

	CHECKLIST: Devices			IRB #: \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
	HRP-441	5/5/2025	1 of 3	Status: \$\$Status\$\$

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving *devices*.

- For initial review, modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB Analyst completes this checklist.
- For expedited reviews: the Designated Reviewer reviews the completed checklist and it is retained in the protocol file.
- For review using the convened IRB: the IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations, in which case this checklist does not need to be retained.

1 Does this study use a medical device as defined by the federal regulations? (If “Yes” use the remainder of this checklist. If “No” device regulations do not apply.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Is the device being used as a medical device which involves the following?</p> <p><input type="checkbox"/> The deviceⁱ is intended for use in the diagnosis of the disease or other condition, or in the cure mitigation, treatment, or prevention of disease in humans; and/or</p> <p><input type="checkbox"/> The device is intended to affect the structure or any function of the body in humans and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals; and/or</p> <p><input type="checkbox"/> The software/AI meets the criteria to be regulated as “software as a medical device”ⁱⁱ.</p>
----------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

2 Device Applicability (If either is “Yes” FDA device regulationsⁱⁱⁱ apply. If both are “No” FDA device regulations do not apply.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Does the activity involve the following?</p> <p><input type="checkbox"/> In the United States: The use of a device in one or more persons that evaluates the safety or effectiveness of that device.</p> <p><input type="checkbox"/> Data regarding subjects or control subjects submitted to or held for inspection by FDA^{iv}.</p> <p><input type="checkbox"/> Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA^v.</p>
----------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does this involve a humanitarian use device (HUD)?
----------------------------------------------------------	----------------------------------------------------

3 IDE/HDE Requirements (One must be “Yes” If all are “No” IDE/HDE information is not complete.) All *clinical investigations*^{vi} of devices must have an approved IDE or be exempt from the IDE regulations.

<input type="checkbox"/> Yes <input type="checkbox"/> No	The device has an IDE or HDE. (Complete Sections 4 and 5)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The device qualifies for an abbreviated IDE. (Complete Section 6)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is exempt from the IDE requirements as identified in 21 CFR §812.2(c) of the IDE regulations. (Complete Section 7)

4 IDE/HDE Validation (At least one must be “Yes” If all are “No”, IDE/HDE cannot be validated.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	Sponsor protocol imprinted with the IDE/HDE number.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Written communication from the sponsor documenting the IDE/HDE number.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Written communication from the FDA documenting the IDE/HDE number. (Required if the investigator holds the IDE/HDE.)

5 Device Control (Must be “Yes” If “No”, information regarding device control is incomplete.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.
----------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

6 Abbreviated IDE requirements for NSR device (All must be “Yes”)- Note* HRP-424 needs to be completed for NSR determinations

<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is not a banned by the FDA.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk ^{vii} .
<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigator will not market or promote the device. (21 CFR §812.7)

7 IDE Exemptions (All criteria under one category must be “Yes” for a category to be met. If none of the categories is met, the device is not exempt from an IDE.)

Cat. #1	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is FDA-approved/cleared. ^v
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.

		CHECKLIST: Devices			IRB #: \$\$IRB Number\$\$
		NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
		HRP-441	5/5/2025	2 of 3	Status: \$\$Status\$\$
Cat. #2	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is a diagnostic device (e.g., in vitro diagnostics (IVDs), testing assays, laboratory developed tests (LDTs), and genomic sequencing).			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing is noninvasive. ^{vi}			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing does not require an invasive sampling procedure that presents significant risk. ^x			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing does not by design or intention introduce energy into a subject			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. ^{vii}			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The sponsor will comply with applicable requirements in 21 CFR 809.10(c).			
Cat. #3	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is 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 does not put subjects at risk.			
Cat. #4	<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is a custom device ^{viii} as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.			

ⁱ The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

ⁱⁱ The FDA may regulate software as a device in certain instances-[Software as a Medical Device \(SaMD\) | FDA](#)

ⁱⁱⁱ FDA regulations apply when a study evaluates the safety or effectiveness of a medical device in subjects, healthy control subjects, or human

^{iv} This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

^v The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and [Expiration Dates](#) (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

^{vi} Clinical Investigation- any experiment that involves a test article and one or more human subjects,” when the test article is or would be FDA-regulated. To determine if a study is FDA-regulated, the Quality Assurance team conducts ancillary reviews for studies using investigational drugs and devices to determine the applicability of FDA regulations. For the FDA, clinical investigation is synonymous with research, clinical research, clinical study, and study. Clinical research that also meets the definition of an “Applicable Clinical Trial” (ACT) must meet additional regulatory requirements for the FDA.

^{vii} The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf>)

^v In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

^{vi} Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive.

^x For example, the FDA considers sampling techniques that require biopsy of a major organ, use of general anesthesia, or placement of a blood access line to an artery or large vein (subclavian, femoral, or iliac) to be significant risk. <https://www.fda.gov/media/71075/download>

^{vii} For an investigational study to be exempt under 21 CFR 812.2(c)(3), clinical investigators must use a medically established means of diagnosis (e.g., another cleared or approved IVD or culture) of the disease or condition as the basis for decisions regarding treatment of all subjects participating in the study. 21 CFR 812.2(c)(3)(iv). Additionally, test results from the exempt IVD investigation should not influence patient treatment or clinical management decisions before the diagnosis is established by a medically established product or procedure. If an investigational test uses a new technology or represents a significant technological advance, established diagnostic products or procedures may not be adequate to confirm the diagnosis provided by the investigational IVD. For example, if an investigational test is designed to identify an infection at the earliest stages of viral infection (before formation of antibodies), established diagnostic products or procedures that rely on the detection of antibodies to the virus would be inadequate to confirm diagnoses. Under these conditions the study would not meet the criteria for exemption under 812.2(c)(3) since the testing could not be confirmed with a medically established diagnostic product or procedure. You may consider whether the device is a non-significant risk device subject to abbreviated IDE requirements (21 CFR 812.2(b)). <https://www.fda.gov/media/71075/download>

^{viii} To be considered a custom device, all of the criteria at section 520(b) of the Federal Food, Drug, and Cosmetic Act must be met, which are summarized below: (1) It 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

	CHECKLIST: Devices			IRB #: \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
	HRP-441	5/5/2025	3 of 3	Status: \$\$Status\$\$

or dentist; (2) The device is not generally available to, or generally used by, other physicians or dentists; (3) It is not generally available in finished form for purchase or for dispensing upon prescription; (4) It is not offered for commercial distribution through labeling or advertising; and (5) It is intended for use by an individual patient named in the order form 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 (such as a particular operating tool).

---FOR REFERENCE---

[Clinical Decision Support Software](#), which interprets and explains the changes in section 520(o)(1)(E) of the FD&C Act, and

[Multiple Function Device Products: Policy and Considerations](#), which interprets and presents FDA's approach to section 520(o)(2) of the FD&C Act. FDA's guidance's related to medical device software, including those listed above, will continue to be updated as FDA's thinking evolves, and should be consulted for FDA's current thinking on these topics.

[How to Determine if Your Product is a Medical Device | FDA](#)