PI: **Click or tap here to enter text.** Protocol # **Click or tap here to enter text.**

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| --- |
| Drugs, Biologics, Cosmetics, Food, or Dietary Supplements |
| Product Name(s) *[If more than 1, list all products here]*: **Click or tap here to enter text.** | [ ]  Product(s) added to submission in PennERA |
| **Section A: Type of Product** |
| 1. Which of the following categorizes the product(s)?

*[If more than one product, check all that apply]* | [ ]  Drug/Biologic: continue to A2[ ]  Dietary Supplement: continue to A3[ ]  Food: continue to A4[ ]  Cosmetic: continue to A5[ ]  Placebo 🡪 ***If investigator-initiated trial, determine who is manufacturing the placebo. If IDS, notify OCR SSU***[ ]  Other: **Click or tap here to enter text.** 🡪 ***Consult with Sr. Administrator, Director, or OCR SSU if not clear how to proceed.***Comments (if necessary): **Click or tap here to enter text.** |
| 1. **Drug/Biologic**:
	1. Is the drug / biologic marketed in the United States (FDA approved)?

*[If more than one product, check all that apply and include any clarifications in the comments]* | [ ]  Yes, continue to 2b[ ]  No, continue to Section B🡪 ***If not marketed in the US, product is investigational, and study must be conducted under an IND***Comments (if necessary): **Click or tap here to enter text.** |
| * 1. Is the drug/biologic being used according to the marketed / approved labelling (indication, dosing, population, and administration)?

*[If more than one product, check all that apply and include any clarifications in the comments]*Note: If the study involves a combination of approved products in an investigational manner or the study involves an investigational product in combination with approved product(s), please note this in the comments. | [ ]  YesPackage Insert: [ ]  **Submitted** or [ ]  **Requested**[ ]  No, **product is investigational** continue to Section BComments (if necessary): **Click or tap here to enter text.** |
| 1. **Dietary supplement**: Is the purpose of the study to evaluate the product’s ability to diagnose, cure, mitigate, treat, or prevent disease?

Note: A dietary supplement does not require an IND if the intention is only to study the effect on the structure or function of the body | [ ]  Yes, continue to Section B[ ]  No 🡪 Study is likely IND exempt. Consult with Sr. Administrator, Director, or OCR SSU as necessary.Supplement Labelling: [ ]  **Submitted** or [ ]  **Requested**[ ]  Unsure🡪 ***Consult with Sr. Administrator, Director, or OCR SSU*** |
| 1. **Food / Food additives**: Is the purpose of the study to…
	1. Evaluate the product’s ability to diagnose, cure, mitigate, treat, or prevent disease?
 | [ ]  Yes, **product is investigational** continue to Section B[ ]  No, continue to 4b[ ]  Unsure🡪 ***Consult with Sr. Administrator, Director, or OCR SSU*** |
| * 1. Evaluate the food product’s effect on the structure or function of the body (*other than from its nutritive value*)?

Note: A food or food additive does not generally require an IND if the intention is to evaluate nutritional effects. | [ ]  Yes 🡪 **product is investigational** continue to Section B[ ]  No 🡪 Study is likely IND exempt. Consult with Sr. Administrator, Director, or OCR SSU as necessary.  |
| 1. **Cosmetic**: Is the purpose of the study to…
	1. Evaluate the product’s effect the structure or function of the body?
 | [ ]  Yes, continue to Section B[ ]  No, continue to 5b[ ]  Unsure🡪 ***Consult with Sr. Administrator, Director, or OCR SSU*** |
| * 1. Evaluate the product’s ability to diagnose, cure, mitigate, treat, or prevent disease?
 | [ ]  Yes 🡪 **product is investigational** continue to Section B[ ]  No 🡪 Study is likely IND exempt. Consult with Sr. Administrator, Director, or OCR SSU as necessary.Labelling: [ ]  **Submitted** or [ ]  **Requested**[ ]  Unsure🡪 ***Consult with Sr. Administrator, Director, or OCR SSU*** |
| **Section B: Product is investigational** |
| 1. Is the study being conducted under an IND?
 | [ ]  Yes🡪 answer 1a-d[ ]  No, continue to 2 |
| 1. IND Number
 | **Click or tap here to enter text.** |
| 1. IND Holder (Regulatory Sponsor)

**\*\*If the PI or another Penn Faculty member is the Regulatory Sponsor, request that he/she register as a Sponsor.** Registration is only required for PSOM Faculty but recommended for Faculty at other schools. Information can be found online here: [www.med.upenn.edu/ocr/sponsor-training.html](http://www.med.upenn.edu/ocr/sponsor-training.html) | [ ]  Drug Manufacturer: **Click or tap here to enter text.**[ ]  Principal Investigator[ ]  The University[ ]  Other: **Click or tap here to enter text.**[ ]  Unclear🡪 ***Request from the PI, and include a stipulation that IND Sponsor or Regulatory Sponsor on the Sponsor Page is appropriately updated*** |
| 1. IND Documentation

The IND number must either match the number on the sponsor protocol with the same title as the proposed research, or be listed on communication from the sponsor specific to the proposed research, or on communication with the FDA. | [ ] Submitted or [ ]  Requested**🡪 Stipulation: *Please provide documentation of the IND number from the sponsor or the FDA that is specific to this research protocol.*** |
| * 1. If this study involves a combination of approved products in an investigational manner OR the study involves an investigational product in combination with approved product(s), do the study documents make clear that the IND covers the combination of products?
 | [ ]  Yes or [ ]  No **🡪**  **Request study team clarify this aspect.** |
| 1. Product Safety Information

Investigator’s Brochure (IB): For investigational productsNote: Single site Sponsor-Investigator trials do not require an IB. Package Insert: For marketed products | [ ] IB 🡪 [ ]  **Submitted or** [ ]  **Requested**[ ]  No IB 🡪 ***Confirm in advance of the meeting that there is no IB and that all relevant product information is present in the protocol.***[ ]  Package Insert: 🡪 [ ]  **Submitted** or [ ]  **Requested** |
| **IND Data Entry and Notes*** Update Penn ERA Summary Page, to add the IND number and the IND Regulatory Sponsor
 |
| 1. Is the study being conducted under an IND Exemption?
 | [ ]  Yes, answer 2a-bPackage Insert: [ ]  **Submitted** or [ ]  **Requested**[ ]  No |
| * 1. Is the documentation of the IND Exemption attached?

  | [ ]  Yes[ ]  No 🡪 continue to 2b |
| * 1. If no documentation is attached, who will make the determination?

Note: An IND exemption may be granted by: **FDA****OCR SSU**: PSOM PIs only; all product types**PSOM** **Department of Radiology:** Imaging agents (incl. Gadolinium)**RRSC**: Nuclear Med. Agents (radiopharmaceuticals)**IRB:** Consult with Sr. Administrator, Director, or OCR SSU as needed. | [ ]  **FDA**[ ]  **OCR SSU** [ ]  **Dept. of Radiology**[ ]  **RRSC****Stipulation: Please submit documentation of the IND exemption that is specific to this research protocol.**[ ]  **IRB** 🡪 all product types🡪 **If > minimal risk study,** add to agenda notes: Note: Investigator is requesting the IRB to make determination at convened meeting-Ask investigator to complete the supplemental form, Research with Investigational Drugs-Contact the Regulatory Representative🡪 **If minimal risk study,** ask investigator to complete the supplemental form, Research with Investigational Drugs. (NOTE: cases will be rare where an investigational product is minimal risk. An example might be: food/food additive, supplement, OTC product, aromatherapy, or other GRAS product that is commercially available).  |
| Comments: **Click or tap here to enter text.** |
| **IND Exemption Data Entry and Notes:** * Update Penn ERA Summary Page, Pending Issue that may Impact Future Reviews to reflect that the study has an IND exemption
* If the IRB is issuing the exemption: Include an exemption note in the letter
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