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Responding to Delaware INBRE RFA
Clinical Trial Forms

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&

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RFA Details

RFA Website:
https://de-inbre.org/de-inbre-drpp-request-for-applications/

1. Research Projects

80K/year for 2 years ($160K total), 50% research/professional effort confirmed by chair.

2. Pilot Projects

40K/year for 1 year, 25% research/professional effort confirmed by chair.
For both, mentor required, if a new/early stage investigator.

Application Timeline

- Letter of Intent (LOI) due: September 23, 2024
- Full Proposal due: October 21, 2024
- Just in Time: March 03, 2025
- All submissions via the Piestar RFx system: https://de-inbre.piestar-rfx.com/rfps

Formatting Requirements

~11 point or larger Arial, Helvetica, Georgia, or Palatino Linotype fonts (non-condensed), single (or higher) paragraph spacing, and ½ inch margins. Similar to those of NIH R type, small grant proposals.

Clinical Trial Form

- Initial Questions-Part 1
  - Does your project involve human subjects? Yes No
  - If there is a non-human subjects component, explain (add attacht.)
  - Does your project involve human subjects? Yes No
  - Is the project exempt from federal regulations? Yes No
  - List the exemption #: Check 1-8

PHS Human Subjects and Clinical Trials Information

View Burden Statement

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

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data? ☒ Yes ☐ No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment | Delete Attachment | View Attachment

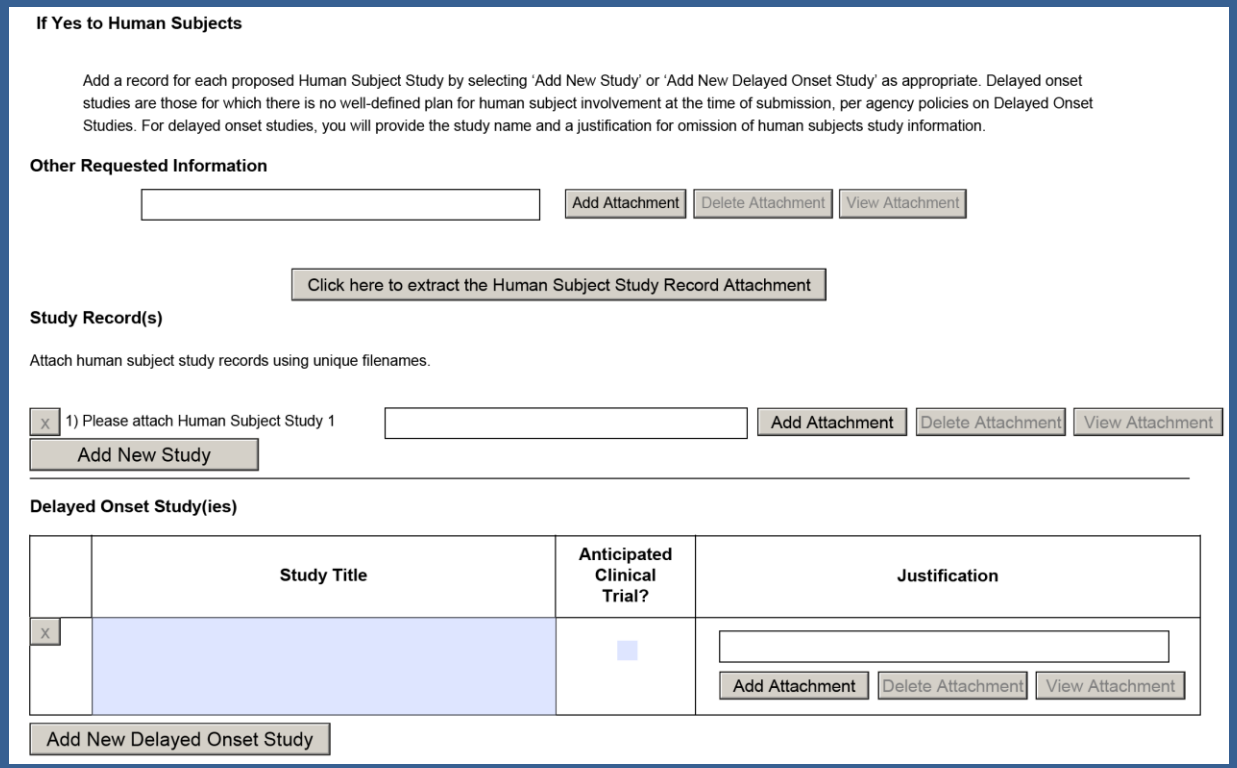
Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?	☒ Yes	☐ No
Is the Project Exempt from Federal regulations?	☐ Yes	☒ No
Exemption number:	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8	

Clinical Trial Form

- Initial Questions-Part 2
  - Extract the study record pdf by clicking the center button.
  - Upload the second form (Study Record) by clicking on "Add attachment".
  - New Delayed Onset Study option is for studies with no well-defined plan of human subjects involvement. You will need to justify omission of human subjects study information.



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2. Study Record Form

- Section 1: Basic Information
- Study Title, Exemption Questions
- Clinical Trial Questionnaire
  - Human Subjects: Y or N
  - Prospective Study: Y or N
  - Does your study evaluate effect of an intervention (even if a few minutes of treatment)? Y or N
  - Is there a health-related biomedical or behavioral outcome? Y or N

Ask for help: human subjects contact/me/mentor

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

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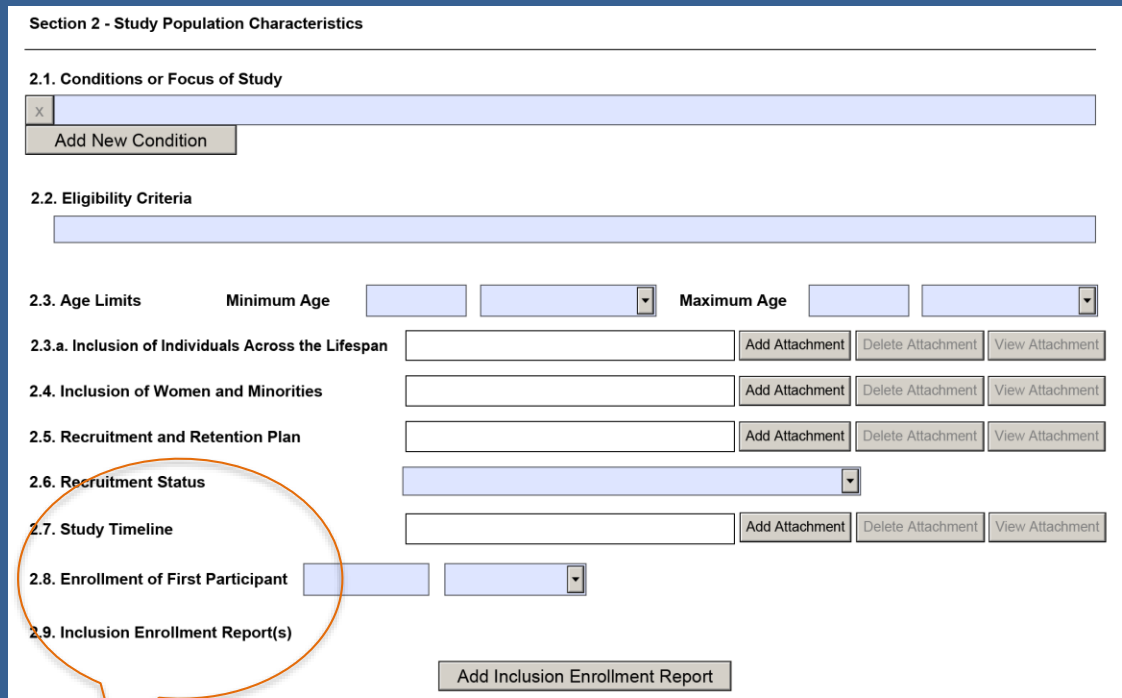
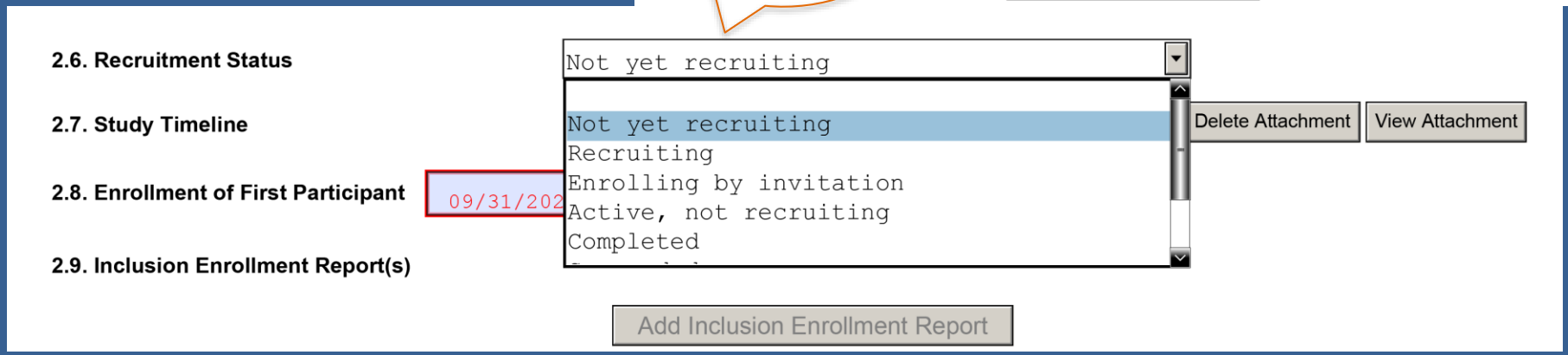
Study Record Form

Section 2: Study / Group Characteristics

- Study Conditions or groups
  e.g., Rhythm vs. Seated Play
- Eligibility Criteria, Age ranges
- Inclusion forms
  Lifespan, Women & Minorities
- Recruitment & Retention Plan
- Recruitment Status
- Study Timeline
- Enrollment Date
- Inclusion Enrollment Report





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Study Record Form

- ## Section 2: Inclusion Enrollment Report
- Enrollment details
- Based on your geo. location, diagnosis, and past study demographics divide your sample based on sex, race, and ethnicity.

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Effects of embodied rhythm interventions on the social-motor, cognitive-motor, and functional participation skills of children with Autism Spectrum Disorder (ASD)

2. * Using an Existing Dataset or Resource ☐ Yes ☒ No

3. * Enrollment Location Type ☒ Domestic ☐ Foreign

4. Enrollment Country(ies)

x USA: UNITED STATES

Add New Country

5. Enrollment Location(s)

Newark, DE & Storrs, CT

6. Comments

Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	7	10	0	0	17
Asian	3	4	0	0	7
Native Hawaiian or Other Pacific Islander	2	4	0	0	6
Black or African American	16	23	6	8	53
White	11	16	4	5	36
More than One Race	0	0	0	1	1
Total	39	57	10	14	120

Study Record Form

- Section 3: Human Subjects Protection & Monitoring
- Protection of Human Subjects
- Single IRB Plan
- Data Safety and Monitoring Plan & DSMB
- Overall Structure of the Study Team

Ask for help: human subjects contact/me/mentor

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects	4AHumSubSection.pdf	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

If yes, describe the single IRB plan	4BSingleIRB.pdf	Add Attachment	Delete Attachment	View Attachment
3.3. Data and Safety Monitoring Plan	4CDSMP.pdf	Add Attachment	Delete Attachment	View Attachment

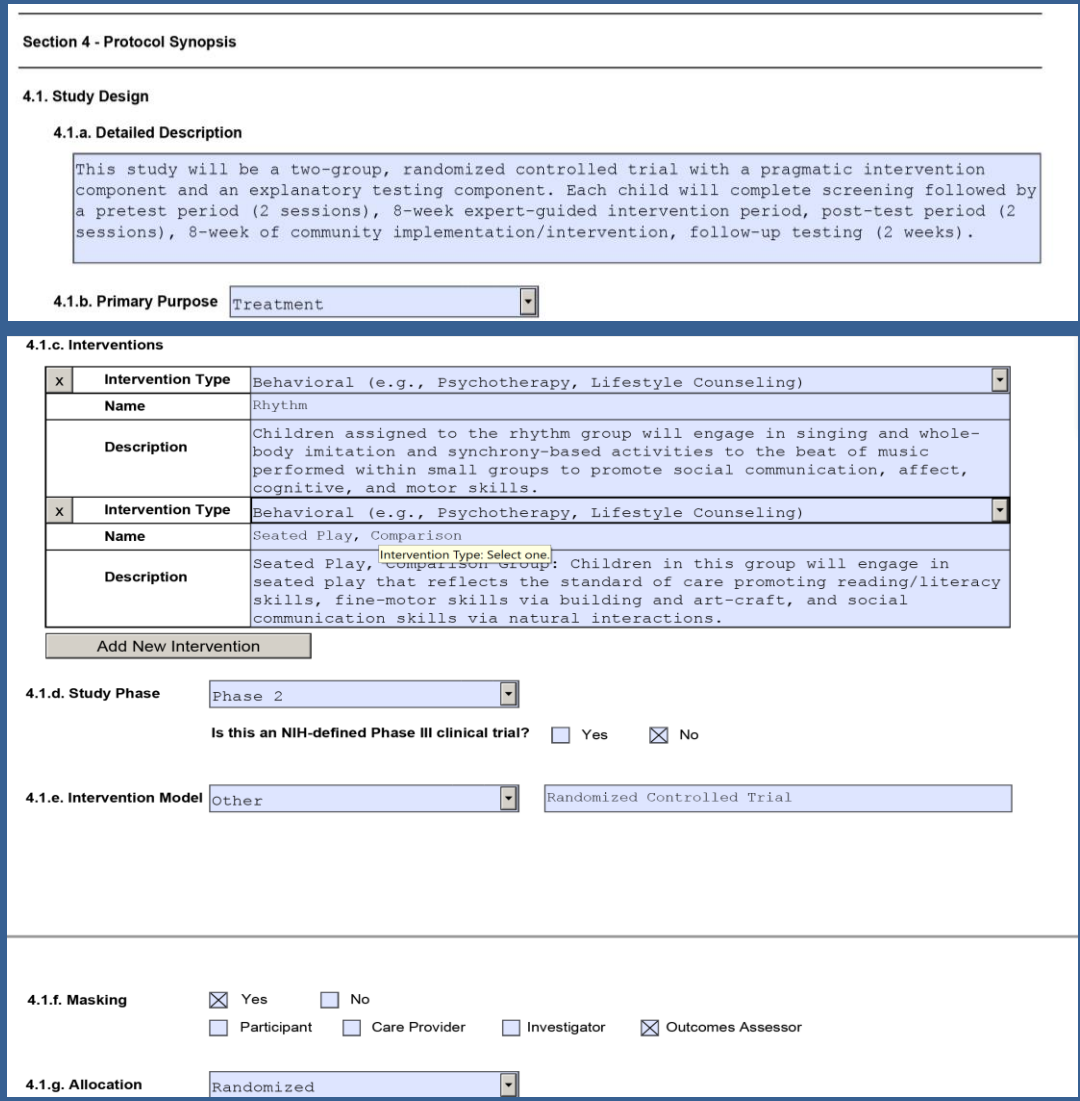
3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☒ No

3.5. Overall Structure of the Study Team	9StrucofTeam.pdf	Add Attachment	Delete Attachment	View Attachment

Study Record Form

- ## Section 4: Protocol Synopsis
- Describe study design, intervention, phase, model, masking, allocation.



Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

This study will be a two-group, randomized controlled trial with a pragmatic intervention component and an explanatory testing component. Each child will complete screening followed by a pretest period (2 sessions), 8-week expert-guided intervention period, post-test period (2 sessions), 8-week of community implementation/intervention, follow-up testing (2 weeks).

4.1.b. Primary Purpose Treatment

4.1.c. Interventions

x	**Intervention Type**	Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
	Name	Rhythm
	Description	Children assigned to the rhythm group will engage in singing and whole-body imitation and synchrony-based activities to the beat of music performed within small groups to promote social communication, affect, cognitive, and motor skills.
x	**Intervention Type**	Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
	Name	Seated Play, Comparison
	Description	Seated Play, ~~Comparison Group~~: Children in this group will engage in seated play that reflects the standard of care promoting reading/literacy skills, fine-motor skills via building and art-craft, and social communication skills via natural interactions.

Intervention Type: Select one.

Add New Intervention

4.1.d. Study Phase Phase 2

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

4.1.e. Intervention Model Other — Randomized Controlled Trial

4.1.f. Masking ☒ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☒ Outcomes Assessor

4.1.g. Allocation Randomized

Study Record Form

- Section 4: Protocol Synopsis
- Outcome Measures

4.2. Outcome Measures

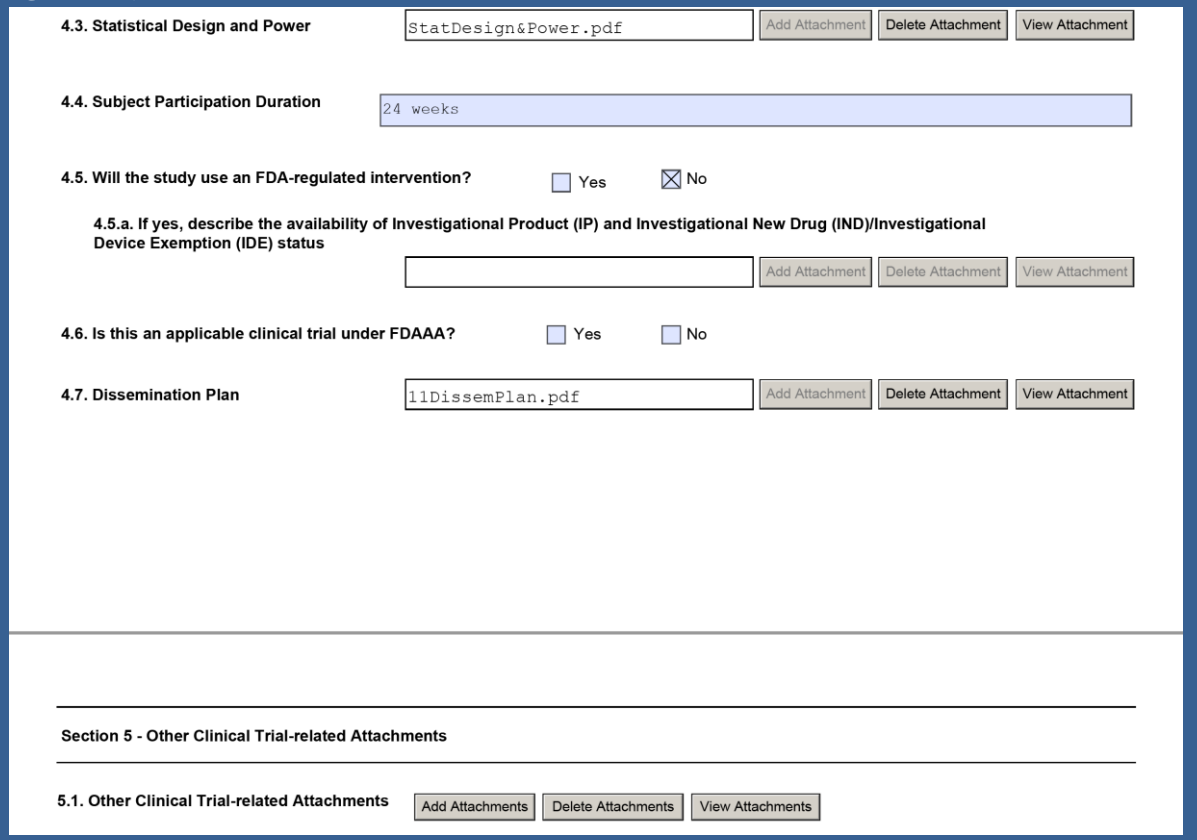
x	**Name**	Developmental Coordination Disorder Questionnaire (DCD-Q) (Wilson, 2009)
	Type	Primary
	Time Frame	10 minutes
	Brief Description	It is a 15-item parent questionnaire to assess a child's gross- and fine-motor coordination during everyday functional/play skills within the child's natural environment using a 5-point Likert scale. The total scores ranging from 15-55 indicate susceptibility to having DCD. This will be administered in the pre, post, and follow-up tests. The measure has high internal consistency and has 75-89% sensitivity.
x	**Name**	Goal Attainment Scaling (GAS) (Kiresuk & Sherman, 1968)
	Type	Primary
	Time Frame	10 minutes
	Brief Description	It will be used to assess improvements on functional training goals co-identified by clinicians and caregivers. The scale will be administered at pretest, posttest, and follow-up. Additionally, the scale will be used to assess progress in training goals on a session-by-session basis during the training period.
x	**Name**	Caregiver and Child Exit Questionnaires
	Type	Primary
	Time Frame	10 minutes
	Brief Description	These will be filled out at the post-test and follow-up to assess children's and caregiver's opinions on the training and their views on enjoyment, utility, and effectiveness of training activities.

Add New Outcome

Study Record Form

- Section 4 & 5: More Study Details
- Statistical Design & Power
- Subject Participation Duration
- Is this FDA regulated intervention & if an applicable clinical trial under FDAAA?
- Dissemination Plan
- Other Attachments – Resource Sharing Plan, etc.

Ask for help: human subjects contact/me/mentor



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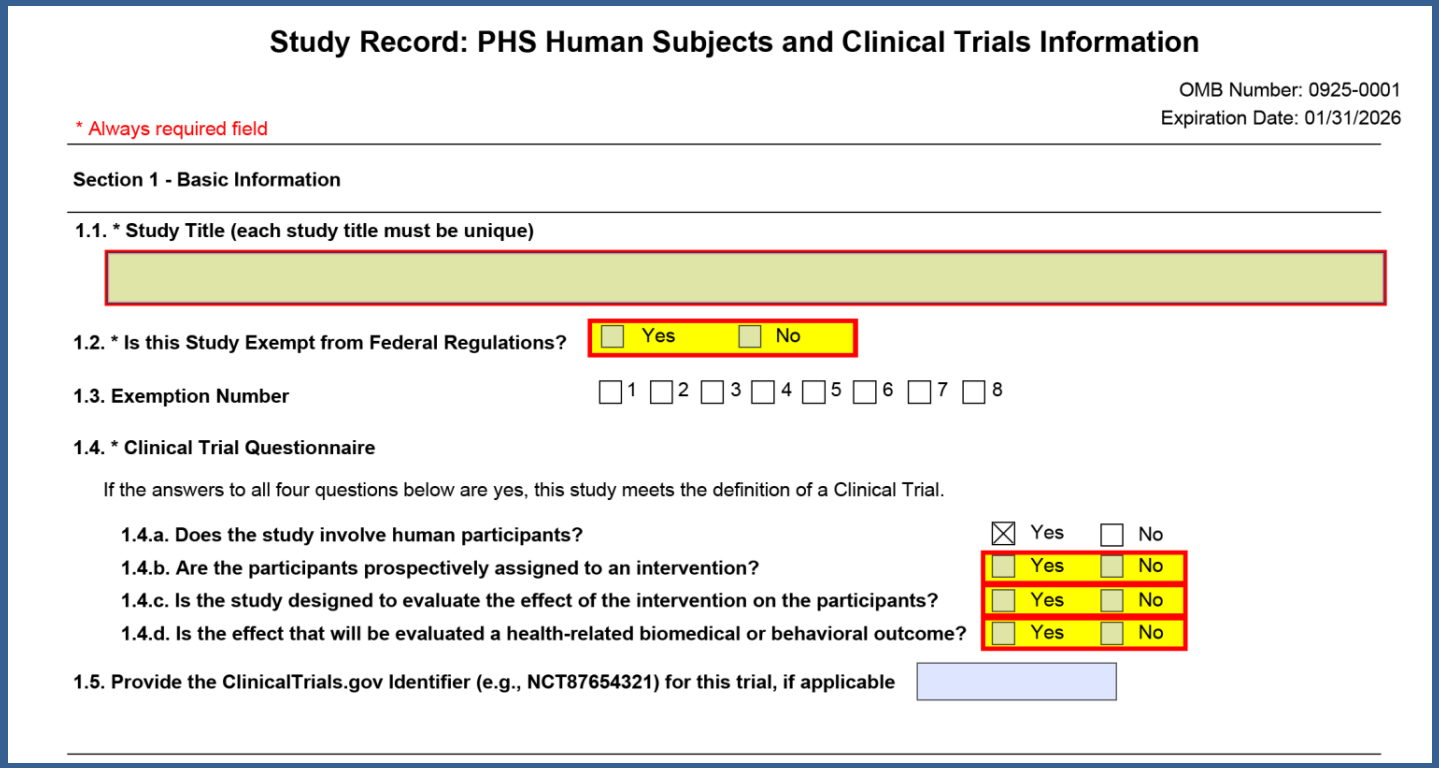
Group 2: Human Subjects but not a Clinical Trial

Group 1: Exempt studies
Group 2: Human Subjects Studies but not trials
Group 3: Clinical Trials (Yes to all questions below)



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

- If Group 2: Sections 1, 2 must be completed
- Section 3.1 on Protection of Human Subjects must be completed

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Important Contacts

Any Questions!

Mentoring Contacts

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