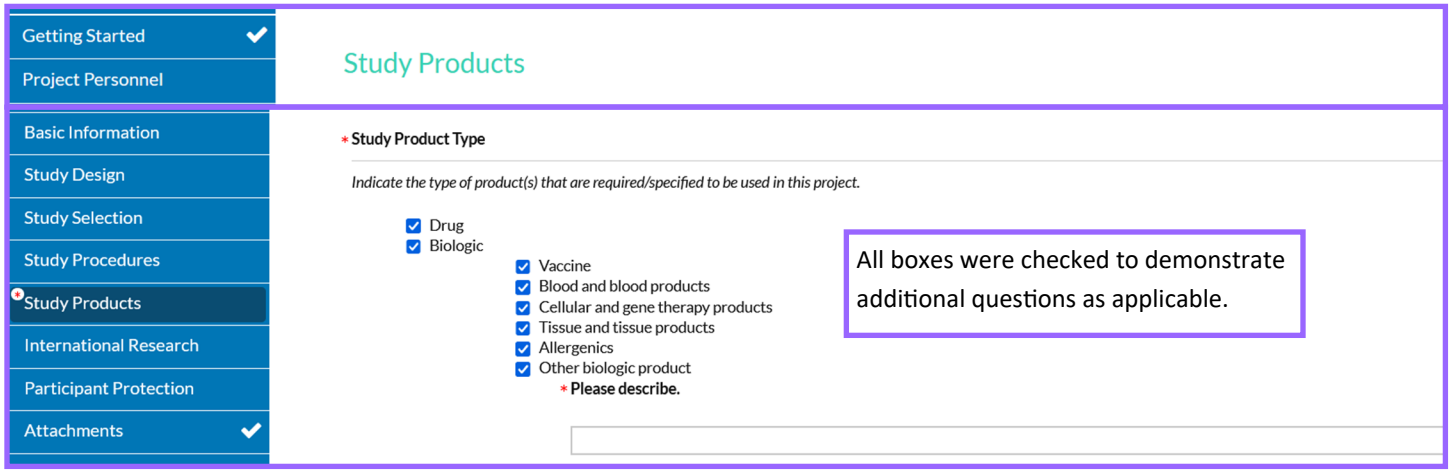
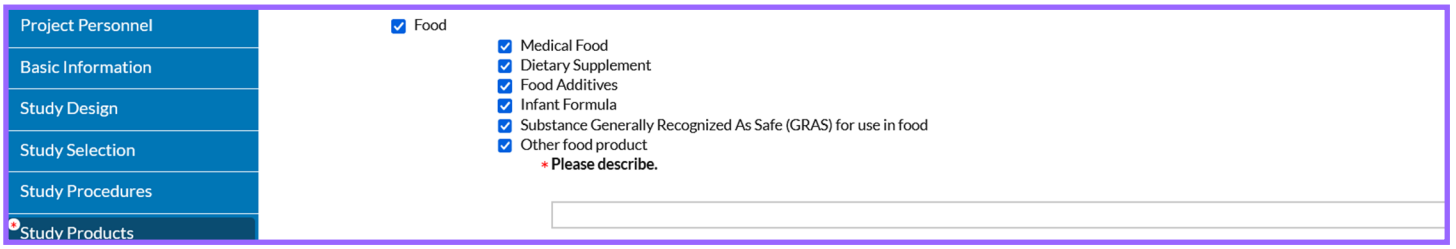
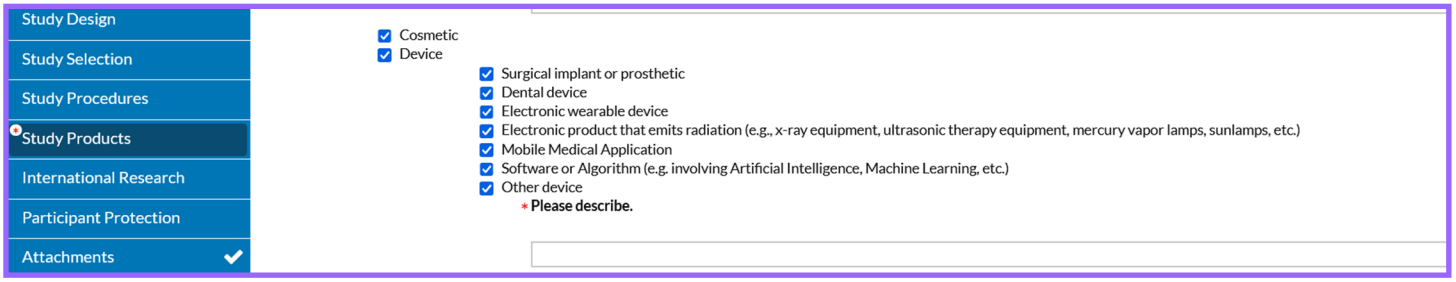
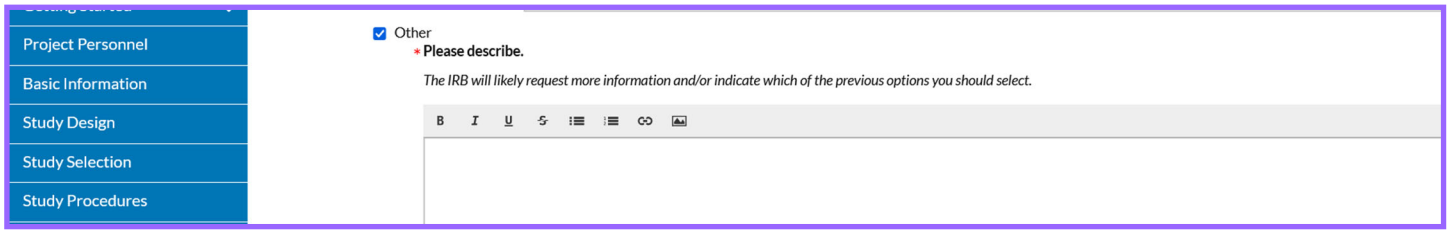
Study Products Section

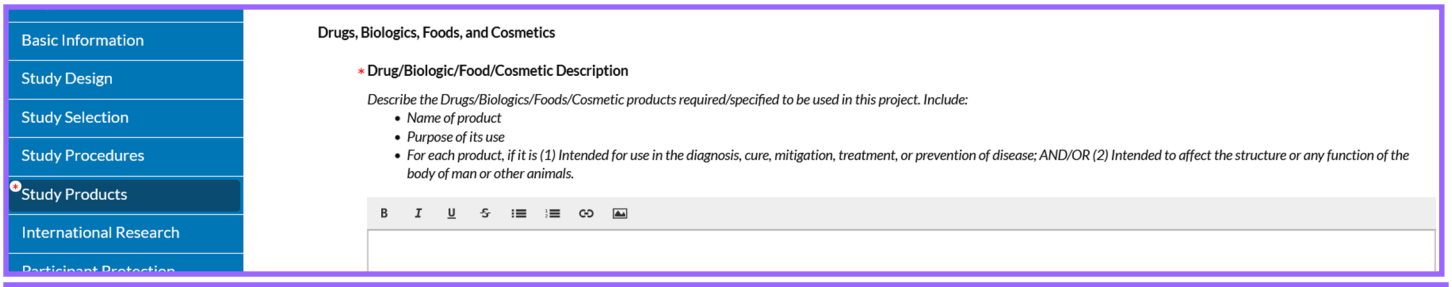
Depending on your responses, additional questions may appear.

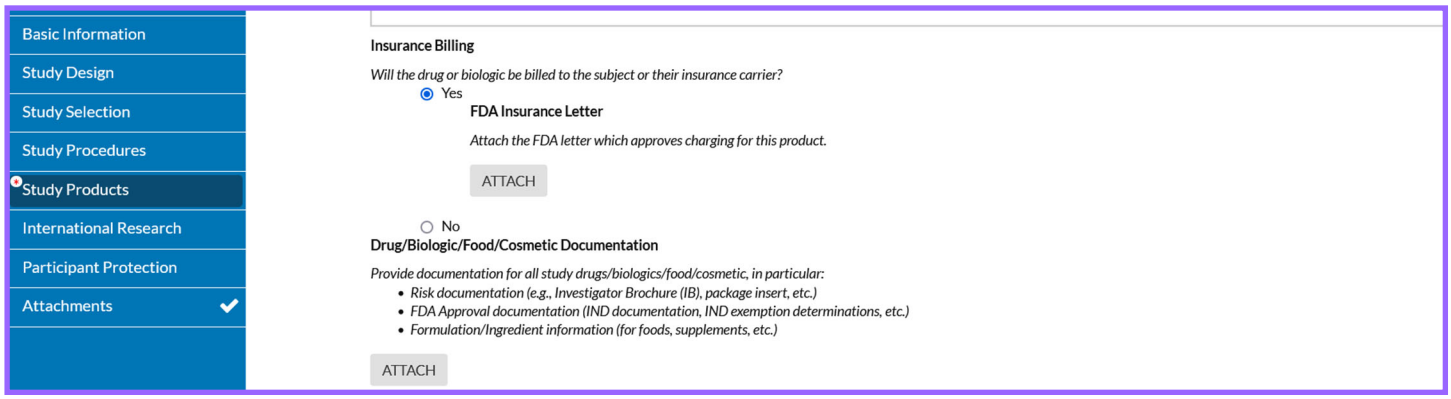


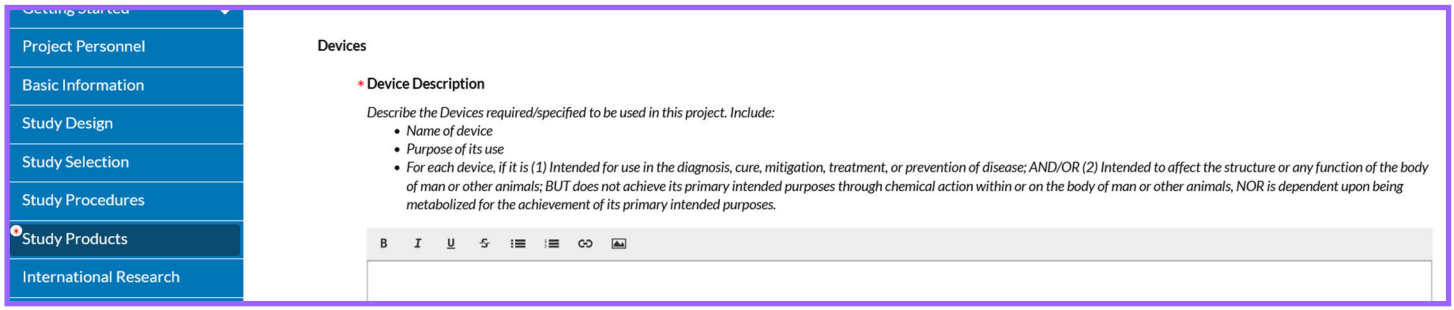


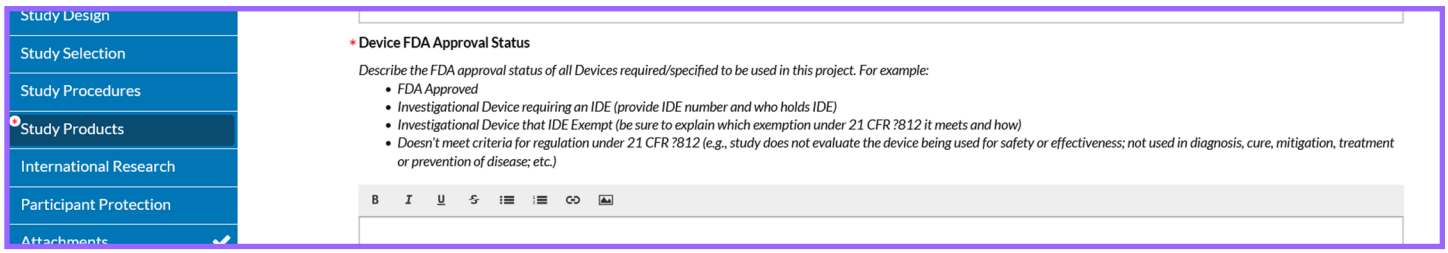


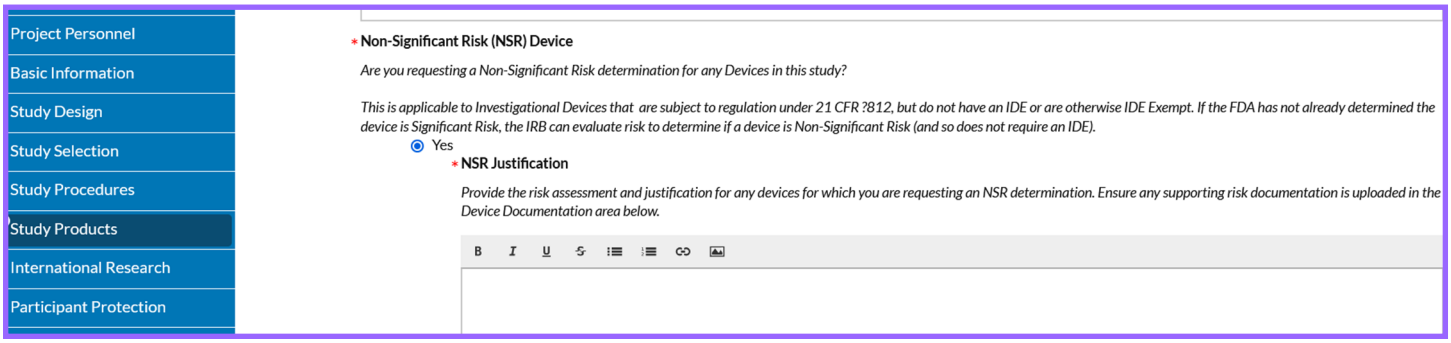


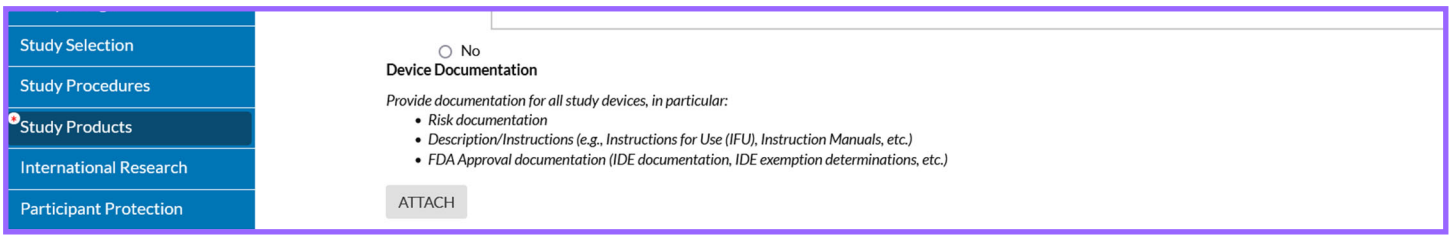



Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
Attachments
Insurance Billing
Will the drug or biologic be billed to the subject or their insurance carrier?
Yes
FDA Insurance Letter
Attach the FDA letter which approves charging for this product.
ATTACH
No
Drug/Biologic/Food/Cosmetic Documentation
Provide documentation for all study drugs/biologics/food/cosmetic, in particular:
Risk documentation (e.g., Investigator Brochure (IB), package insert, etc.)
FDA Approval documentation (IND documentation, IND exemption determinations, etc.)
Formulation/Ingredient information (for foods, supplements, etc.)
ATTACH


Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Devices
* Device Description
Describe the Devices required/specified to be used in this project. Include:
Name of device
Purpose of its use
For each device, if it is (1) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; AND/OR (2) Intended to affect the structure or any function of the body of man or other animals; BUT does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, NOR is dependent upon being metabolized for the achievement of its primary intended purposes.


Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
Attachments
* Device FDA Approval Status
Describe the FDA approval status of all Devices required/specified to be used in this project. For example:
FDA Approved
Investigational Device requiring an IDE (provide IDE number and who holds IDE)
Investigational Device that IDE Exempt (be sure to explain which exemption under 21 CFR ?812 it meets and how)
Doesn't meet criteria for regulation under 21 CFR ?812 (e.g., study does not evaluate the device being used for safety or effectiveness; not used in diagnosis, cure, mitigation, treatment or prevention of disease; etc.)


Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
* Non-Significant Risk (NSR) Device
Are you requesting a Non-Significant Risk determination for any Devices in this study?
This is applicable to Investigational Devices that are subject to regulation under 21 CFR ?812, but do not have an IDE or are otherwise IDE Exempt. If the FDA has not already determined the device is Significant Risk, the IRB can evaluate risk to determine if a device is Non-Significant Risk (and so does not require an IDE).
Yes
* NSR Justification
Provide the risk assessment and justification for any devices for which you are requesting an NSR determination. Ensure any supporting risk documentation is uploaded in the Device Documentation area below.


Study Selection
Study Procedures
Study Products
International Research
Participant Protection
No
Device Documentation
Provide documentation for all study devices, in particular:
Risk documentation
Description/Instructions (e.g., Instructions for Use (IFU), Instruction Manuals, etc.)
FDA Approval documentation (IDE documentation, IDE exemption determinations, etc.)
ATTACH