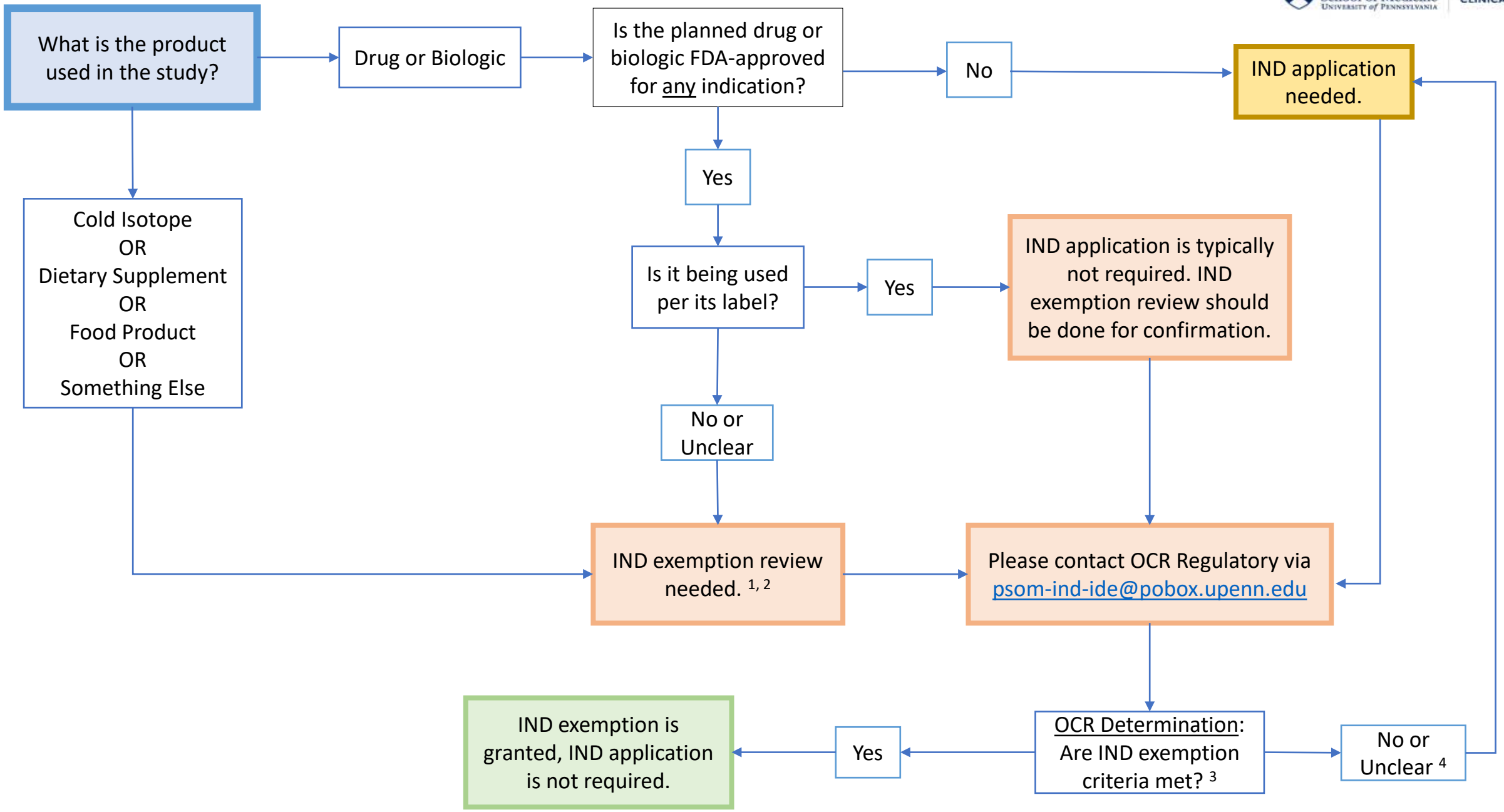

Footnotes

1. Penn investigators are not permitted to self-exempt from IND regulations.
2. Please send the following for review:
   - Protocol (draft OK)
   - Drug information
3. IND Exemption Criteria:
   - The investigational drug is lawfully marketed in the United States.
   - The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use of the drug product.
   - The investigation is not intended to support a significant change in advertising to an existing lawfully marketed prescription drug product.
   - The investigation 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.
   - The investigation is conducted in compliance with the requirements for institutional review (21 CFR 56) and informed consent (21 CFR 50).
   - The investigation is conducted in compliance with the requirements of 21 CFR 312.7: i.e., the drug may not be represented as safe or effective, nor may it be commercially distributed, for the purposes for which it is under investigation.
4. In certain cases, OCR may defer to the FDA for the exemption determination. In these cases, OCR will assist in submitting an IND Exemption Request to the FDA.