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| **FDA – IDE REVIEWER CHECKLIST** |

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| **HRPP USE ONLY** |
| **IRB Application Number:** |  |

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| **PURPOSE**  |

This checklist is a supplement to the non-Exempt reviewer checklist. It should be used as a tool for providing information and support for individuals assessing whether an FDA-regulated study needs an IDE approval from the FDA before conducting the research.

In order to qualify for an abbreviated IDE, the convened IRB (or the assigned reviewer(s) for research eligible for review under expedited category 1) must determine that the device is “non-significant risk”. To make this determination, the IRB should use: **(1)** the criteria in Section 1 of this worksheet; **(2)** the FDA guidance, “[Significant Risk and Nonsignificant Risk Medical Device Studies](https://www.fda.gov/media/75459/download)”.

If a “significant risk” determination is made, the device does not qualify for an abbreviated IDE and the researchers must obtain IDE approval from the FDA.

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| **FDA GUIDANCE** |

Per further FDA guidance, [IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed](https://www.fda.gov/media/85294/download), reviewers should pay particular attention to an investigator’s qualifications to conduct a study submitted for approval to the IRB if the study involves one or more of the following:

* A sponsor- investigator
* A study that is outside the investigator’s area of expertise; or
* Any study design features of other characteristic(s) that may significantly increase potential risks to participants.

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| **RELATED MATERIALS & REGULATORY REFERENCES** |

* [IRB Manual](https://irb.wsu.edu/documents/2022/09/hrpp-manual.pdf) – Section 7, “FDA Regulated Research”
* [21 CFR 56](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56)
* [21 CFR 312](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312)
* [21 CFR 320](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-320)
* [21 CFR 361](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-361)
* FDA Guidance, “[*IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed*](https://www.fda.gov/media/85294/download)”, August 2013
* FDA Guidance, “[*FDA Decisions for Investigational Device Exemption Clinical Investigations*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-decisions-investigational-device-exemption-clinical-investigations)” August, 2014
* FDA Information Sheet Guidance, “[*Frequently Asked Questions About Medical Devices*](https://www.fda.gov/files/about%20fda/published/Frequently-Asked-Questions-About-Medical-Devices---Information-Sheet.pdf)” January, 2006
* FDA Information Sheet Guidance, “[*Significant Risk and Nonsignificant Risk Medical Device Studies*](https://www.fda.gov/media/75459/download)” January 2006

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| **SECTION 1: IS THE USE EXEMPT FROM THE IDE REQUIREMENT?** |

**The use of the device for a specific research study is IDE exempt and does not require IDE approval from the FDA if *all aspects are met within one category listed below (every box should be checked as “Met” in order to qualify)***.

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| **IDE Not Required** | **Met** |
| The project does not qualify for any of the FDA exemption categories (please proceed to evaluation of the PI qualifications and research site) |[ ]

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| **Category 1 – Legally Marketed Device** | **Met** |
| The device is FDA-approved/cleared* In addition to devices that have standard FDA approval, this includes devices cleared for marketing under Premarket Notification 510(k) based on equivalence to another cleared device, and devices that are 501(k) exempt.
 | [ ]  |
| The device being used or investigated in accordance with the indications in the FDA approved/cleared labeling. | [ ]  |
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| **Category 2 – Diagnostic Device** | **Met** |
| The device is a diagnostic device | [ ]  |
| The testing is non-invasive* Blood sampling that involves venipuncture is considered non-invasive for this purpose. The use of surplus samples of body fluids or tissues that are leftover from samples taken for non-investigational purposes is also considered non-invasive.
 | [ ]  |
| The testing does not require an invasive sampling procedure that presents significant risk. | [ ]  |
| The testing does not by design or intention introduce energy into a subject. | [ ]  |
| The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure. | [ ]  |
| The sponsor will comply with applicable requirements (21 CFR 809.10(c)) about labeling of in vitro diagnostic (IVD) products. * If this is not applicable because the device is not an IVD, check the box.
 | [ ]  |
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| **Category 3 – Not Being Evaluated for Safety or Effectiveness** | **Met** |
| The research involves the device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution. | [ ]  |
| The testing is not for the purpose of determining safety or effectiveness. | [ ]  |
| The testing does not put subjects at risk. | [ ]  |
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| **Category 4 – Custom Device Not Being Evaluated for Safety or Effectiveness for Commercial Distribution** | **Met** |
| The device is a custom device that:* Necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician or dentist **-and-**
* Is not generally available to, or generally used by, other physicians or dentists **-and-**
* Is not generally available in finished form for purchase or for dispensing upon prescription **-and-**
* Is not offered for commercial distribution through labeling or advertising **-and-**
* One or both of the following:
	+ 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
 | [ ]  |
| The device is not being used to determine safety or effectiveness for commercial distribution. | [ ]  |
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| **Category 5 – FDA Determination** | **Met** |
| The FDA has provided a documented determination that an IDE is not required for this use of the device. | [ ]  |

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| **SECTION 2: DOES THE USE QUALIFY FOR AN ABBREVIATED IDE?** |

**Please complete this section if any of the exemption categories from Section 1 apply.**

A non-significant risk investigational device study requires only IRB approval prior to starting the study and does not require the submission of an IDE application to the FDA for approval. Instead of calling these studies “exempt”, the FDA considers them to have an approved IDE. This is also known as an abbreviated IDE. To qualify for an abbreviated IDE all of the criteria in the table below must be met.

If the study does not meet the criteria for an abbreviated IDE, an IDE application must be submitted to the FDA for approval to conduct the research.

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| **Abbreviated IDE Criteria** | **Met** |
| The device is not banned by the FDA. | [ ]  |
| **The convened IRB must determine that the device is not a significant risk device.** The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. The IRB should use the **SOP FDA Regulated Research** and the FDA guidance, “[Significant Risk and Nonsignificant Risk Medical Device Studies](https://www.fda.gov/media/75459/download)”. To make a “non-significant risk" determination, ***the following five boxes in this section must be checked***. |
| * 1. It **is not** intended as an implant and **does not** present a potential for serious risk to the health, safety, or welfare of a subject.
 | [ ]  |
| * 2. It **is** **not** purported or represented to be for a use in supporting or sustaining human life and **does not** present a potential for serious risk to the health, safety, or welfare of a subject.
 | [ ]  |
| * 3. It **is** **not** for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and **does not** present a potential for serious risk to the health, safety, or welfare of a subject.
 | [ ]  |
| * 4. It **does not** otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
 | [ ]  |
| * 5. The FDA **has** **not** determined it is “significant risk”.
 | [ ]  |
| The device is labeled by the sponsor in accord with FDA regulations (21 CFR 812.5) and must bear the statement “Caution – Investigational Device. Limited by Federal (or United States) law to investigational use.” | [ ]  |
| The sponsor will comply with FDA requirements for monitoring investigations (21 CFR 812.46). | [ ]  |
| The sponsor and investigator will comply with FDA requirements for records and reports (21 CFR 812.140, 21 CFR 812.150). | [ ]  |
| The sponsor will not market, promote, commercialize, or misrepresent the device (21 CFR 812.7). | [ ]  |

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| **SECTION 3: IS THE INVESTIGATOR QUALIFIED TO CONDUCT FDA-REGULATED RESEARCH?** |

The regulations at [21 CFR 56.107(a)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-B/section-56.107#p-56.107(a)) require that an IRB "...be able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice..." In addition, the regulations at [21 CFR 56.111](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-C/section-56.111) require that an IRB determine that the proposed research satisfies the criteria for approval, including that "...risks to subjects are minimized...[and] reasonable in relation to anticipated benefits, if any, to subjects..." In order to fulfill these responsibilities, the IRB needs information about the qualifications of the investigator(s) to conduct and supervise the proposed research.

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| **PI Qualification** | **Yes** | **No** | **N/A** |
| The PI is qualified to conduct the proposed research. Verification of this has been provided via* Previous WSU IRB approvals, or
* a statement from the department chair has been provided, or
* the curriculum vitae of the PI (or other sub-investigators or study staff) has been included with the submission, or
* for vulnerable participant populations, previous specific experience as shown by recent presentations, or publications, and prior clinical experience with the test article or study-related procedures.
 |[ ] [ ] [ ]
| The FDA’s website has been checked to determine whether a clinical investigator has been the subject of an inspection by the agency and the results have been reviewed.* [FDA Warning Letters](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)
* [Clinical Investigator List](https://www.fda.gov/vaccines-blood-biologics/compliance-actions-biologics/clinical-investigator-status-biologics)

[Clinical Investigator-Disqualification Proceedings](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/clinical-investigators-disqualification-proceedings)* Investigators who conducted a device study from 2009 to present are included in the [Inspection Classification Database](https://datadashboard.fda.gov/ora/index.htm) maintained by FDA’s Office of Regulatory Affairs
* [FDA Debarment List](https://www.fda.gov/fda-debarment-list)
 |[ ] [ ] [ ]

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| **SECTION 4: IS THE RESEARCH SITE ADEQUATE?** |

FDA’s regulations require that before an IRB can approve research covered by the regulations at [21 CFR 56.107(a)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-B/section-56.107#p-56.107(a)), the IRB must "...be able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice..." The regulations also require that each IRB have sufficient information to determine that the proposed research satisfies the criteria for approval at [21 CFR 56.111](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-C/section-56.111).

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| **Site Adequacy – WSU or a major medical institution** | **Yes** | **No** | **N/A** |
| The site is in a WSU facility that is appropriate for the study or the site is part of a major medical institution. |[ ] [ ] [ ]
| **Site Adequacy – Research outside of WSU or a major medical institution** | **Yes** | **No** | **N/A** |
| A statement has been provided from an appropriate person or persons at the stie or institution stating that the facilities are adequate |[ ] [ ] [ ]
| The PI has provided a description of the facility where the research will take place, including it’s staffing and resources relevant to the research under review. |[ ] [ ] [ ]

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| **DETERMINATION** |
| Reviewer notes/Comments: **Please note: THESE WILL NOT BE SENT TO THE PI. Add required changes to the Non-Exempt Review Checklist.** |  |
| Qualifications of the investigator: | [ ]  The PI is qualified to oversee and conduct this research.[ ]  The PI is not qualified to oversee and conduct this research. |
| Research site is adequate: | [ ]  The research site(s) **is/are** adequate for the needs of the study.[ ]  The research site(s) **is/are** **not** adequate for the needs of the study. |
| Device risk: | [ ]  The device is non-significant risk.[ ]  The device is significant risk. |
| Exemption Determination: | [ ]  This study is exempt from an IDE.[ ]  Category 1 – Legally Marketed Device[ ]  Category 2 – Diagnostic Device[ ]  Category 3 – Not Being Evaluated for Safety or Effectiveness[ ]  Category 4 – Custom Device Not Being Evaluated for Safety or Effectiveness for Commercial Distribution[ ]  Category 5 – FDA Determination[ ]  This study does not qualify for an IDE exemption. The sponsor/PI must submit an IDE application to the FDA. |
| **Reviewer name:** |  | **Date:** |  |