

	CHECKLIST: Drugs and Biologics			IRB #: \$\$IRB Number\$\$
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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 *drugs or biologics*.

- 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 Drug Applicability

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the activity involve any the following? (Check all that apply) If “No” to both, FDA regulations do not apply. <ul style="list-style-type: none"> <input type="checkbox"/> In the United States: The use of a drugⁱ or a biological product (biologic)ⁱⁱ in one or more persons other than use of an approved drug in the course of medical practiceⁱⁱⁱ. <input type="checkbox"/> Data regarding subjects or control subjects submitted to or held for inspection by FDA^{iv}.
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2 IND Requirements^v (One must be “Yes” If all are “No” IND information is not complete.)¹

<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug has a valid IND. (Complete Sections 3 and 4)
<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug is exempt from the IND requirements (Complete Section 5)

3 IND Validation (At least one must be “Yes” If all are “No” IND cannot be validated.)²

<input type="checkbox"/> Yes <input type="checkbox"/> No	Sponsor protocol imprinted with the IND number.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Written communication from the sponsor documenting the IND number.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Written communication from the FDA documenting the IND number. <i>(Required if the investigator holds the IND.)</i> For investigator held INDs: <ul style="list-style-type: none"> <input type="checkbox"/> The “30-day” waiting period for IND activation has been exhausted. <input type="checkbox"/> The “30-day” waiting period for IND activation has NOT been exhausted. <input type="checkbox"/> The investigator has a “study may proceed” in advance of the “30-day” waiting period for IND activation from the FDA

4 Drug or Biologic Control (Must be “Yes” If “No” information regarding drug control is incomplete.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The plan for storage, control, and dispensing of the drug or biologic is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent. ^{vi}
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5 IND Exemptions (All criteria under one category must be “Yes” for a category to be met. If none of the categories is met, the drug is not exempt from an IND.)

Cat. #1	<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug or biologic is lawfully marketed in the United States.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not intended to support a significant change in the advertising for the product.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The research does not involve a route of administration or dosage level or use in a patient 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="checkbox"/> Yes <input type="checkbox"/> No	The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).
Cat. #2	<input type="checkbox"/> Yes <input type="checkbox"/> No	A clinical investigation for an in vitro diagnostic ^{vii} biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The diagnostic test is shipped in compliance with 21 CFR §312.160.
Cat. #3	<input type="checkbox"/> Yes <input type="checkbox"/> No	A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND.

¹ The investigator is responsible for obtaining the IND number and providing it to the IRB. Studies that involve FDA-regulated products that are submitted without a IND number will be reviewed by the IRB with respect to determining the need for an IND, based on federal requirements and the investigator’s response to questions posed by the IRB.

² Most INDs are passively approved. When the FDA receives the application, the FDA assigns an IND number. A letter is sent to the applicant providing the IND number, however, this number should not be mistaken as an “approval letter.” In most cases, passive approval is assumed if there has been no formal contact from the FDA within 30 days of the submission of the IND application to the FDA. Studies cannot be initiated until after the 30-day period (and until the IRB has approved the study).

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Cat. #4	<input type="checkbox"/> Yes <input type="checkbox"/> No	The active moiety in the drug product is identical to that in an FDA approved drug.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug product is not radioactively labeled.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug is not cytotoxic			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1) and safety reporting in 21 CFR 320.31(d)(3).			
Cat. #5	<input type="checkbox"/> Yes <input type="checkbox"/> No	The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)			
Cat. #6	<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies.			
	<input type="checkbox"/> Yes <input type="checkbox"/> No	The quality of the cold isotope meets relevant quality standard			

ⁱ The term "drug" means:

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

ⁱⁱ The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

ⁱⁱⁱ "Other than the use of an approved drug in the course of medical practice" refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

^{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.

^{vi} 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. The investigator must maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.

^{vii} An in vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health Service Act.

Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND – FDA guidance for Clinical Investigators, Sponsors and IRBs (SEPTEMBER 2013) <https://www.fda.gov/media/79386/download>