THE OHIO STATE UNIVERSITY

FDA-Regulated Drug Studies
Tools for Investigators

The Office of Responsible Research Practices has created several tools to assist Ohio State investigators in completing application materials when research reviewed by an Ohio State IRB involves articles regulated by the FDA as drugs. The tools are designed to be used sequentially.

Note: These tools do not account for emergency use, expanded access, or other "compassionate use" scenarios.

Step 1: Determine whether your study involves a drug as defined by the FDA.
"Drug" means any article that is:
- *Recognized by the FDA as an approved drug; or*
- *Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or*
- *Not a food or dietary supplement but is intended to affect the structure or any function of the body.*

Step 2: Use the **Common Drug Research Scenarios Decision Tree** to determine which of the **five drug scenarios** applies to your research.

Step 3: Use the **Buck-IRB Cheat Sheet** for drug research to see a list of Buck-IRB pages that must reflect the administration and/or evaluation of drugs, as well as which documents must be revised and/or provided for IRB review.

Step 4: Refer to the **Buck-IRB Drug Research Screenshots** for details about how to complete the Buck-IRB application form to reflect the drug research scenarios involved in your study.

Remember:

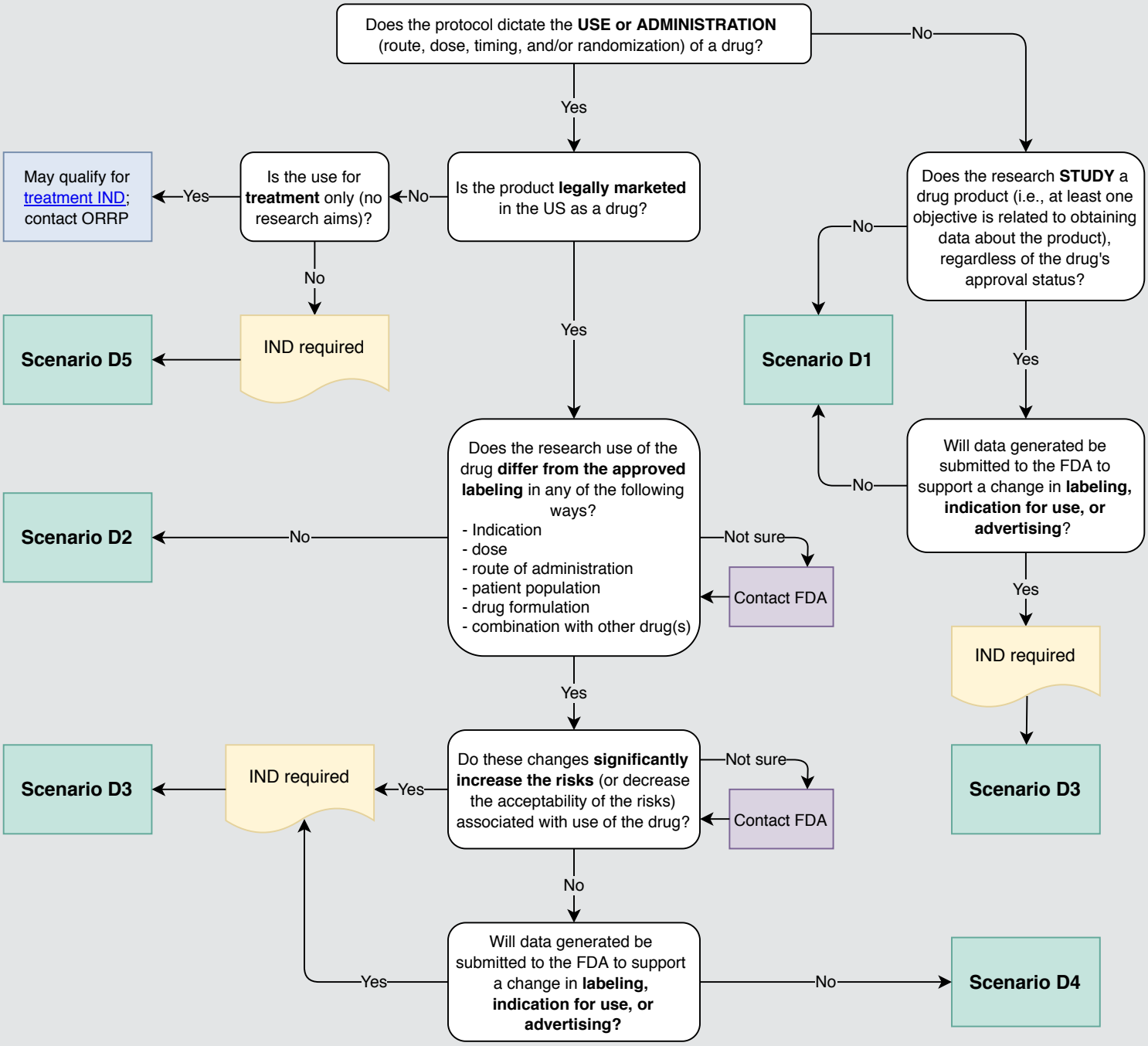
- Multiple drug scenarios may be applicable to a single study.
- If multiple drugs are studied/administered, use the decision tree and tools *for each drug separately*.
- Questions? Contact ORRP for further guidance.

These tools are provided for educational purposes only and should not be considered official regulatory documents.

THE OHIO STATE UNIVERSITY

DECISION TREE:
COMMON DRUG RESEARCH SCENARIOS

*If your study involves administering a drug product[1] or has aims related to drug products, use the decision tree to determine which of the **five most common drug research scenarios** applies to your research and whether or not an IND may be required. Please note, the decision tree does not account for every possible scenario or IND exemption.*



[1] "Drug" means any article that is (1) recognized by the FDA as an approved drug; (2) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or (3) not a food or dietary supplement but is intended to affect the structure or any function of the body. In the context of FDA-regulated clinical investigations, drugs include not only prescription and over-the-counter drug products, but also biologics, foods, dietary supplements, cosmetics, and tobacco products when the intended use in the study meets meets the definition above.

This decision tree is provided for educational purposes only and should not be considered an official regulatory document.

Buck-IRB Cheat Sheet: FDA-Regulated Drug Research

This cheat sheet reflects the five most common drug research scenarios. It does not account for every possible scenario or IND exemption.

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect drug information
Scenario D1	Drug(s) **not** administered per protocol, may or may not be focus of research *Examples:* *Exercise intervention in ex-smokers currently using nicotine patch (drug) vs. current smokers* *Comparison of three commonly prescribed antibiotics following surgery; treating physicians (not researchers) determine appropriate dose/drug for their patients*	Clinical investigation: No* IND: No*	Required • None As applicable‡ • Funding & Financial Conflicts (if support provided by drug manufacturer) • Participant Population (if drug(s) are related to eligibility criteria) • Confidentiality of Data (if drug manufacturer will receive study data)	Required • Protocol As applicable • Consent form (should not include risks of drugs)
Scenario D2	**Approved drug(s)** administered and: • the use is **dictated by protocol** • used **according to label** ("on label") • may or may not be focus of research *Examples:* *Lidocaine administered during research biopsy; lidocaine not focus of research* *Comparison of three commonly prescribed antibiotics following surgery; participants are randomized to one of three drugs*	Clinical Investigation: Yes IND: No*	Required • Research Methods & Activities • Drugs or Biologics • Drugs (Supplemental Questions) • Alternatives to Study Participation • Risks, Harms, and Discomforts As applicable‡ • Funding & Financial Conflicts (if support provided by drug manufacturer) • Participant Population (if drug(s) are related to eligibility criteria) • Confidentiality of Data (if drug manufacturer will receive study data) • Monitoring (if greater than minimal risk)	Required • Approved labeling for each drug (package insert, generic drug monograph) • Protocol • Consent form As applicable • Recruitment materials • Subject materials/instructions, etc.

Buck-IRB Cheat Sheet: FDA-Regulated Drug Research

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect drug information
Scenario D3	**Approved drug(s)** administered and: • the use is **dictated by protocol** • used **"off label"** (different indication, dose, route of administration, population, or drug combination) • off-label use **significantly increases the risk** or decreases the acceptability of the risk of the drug product *Example:* *Participants receive experimental ("off-label") combination therapy of two approved drugs where drug interactions are unknown*	Clinical investigation: Yes IND: Yes	Required • Research Methods & Activities • Drugs or Biologics • Drugs (Supplemental Questions) • Alternatives to Study Participation • Risks, Harms, and Discomforts As applicable‡ • Funding & Financial Conflicts (if support provided by drug manufacturer) • Participant Population (if drug(s) are related to eligibility criteria) • Confidentiality of Data (if drug manufacturer will receive study data) • Monitoring (if greater than minimal risk)	Required • Approved labeling for each drug (package insert, generic drug monograph) or Investigator's Brochure • IND Documentation: FDA IND "study may proceed letter" (for investigator-initiated studies) or IND# on protocol (if sponsor is external to Ohio State) • Protocol • Consent form As applicable • Recruitment materials • Subject materials/instructions, etc.
Scenario D4	**Approved drug(s)** administered and: • use **dictated by protocol** • **used "off-label"** (different indication, dose, route of administration, population, or drug combination) • Off-label use **does not** significantly increase the risk or decrease the acceptability of the risk of the drug product *Example:* *Participants receive experimental ("off-label") combination therapy of two approved drugs where off-label use is widely recognized as standard of care and/or where existing literature suggests low risk of adverse drug interactions*	Clinical investigation: Yes IND: No*	Required • Research Methods & Activities • Drugs or Biologics • Drugs (Supplemental Questions) • Alternatives to Study Participation • Risks, Harms, and Discomforts As applicable‡ • Funding & Financial Conflicts (if support provided by drug manufacturer) • Participant Population (if drug(s) are related to eligibility criteria) • Confidentiality of Data (if drug manufacturer will receive study data) • Monitoring (if greater than minimal risk)	Required • Approved labeling for each drug (package insert, generic drug monograph) or Investigator's Brochure • Documentation of IND exemption from FDA (if available) or explanation of how study meets IND exemption criteria • Protocol • Consent form As applicable • Recruitment materials • Subject materials/instructions, etc.

Buck-IRB Cheat Sheet: FDA-Regulated Drug Research

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect drug information
Scenario D5	**Unapproved drug(s)** administered; may or may not be object of study *Examples:* *First-in-human study of novel drug therapy* *Evaluation of cranberry juice as treatment for urinary tract infection* *Unapproved formulation of approved drug (e.g., compounded at commercial pharmacy/"homemade" formulation) is administered*	Clinical investigation: Yes IND: Yes	Required • Research Methods & Activities • Drugs or Biologics • Drugs (Supplemental Questions) • Alternatives to Study Participation • Risks, Harms, and Discomforts As applicable‡ • Funding & Financial Conflicts (if support provided by drug manufacturer) • Participation Population (if drug(s) are related to eligibility criteria) • Confidentiality of Data (if drug manufacturer will receive study data) • Monitoring (if greater than minimal risk)	Required • Investigator's Brochure for each unapproved drug • IND Documentation: FDA IND "study may proceed letter" (for investigator-initiated studies) or IND# on protocol (if sponsor is external to Ohio State) • Protocol • Consent form As applicable • Recruitment materials • Subject materials/instructions, etc.

* Unless data will be submitted to FDA. If the drug manufacturer is sponsoring the research (including providing study drug) or will receive study data, the study is likely FDA-regulated and may require an IND.

‡ Buck-IRB page designated "as applicable" are not represented in the Buck-IRB Screenshots that follow.

Drug Scenario D1

Drug(s) NOT administered per protocol; may or may not be focus of research

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

As drugs are not part of the research intervention, they should not be described here (except to differentiate groups of participants or to describe analysis of data related to the drug(s)).

Check all research activities and/or components that apply.

- ☐ Anesthesia (general or local) or sedation
- ☐ Audio, video, digital, or image recordings
- ☐ Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- ☐ Biological sampling (other than blood)
- ☐ Blood drawing
- ☐ Coordinating center
- ☐ Data repositories (future unspecified use, including research databases)
- ☐ Data, not publicly available
- ☐ Data, publicly available (e.g., census data, unrestricted data sets)
- ☐ Deception
- ☐ Devices
- ☐ Diet, exercise, or sleep modifications
- ☐ Drugs or biologics (including dietary supplements/ingredients)
- ☐ Emergency research

Drugs should NOT be checked in this scenario

- [ ] Focus groups
- [ ] Food supplements
- [ ] Gene transfer
- [ ] Genetic testing
- [ ] Internet or e-mail data collection
- [ ] Magnetic resonance imaging (MRI)
- [ ] Materials that may be considered sensitive, offensive, threatening, or degrading
- [ ] Non-invasive medical procedures (e.g., EKG, Doppler)
- [ ] Observation of participants (including field notes)
- [ ] Oral history (does not include dental or medical history)
- [ ] Placebo
- [ ] Pregnancy testing
- [ ] Program Protocol (Umbrella Protocol)
- [ ] Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
- [ ] Randomization
- [ ] Record review (which may include PHI)
- [ ] Specimen research
- [ ] Stem cell research
- [ ] Storage of biological materials (future unspecified use, including repositories)
- [ ] Surgical procedures (including biopsies)
- [ ] Surveys, questionnaires, or interviews (group)
- [ ] Surveys, questionnaires, or interviews (one-on-one)
- [ ] Other (Specify)

Drug Scenario D2

Legally marketed drug(s) used per label; use dictated by protocol

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

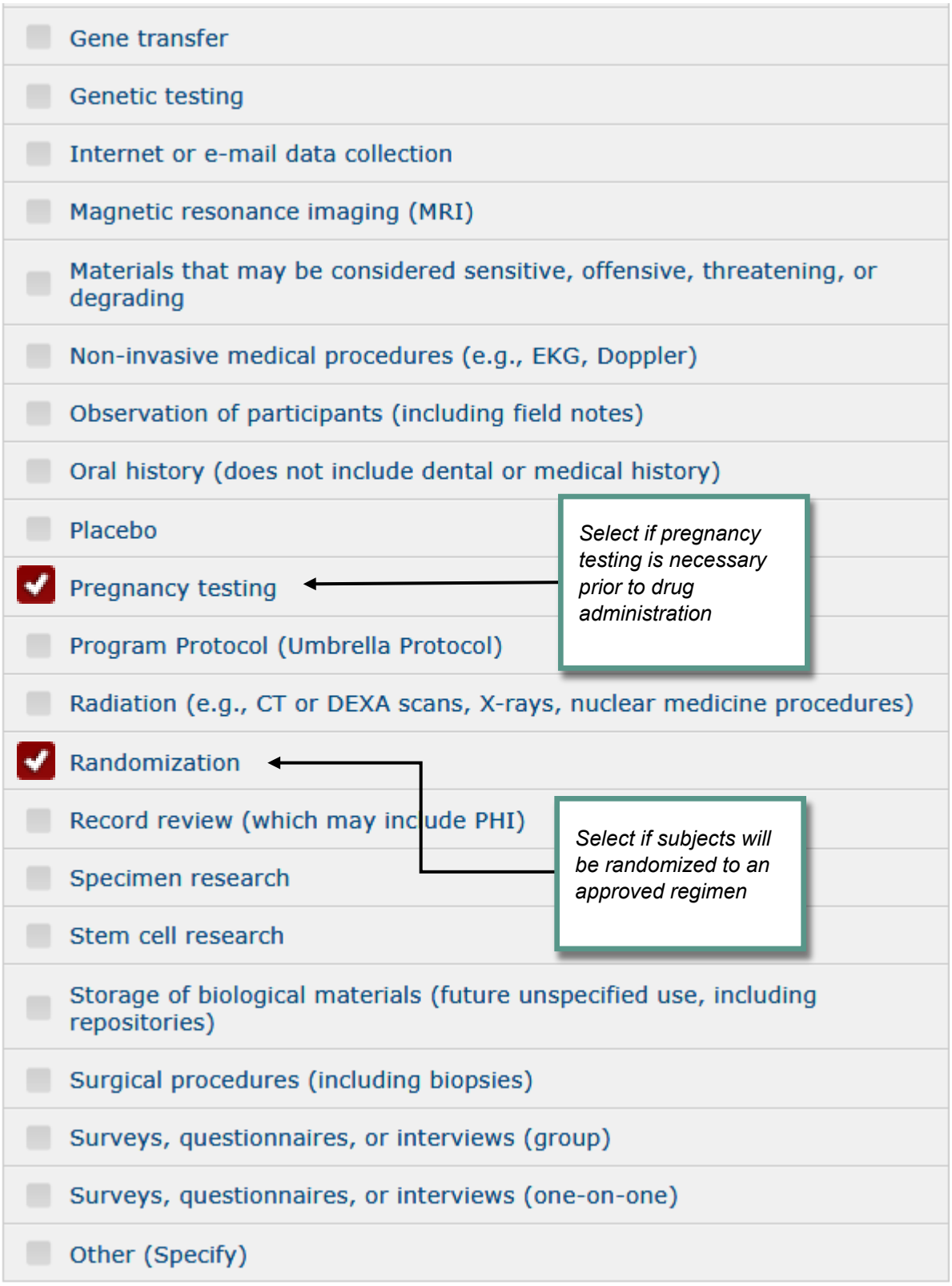
Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of drug here, including how administration is dictated by the protocol (e.g., randomization, timing, dose, etc.).

Check all research activities and/or components that apply.

- [x] Anesthesia (general or local) or sedation
- [ ] Audio, video, digital, or image recordings
- [ ] Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- [ ] Biological sampling (other than blood)
- [ ] Blood drawing
- [ ] Coordinating center
- [ ] Data repositories (future unspecified use, including research databases)
- [ ] Data, not publicly available
- [ ] Data, publicly available (e.g., census data, unrestricted data sets)
- [ ] Deception
- [ ] Devices
- [ ] Diet, exercise, or sleep modifications
- [x] Drugs or biologics (including dietary supplements/ingredients)
- [ ] Emergency research
- [ ] Focus groups
- [ ] Food supplements

If the research includes the use of an anesthetic (lidocaine, etc.), this box should be checked.


Gene transfer
Genetic testing
Internet or e-mail data collection
Magnetic resonance imaging (MRI)
Materials that may be considered sensitive, offensive, threatening, or degrading
Non-invasive medical procedures (e.g., EKG, Doppler)
Observation of participants (including field notes)
Oral history (does not include dental or medical history)
Placebo
Pregnancy testing
Program Protocol (Umbrella Protocol)
Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
Randomization
Record review (which may include PHI)
Specimen research
Stem cell research
Storage of biological materials (future unspecified use, including repositories)
Surgical procedures (including biopsies)
Surveys, questionnaires, or interviews (group)
Surveys, questionnaires, or interviews (one-on-one)
Other (Specify)
Select if pregnancy testing is necessary prior to drug administration
Select if subjects will be randomized to an approved regimen

Drugs or Biologics

Select from the options below to request inclusion of drugs or biologics (e.g., vaccines, cellular products, blood- or plasma-derived products) in the proposed research. Include only those drugs or biologics that are to be administered as part of the research protocol (i.e., not those administered for routine care or evaluation). Enter as many drugs or biologics as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining INDs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For assistance with drug accountability and recordkeeping procedures, contact the OSUMC Department of Pharmacy at 614-293-8470. For more information on the requirements for conducting research involving investigational drugs or biologics, see HRPP policy Research Involving Investigational Drugs.

Add each legally marketed drug that will be administered per label, even if multiple drugs will be used for the same purpose (e.g., two anesthetics being used per protocol)

FDA Approved Products

Includes drugs or biologics approved for this indication, route/dose, or study population.

Name of drug or biologic	**Name of drug(s)**
Generic name or active ingredient	**Generic name or active ingredients of drug(s)**
Brand name	**Brand name(s)**
Dose and dosage form (e.g., 10mg tablet)	**Note that this is the *approved* dosage/route of administration, as the drugs are used per label in this scenario.**

Frequency and route of administration

Describe frequency of use and route of administration (Note: if frequency/route of administration differs from the approved labeling, Scenario 3 or 4 will apply rather than Scenario 2)

Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

Describe drug here.

Provide the proposed rationale for choice of this agent in the research (compared to other drugs that could have been used).

Explain why the drug is being used in this research.

Summarize the potential side effects (including serious warnings and more common side effects).

Provide a snapshot of the *most common* side effects; these may be summarized by grouping side effects into general categories (e.g., "mild to moderate short-term GI side effects"), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the drug packaging.

Is preparation or repackaging of the supplied product necessary before administration or dispensing?

Yes	No

State who will perform these activities and where they will be performed.

Note: This question appears only when "Yes" is selected above.

Provide a copy of the drug or biologic manufacturer's approved labeling (i.e., package insert), Investigator's Brochure (IDB), or other equivalent information.

UPLOADED FILES

No files have been uploaded.

See next page for an example of approved labeling.

Click Select Files to add files to this form.
files greater than 20MB, please see instructions for large files.

For approved products, ensure that the package insert is readable. See Drugs at FDA or the manufacturer's website for printable versions.

SELECT FILES

Use this link to download up-to-date approved labeling

Page 1 of approved label for Tylenol (example)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Acetaminophen Injection safely and effectively. See full prescribing information for Acetaminophen Injection.

Acetaminophen Injection, for intravenous use
Initial U.S. Approval: 1951

WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY
See full prescribing information for complete boxed warning

Take care when prescribing, preparing, and administering Acetaminophen Injection to avoid dosing errors which could result in accidental overdose and death. (5.3)

Acetaminophen Injection contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product. *(5.1)*.

----------INDICATIONS AND USAGE----------
Acetaminophen injection is indicated for the:
- Management of mild to moderate pain. (1)
- Management of moderate to severe pain with adjunctive opioid analgesics. (1)
- Reduction of fever. (1)

----------DOSAGE AND ADMINISTRATION----------
- Acetaminophen injection may be given as a single or repeated dose. (2.1)
- Acetaminophen injection should be administered only as a 15 minute intravenous infusion. (2.4)

Adults and Adolescents Weighing 50 kg and Over:
- 1,000 mg every 6 hours or 650 mg every 4 hours to a maximum of 4,000 mg per day. Minimum dosing interval of 4 hours. (2.2)

Adults and Adolescents Weighing Under 50 kg:
- 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours. (2.2)

Children:
- Children 2 to 12 years of age: 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
- Injection for intravenous infusion.
- Each 100 mL flexible plastic container has 1,000 mg acetaminophen (10 mg/mL). (3)

----------CONTRAINDICATIONS----------
Acetaminophen is contraindicated:
- In patients with known hypersensitivity to acetaminophen or to any of the excipients in the IV formulation. (4)
- In patients with severe hepatic impairment or severe active liver disease. (4)

----------WARNINGS AND PRECAUTIONS----------
- Administration of acetaminophen in doses higher than recommended (by all routes of administration and from all acetaminophen-containing products including combination products) may result in hepatic injury, including the risk of liver failure and death. (5.1)
- Do not exceed the maximum recommended daily dose of acetaminophen (by all routes of administration and all acetaminophen-containing products including combination products). (5.1)
- Take care when prescribing, preparing, and administering acetaminophen injection to avoid dosing errors which could result in accidental overdose and death. (5.3)
- Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, in cases of alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment (creatinine clearance ≤ 30 mL/min). (5.1)
- Discontinue acetaminophen immediately at the first appearance of skin rash and if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. (5.2, 5.4)

----------ADVERSE REACTIONS----------
The most common adverse reactions in patients treated with acetaminophen were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, Vigilance & Medical Affairs at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential. (7.1)
- Chronic oral acetaminophen use at a dose of 4,000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant. (7.2)

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Category C. There are no studies of intravenous acetaminophen in pregnant women. Use only if clearly needed. (8.1)
- Nursing Mothers: Caution should be exercised when administered to a nursing woman. (8.3)
- Pediatric Use: The effectiveness of acetaminophen for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age. The safety and effectiveness of acetaminophen in pediatric patients older than 2 years is supported by evidence from adequate and well-controlled studies in adults with additional safety and pharmacokinetic data for this age group. (8.4)
- Geriatric Use: No overall differences in safety or effectiveness were observed between geriatric and younger subjects. (8.5)
- Hepatic Impairment: Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. (4, 5.1, 8.6)
- Renal Impairment: In cases of severe renal impairment, longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted. (5.1, 8.7)

Revised: 10/2015

FULL PRESCRIBING INFORMATION: CONTENTS*

Reference ID: 3839318

Drugs (Supplemental Questions)

Does the research involve the use of Botox, Xeomin, Dysport or any formulation containing botulinum toxin at any dose?

Yes | No

Select Yes or No as appropriate

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes | No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different drug(s) or other treatment**
- **Receiving the drug(s) at a dose, frequency, and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of drugs listed elsewhere or copy a comprehensive list of side effects from drug labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual side effects of study drugs.

Drug Scenario D3

Legally marketed drugs used off-label; does not meet IND exemption criteria

Research Methods & Activities

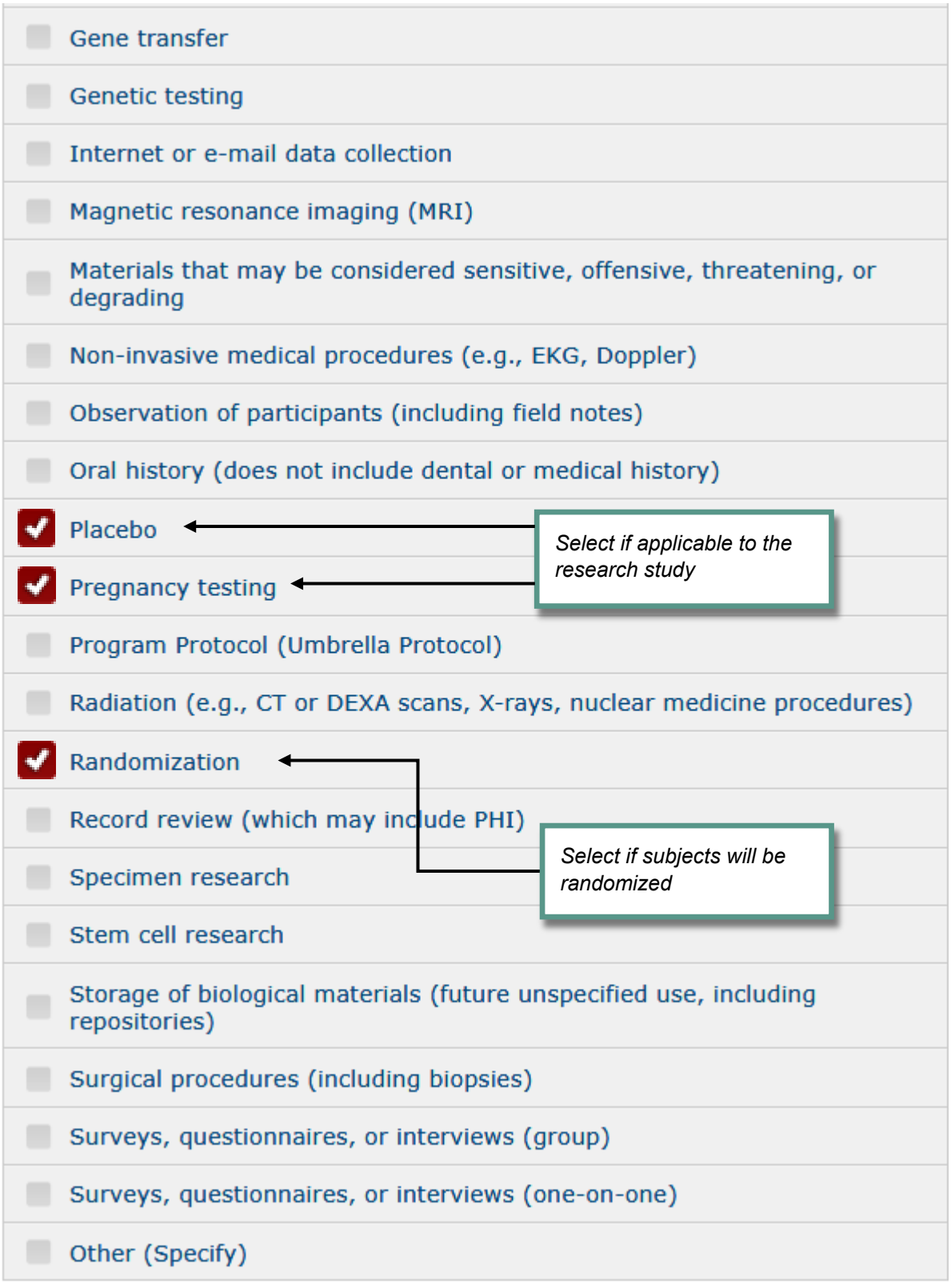
Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of drug here. Describe how the drug is dictated per the protocol (e.g., randomization, timing, etc.).

Check all research activities and/or components that apply.

- [ ] Anesthesia (general or local) or sedation
- [ ] Audio, video, digital, or image recordings
- [ ] Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- [ ] Biological sampling (other than blood)
- [ ] Blood drawing
- [ ] Coordinating center
- [ ] Data repositories (future unspecified use, including research databases)
- [ ] Data, not publicly available
- [ ] Data, publicly available (e.g., census data, unrestricted data sets)
- [ ] Deception
- [ ] Devices
- [ ] Diet, exercise, or sleep modifications
- [x] Drugs or biologics (including dietary supplements/ingredients)
- [ ] Emergency research
- [ ] Focus groups
- [ ] Food supplements


Gene transfer
Genetic testing
Internet or e-mail data collection
Magnetic resonance imaging (MRI)
Materials that may be considered sensitive, offensive, threatening, or degrading
Non-invasive medical procedures (e.g., EKG, Doppler)
Observation of participants (including field notes)
Oral history (does not include dental or medical history)
Placebo
Pregnancy testing
Select if applicable to the research study
Program Protocol (Umbrella Protocol)
Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
Randomization
Record review (which may include PHI)
Specimen research
Select if subjects will be randomized
Stem cell research
Storage of biological materials (future unspecified use, including repositories)
Surgical procedures (including biopsies)
Surveys, questionnaires, or interviews (group)
Surveys, questionnaires, or interviews (one-on-one)
Other (Specify)

Drugs or Biologics

Select from the options below to request inclusion of drugs or biologics (e.g., vaccines, cellular products, blood- or plasma-derived products) in the proposed research. Include only those drugs or biologics that are to be administered as part of the research protocol (i.e., not those administered for routine care or evaluation). Enter as many drugs or biologics as required for the research.

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For assistance with drug accountability and recordkeeping procedures, contact the OSUMC Department of Pharmacy at 614-293-8470. For more information on the requirements for conducting research involving investigational drugs or biologics, see HRPP policy Research Involving Investigational Drugs.

Each drug used off-label in the research should be listed separately, even if the drugs share an IND number

Investigational Drugs/Biologics or Investigational/Research Use of FDA Approved Product

Includes drugs or biologics that are not approved for this indication, route/dose, or study population.

Name of drug or biologic	**Name of drug(s)**
Generic name or active ingredient	**Generic name or active ingredients of drug(s)**
Brand name, if applicable	**Brand name(s)**
Manufacturer	**Manufacturer**

The drug/biologic is (select one)

- ○ Investigational
- ☑ Approved, but its use in this research is investigational

Provide a copy of the drug or biologic manufacturer's approved labeling (i.e., package insert).

Appears if "Approved, but its use in this research is investigational" is selected.

See Drugs at FDA or the manufacturer's website for printable versions.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Most research in this scenario will not utilize an Investigator's Brochure and will instead provide approved drug labeling (example below)

Page 1 of approved label for Tylenol (example)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Acetaminophen Injection safely and effectively. See full prescribing information for Acetaminophen Injection.

Acetaminophen Injection, for intravenous use
Initial U.S. Approval: 1951

WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY
See full prescribing information for complete boxed warning

Take care when prescribing, preparing, and administering Acetaminophen Injection to avoid dosing errors which could result in accidental overdose and death. (5.3)

Acetaminophen Injection contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product. *(5.1)*.

----------INDICATIONS AND USAGE----------
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- Reduction of fever. (1)

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Adults and Adolescents Weighing 50 kg and Over:
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Adults and Adolescents Weighing Under 50 kg:
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- In patients with known hypersensitivity to acetaminophen or to any of the excipients in the IV formulation. (4)
- In patients with severe hepatic impairment or severe active liver disease. (4)

----------WARNINGS AND PRECAUTIONS----------
- Administration of acetaminophen in doses higher than recommended (by all routes of administration and from all acetaminophen-containing products including combination products) may result in hepatic injury, including the risk of liver failure and death. (5.1)
- Do not exceed the maximum recommended daily dose of acetaminophen (by all routes of administration and all acetaminophen-containing products including combination products). (5.1)
- Take care when prescribing, preparing, and administering acetaminophen injection to avoid dosing errors which could result in accidental overdose and death. (5.3)
- Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, in cases of alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment (creatinine clearance ≤ 30 mL/min). (5.1)
- Discontinue acetaminophen immediately at the first appearance of skin rash and if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. (5.2, 5.4)

----------ADVERSE REACTIONS----------
The most common adverse reactions in patients treated with acetaminophen were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, Vigilance & Medical Affairs at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential. (7.1)
- Chronic oral acetaminophen use at a dose of 4,000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant. (7.2)

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Category C. There are no studies of intravenous acetaminophen in pregnant women. Use only if clearly needed. (8.1)
- Nursing Mothers: Caution should be exercised when administered to a nursing woman. (8.3)
- Pediatric Use: The effectiveness of acetaminophen for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age. The safety and effectiveness of acetaminophen in pediatric patients older than 2 years is supported by evidence from adequate and well-controlled studies in adults with additional safety and pharmacokinetic data for this age group. (8.4)
- Geriatric Use: No overall differences in safety or effectiveness were observed between geriatric and younger subjects. (8.5)
- Hepatic Impairment: Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. (4, 5.1, 8.6)
- Renal Impairment: In cases of severe renal impairment, longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted. (5.1, 8.7)

Revised: 10/2015

FULL PRESCRIBING INFORMATION: CONTENTS*

Reference ID: 3839318

Frequency and route of administration

Describe frequency and route of administration as dictated by the protocol. Clearly identify how administration differs from approved labeling, as applicable.

Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

Briefly describe drug

Does the drug/biologic have an Investigational New Drug (IND) number?

Yes | No

Investigational New Drug #

Provide the IND# for the drug or combination of drugs.

*Note: Documentation confirming the IND number **must** accompany the submission. Acceptable forms of documentation are as follows:*

- *Preferred documentation: **FDA IND Study May Proceed letter** (see example below).*
  - *This document is required for clinical investigations initiated by Ohio State investigators.*
  - *The letter can be uploaded on the **Other Files/Comments** page of Buck-IRB or in the "approved labeling" upload box above.*
- *Alternative documentation: IND number is identified on the protocol document. This method is acceptable when the IND sponsor is external to Ohio State.*

Page 1 of IND Study May Proceed letter from the FDA (example)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND [redacted]

STUDY MAY PROCEED

[redacted]MD
Principal Investigator
[redacted]University
[redacted]

Dear Dr. [redacted]

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for nivolumab.

We have completed our safety review of your application and have concluded that you may proceed with your proposed treatment use for relapsed or refractory classical Hodgkin Lymphoma.

ADDITIONAL IND RESPONSIBILITIES

As sponsor of this IND, you are responsible for compliance with the FDCA (21 U.S.C. §§ 301 et. seq.) as well as the implementing regulations [Title 21 of the Code of Federal Regulations (CFR)]. A searchable version of these regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. Your responsibilities include:

- Reporting any unexpected fatal or life-threatening suspected adverse reactions to this Division no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)].

- Submit 7-day reports electronically in eCTD format via the FDA Electronic Submissions Gateway (ESG). To obtain an ESG account, see information at the end of this letter.

- Reporting any (1) serious, unexpected suspected adverse reactions, (2) findings from other clinical, animal, or in-vitro studies that suggest significant human risk, and (3) a clinically important increase in the rate of a serious suspected adverse reaction to this Division and to all investigators no later than 15 calendar days after determining that the information qualifies for reporting [21 CFR 312.32(c)(1)]. Submit 15-day reports to FDA electronically in eCTD format via the ESG; and

State who holds the IND (sponsor, investigator, other)

State who holds the IND

Describe the process for investigational drug accountability, storage, and recordkeeping to ensure that the drug will be used according to the approved protocol, under the direction of approved investigator(s).

Indicate if the OSUWMC Investigational Drug Service (IDS) will handle storage and dispensing of the drug; if not, describe alternative arrangements, including record keeping.

For an investigator-held IND, describe the process for assuring compliance with FDA regulations pertaining to sponsors (e.g., recordkeeping, reporting).

This section should describe how serious adverse events are reported, to whom, and the time frame in which it is done.
Reminder: Sponsor here refers to sponsor-investigator (i.e., the PI).

Study phase

- ○ Phase I
- ○ Phase II
- ○ Phase III
- ○ Phase IV (post marketing)
- ○ Other

Summarize the potential side effects (including serious warnings and more common side effects).

Provide a snapshot of the *most common* side effects, with particular attention to how the off-label use increases the risks (or decreases the acceptability of the risks) associated with use of the drug.

Side effects may be grouped into general categories (e.g., "mild to moderate short-term GI side effects"), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the drug packaging.

Is preparation or repackaging of the supplied product necessary before administration or dispensing?

Yes	No

State who will perform these activities and where they will be performed.

Note: This question appears only when "Yes" is selected above.

Drugs (Supplemental Questions)

Does the research involve the use of Botox, Xeomin, Dysport or any formulation containing botulinum toxin at any dose?

Yes | No

Select Yes or No as appropriate

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes	No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different drug(s) or other treatment**
- **Receiving the drug(s) at a dose, frequency, and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of drugs listed elsewhere or copy a comprehensive list of side effects from drug labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual side effects of study drugs.

Drug Scenario D4

Legally marketed drugs used off-label; meets IND exemption criteria

Research Methods & Activities

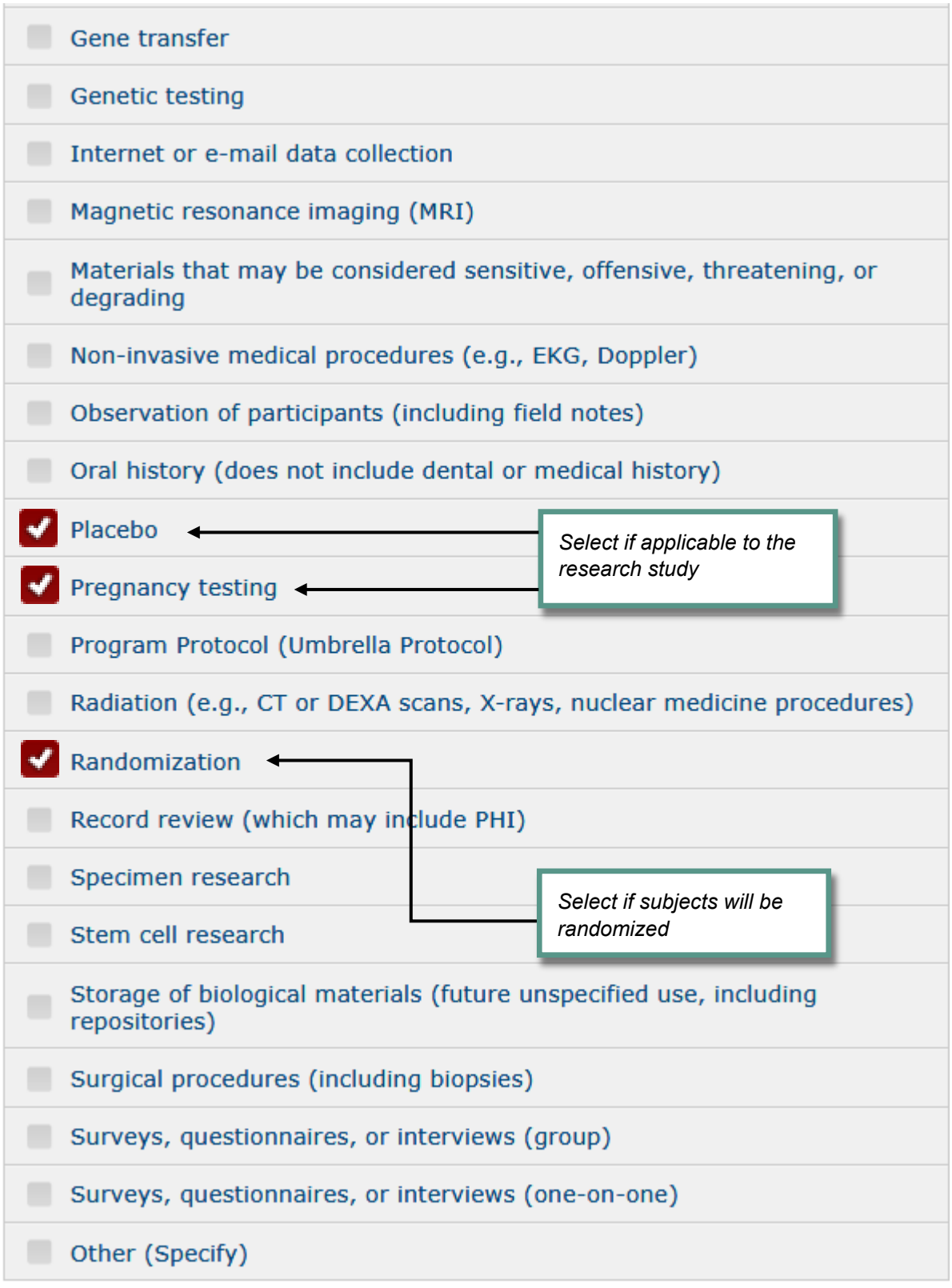
Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of drug(s) here. Describe how the drug is dictated per the protocol (e.g., randomization, timing, etc.).

Check all research activities and/or components that apply.

- [ ] Anesthesia (general or local) or sedation
- [ ] Audio, video, digital, or image recordings
- [ ] Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- [ ] Biological sampling (other than blood)
- [ ] Blood drawing
- [ ] Coordinating center
- [ ] Data repositories (future unspecified use, including research databases)
- [ ] Data, not publicly available
- [ ] Data, publicly available (e.g., census data, unrestricted data sets)
- [ ] Deception
- [ ] Devices
- [ ] Diet, exercise, or sleep modifications
- [x] Drugs or biologics (including dietary supplements/ingredients)
- [ ] Emergency research
- [ ] Focus groups
- [ ] Food supplements


Gene transfer
Genetic testing
Internet or e-mail data collection
Magnetic resonance imaging (MRI)
Materials that may be considered sensitive, offensive, threatening, or degrading
Non-invasive medical procedures (e.g., EKG, Doppler)
Observation of participants (including field notes)
Oral history (does not include dental or medical history)
Placebo
Pregnancy testing
Select if applicable to the research study
Program Protocol (Umbrella Protocol)
Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
Randomization
Record review (which may include PHI)
Specimen research
Stem cell research
Select if subjects will be randomized
Storage of biological materials (future unspecified use, including repositories)
Surgical procedures (including biopsies)
Surveys, questionnaires, or interviews (group)
Surveys, questionnaires, or interviews (one-on-one)
Other (Specify)

Drugs or Biologics

Select from the options below to request inclusion of drugs or biologics (e.g., vaccines, cellular products, blood- or plasma-derived products) in the proposed research. Include only those drugs or biologics that are to be administered as part of the research protocol (i.e., not those administered for routine care or evaluation). Enter as many drugs or biologics as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining INDs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For assistance with drug accountability and recordkeeping procedures, contact the OSUMC Department of Pharmacy at 614-293-8470. For more information on the requirements for conducting research involving investigational drugs or biologics, see HRPP policy Research Involving Investigational Drugs.

Each drug used off-label in the research should be listed separately

Investigational Drugs/Biologics or Investigational/Research Use of FDA Approved Product

Includes drugs or biologics that are not approved for this indication, route/dose, or study population.

Name of drug or biologic	**Name of drug(s)**
Generic name or active ingredient	**Generic name or active ingredients of drug(s)**
Brand name, if applicable	**Brand name(s)**
Manufacturer	**Manufacturer**

The drug/biologic is (select one)

- ○ Investigational
- ☑ Approved, but its use in this research is investigational

Provide a copy of the drug or biologic manufacturer's approved labeling (i.e., package insert).

Appears if "Approved, but its use in this research is investigational" is selected.

See Drugs at FDA or the manufacturer's website for printable versions.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Most research in this scenario will not utilize an Investigator's Brochure and will instead provide approved drug labeling (example below)

Page 1 of approved label for Tylenol (example)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Acetaminophen Injection safely and effectively. See full prescribing information for Acetaminophen Injection.

Acetaminophen Injection, for intravenous use
Initial U.S. Approval: 1951

WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY
See full prescribing information for complete boxed warning

Take care when prescribing, preparing, and administering Acetaminophen Injection to avoid dosing errors which could result in accidental overdose and death. (5.3)

Acetaminophen Injection contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product. *(5.1)*.

----------INDICATIONS AND USAGE----------
Acetaminophen injection is indicated for the:
- Management of mild to moderate pain. (1)
- Management of moderate to severe pain with adjunctive opioid analgesics. (1)
- Reduction of fever. (1)

----------DOSAGE AND ADMINISTRATION----------
- Acetaminophen injection may be given as a single or repeated dose. (2.1)
- Acetaminophen injection should be administered only as a 15 minute intravenous infusion. (2.4)

Adults and Adolescents Weighing 50 kg and Over:
- 1,000 mg every 6 hours or 650 mg every 4 hours to a maximum of 4,000 mg per day. Minimum dosing interval of 4 hours. (2.2)

Adults and Adolescents Weighing Under 50 kg:
- 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours. (2.2)

Children:
- Children 2 to 12 years of age: 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Minimum dosing interval of 4 hours. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
- Injection for intravenous infusion.
- Each 100 mL flexible plastic container has 1,000 mg acetaminophen (10 mg/mL). (3)

----------CONTRAINDICATIONS----------
Acetaminophen is contraindicated:
- In patients with known hypersensitivity to acetaminophen or to any of the excipients in the IV formulation. (4)
- In patients with severe hepatic impairment or severe active liver disease. (4)

----------WARNINGS AND PRECAUTIONS----------
- Administration of acetaminophen in doses higher than recommended (by all routes of administration and from all acetaminophen-containing products including combination products) may result in hepatic injury, including the risk of liver failure and death. (5.1)
- Do not exceed the maximum recommended daily dose of acetaminophen (by all routes of administration and all acetaminophen-containing products including combination products). (5.1)
- Take care when prescribing, preparing, and administering acetaminophen injection to avoid dosing errors which could result in accidental overdose and death. (5.3)
- Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, in cases of alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment (creatinine clearance ≤ 30 mL/min). (5.1)
- Discontinue acetaminophen immediately at the first appearance of skin rash and if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. (5.2, 5.4)

----------ADVERSE REACTIONS----------
The most common adverse reactions in patients treated with acetaminophen were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, Vigilance & Medical Affairs at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential. (7.1)
- Chronic oral acetaminophen use at a dose of 4,000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant. (7.2)

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Category C. There are no studies of intravenous acetaminophen in pregnant women. Use only if clearly needed. (8.1)
- Nursing Mothers: Caution should be exercised when administered to a nursing woman. (8.3)
- Pediatric Use: The effectiveness of acetaminophen for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age. The safety and effectiveness of acetaminophen in pediatric patients older than 2 years is supported by evidence from adequate and well-controlled studies in adults with additional safety and pharmacokinetic data for this age group. (8.4)
- Geriatric Use: No overall differences in safety or effectiveness were observed between geriatric and younger subjects. (8.5)
- Hepatic Impairment: Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. (4, 5.1, 8.6)
- Renal Impairment: In cases of severe renal impairment, longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted. (5.1, 8.7)

Revised: 10/2015

FULL PRESCRIBING INFORMATION: CONTENTS*

Reference ID: 3839318

Frequency and route of administration

Describe frequency and route of administration as dictated by the protocol. Clearly identify how administration differs from approved labeling, as applicable.

Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

Briefly describe drug

Does the drug/biologic have an Investigational New Drug (IND) number?

Yes | No

IRB approval cannot be granted until documentation of the IND (or exemption) has been provided

Explain how the use of the drug/biologic in this research meets one of the FDA exemptions from the requirements for an IND or provide documentation of exemption from FDA (i.e., letter indicating an IND is not required).

If an FDA letter confirming IND exemption is not available, explain how the use of the drug meets the IND exemption criteria. For most studies, the rationale for IND exemption should address the following:

Risk Assessment

- Specify how the use of the drug in the study differs from the approved labeling. Specifically, consider:
  - Indication(s) for use
  - Patient population
  - Route of administration
  - Dose
  - Combination with another drug product
  - Modification of the drug product
- Provide evidence that the proposed off-label use in this investigation does not significantly increase the risks (or decrease the acceptability of the risks) associated with the use of the drug product. Consider, at a minimum:
  - Potential for increased frequency/severity of side effects
  - Impacts on drug effectiveness (e.g., if administered at a lower dose)
  - Whether the off-label use is considered standard of care for the study population
  - Availability of other therapies/treatments for the study population

  As much as possible, provide/refer to literature supporting your risk assessment of off-label use.

Attestation of additional exemption criteria

- Confirm that the product is **lawfully marketed** in the United States *as a drug*. (This should be clear from the FDA-approved labeling provided above.)
- Confirm that the investigation **will not be reported to FDA** or otherwise used to support approval of a new indication, a change in labeling, or a change in advertising.
- Confirm that study materials, including the consent form, will **not promote the drug as safe or effective** for the purposes for which it is under investigation.

Study phase

- ○ Phase I
- ○ Phase II
- ○ Phase III
- ○ Phase IV (post marketing)
- ○ Other

Provide the proposed rationale for choice of this agent in the research (compared to other drugs that could have been used).

Explain why the drug is being used in this research, noting how it differs from on label use.

Summarize the potential side effects (including serious warnings and more common side effects).

Provide a snapshot of the *most common* side effects, with particular attention to how the off-label use increases the risks (or decreases the acceptability of the risks) associated with use of the drug.

Side effects may be grouped into general categories (e.g., "mild to moderate short-term GI side effects"), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the drug packaging.

Is preparation or repackaging of the supplied product necessary before administration or dispensing?

Yes | No

State who will perform these activities and where they will be performed.

Note: This question appears only when "Yes" is selected above.

Drugs (Supplemental Questions)

Does the research involve the use of Botox, Xeomin, Dysport or any formulation containing botulinum toxin at any dose?

Yes | No

Select Yes or No as appropriate

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes | No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different drug(s) or other treatment**
- **Receiving the drug(s) at a dose, frequency, and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of drugs listed elsewhere or copy a comprehensive list of side effects from drug labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual side effects of study drugs.

Drug Scenario D5

Unapproved drug(s) administered as part of the study

Research Methods & Activities

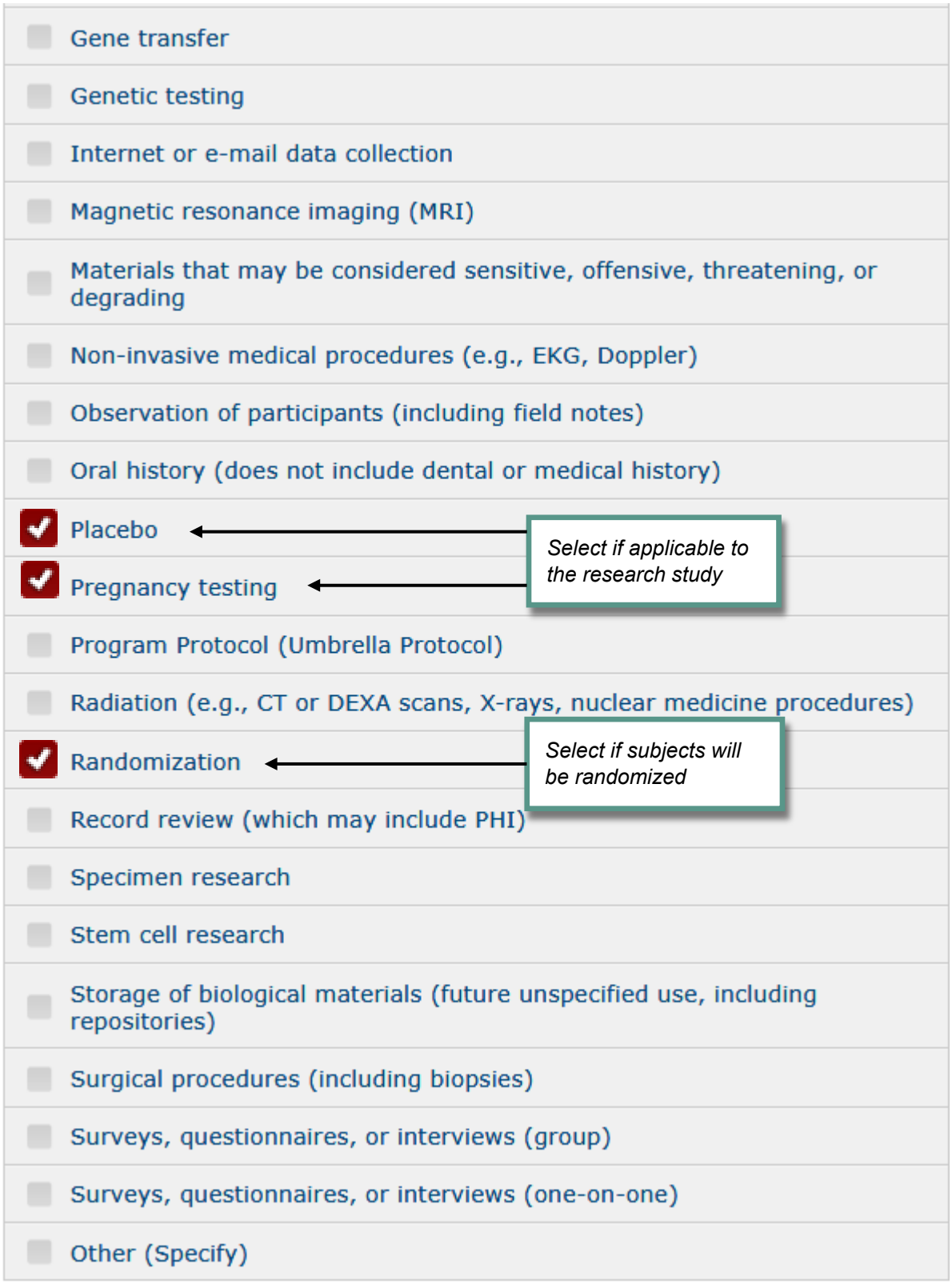
Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe use of unapproved drug(s) in research.

Check all research activities and/or components that apply.

- [ ] Anesthesia (general or local) or sedation
- [ ] Audio, video, digital, or image recordings
- [ ] Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- [ ] Biological sampling (other than blood)
- [ ] Blood drawing
- [ ] Coordinating center
- [ ] Data repositories (future unspecified use, including research databases)
- [ ] Data, not publicly available
- [ ] Data, publicly available (e.g., census data, unrestricted data sets)
- [ ] Deception
- [ ] Devices
- [ ] Diet, exercise, or sleep modifications
- [x] Drugs or biologics (including dietary supplements/ingredients)
- [ ] Emergency research
- [ ] Focus groups
- [ ] Food supplements


Gene transfer
Genetic testing
Internet or e-mail data collection
Magnetic resonance imaging (MRI)
Materials that may be considered sensitive, offensive, threatening, or degrading
Non-invasive medical procedures (e.g., EKG, Doppler)
Observation of participants (including field notes)
Oral history (does not include dental or medical history)
Placebo
Pregnancy testing
Select if applicable to the research study
Program Protocol (Umbrella Protocol)
Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
Randomization
Select if subjects will be randomized
Record review (which may include PHI)
Specimen research
Stem cell research
Storage of biological materials (future unspecified use, including repositories)
Surgical procedures (including biopsies)
Surveys, questionnaires, or interviews (group)
Surveys, questionnaires, or interviews (one-on-one)
Other (Specify)

Drugs or Biologics

Select from the options below to request inclusion of drugs or biologics (e.g., vaccines, cellular products, blood- or plasma-derived products) in the proposed research. Include only those drugs or biologics that are to be administered as part of the research protocol (i.e., not those administered for routine care or evaluation). Enter as many drugs or biologics as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining INDs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For assistance with drug accountability and recordkeeping procedures, contact the OSUMC Department of Pharmacy at 614-293-8470. For more information on the requirements for conducting research involving investigational drugs or biologics, see HRPP policy Research Involving Investigational Drugs.

Add each non-legally marketed drug that will be administered for any purpose in the study.

Investigational Drugs/Biologics or Investigational/Research Use of FDA Approved Product

Includes drugs or biologics that are not approved for this indication, route/dose, or study population.

Name of drug or biologic	**Name of drug(s)**
Generic name or active ingredient	**Generic name or active ingredients of drug(s)**
Brand name, if applicable	**Brand name(s)**
Manufacturer	**Manufacturer**

The drug/biologic is (select one)

- [x] Investigational
- [ ] Approved, but its use in this research is investigational

Provide a copy of the Investigator's Brochure or equivalent information if not available.
Appears if "Investigational" is selected

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Provide the most up-to-date Investigator's Brochure (IB) for the investigational drug(s) used in the study. See next page for an example of an IB.

IB example (title page only)

NOVARTIS

Oncology Global Drug Development

BYL719

Alpelisib

Investigator's Brochure

Document type:	Investigator's Brochure
Edition number:	Edition 11, replacing Edition 10 dated 12-Jul-2017
Release date:	05-Jul-2018
Safety cut-off date:	13-May-2018

IB Template version 3.0, 02-Dec-2016

Frequency and route of administration

Describe frequency and route of administration

Provide a brief description of the drug/biologic (e.g., drug class, mode of action).

Briefly describe drug

Does the drug/biologic have an Investigational New Drug (IND) number?

Yes | No

Investigational New Drug #

Provide the IND# for the drug or combination of drugs.

*Note: Documentation confirming the IND number **must** accompany the submission. Acceptable forms of documentation are as follows:*

- *Preferred documentation: **FDA IND Study May Proceed letter** (see example below).*
  - *This document is required for clinical investigations initiated by Ohio State investigators.*
  - *The letter can be uploaded on the **Other Files/Comments** page of Buck-IRB or in the "approved labeling" upload box above.*
- *Alternative documentation: IND number is identified on the protocol document. This method is acceptable when the IND sponsor is external to Ohio State.*

Page 1 of IND Study May Proceed letter from the FDA (example)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND [redacted]

STUDY MAY PROCEED

[redacted] MD
Principal Investigator
[redacted] University
[redacted]

Dear Dr. [redacted]

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for nivolumab.

We have completed our safety review of your application and have concluded that you may proceed with your proposed treatment use for relapsed or refractory classical Hodgkin Lymphoma.

ADDITIONAL IND RESPONSIBILITIES

As sponsor of this IND, you are responsible for compliance with the FDCA (21 U.S.C. §§ 301 et. seq.) as well as the implementing regulations [Title 21 of the Code of Federal Regulations (CFR)]. A searchable version of these regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. Your responsibilities include:

- Reporting any unexpected fatal or life-threatening suspected adverse reactions to this Division no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)].

- Submit 7-day reports electronically in eCTD format via the FDA Electronic Submissions Gateway (ESG). To obtain an ESG account, see information at the end of this letter.

- Reporting any (1) serious, unexpected suspected adverse reactions, (2) findings from other clinical, animal, or in-vitro studies that suggest significant human risk, and (3) a clinically important increase in the rate of a serious suspected adverse reaction to this Division and to all investigators no later than 15 calendar days after determining that the information qualifies for reporting [21 CFR 312.32(c)(1)]. Submit 15-day reports to FDA electronically in eCTD format via the ESG; and

State who holds the IND (sponsor, investigator, other)

State who holds the IND

Describe the process for investigational drug accountability, storage, and recordkeeping to ensure that the drug will be used according to the approved protocol, under the direction of approved investigator(s).

Indicate if the OSUWMC Investigational Drug Service (IDS) will handle storage and dispensing of the drug; if not, describe alternative arrangements, including record keeping.

For an investigator-held IND, describe the process for assuring compliance with FDA regulations pertaining to sponsors (e.g., recordkeeping, reporting).

This section should describe how serious adverse events are reported, to whom, and the time frame in which it is done.
Reminder: Sponsor here refers to sponsor-investigator (i.e., the PI).

Summarize the potential side effects (including serious warnings and more common side effects).

Provide a snapshot of the *most common* side effects; these may be summarized by grouping side effects into general categories (e.g., "mild to moderate short-term GI side effects"), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the drug packaging.

Is preparation or repackaging of the supplied product necessary before administration or dispensing?

Yes | No

State who will perform these activities and where they will be performed.

Note: This question appears only when "Yes" is selected above.

Drugs (Supplemental Questions)

Does the research involve the use of Botox, Xeomin, Dysport or any formulation containing botulinum toxin at any dose?

Yes | No

Select Yes or No as appropriate

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes | No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different approved drug(s) or other treatment**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of drugs listed elsewhere or copy a comprehensive list of side effects from drug labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual side effects of study drugs.