



Edit: Board Checklist - CHK\_00007054

&lt;&lt; Back

Save | Exit | Hide/Show Errors | Print... | Jump To: -

Continue &gt;&gt;

IND Determination Checklist ▾

## REVIEWER CHECKLIST

### IND DETERMINATION FOR INVESTIGATIONAL DRUGS

#### DEFINITION:

**Investigational New Drug** means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of 21 CFR Part 312.

Please see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312> for further information on IND regulations.

*After selecting one of the following categories, please answer "True" or "False" to the statements in the tables on the subsequent page to determine whether the drug in this study requires an IND according to federal regulations. Please indicate any revisions or necessary clarifications and your final determination in the area provided on the subsequent page.*

**NOTE: Please keep in mind when all statements of a particular category are true an IND is NOT required. Please select the most appropriate category and press "Continue" to make a final determination.**

- |                                   |   |
|-----------------------------------|---|
| <input type="radio"/> Category #1 | Approved Drugs                          |
| <input type="radio"/> Category #2 | In Vitro Diagnostic Biological Products |
| <input type="radio"/> Category #3 | In Vitro or Animal Use                  |
| <input type="radio"/> Category #4 | FDA Determination of Exemption          |

[Clear](#)

&lt;&lt; Back

Save | Exit | Hide/Show Errors | Print... | Jump To: -

Continue &gt;&gt;

IND Determination Checklist ▾



Edit: Board Checklist - CHK\_00007054

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 1 ▾

Continue >>

**REVIEWER CHECKLIST  
IND DETERMINATION FOR INVESTIGATIONAL DRUGS**

**Category #1: Approved Drugs**

If you answer "TRUE" to all of the following statements, an IND is NOT required.

<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The drug being used in the research is lawfully marketed in the United States.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research is not intended to support a significant change in the advertising for the product.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research is conducted in compliance with FDA requirements for IRB review and informed consent.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The participant or the participant's representative will date the consent document.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Consent documents include a statement that notes the possibility that the FDA may inspect the records.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The requirement for informed consent will not be waived.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The requirement to obtain written documentation of informed consent will not be waived because the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Based upon the protocol, the sponsor or investigator will not commercially distribute or test market the drug.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The protocol indicates that the drug will be provided for free or the FDA has given prior written approval to charge for the drug.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research does not request a waiver from the requirement for informed consent.

**\* Final IND Determination:**

- It is determined that this study requires an IND.
- It is determined that this study meets the federal requirements and does NOT require an IND.
- [Clear](#)

**Comments and Revisions:**

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 1 ▾

Continue >>



Edit: Board Checklist - CHK\_00007054

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 2 ▾

Continue >>

**REVIEWER CHECKLIST**  
**IND DETERMINATION FOR INVESTIGATIONAL DRUGS**

**Category #2: In Vitro Diagnostic Biological Products**

If you answer "True" to all of the following statements, an IND is NOT required.

<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research involves one of the following: Blood grouping serum Reagent red blood cells Anti-human globulin
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The article will be used in a diagnostic procedure that confirms the diagnosis made by another medically established diagnostic product or procedure.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The article is shipped in compliance with <a href="#">§312.160</a> .

**\* Final IND Determination:**

- 
- It is determined that this study requires an IND.
- 
- It is determined that this study meets the federal requirements and does NOT require an IND.
- [Clear](#)

**Comments and Revisions:**

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 2 ▾

Continue >>



Edit: Board Checklist - CHK\_00007054

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 3 ▾

Continue >>

**REVIEWER CHECKLIST  
IND DETERMINATION FOR INVESTIGATIONAL DRUGS**

**Category #3: In Vitro or Animal Use**

If you answer "True" to all of the following statements, an IND is NOT required.

<input type="radio"/> True	<input type="radio"/> False	<a href="#">Clear</a>	The drug is intended solely for tests in vitro or in laboratory research animals.
<input type="radio"/> True	<input type="radio"/> False	<a href="#">Clear</a>	The article is shipped in compliance with §312.160.

**\* Final IND Determination:**

- It is determined that this study requires an IND.
- It is determined that this study meets the federal requirements and does NOT require an IND.

[Clear](#)

**Comments and Revisions:**

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 3 ▾

Continue >>



Edit: Board Checklist - CHK\_00007054

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 4 ▾

Continue >>

**REVIEWER CHECKLIST  
IND DETERMINATION FOR INVESTIGATIONAL DRUGS**

**Category #4: FDA Determination of Exemption**

The research has been submitted to the FDA who determined in writing that an IND is not required.

**\* Final IND Determination:**

- It is determined that this study requires an IND.
- It is determined that this study meets the federal requirements and does NOT require an IND.

Clear

**Comments and Revisions:**

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Category 4 ▾

Continue >>