Columbia University Medical Center
IDE Decision Worksheet
For Investigator-Initiated Clinical Studies

**Note:** The following worksheet is intended to help determine whether an IDE is required for FDA approval prior to initiating your Investigator-Initiated Medical Device Study.

**Device Name and Manufacturer:**

<table>
<thead>
<tr>
<th>IDE Requirements Decision Criteria</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (a) Does the study involve a Medical Device that is being used outside the indications for which labeling that has been approved / cleared by the FDA?</td>
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<tr>
<td>1 (b) Is the investigation intended to be used to support any other significant change in the labeling for the device?</td>
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**If yes to either a or b, proceed to question #2. If no to both, then an FDA approved IDE is not required.**

2. Is the Medical Device a Diagnostic Device?

3. **If answer to question # 2 is NO, skip to question # 4. If YES and the study will involve a Diagnostic Device, it may be exempt from IDE regulations.** According to 21 CFR § 812.2(b)(3), a Diagnostic Device may be considered exempt from IDE regulations if **ALL** of the following are true:

   3(a) The Diagnostic Device complies with the labeling requirements of 21 CFR § 809.10(c).
   3(b) The testing is non-invasive.
   3(c) The testing does **not** require an invasive sampling procedure that presents Significant Risk.
   3(d) The testing does not by design or intention introduce energy into a subject.
   3(e) The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

   **If the device is a diagnostic device and all of the above statements apply, then an IDE is not required.**

4 (a) Is the Investigational Device a **Significant Risk (SR) Device** (per 21 CFR § 812.3(m) and 812.20(a) (1))? **Note: a device is significant risk if any of the following apply (b – e):**

   4 (b) Is the investigational device intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject?
   4 (c) Is the investigational device purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the

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health, safety, or welfare of a subject?

4 (d) Is the investigational device for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject?

4 (e) Does the investigational device otherwise present a potential for serious risk to the health, safety, or welfare of a subject?

If any of questions 4b through 4e is answered YES, the study utilizes a Significant Risk Investigational Device and therefore does require an IDE Approval from the FDA prior to study initiation.

If ALL #4 questions were answered NO, then the Investigator / Sponsor will need to comply with the “Abbreviated IDE Requirements” per 21 CFR § 812.2(b) in addition to the Informed Consent and IRB regulations of 21 CFR § 50 and 56.

Principal Investigator Name (print)

Principal Investigator Signature

Date

IND/IDE Assistance Program USE ONLY:

□ IRB and FDA Approval Required (SR Device)
□ Abbreviated IDE with IRB approval required (NSR device)
□ IDE not needed pending final review from IRB

These preliminary recommendations are based on discussions with the Principal Investigator. Final determination is subject to review and approval by the CUMC IRB.

CTO Medical Director
Signature and Date

CTO Director, Regulatory Affairs & Clinical Development; Signature and Date

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