



# **NIH Applications & Human Subjects Research**

**(when “no” requires a justification in the application)**

**Cynthia Sylvester**  
**Office of Sponsored Projects**  
**& Industry Partnerships**



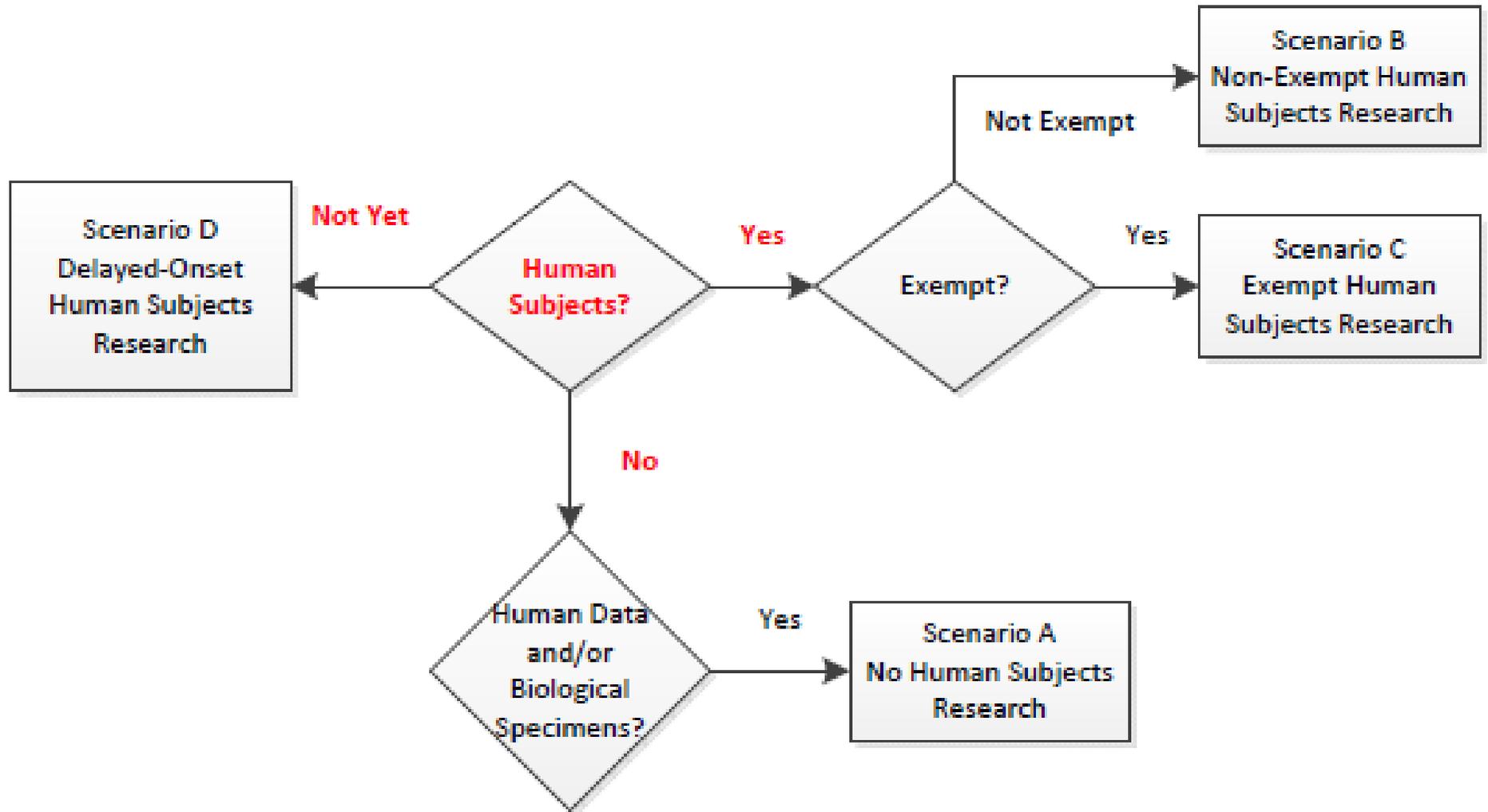
# Not a simple question

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- **If there is any mention of human data, biological specimens, or human subjects in the research section of the application, it might not be a simple answer.**

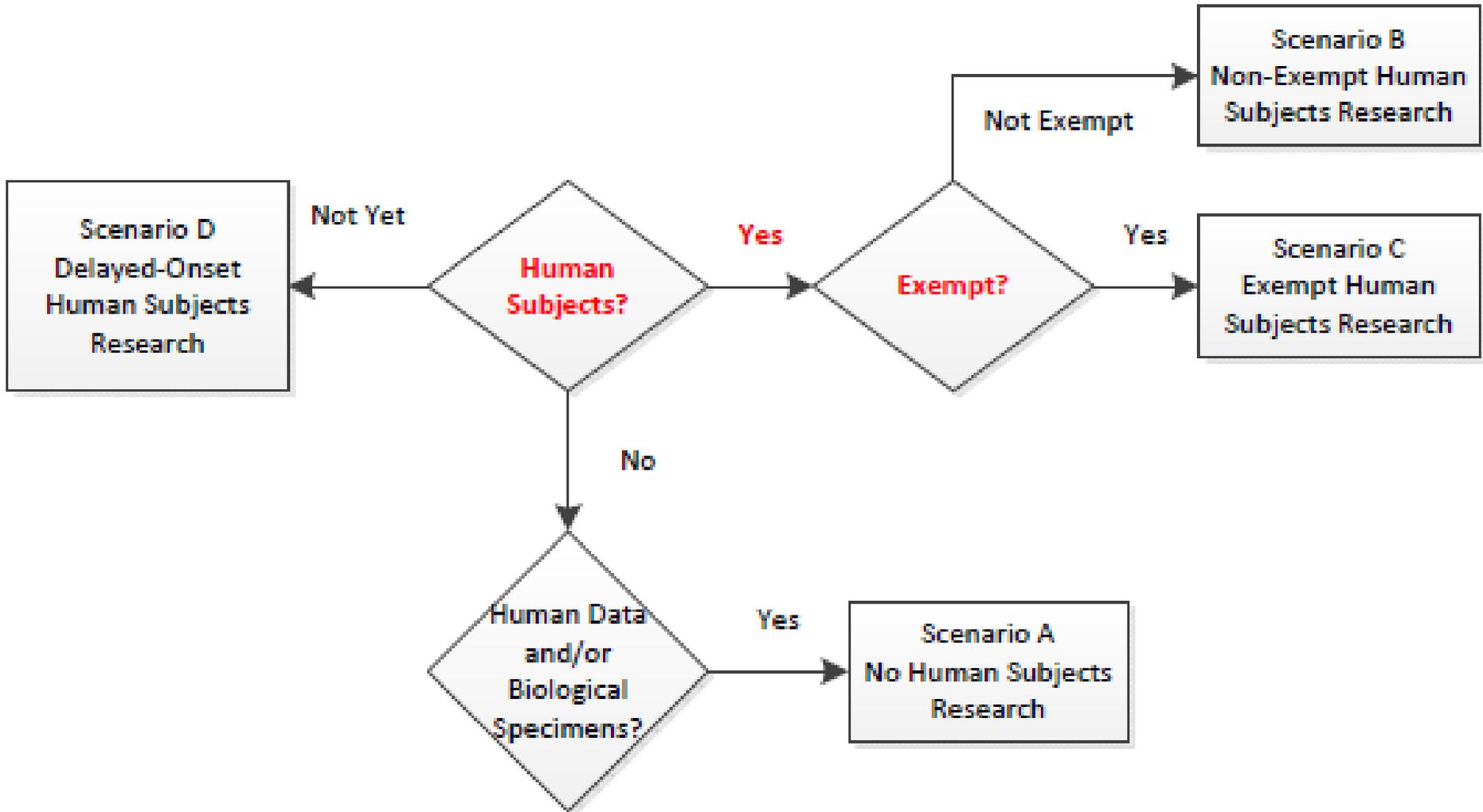


# Human Subjects ?





# Yes – Human Subjects Exempt ?





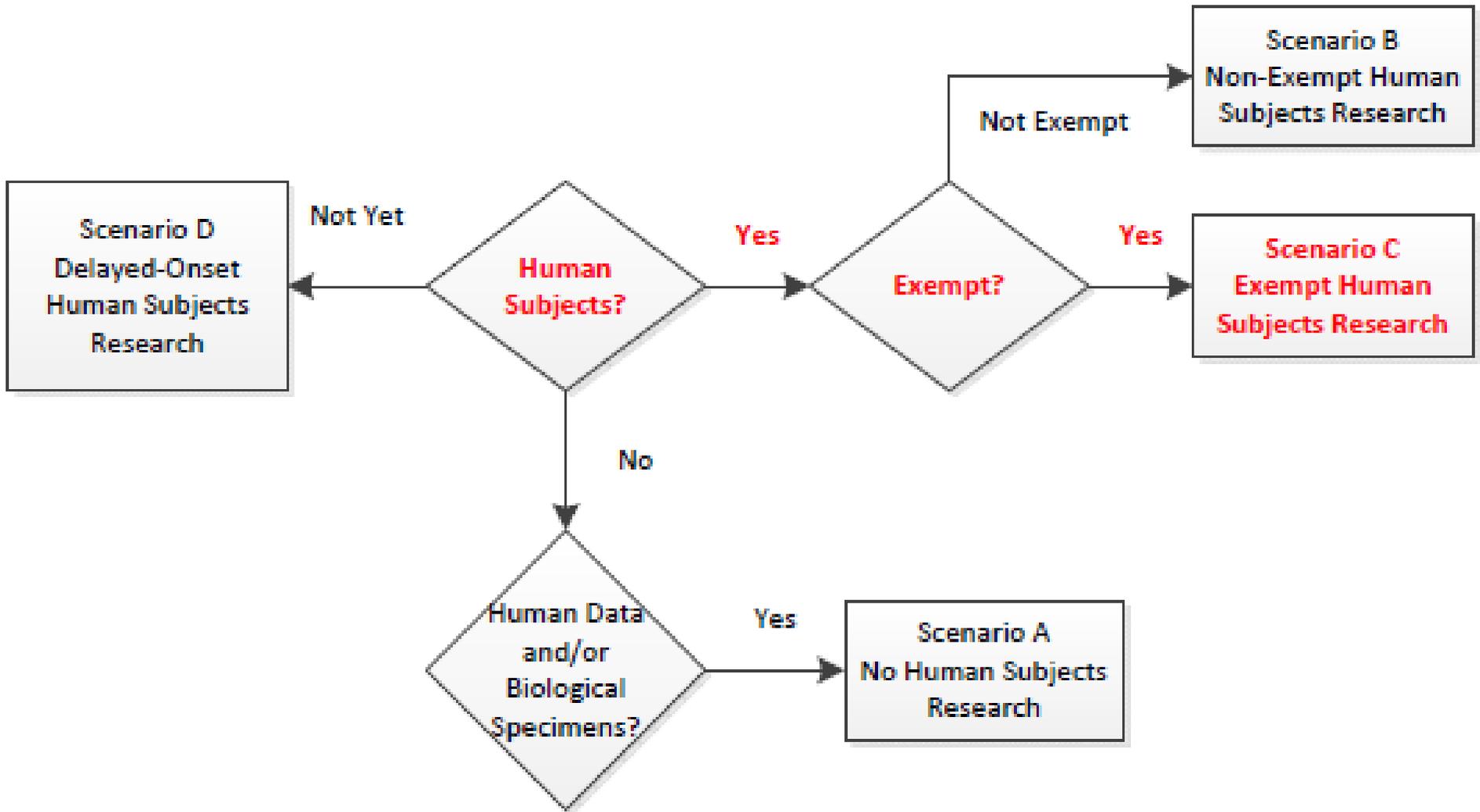
# Exemptions

- There are six exemptions
- Check the NIH website for more informaton

<http://grants.nih.gov/grants/policy/hs/>

- Look in the Frequently Asked Question Section for more information about Human Subjects Research Exemptions
- Note: **Exemption 4 is rarely used.** If your PI thinks the research qualifies as exemption 4, check with HARC. The correct answer might be by “No Human Use”

**No Human Use ≠ Exemption 4**





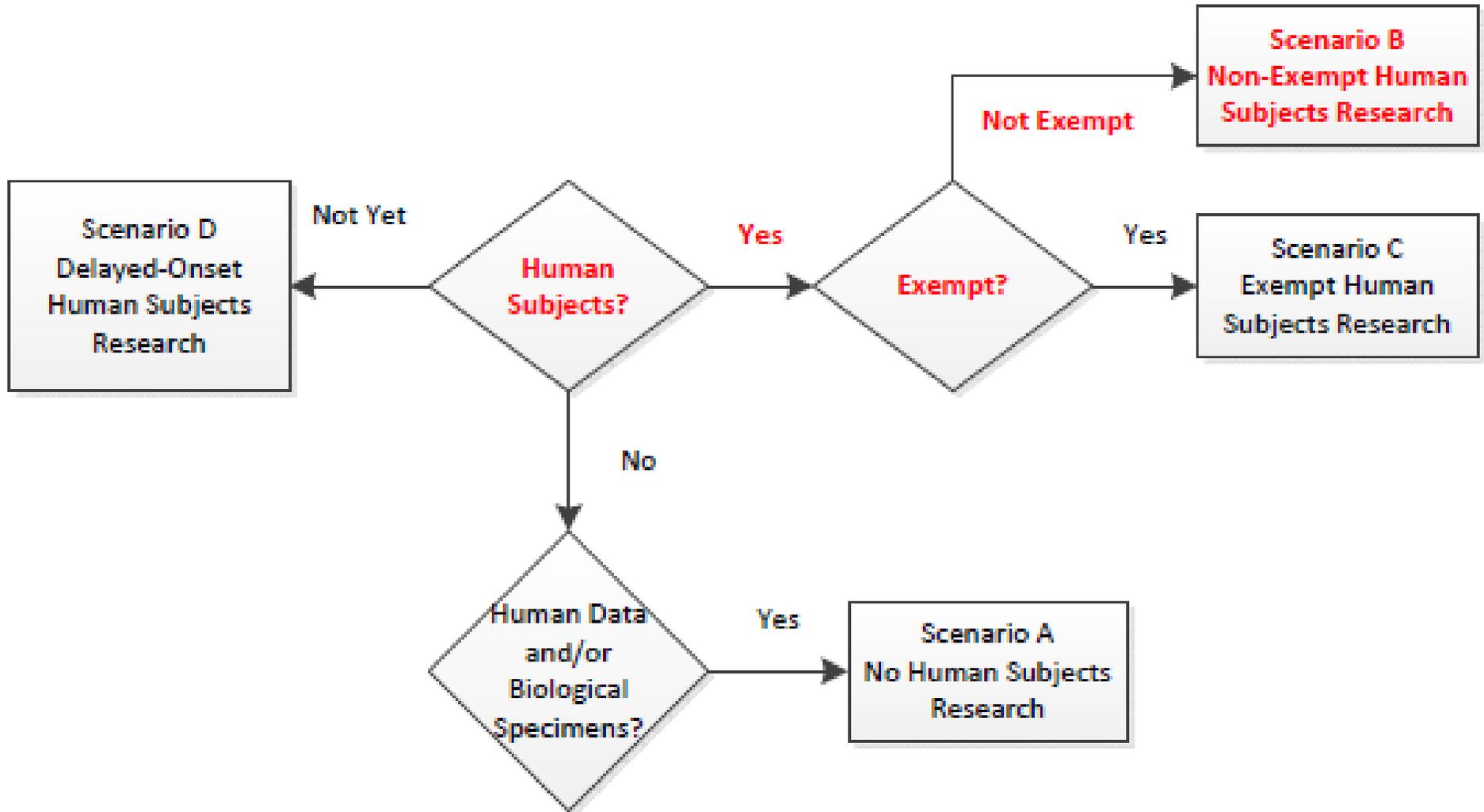
## Scenario C: Exempt HS

- Protection of Human Subjects – required with very specific language – **see SF424 instructions for details**
- Inclusion of Women and Minorities – might be required
- Targeted/Planned Enrollment – might be required
- Inclusion of Children – might be required
  
- Clinical trials require additional information

(Exemption 4 does not need Inclusion of Women and Minorities, Target/Planned Enrollment, or Inclusion of Children sections.)



# Non-Exempt Human Subjects Research





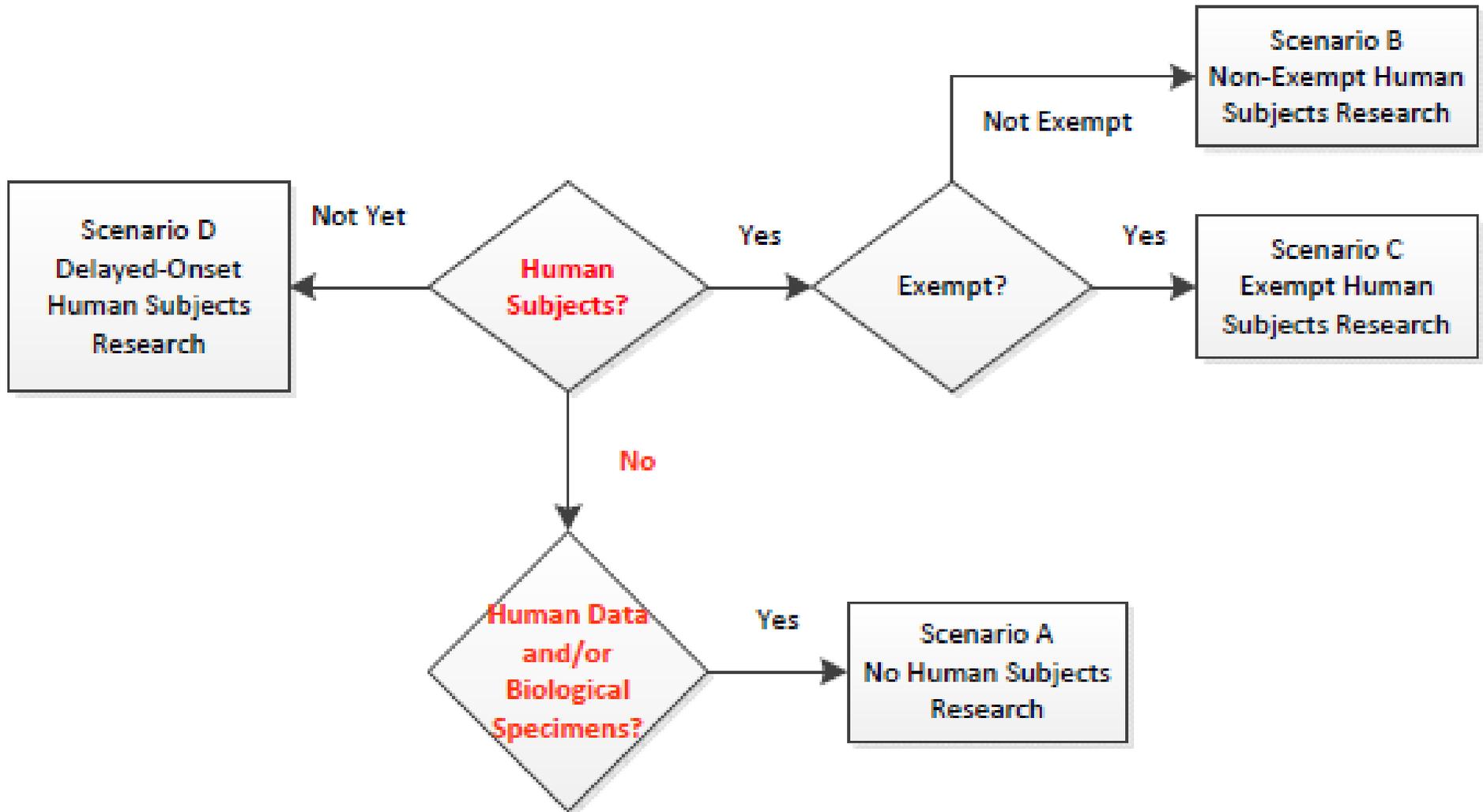
## Scenario B: Non-Exempt HS

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- **Protection of Human Subjects – required**
- **Inclusion of Women and Minorities – required**
- **Targeted/Planned Enrollment – required**
- **Inclusion of Children – required**



# Human Subjects ? “No”





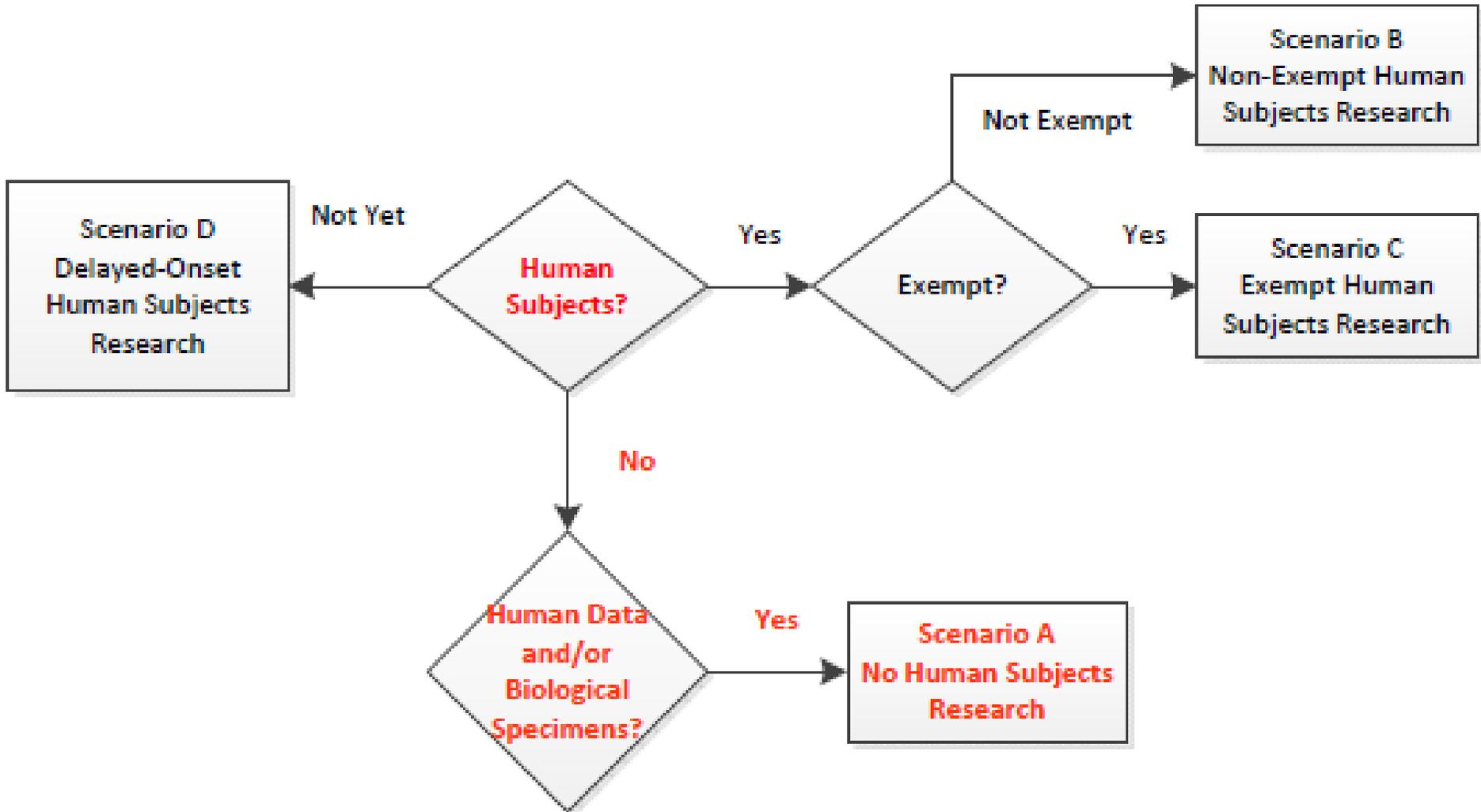
## **“No” might need to be justified**

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- If the application includes any mention of human data or biological specimens then the “no” answer must be justified**



# Human Data and/or Biological Specimens





# Scenario A: No HS

- Proposed studies using human data and/or biological specimens
- Provide an explanation of why the proposed studies do not constitute research involving human subjects
- Upload in Protection of Human Subjects section of application

## 8.4 Human Subject Section

8.4.a Protection of Human Subjects:

~~8.4.b Inclusion of Women and Minorities:~~

~~8.4.c Targeted/Planned Enrollment Table:~~

~~8.4.d Inclusion of Children:~~



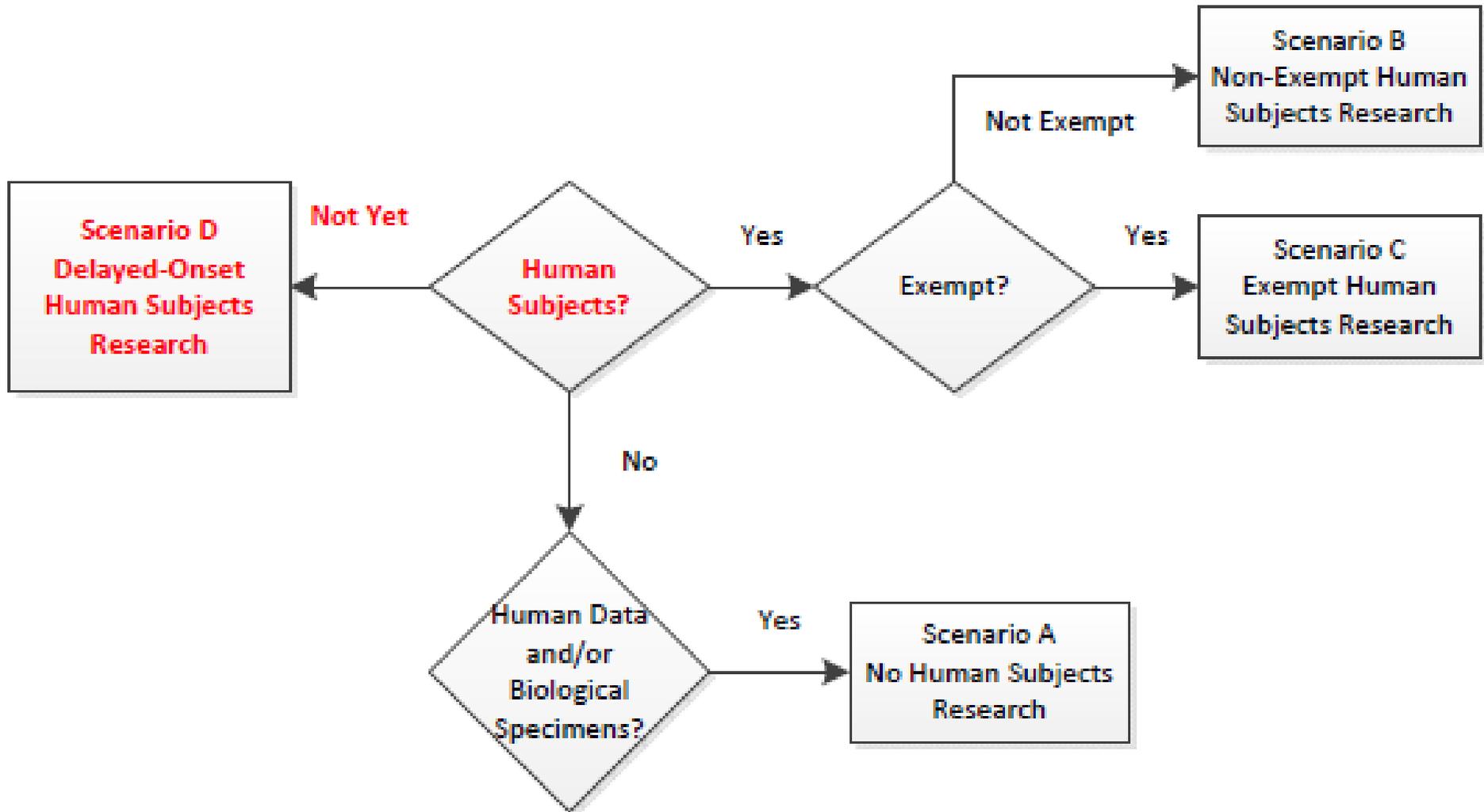
## Explanation Should Include:

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- **Description of the source of the data/biological specimens**
- **Whether there is any intervention or interaction with the subjects in order to obtain the specimens and data**
- **What identifiers will be associated**
- **The role(s) of providers of the data/biological specimens in the proposed research**
- **The manner by which the privacy of research participants and confidentiality of data will be protected**



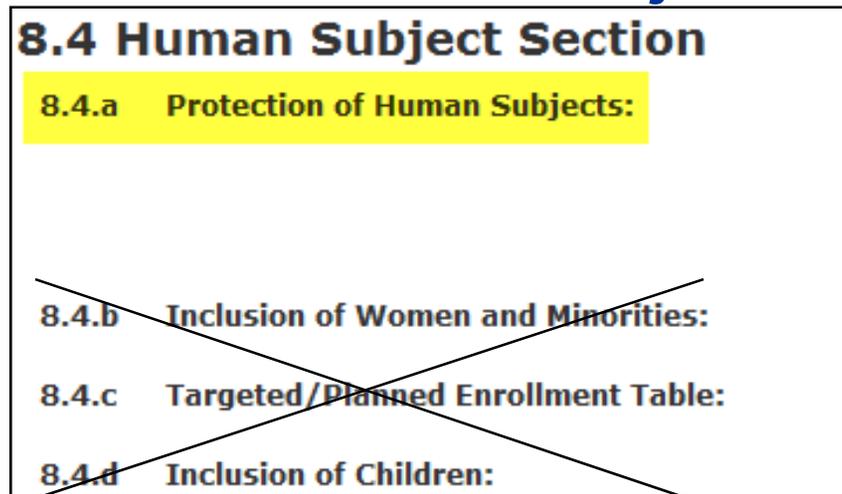
# Delayed-Onset





## Scenario D: Delayed Onset

- Humans are involved
- Plans are so indefinite that it is not possible to describe the involvement of human subjects in the application
- Provide an explanation of why the involvement of human subjects cannot be fully described
- Upload in Protection of Human Subjects section of application





# Delayed Onset Explanation

- **Explanation should be specific**
- **Should be directly related the Specific Aims in the application**
- **If human subjects involvement depends on information not presently available, be explicit about the information and the factors affecting availability**
- **Describe the information that will be necessary in order to develop definite plans, why that information is not currently available, and when the information is expected to become available**



# Ready to Start Human Subject Research

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- **BEFORE** the involvement of human subjects you must submit to the NIH awarding office information for prior approval – **see SF424 instructions for details**
- **See NOT-OD-12-130** for more information about Delayed Onset awards and how to proceed