UNC-CH Investigational Device Worksheet

IRB Study #: **PI Name:**

Name of Device:

Based on your responses to Section A.4.A.6 of the IRB application, you must complete this worksheet. **Please upload** completed form as attachment to your IRB application, **select document type-"Investigational Device"**. If you have questions or need assistance completing this form, please contact the IRB at 919-966-3113.

Complete **Section I** to request an exemption from the IDE requirements. Complete one part only (A, B, C or D).
OR
Complete **Section II** if you are requesting a Non-Significant Risk (NSR) determination.

SECTION I: COMPLETE Part A, B, C or D if you are requesting an Exemption for the IDE requirements.

Part A—LEGALLY MARKETED MEDICAL DEVICE	
If you are requesting an exemption from IDE requirements for the use of a **legally marketed medical device,** please complete this section.	
1. The device being studied is being used in accordance with its cleared/approved labeling.	☐ Yes ☐ No
If YES, your study may be exempt from IDE requirements. **Please provide documentation describing the device and FDA approval or clearance.** Device approval indications may be found by searching one of the FDA Device Approvals and Clearances databases. **If NO,** this exemption does not apply.	

Part B—DIAGNOSTIC DEVICE	
If you are requesting an exemption from IDE requirements for the use of a **diagnostic device,** please complete this section.	
The device(s) being used limited to a diagnostic device(s) (including In vitro devices) and…	
1. The device is non-invasive	☐ Yes ☐ No
2. The device does not require invasive sampling that presents significant risk	☐ Yes ☐ No
3. The device does not introduce energy into the subject Examples of devices that introduce energy: Surgical lasers, MRI, lithotripters, therapeutic X-ray, muscle stimulators; powered dental hand pieces, hearing aids, phototherapy equipment, and ultrasound.	☐ Yes ☐ No
4. The results will not be used to diagnosis or make treatment decisions *without* confirmation using a medically established test	☐ Yes ☐ No
If YES to ALL of questions 1-4, your study may be exempt from the IDE requirements. Please provide documentation describing the device and its use and any information that supports exemption from IDE requirements. Upload as attachment to IRB application using document type "Investigational Device". **If you responded NO to any of questions 1-4,** this exemption does not apply.	

Part C—CUSTOM DEVICE
If you are requesting an exemption from IDE requirements for the use of a **custom device,** please complete this section. A "custom device" is a very specific type of devise. Please review the regulatory definition (21CFR812.3(b)): Custom device means a device that: (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist; (2) Is not generally available to, or generally used by, other physicians or dentists; (3) Is not generally available in finished form for

purchase or for dispensing upon prescription; (4) Is not offered for commercial distribution through labeling or advertising; and (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice. Please refer to *Custom Device Exemption – FDA Guidance Document (9/24/2014)* for additional information.

The devices being used in the study is a custom device and…	
1. The device deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;	☐ Yes ☐ No
2. Is not generally available to, or generally used by, other physicians or dentists;	☐ Yes ☐ No
3. Is not generally available in finished form for purchase or for dispensing upon prescription;	☐ Yes ☐ No
4. Is not offered for commercial distribution through labeling or advertising; and	☐ Yes ☐ No
5. Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.	☐ Yes ☐ No

If YES to ALL of questions 1-5, your study may be exempt from IDE requirements. Please provide documentation describing the device and its use. Upload as attachment to IRB application using document type "Investigational Device".
If NO to one or more of questions 1-5, this exemption does not apply.

Part D—CONSUMER PREFERENCE TESTING

If you are requesting an exemption from IDE requirements for a device undergoing **consumer preference testing,** please complete this section.

Is the device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution and the testing is not for the purpose of determining safety or effectiveness and the device, as used in the study, does not place subjects at risk?	☐ Yes ☐ No

If YES, your study may not subject to IDE regulations. Please provide documentation describing the device and its use. Upload as attachment to IRB application using document type "Investigational Device".
If NO, this exemption does not apply.

SECTION II: Complete if you are requesting a Non-Significant Risk Device determination for this investigation.

Please refer to *Significant Risk and Non-significant Risk Medical Device Studies – FDA Guidance, January 2006* for additional information.
An NSR investigation is one that does not meet the definition for a significant risk (SR) device investigation. The Sponsor is responsible for making the initial risk determination and presenting it to the IRB. The following information will be used by the IRB to make a final risk determination. **IMPORTANT: The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.**

1. Is the investigational device **intended as an implant** and presents a potential for serious risk to the health, safety, or welfare of a subject?	☐ Yes ☐ No

2. 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 health, safety, or welfare of a subject?	☐ Yes ☐ No
3. 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?	☐ Yes ☐ No
4. Does the investigational device **otherwise present a potential for serious risk to the health, safety, or welfare of a subject**?	☐ Yes ☐ No
Justify why the device being studied does not meet criteria for a significant risk device:	

If NO to ALL of questions 1-4, the device meets the definition of a NSR device. Please provide documentation, including related publications, describing device (e.g., manufacturer's manual, illustrations, pictures), and its use. Upload as attachments to IRB application using document type "Investigational Device". The FDA considers an investigation of a non-significant risk device to have an approved IDE when IRB concurs with the non-significant risk determination and approves the study. The sponsor and investigator must comply with "abbreviated IDE requirements" [21 CFR 812.2(b)], and informed consent and IRB regulations [21 CFR parts 50 and 56]. If YES to one or more of questions 1-4, the investigational device being used in this study meets the criteria for a SR device and requires submission of an IDE application to the FDA.

For additional information, please refer to the following guidance documents (Copies can be found here).

1. Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – FDA Guidance, April, 25, 2006

2. Mobile Medical Applications – FDA Guidance, September 25, 2013

3. FDA Decisions for Investigational Device Exemption Clinical Investigations – FDA Guidance, August 19, 2014

4. Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs) –FDA Guidance, June 18, 2015

5. Custom Device Exemption – FDA Guidance September 24, 2014

6. Significant Risk and Non-significant Risk Medical Device Studies – FDA Guidance, January 2006