NIH Proposal Writing Workshop

DAY 2 | 5.11.2024 | MORNING SESSION

FACENTE CONSULTING
UNDERSTAND • IMPLEMENT • TELL YOUR STORY

Plan for the Morning

1. Human Subjects Documents
2. Biosketches

Plan for the Morning

1. **Human Subjects Documents**
2. Biosketches

Human Subjects

Ethics: Two high-level questions

1. Does my research involve human subjects?
2. Does my research involve a clinical trial (per NIH definition)?

Am I involving human subjects?

Human subject = a living individual about whom an investigator is conducting research

"Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

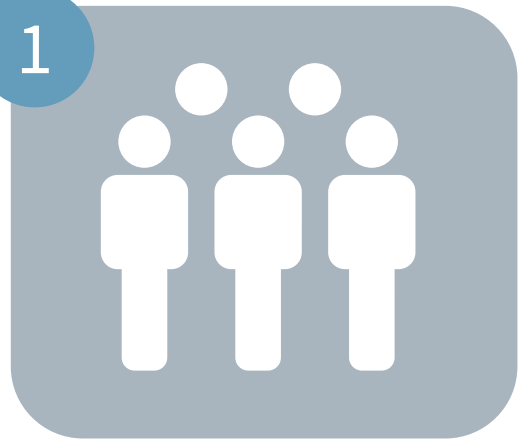
Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

NIH Decision tool:
https://grants.nih.gov/policy/humansubjects/hs-decision.htm

If yes to human subjects…is it a clinical trial?

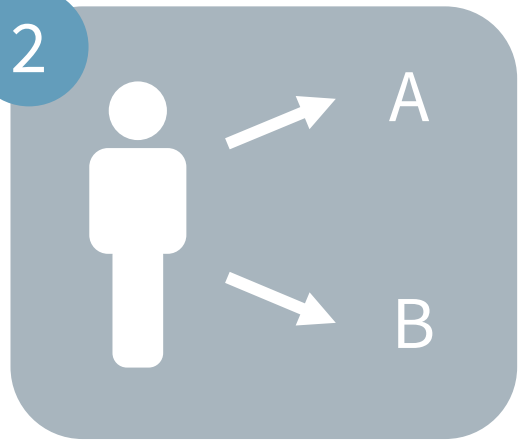
NIH uses 4 questions to define clinical trials:

1



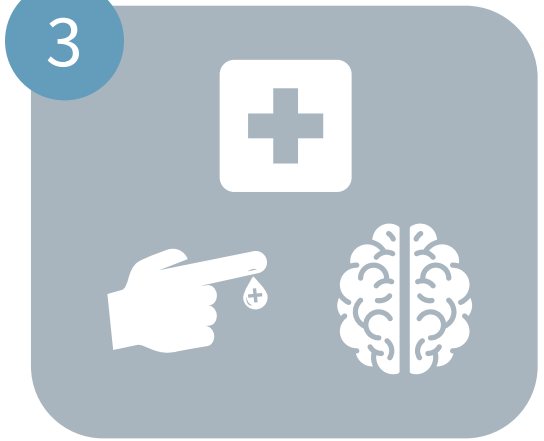
Human participants?

2



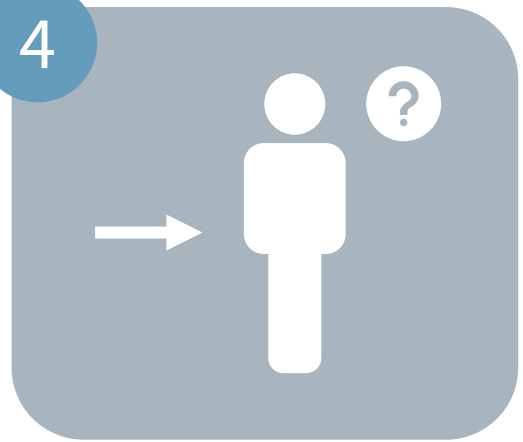
Participants prospectively assigned to intervention*?

3



Health-related biomedical or behavioral outcome?

4



Evaluates effect of intervention on participants?

The answers tell you what forms you need

NIH required	NO human subjects (HS)	HS & NO clinical trial	HS & YES clinical trial
Study Record: PHS Human Subjects and Clinical Trials Information Form	Yes *(Section 1 only)*	Yes *(Sections 1-3; #2.7, 3.3-3.5 optional)*	Yes (ALL sections)
Protection of Human Subjects	Yes (brief statement on why no human subjects)	Yes	Yes
Inclusion of Women and Minorities	N/A	Yes	Yes
Inclusion of Individuals Across Lifespan	N/A	Yes	Yes
Recruitment and Retention Plan	N/A	Yes	Yes
Study Timeline	N/A	Optional	Yes
Data and Safety Monitoring Plan	N/A	Optional (if warranted)	Yes
Overall Structure of the Study Team	N/A	Optional	Yes
Statistical Design and Power	N/A	N/A	Yes
Dissemination Plan	N/A	N/A	Yes
IP/IND/IDE status	N/A	N/A	Yes *if FDA regulated (#4.6)*
Single IRB Plan	N/A in most cases	N/A in most cases	N/A in most cases

Study Record: PHS Human Subjects and Clinical Trials Information Form

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

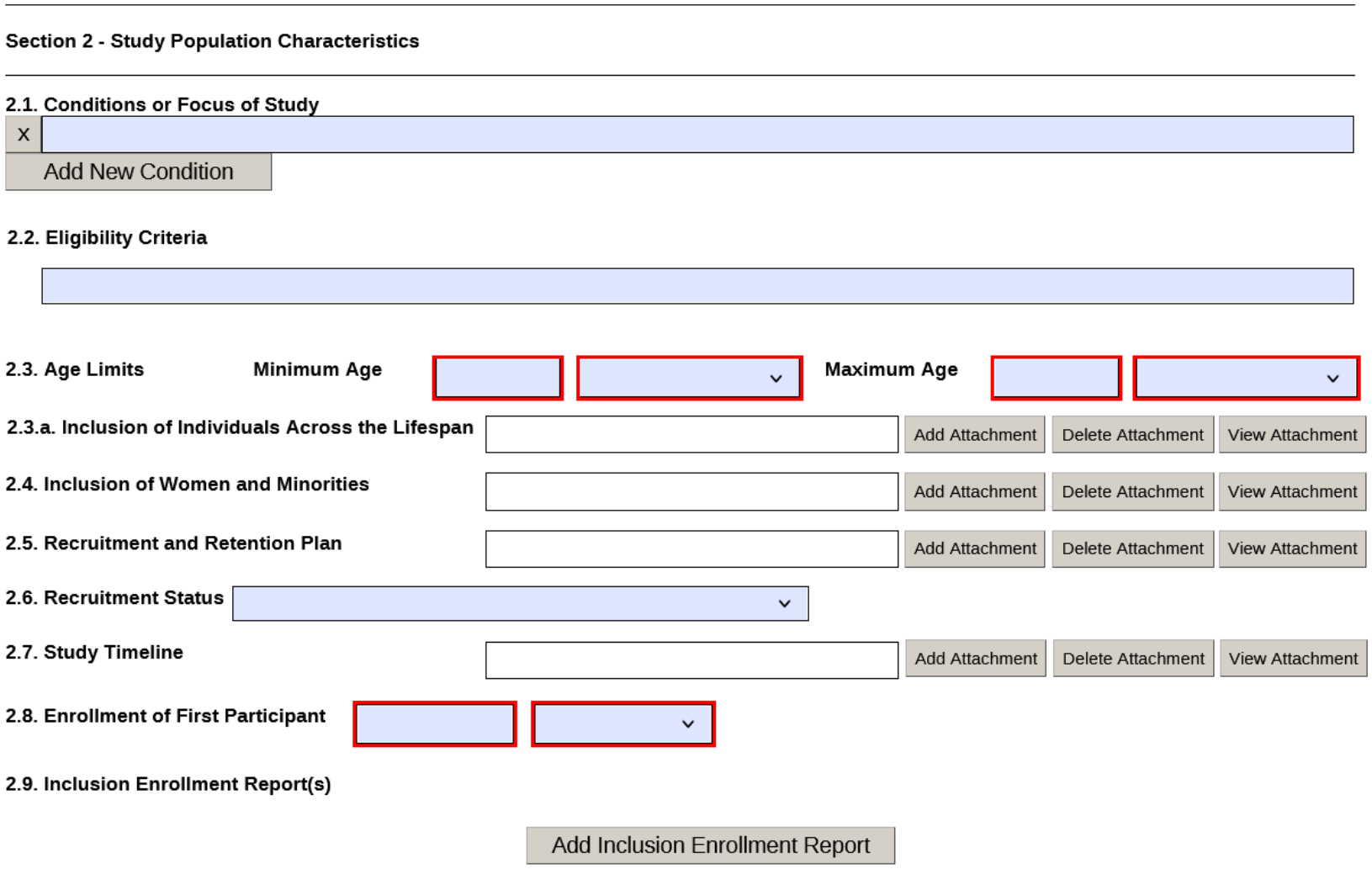
1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

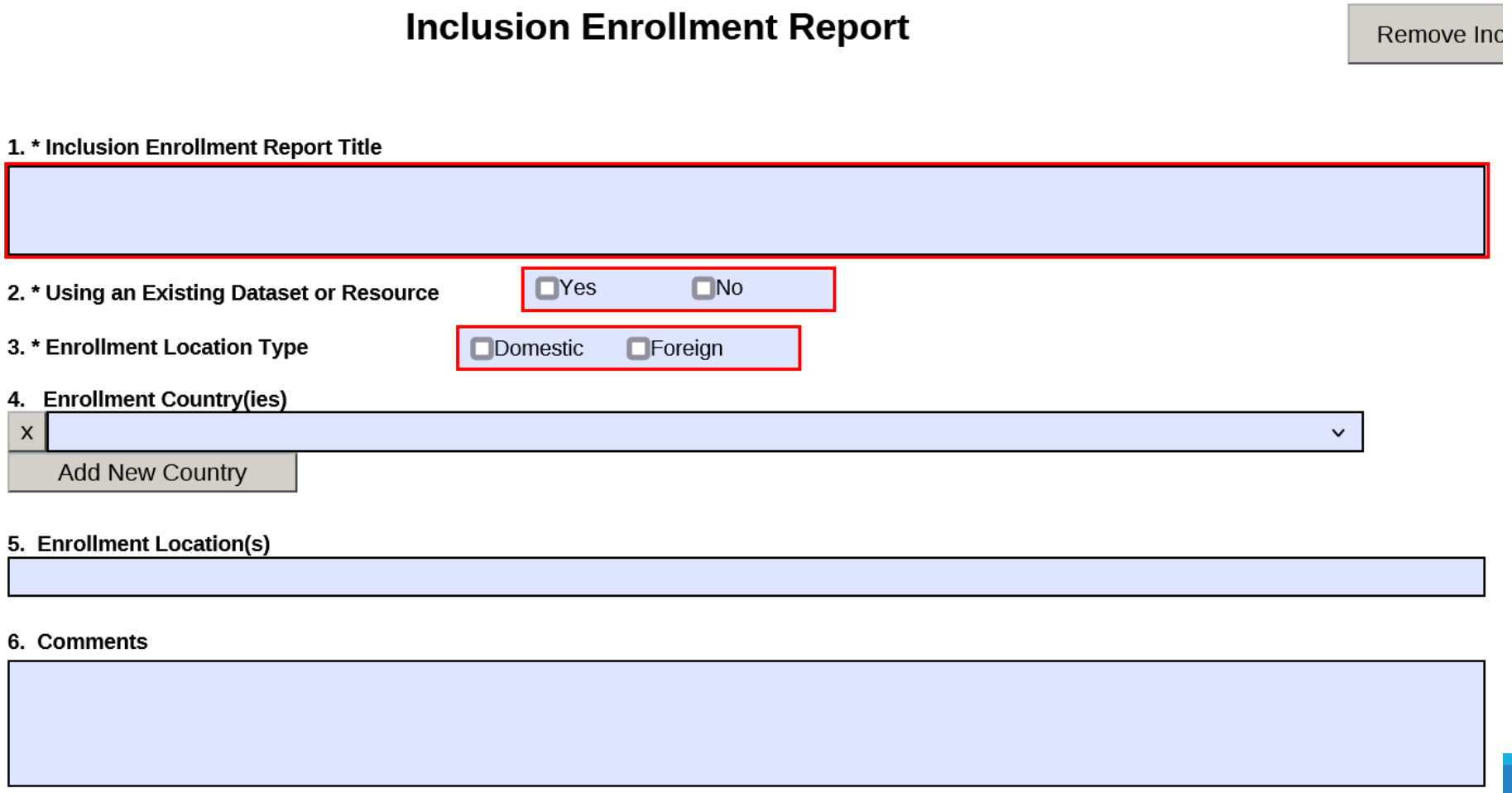
1.4.a. Does the study involve human participants?	☐ Yes ☐ No
1.4.b. Are the participants prospectively assigned to an intervention?	☐ Yes ☐ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	☐ Yes ☐ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form

Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	
Asian	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	
Black or African American	0	0	0	0	
White	0	0	0	0	
More than One Race	0	0	0	0	
Total					

Study Record: PHS Human Subjects and Clinical Trials Information Form

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects Add Attachment | Delete Attachment | View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

Single IRB plan attachment Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan Add Attachment | Delete Attachment | View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No

3.5. Overall Structure of the Study Team Add Attachment | Delete Attachment | View Attachment

Study Record: PHS Human Subjects and Clinical Trials Information Form

Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

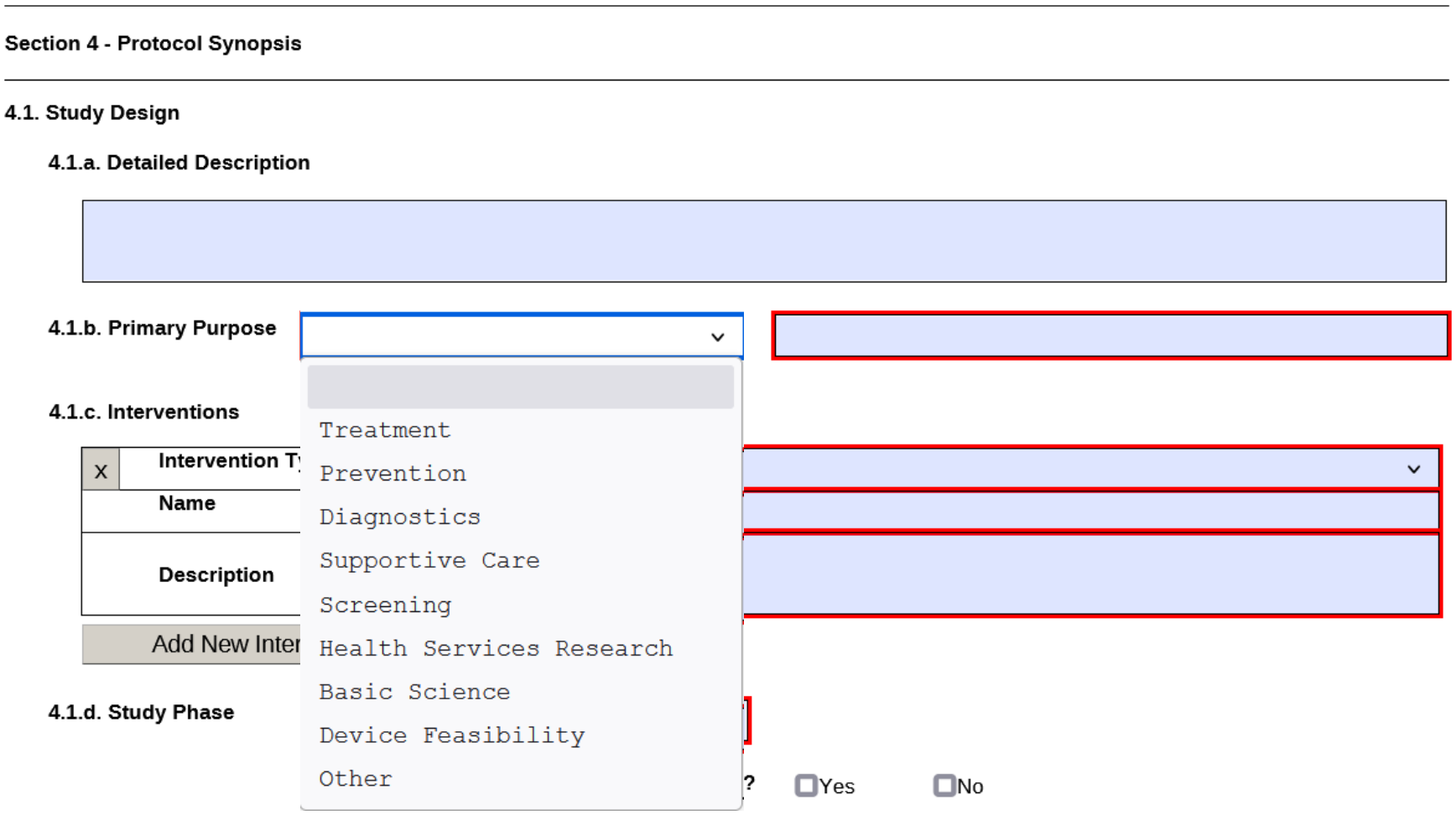
X	**Intervention Type**	
	Name	
	Description	

Add New Intervention

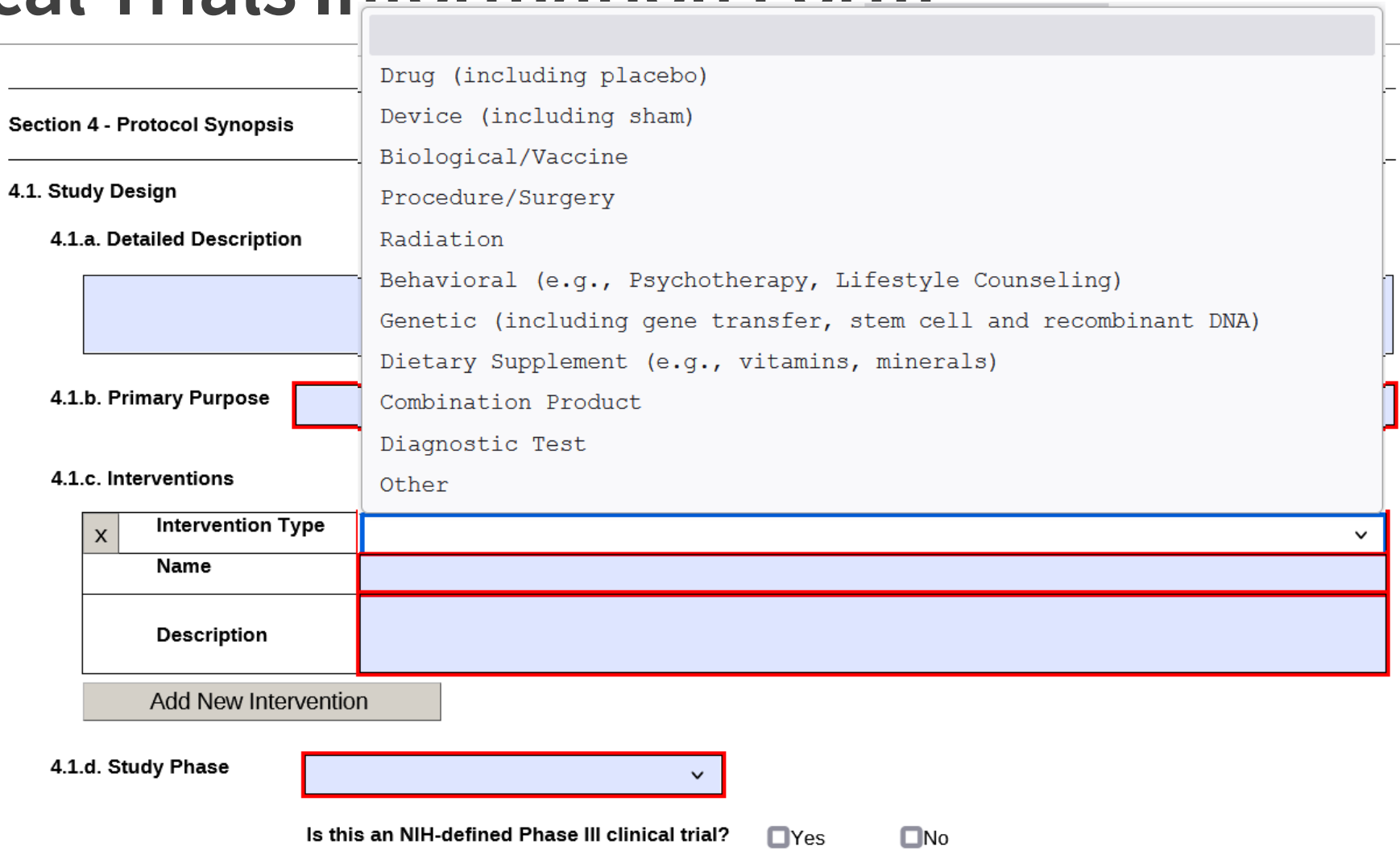
4.1.d. Study Phase

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

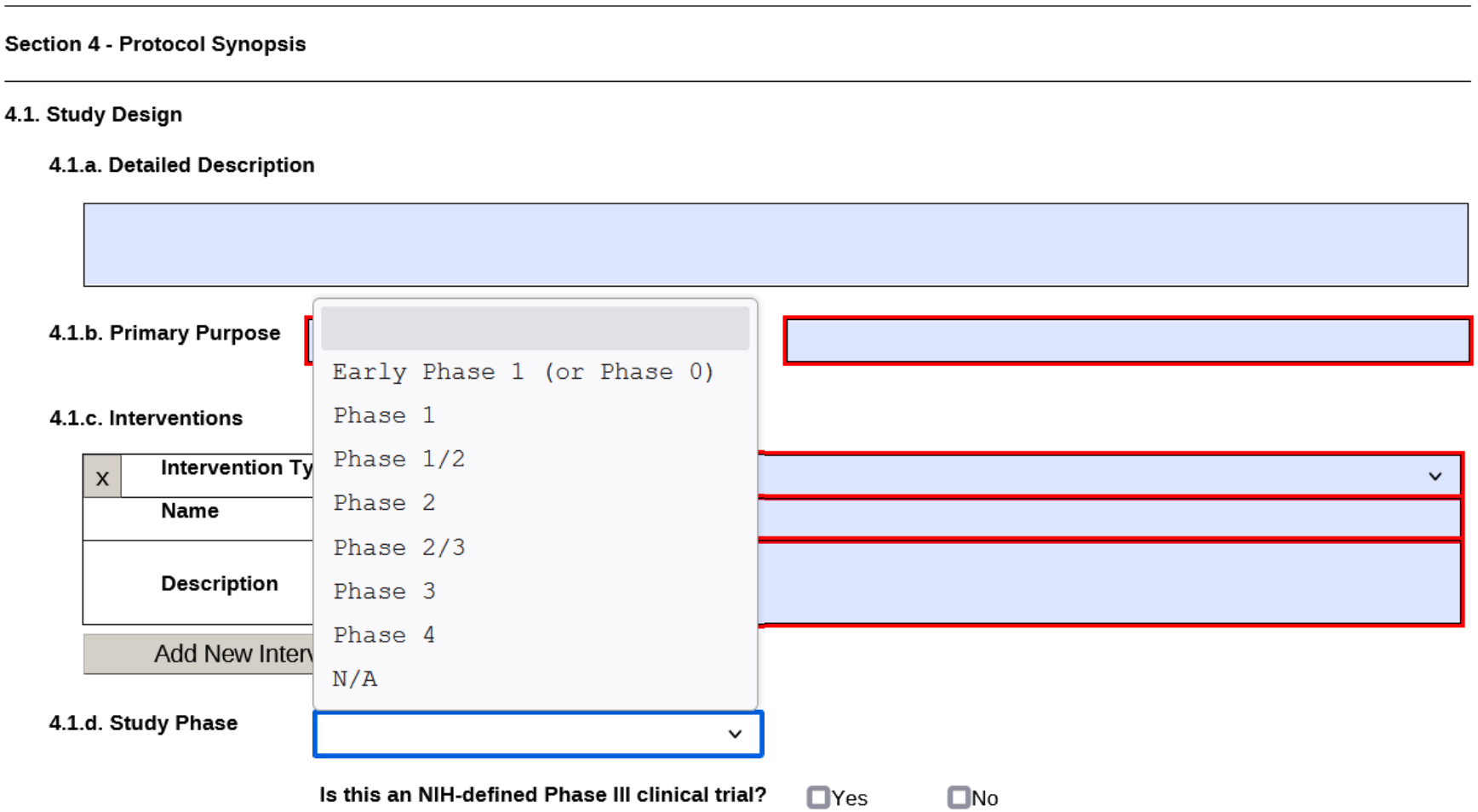
Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form

4.1.e. Intervention Model

4.1.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

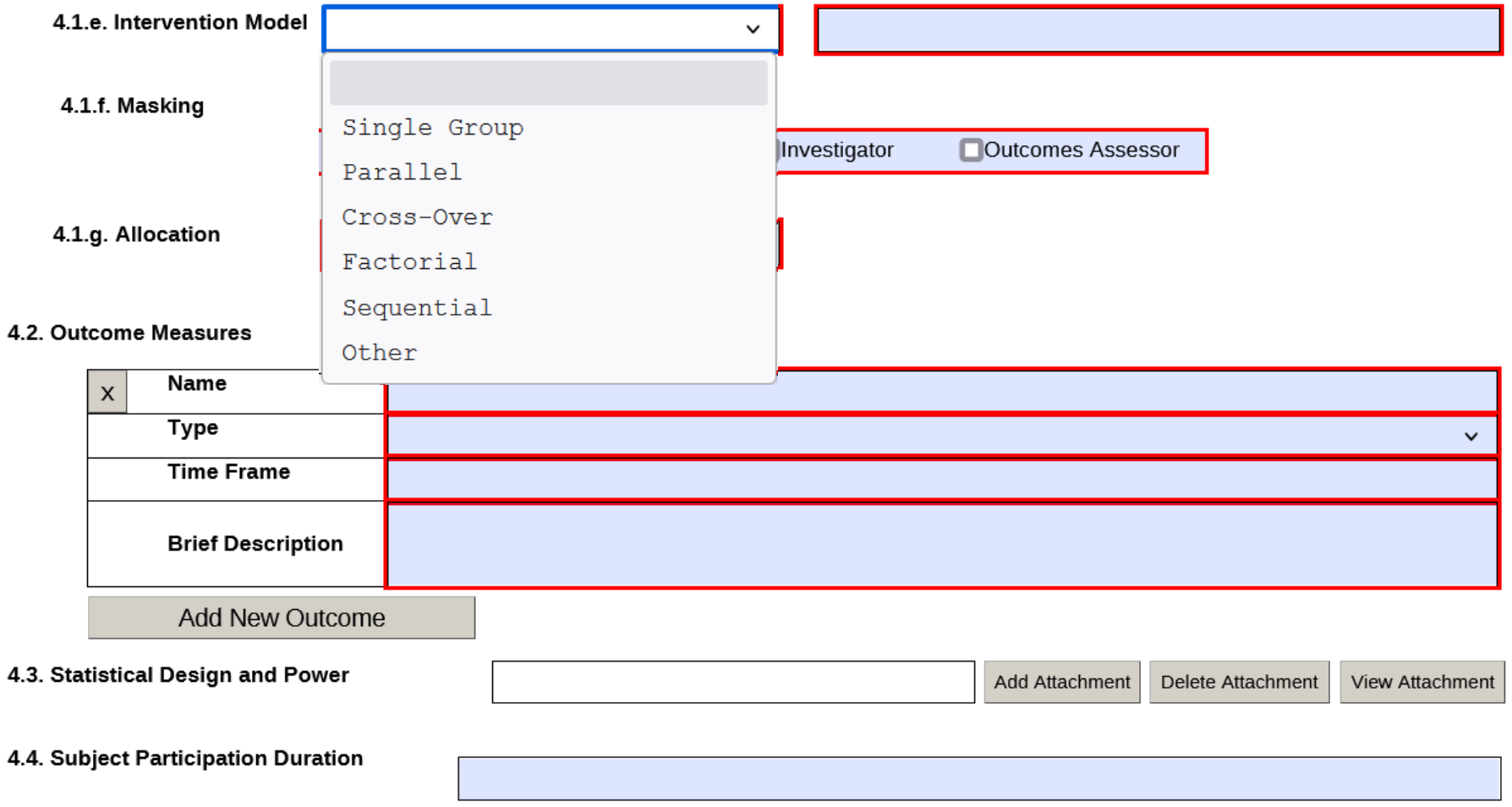
X	**Name**	
	Type	
	Time Frame	
	Brief Description	

Add New Outcome

4.3. Statistical Design and Power Add Attachment Delete Attachment View Attachment

4.4. Subject Participation Duration

Study Record: PHS Human Subjects and Clinical Trials Information Form



Study Record: PHS Human Subjects and Clinical Trials Information Form

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Add Attachment | Delete Attachment | View Attachment

4.6. Is this an applicable clinical trial under FDAAA? ☐ Yes ☐ No

4.7. Dissemination Plan

Add Attachment | Delete Attachment | View Attachment

Protection of Human Subjects

- Usually 3-5 pages
- NIH is very specific about what to include:

1. Risks to Human Subjects
   a. Human Subjects Involvement, Characteristics, and Design
   b. Study Procedures, Materials, and Potential Risks
2. Adequacy of Protection Against Risks
   a. Informed Consent and Assent
   b. Protections Against Risk
   c. Vulnerable Subjects *(if applicable)*
3. Potential Benefits of the Proposed Research to Research Participants and Others
4. Importance of the Knowledge to be Gained

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1

Potential Risks

- Side effects from medication
- Discomfort with blood draw or resulting infection
- Experimental treatment may not work!

- Anxiety or distress related to discussing their health status or other sensitive information (e.g. behaviors)

- Social harm (discrimination, rumors) if participation becomes known to others
- Intimate partner violence

***Can also mention prior experience in which studies of similar nature suggest minimal risk*

Protection Against Risks

Category	Risk	Protection?
	• Side effects from medication • Discomfort with blood draw or resulting infection • Experimental treatment may not work!	• Using an already established antibiotic • Follow-up calls to discuss side effects / visit if needed • Trained study staff to draw blood • Document adverse events (Data & Safety Monit. Plan) • If not cured at 9 months, receive standard of care
	• Anxiety or distress related to discussing their health status or other sensitive information (e.g. behaviors)	• Study staff trained to handle conversations about this health issue or sensitive information • Study staff culturally competent • Protocols to offer support (counseling) as needed
	• Social harm (discrimination, rumors) if participation becomes known to others • Intimate partner violence	• Protection of privacy and confidentiality • Standard data collection protocols, trained staff, unique participant ID numbers, etc. • IPV prevention counseling

Inclusion of Women and Minorities

- Describe the planned (expected) distribution of subjects by sex/gender, race, and ethnicity.
- Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
- Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups.
- If a Clinical Trial, this attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial *(more info about valid analysis at the link below)*.

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4

Inclusion of Individuals Across the Lifespan

- Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. In addition, address the following points:
  - Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable.
  - If individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion.
- Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.
- When children are involved in research, the policies under HHS' 45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment.

Recruitment and Retention Plan

- Describe how you will recruit and retain participants in your study.
- You should address both planned recruitment activities as well as proposed engagement strategies for retention.
- As with all these attachments, reviewers will usually look at this closely!
- This is an opportunity to save space in your Research Strategy (don’t duplicate)

Study Timeline

- Provide a description or diagram describing the study timeline.
- **The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.**
- Again, if you include this here, don’t include in the Research Strategy!

Data and Safety Monitoring Plan

- NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the clinical trial, its size, and its complexity.
- Include:
  - How many and what type of entity will provide safety monitoring
  - The overall monitoring framework (e.g. what will be monitored)
  - Frequency of monitoring
  - Process by which Adverse Events (including Serious Adverse Events) will be handled

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3

Overall Structure of the Study Team

- Provide a brief overview of the organizational/administrative structure and function of the study team
  - Particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.
  - **Who will do what? (Make clear why the different roles exist; there is no unnecessary overlap)**
- May include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported
- **Do not include study team members' individual professional experiences (i.e., biosketch information)**

Statistical Design and Power

- Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use **with respect to each outcome measure you listed in 4.2 Outcome Measures**
- Demonstrate that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions
- For trials that randomize groups or deliver interventions to groups, special methods are required and must be described

Dissemination Plan

- Include sufficient information to assure reviewers you will:
  - Ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov according to the specific terms and timelines stated in the policy;
  - Include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov in your informed consent forms; and
  - Have an internal policy in place at the applicant institution to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.
- **Do not include informed consent documents in the Dissemination Plan attachment.**

IP/IND/IDE status

- Only if you answered "Yes" to the "Will the study use an FDA-regulated intervention?"
- Provide a summary describing the availability of study agents and support for the acquisition and administration of the study agent(s).
- Indicate, if applicable, the IND/IDE status of the study agent, including whether a clinical investigation is exempt from the IND/IDE requirement.
- Indicate whether the investigators have had any interactions with the FDA (e.g., indicate if the FDA has stated that research may proceed).
- If the study agent currently has an IND/IDE number, provide that information.
- Do not include the IND/IDE application, manufacturer's product specifications, study protocol, or protocol amendments in this attachment.

Single IRB Plan

- Only applies to participating sites in the United States, if there are multiple domestic sites and the application is subject to the revised Common Rule.

Reminder: Formatting!

- U.S. Letter Size Paper (not A4)
- Minimum 11 point font
- Typical font (e.g. Arial, Times, Calibri)
- 0.5” minimum margins
- Be consistent with formatting for Research Strategy/Aims
- For human subjects/clinical trials: no page limits
  - But doesn’t mean you should submit huge files!
  - Provide thorough information, but as succinct as possible

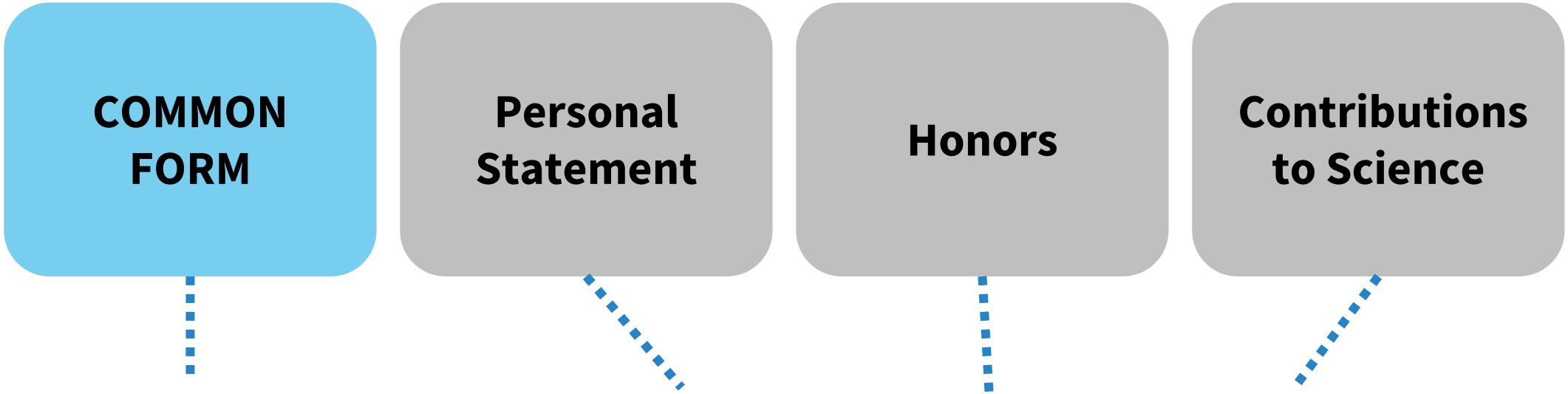
Plan for the Morning

1. Human Subjects Documents
2. **Biosketches**

CURRENTLY UNDERGOING AN OVERHAUL, WITH NEW INSTRUCTIONS RELEASED/REQUIRED FOR NIH PROPOSALS SUBMITTED MAY 2025 AND ONWARD

BEGINNING MAY 2025….

Biosketches: The Big Picture



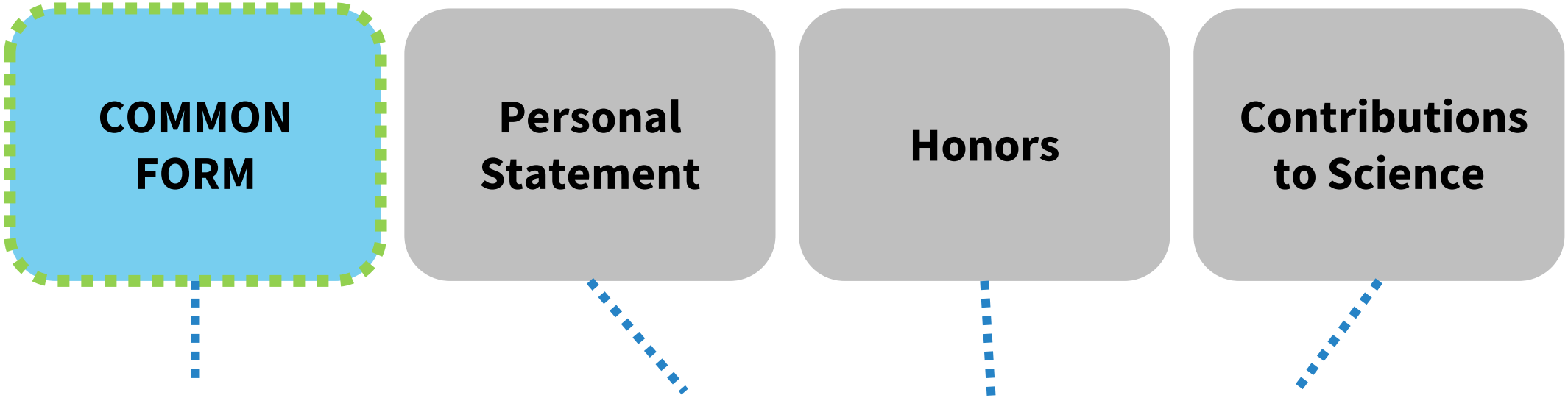
Standardized form used across federal funding (new for NIH grants)

Parts of current NIH biosketch that are not included in the standardized federal common form

https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

BEGINNING MAY 2025….

Biosketches: The Big Picture



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BEGINNING MAY 2025….

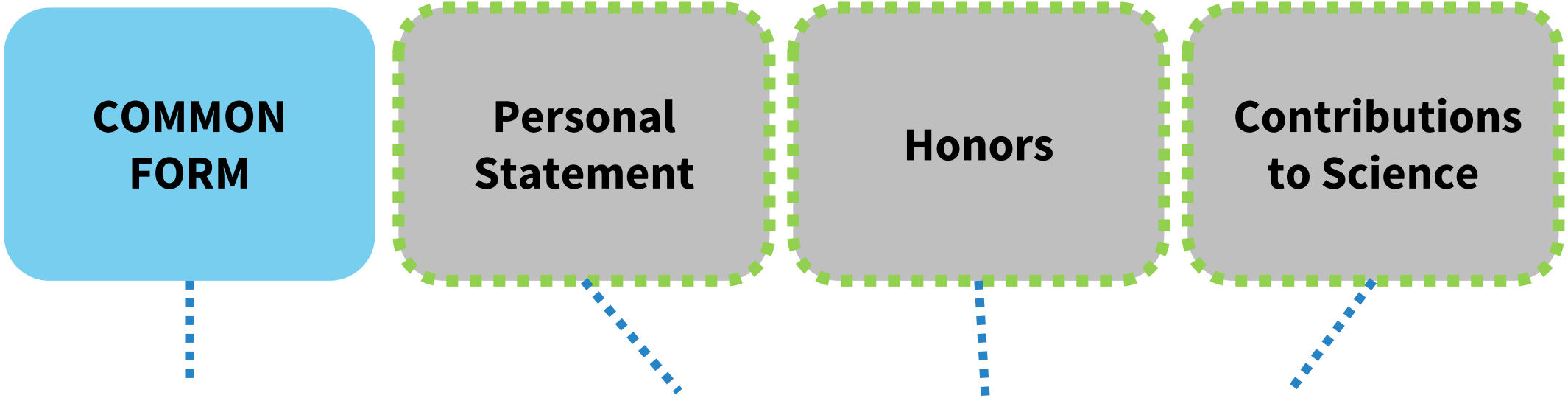
What do we know about the common form?

- Key required elements will likely include basic information:
  - Name
  - Position Title (in everyday life)
  - Organization & Location
  - Professional Preparation (education/training)
  - Appointments and Position
  - Products (publications, conference papers, presentations, websites, technologies, inventions, licenses, patent applications, etc.)
  - Certification that information provided is true and meets certain criteria

https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

BEGINNING MAY 2025….

Biosketches: The Big Picture



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https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

BEGINNING MAY 2025….

What about the other parts of the new biosketch?

- We don’t know much about the specifics!
- But we can guess based on what the requirements are currently for personal statements, honors, and contributions to science

https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

CURRENT & LIKELY FUTURE BIOSKETCH ELEMENT

Personal Statement

- In current biosketches for research proposals, the personal statement focuses on explaining why you are well-suited for your role on the project based on your expertise, training, previous research, previous collaborations, institution, etc.
- In this section, you can directly cite up to four publications/research projects that show your qualifications
  - Use a proper citation, with PMCID#, if available
  - Interim research products require specific citations
  - These should not be duplicated elsewhere in the biosketch

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm#Instructions

Example from NIH website (three slides)

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with substance use disorders. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of substance use disorders. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to older people with substance use disorders, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2015-2016, my career was disrupted due to family obligations. However, upon returning to the field, I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have the expertise, leadership, training, expertise, and motivation necessary to successfully carry out the proposed research project.

Example from NIH website (three slides)

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression, and substance use among older adults

R21 AA998075
Hunt (PI)
01/01/19-12/31/21
Community-based intervention for alcohol abuse

Example from NIH website (three slides)

Name of person writing biosketch bolded

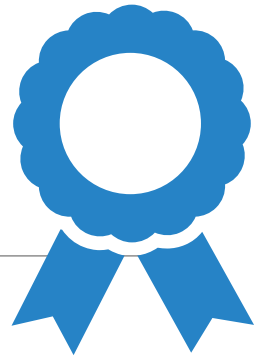
Citations:

1. Merryle, R.J. & **Hunt, M.C.** (2015). Independent living, physical disability and substance use among older adults. Psychology and Aging, 23(4), 10-22.
2. **Hunt, M.C.**, Jensen, J.L. & Crenshaw, W. (2018). Substance use and mental health among community-dwelling older adults. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. **Hunt, M.C.**, Wiechelt, S.A. & Merryle, R. (2019). Predicting the substance use treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Merryle, R. & **Hunt, M.C.** (2020). Randomized clinical trial of cotinine in older people with nicotine use disorder. Age and Aging, 38(2), 9-23. PMCID: PMC9002364

PMCID# when applicable

CURRENT & LIKELY FUTURE BIOSKETCH ELEMENT

Honors



- In current biosketch for research proposals, there is a section for positions, scientific appointments, and honors
- However, positions and appointments appear to move to the common form, just leaving honors
- Honors, such as awards, certifications, traineeships, etc., are listed in reverse chronological order, by year

https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

Example from NIH website

Honors

2020	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
2019	Excellence in Teaching, Washington University, St. Louis, MO
2018	Outstanding Young Faculty Award, Washington University, St. Louis, MO

CURRENT & LIKELY FUTURE BIOSKETCH ELEMENT

Contributions to Science (next two slides)

- In current biosketches for research proposals, the Contributions to Science section allows for up to 5 descriptions (up to half a page each) of your most significant contributions to science, describing:
  - “the historical background that frames the scientific problem;
  - the central finding(s);
  - the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology;
  - and your specific role in the described work.”

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm#Instructions

CURRENT & LIKELY FUTURE BIOSKETCH ELEMENT

Contributions to Science

- May cite up to **four** of your research products for each of the **five** contributions
  - Use a proper citation, with PMCID#, if available
  - Interim research products require specific citations
  - These should not be duplicated elsewhere in the biosketch
- Link to full published works in MyBibliography at end of this section
- As with all parts of the biosketch, no graphics, figures, tables, links, or attachments

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm#Instructions

Example from NIH website
(just one of 5 possible contributions shown here)

3. Methadone maintenance has been used to treat people with substance use disorder for many years, but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Older adults were shown, in carefully constructed ethnographic studies, to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

    a. **Hunt, M.C.** & Jensen, J.L. (2013). Morbidity among older adults with substance use disorders. Journal of the Geriatrics, 60(4), 45-61.
    b. **Hunt, M.C.** & Pour, B. (2015). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
    c. Merryle, R. & **Hunt, M.C.** (2018). The use of various nicotine delivery systems by older people with nicotine use disorder. Journal of Aging, 54(1), 24-41. PMCID: PMC9112304
    d. **Hunt, M.C.**, Jensen, J.L. & Merryle, R. (2020). Aging and substance use disorder: ethnographic profiles of older people with substance use disorder. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1ICifFFV4VYQZE/bibliography/public/

CURRENT BIOSKETCHES…

Common Biosketch Mistakes

- Not following the strict formatting required by NIH:
  - Too many pages (current restriction is up to 5)
  - Too many contributions to science (only can have 5)
  - Too many publications per contribution to science (up to 4 per contribution)
  - Including hyperlinks or graphics
- Not tailoring the personal statement enough:
  - Including generic information about your skills/expertise instead of making it really support this research project

https://grants.nih.gov/grants-process/write-application/forms-directory/biosketch

TO CREATE YOUR BIOSKETCH (BEFORE MAY 2025)

Use template or generate in SciENcv

- Current Word template for non-fellowship proposals:
  - https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx
- Link to SciENCV (requires you create an NIH log-in):
  - http://www.ncbi.nlm.nih.gov/sciencv/
- Current instructions for non-fellowship biosketch:
  - https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm#Instructions

SEE NIH WEBSITE FOR FUTURE INSTRUCTIONS FOR BIOSKETCHES STARTING MAY 2025

What the Word template looks like (before May 2025)

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 01/31/2026)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science

What the sciENcv interface looks like (before May 2025)

Edit each section

My NCBI » SciENcv » Test biosketch

SciENcv: About | Using

Profile name: Test biosketch [Edit]

Download: PDF Word XML

Profile type: NIH Biosketch NIH Biographical Sketch Instructions

Last Updated: 17 October 2024

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NAME [Edit]
Facente, Shelley

Click here to link eRA Commons account

EDUCATION/TRAINING

(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)
You have not listed any degree or training. Please add one.

A. Personal Statement [Edit statement]

You have not yet provided a personal statement.

Optional: You may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.

[Select citations]

You have not listed any citations.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments
You have not listed any employment. Please add one.

Honors
You have not listed any honors. Please add one.

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C. Contribution to Science [Edit section]

This section is currently empty. Click on edit section to add your contributions.

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