**INVESTIGATIONAL DEVICE CHECKLIST**

**Screening Information - Is an IDE Application to FDA Necessary?**

|  |  |
| --- | --- |
| 1. Is the investigation within the categories exempt from the IDE regulation under [§812.2(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2)? (If yes, STOP. An IDE application is not required. ***IRB clearance and informed consent is still required.***) | **Yes/No** |
| 2. Is this a non-significant risk (NSR) device investigation? (If yes, STOP. Submission to and approval from FDA is not required for NSR devices. ***IRB clearance and informed consent is still required.*** | **Yes/No** |
| ***If the answer to both of these questions is no, an IDE application must be submitted to FDA and approval must be obtained from both FDA and the IRB before the study may begin.*** |  |

**Checklist for IDE Cover Letter**

|  |  |
| --- | --- |
| **Element** | **Included** |
| Statement that submission is an original IDE application. | Yes/No |
| Device Information:   * Device Name * Intended Use | Yes/No |
| Sponsor – (must be located in United States) [[§812.18(a)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.18)]:   * Name * Address * Contact Person * Telephone Number * Fax * Email address | Yes/No |
| Manufacturer Information   * Name * Address * Contact Person * Telephone Number * Fax | Yes/No |
| Correspondent Information (Note: IDE application will not be approved without a U.S. sponsor) [[§812.18(a)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.18)]   * Name * Address * Contact Person * Telephone Number * Fax | Yes/No |
| If applicable, provide the following information:   * Q-Submission/Pre-Submission Number * Significant Risk Determination Q-Submission Number * Waiver Requests/Justification * Referenced Files | Yes/No |

**Checklist for an IDE Application**

|  |  |
| --- | --- |
| **Elements [**[**§812.20(b)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)**]** | **Included** |
| Format for submission: Table of contents (recommended) Paginated pages (recommended) | Yes/No |
| **Report of Prior Investigations (**[**§812.27**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27)**):**  Are the following items provided and are they comprehensive and adequate to justify the proposed investigation? |  |
| * Report of all prior clinical, animal and laboratory testing | Yes/No |
| * Bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety and effectiveness of the device | Yes/No |
| * Copies of all published and unpublished adverse information | Yes/No |
| * Summary of all other unpublished information, whether adverse or supportive, that is relevant to an evaluation of safety and effectiveness of the device | Yes/No |
| * Statement whether nonclinical tests comply with the good laboratory practice (GLP) regulations in Part 58   If any studies were not conducted in compliance with the GLP regulation, a brief statement of the reason for the noncompliance must be provided. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study. | Yes/No |
| If any item is not provided, a justification for its omission must be provided. |  |
| **Investigational Plan (**[**§812.25**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25)**):**  Are the following items included, preferably in the following order? |  |
| Purpose: Are the following clearly defined?   * name and intended use of the device * objectives of the investigation * duration of the investigation (specify in months and years) | Yes/No |
| Protocol: Are the following items provided and adequate?   * a written protocol describing the methodology to be used including: * objectives, hypothesis to be tested, or question to be answered * description of the type of trial (i.e., controlled/open, double-blind/single-blind, etc.) * detailed description of the conduct of the trial * description of statistical methods * case report forms * an analysis of the protocol demonstrating its scientific soundness | Yes/No |
| Risk Analysis: Are the following items provided and adequate to determine that the benefit and knowledge to be gained from the investigation outweigh the risks to the subjects?   * a description and analysis of all increased risks to the research subjects * the manner in which risks will be minimized * a justification for the investigation * a description of patient population, including number, age, sex and condition | Yes/No |
| Description of the Device: Are the following items provided and adequate?   * a description of each important component, ingredient and property * the principle of operation of the device * a description of any anticipated changes in the device during the investigation | Yes/No |
| Monitoring Procedures: Are the following items present?   * the written procedure for monitoring the investigation * the name and address of the individual(s) who will monitor the study | Yes/No |
| **Manufacturing Information: [**[**§812.20(b)(3)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)**]**  Is adequate manufacturing information provided to allow a judgement about the quality control of the device (e.g., that the device will meet the intended specifications) based on the description of methods, facilities and controls used for:  a. manufacturing b. processing c. packing d. storage e. installation | Yes/No |
| **Investigator Information: [**[**§812.20(b)(4)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)**]**  Are the following items included? |  |
| Example of investigator agreement [[§812.43(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=812.43)] which should include:   1. the investigator's curriculum vitae; 2. where applicable, a statement of the investigator's relevant experience (including the dates, location, extent and type of experience); 3. if the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination; and 4. a statement of the investigator's commitment to:  * conduct the investigation in accordance with the agreement, the investigational plan, Part 812 and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB and FDA; * supervise all testing of the device involving human subjects; and * ensure that the requirements for obtaining informed consent are met * Investigator’s commitment to provide sufficient and accurate financial disclosure information and update information if any relevant changes occur during the investigation and for one year following the completion of the study. | Yes/No |
| Certification that all participating investigators have signed the agreement and that no investigator will be added until the agreement is signed. [[§812.20(b)(5)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)] | Yes/No |
| Name and address of investigators who have signed the agreement. | Yes/No |
| **IRB Information:**  Are the following items included? |  |
| Name, address, and chairperson of each IRB | Yes/No |
| Certification of the action taken by each IRB, (i.e., approval letter)   * How many IRBs have approved the investigation? * How many IRBs are currently reviewing the investigation or will review it in the future? | Yes/No |
| Names and addresses of any institutions (other than those identified above) where a part of the investigation may be conducted | Yes/No |
| **Sales Information: [**[**812.7(b)]**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.7)  Is the following information provided? |  |
| Is the device to be sold? | Yes/No |
| If yes, is the amount to be charged provided? | Yes/No |
| Explanation of why sale does not constitute commercialization | Yes/No |
| [§812.7(b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.7) prohibits the commercialization of an investigational device by charging subjects or investigators for a device a price larger than necessary to recover costs of manufacture, research, development, and handling. |  |
| Environmental Impact Assessment: [[§812.20(b)(9)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)]  An environmental impact assessment or a claim for categorical exclusion is no longer required. [[§25.34(g)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=25.34)] |  |
| Labeling: [[§812.5](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5)] Are copies of all labeling for the device provided and include the following? |  |
| Does the labeling contain the statement "CAUTION-Investigational Device.” Limited by Federal (or United States) Law to Investigational Use." [[§ 812.5(a))](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5)] | Yes/No |
| Does the labeling contain adequate information for the purposes of the investigation, in accordance with [§812.5(a)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5), including the name and place of business of the manufacturer, packer, or distributor, the quantity of contents, and a description of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions?  If any item is not addressed, a justification for its omission must be provided. | Yes/No |
| Note: The device may not be promoted as safe and effective for the use for which it is being investigated. [[§812.7(d)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.7)] |  |
| **Informed Consent Materials: [**[**21 CFR 50, 812.25(g)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25)**]** |  |
| Are all forms and informational materials to be presented to the subject included? | Yes/No |
| Does the informed consent form seek consent from the subject or a legally authorized representative, when appropriate (e.g., when the subject is a minor)? | Yes/No |
| Does the informed consent form contain the [basic required elements](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.2)?  Required Elements:   * a statement that the study involves research * an explanation of the purposes of the research * the expected duration of the subject's participation * a description of the procedures to be followed * identification of any procedures which are experimental * a description of any reasonably foreseeable risks or discomforts to the subject * a description of any benefits to the subject or others * a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject * a statement describing the extent to which confidentiality of the subject's records will be maintained and that FDA may inspect the records * an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of or sources of further information * an explanation of whom to contact for answers to questions about the study and the subject's rights and whom to contact in the event of a research-related injury * a statement that participation is voluntary and that subjects may refuse to participate or discontinue participation at any time without penalty or loss of benefits | Yes/No |
| Additional Elements Required When Justified:   * A statement that the procedure or treatment may involve unforeseeable risks to subject, or to the embryo or fetus if the subject were to become pregnant * Anticipated circumstances under which the investigator may terminate the subject's participation without regard to the subject's consent * Any additional costs to subject as a result of participation * Consequences of a subject's decision to withdraw and procedures for withdrawal * A statement that significant new findings which may relate to the subject's willingness to participate will be provided to the subjects * The approximate number of subjects involved in the study * Does the consent process involve a "short form" written consent [21 CFR Part 50.27(b)(2))]. If yes, a copy of the "short form" and a written summary of what is to be said to the subject or representative should be provided. | Yes/No/NA |
| The informed consent form may not contain exculpatory language [[21 CFR Part 50.20](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.2)] |  |
| Elements: Informed Consent and Clinical Trials.gov | Included |
| Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA) expanded the ClinicalTrials.gov database to include mandatory registration and reporting of results for applicable clinical trials of human drugs and devices. You should review 42 U.S.C. 282(j) to determine whether the requirements of FDAAA apply to this application/submission. Additional information on registering your clinical trials is available at the Protocol Registration System (PRS) Information Site at <https://prsinfo.clinicaltrials.gov/>.  If this is an “applicable clinical trial” (<https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>), does the informed consent form contain the following statement?:  “A description of this clinical trial will be available on <https://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” | Yes/No/NA |
| Other Information:  Provide additional information supportive of the investigation and any information FDA has identified (through previous contact with the agency or through guidance documents) as required.  If any item is not provided, a justification for its omission must be provided. |  |