, and contact information
  - It is also recommended to provide the name and contact information of an alternate contact who is designated to receive FDA communications about the application. An alternate contact is very helpful given that FDA expects frequent and rapid exchanges while reviewing IDE submissions, and can extend the review period if investigators are not able to return information on time.
4. **Report of Prior Investigations:** A complete report of prior investigations of the test including analytical validity data and an accurate summary of the proposed investigation, including the intended use of the device (this may be the clinical protocol submitted to the IRB).
  - The report of prior investigations must be specific to the intended use in the study.
5. **Investigational Plan:** This section describes the purpose of the study, its protocol, an analysis of all risks to which participants may be exposed during the study, a description of the test pipeline, and monitoring procedures. It is helpful to provide reviewers with a detailed description of the test pipeline explaining its components, how these components work, procedures for use, and picture and diagrams if applicable.

6. **Manufacturing Information:** A description of the methods, facilities, and controls used for manufacture, processing, packing, and storage of the test. *\*This section may not apply in the context of an academic research setting since the investigators do not plan to manufacture and distribute the tests.\**
7. **Investigators Agreement:** A copy of an agreement that will be entered into by all investigators involved in the study should be included. This agreement will state intention to conduct the investigation in accordance with the agreement, the investigational plan, FDA regulations, and conditions of approval imposed by IRB or FDA.<sup>[2][3]</sup> This could include, for example, educational materials describing the test to participants and the test report template. Because genomics tests are not typically discrete devices and not distributed, but are instead run as laboratory developed tests, the information relevant to the test, including the required statement, may be provided on the test report. The labeling may not contain any false or misleading statements or imply that the test is safe and effective. Given the potentially broad nature of labeling, which could extend to published research reports or reviews, depending on the situation, should be careful about making unsupported claims about the device. The labeling may not contain any false or misleading statements or imply that the test is safe and effective.
8. **Copies of Informed Consent:** Briefly summarize what participants will consent to do and the process for obtaining consent. Provide copies of all forms and informational materials that will be provided to the participants in order to obtain informed consent.
9. **Additional Information:** If applicable, include copies of information or correspondence previously submitted or exchanged with FDA regarding the IDE applications. This includes communications surrounding pre-submission meetings.

## Footnotes

[1] Alternatively, investigators may elect to submit FDA's [form 3514](#) in place of the cover letter. The cover letter may allow more flexibility.

[2] The investigators agreement is described in [21 CFR 812.43](#).

[3] For an investigation, the label must include the following statement: "CAUTION Investigational device. Limited by Federal (or United States) law to investigational use." The labeling must also include: all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

*Posted: July 25, 2017*