Preparing the NIH Protection of Human Subjects Section and an Overview of NIH's New Policies

Dawn Corbett (NIH/OER)

National Institutes of Health
Office of Extramural Research

Goals

- Learn how to complete the protection of human subjects section of the NIH Human Subjects and Clinical Trials Information Form
- Understand how NIH evaluates human subjects and inclusion in grant applications
- Identify the requirements for research involving human subjects for NIH awards
- Understand new NIH policies regarding human subjects research and how they relate to your application

Have you conducted human subjects research?

A. Yes, I am conducting or have conducted HS research.

B. No, but I plan to.

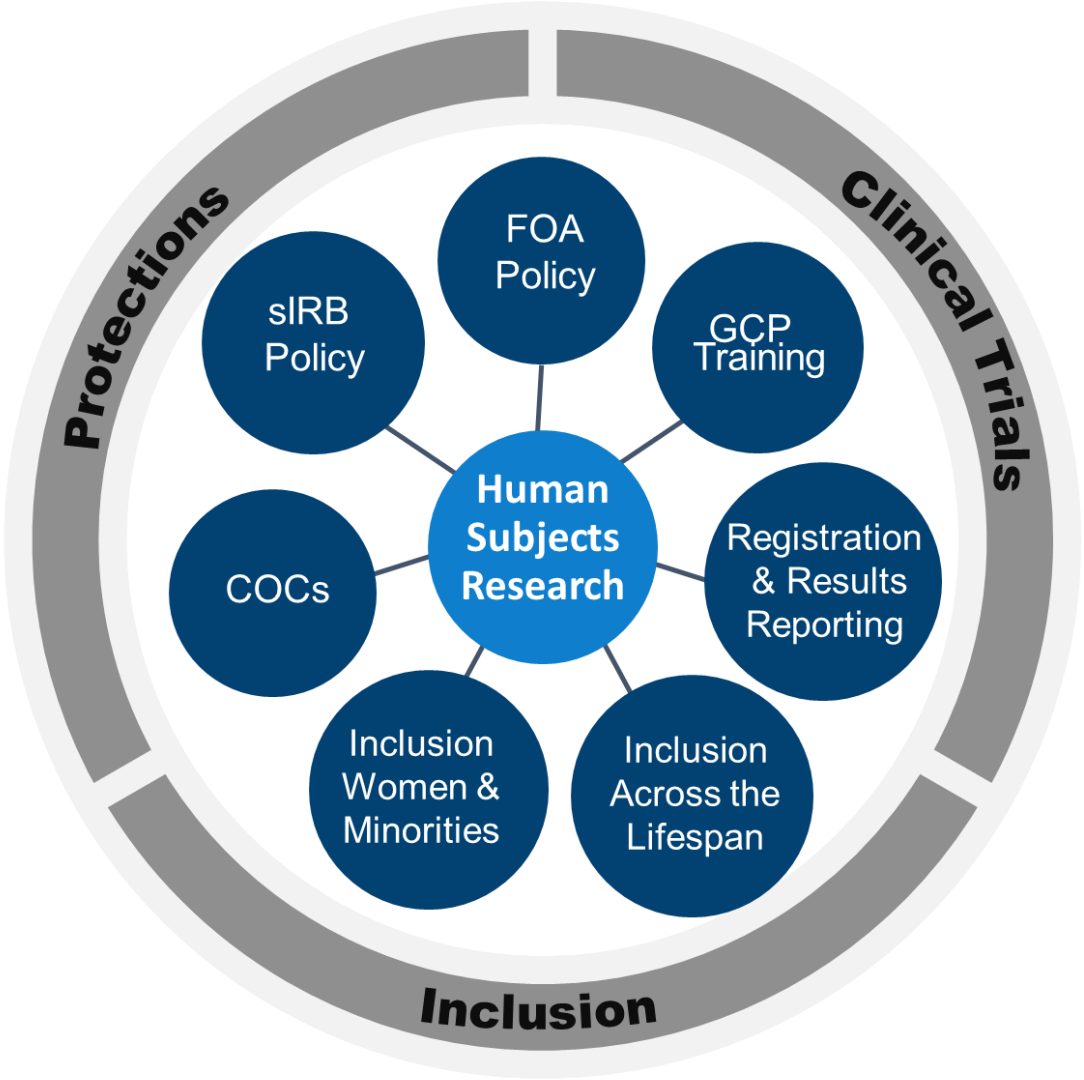
C. No, but I provide oversight of human subjects research at my institution

D. I'm not sure.

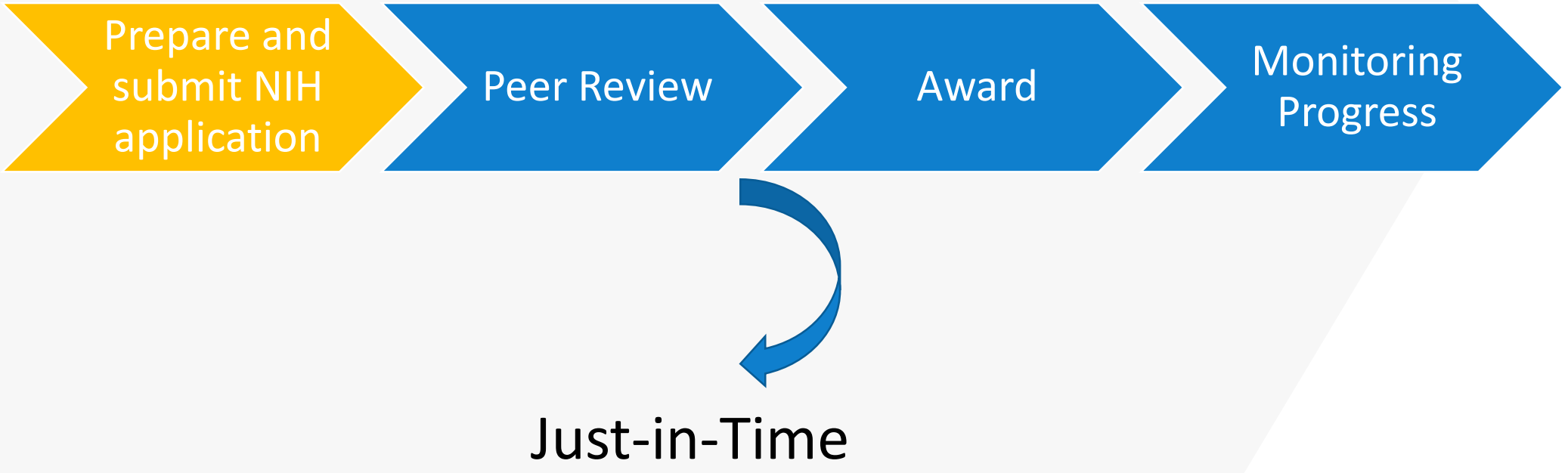
NIH's Role

- Evaluate applications/proposals involving human subjects for
  - Risks
  - Adequacy of protections
  - Benefits
  - Importance of knowledge to be gained
- NIH delegates to peer review

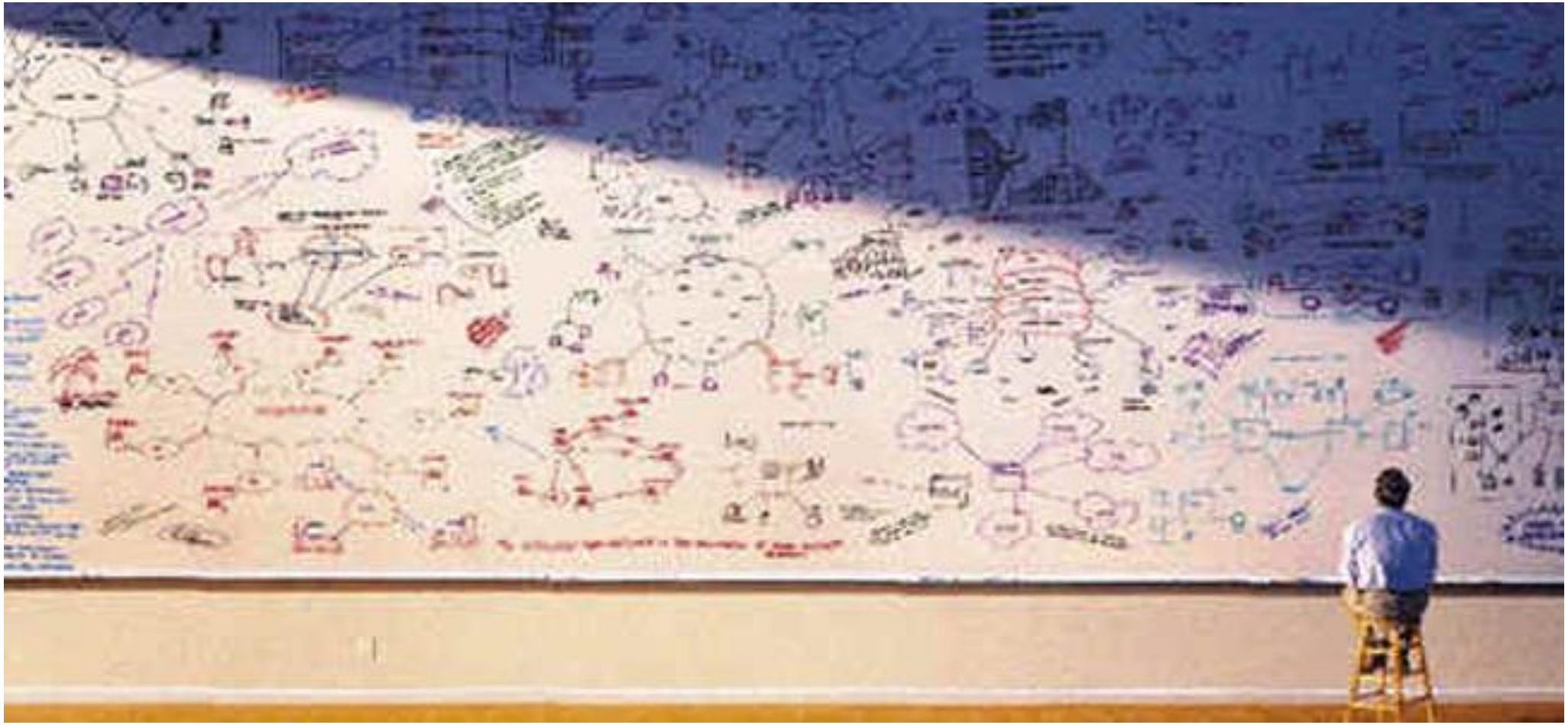
Human Subjects Research Policies



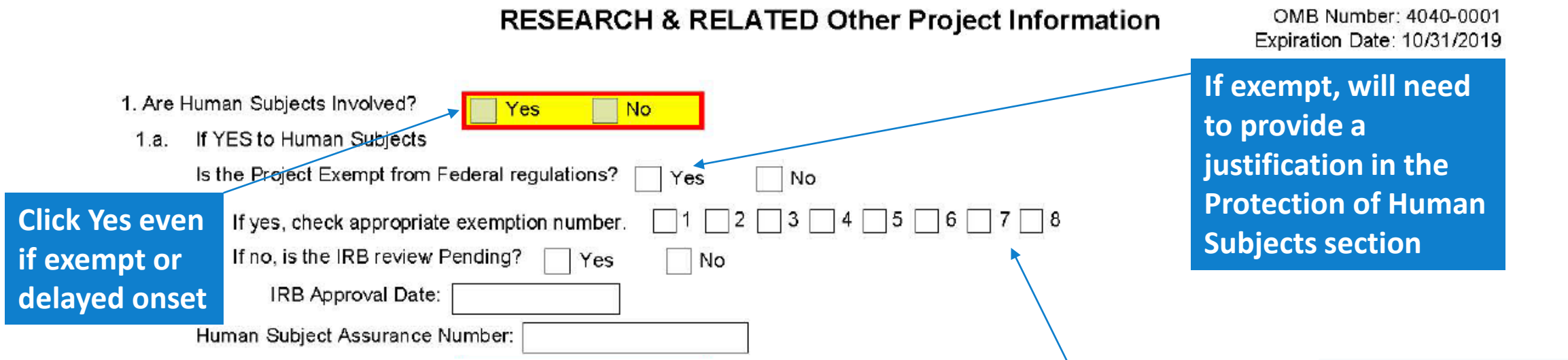
Lifecycle of NIH Award



Applying for NIH Funding



G.220 - R&R Other Project Information Form



RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

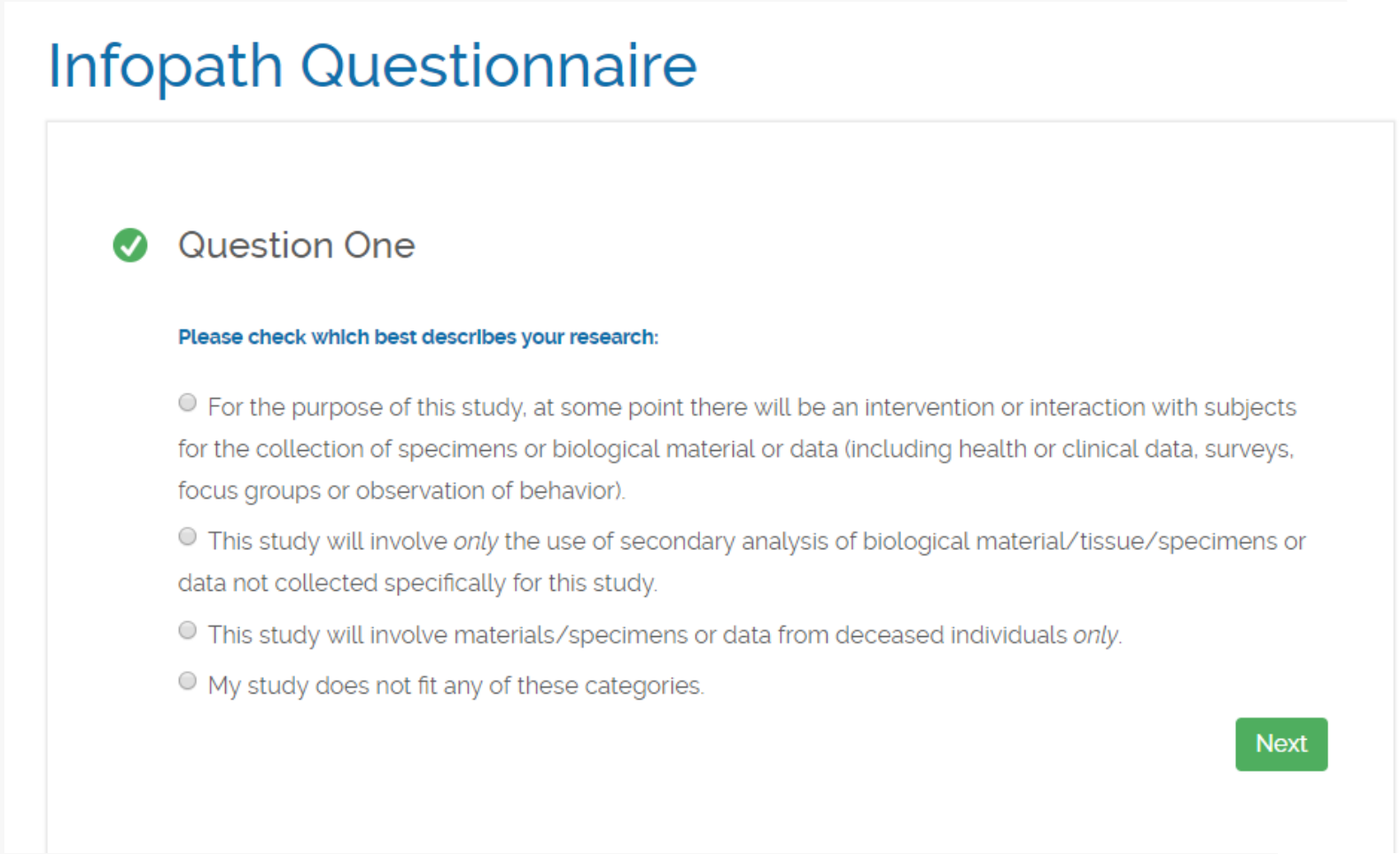
Human Subject Assurance Number:

Click Yes even if exempt or delayed onset

If exempt, will need to provide a justification in the Protection of Human Subjects section

Exemption 7 & 8 fields available for use for applications submitted on or after January 25, 2019

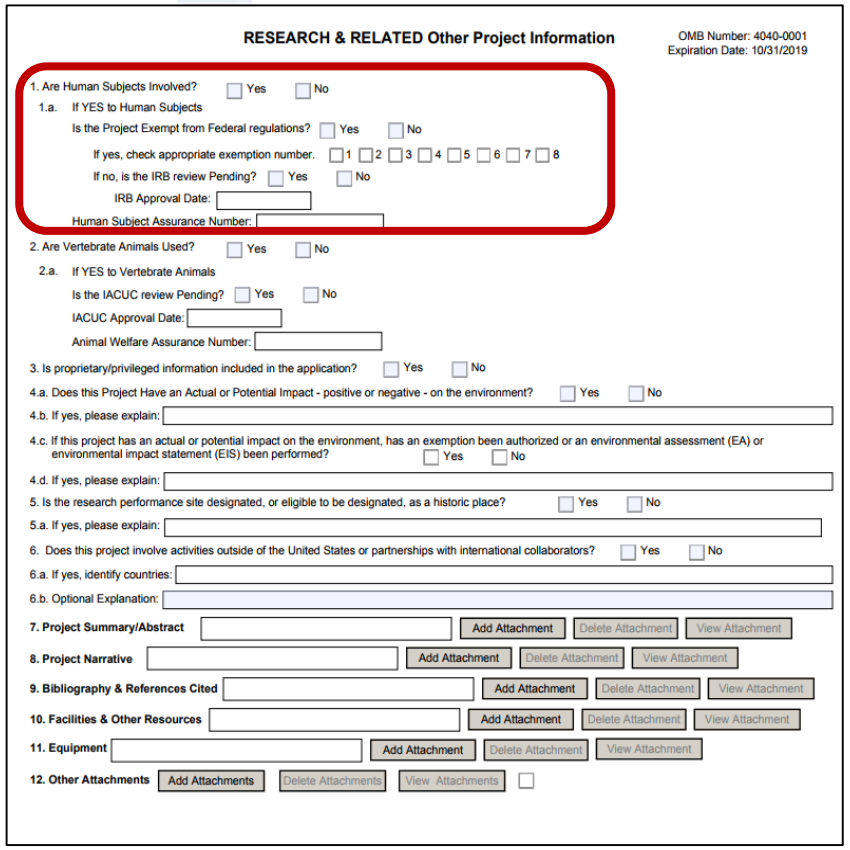
Tool to Help Determine if a Study Involves Human Subjects or Meets Criteria for an Exemption



https://humansubjects.nih.gov/questionnaire

PHS Human Subjects and Clinical Trials Information Form

1

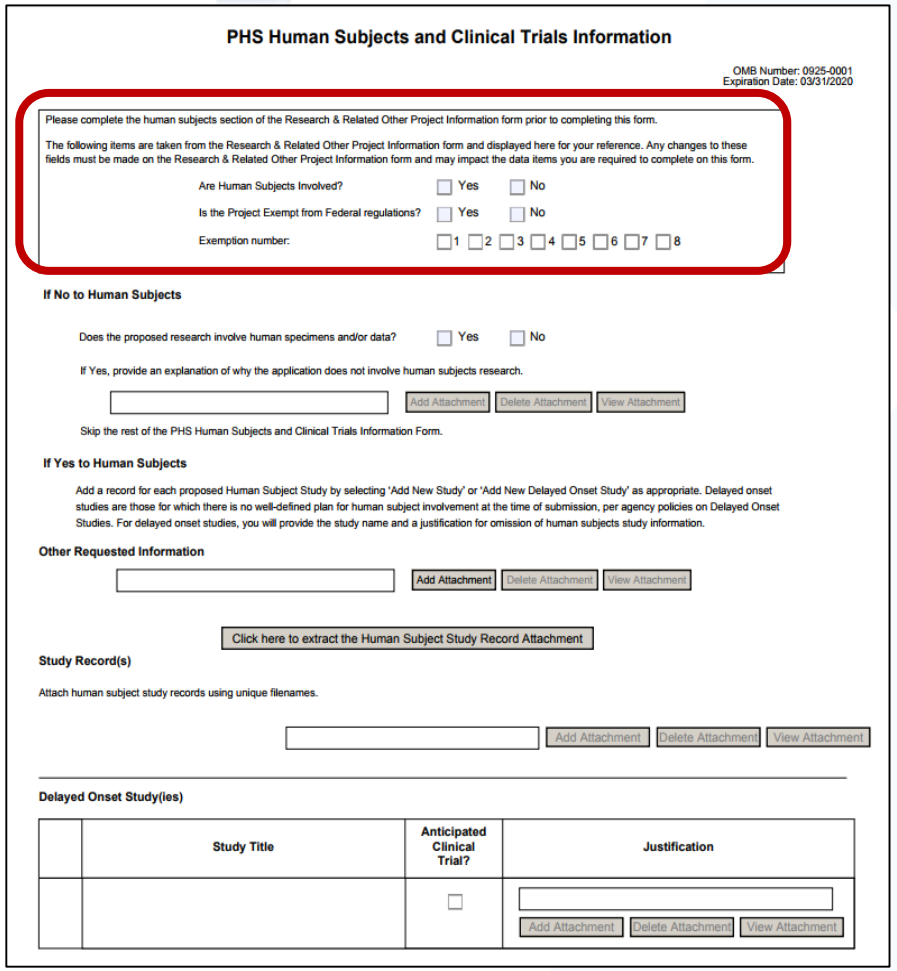


RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

1. Are Human Subjects Involved? ☐ Yes ☐ No
   1.a. If YES to Human Subjects
   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
   If yes, check appropriate exemption number. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8
   If no, is the IRB review Pending? ☐ Yes ☐ No
   IRB Approval Date:
   Human Subject Assurance Number:
2. Are Vertebrate Animals Used? ☐ Yes ☐ No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? ☐ Yes ☐ No
   IACUC Approval Date:
   Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No
4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No
4.b. If yes, please explain:
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No
4.d. If yes, please explain:
5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No
5.a. If yes, please explain:
6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No
6.a. If yes, identify countries:
6.b. Optional Explanation:
7. Project Summary/Abstract Add Attachment | Delete Attachment | View Attachment
8. Project Narrative Add Attachment | Delete Attachment | View Attachment
9. Bibliography & References Cited Add Attachment | Delete Attachment | View Attachment
10. Facilities & Other Resources Add Attachment | Delete Attachment | View Attachment
11. Equipment Add Attachment | Delete Attachment | View Attachment
12. Other Attachments Add Attachments | Delete Attachments | View Attachments ☐

2



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

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

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

"No" Human Subjects Involved

- If research involves use of human materials, a justification for "No Human Subjects" designation is needed

Key Points of Justification

- Material is NOT collected for your proposed research
  - Discuss source (repository, purchased commercially)
- NO investigator has access to ID, including access to code key)
  - Investigator = anyone involved in conduct of the research beyond providing samples/data

Forms-E – PHS HS/CT Info Form; specific attachment to explain

Tips for Writing Explanation of No Human Subjects Involvement

- Address the following in your justification:
  - Source (e.g. repository, purchased commercially)
  - Purpose of collection (for your study? Another study?)
  - Access to identifiers
    - Does anyone on the study team have access, including access to the code key?
    - Describe role of those with access – are they involved in the conduct of research beyond providing samples or data?
- Provide detail so that reader can understand there are NO circumstances in which identify can be determined
  - Avoid vague terminology (e.g. de-identified, anonymized, collection samples w/o identifiers)

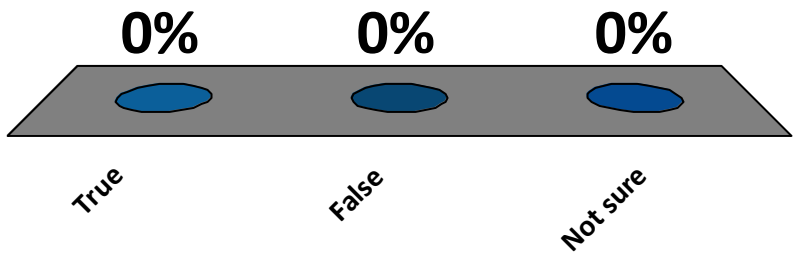
Never assume. Make sure it's in the application

All applications involving the use of human materials must mark "yes" to human subjects.

A. True

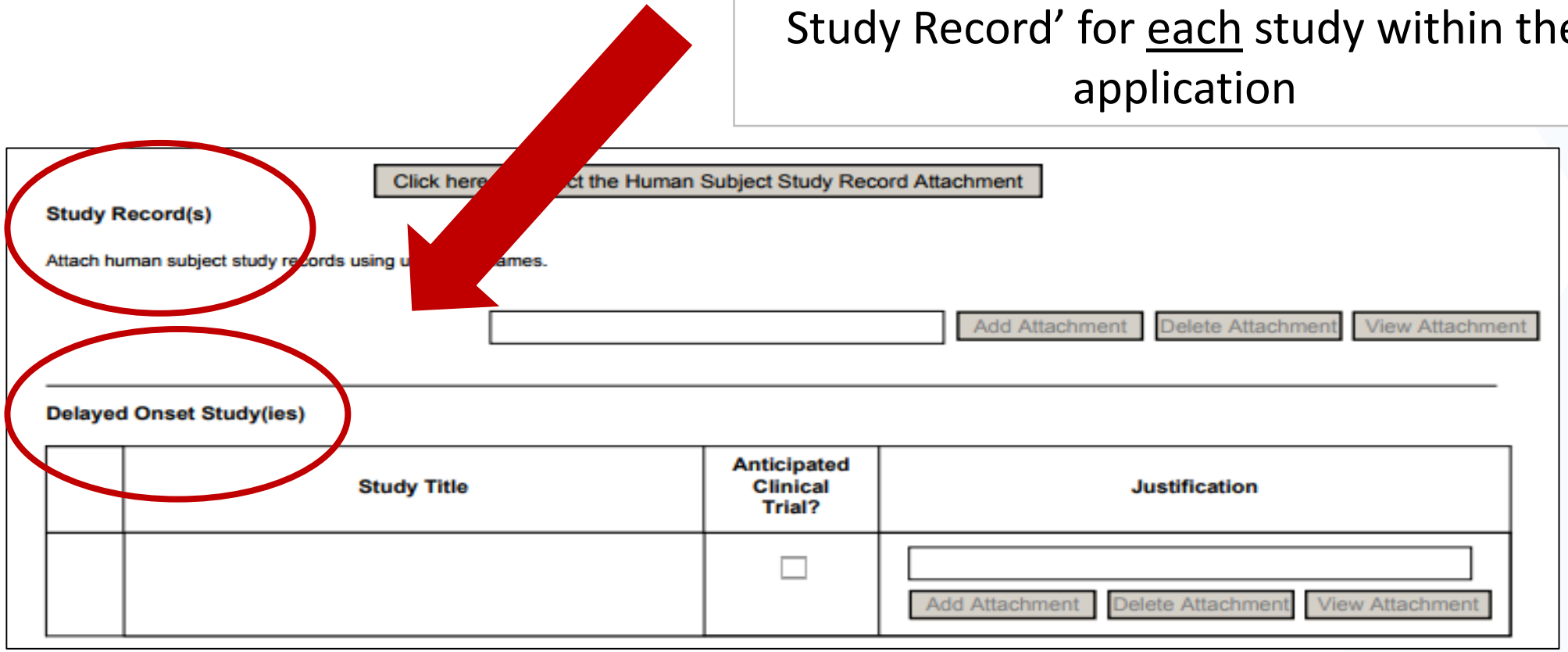
✓ B. False

C. Not sure



Main Landing Page

Add ‘Study Record’ or ‘Delayed Onset Study Record’ for <u>each</u> study within the application



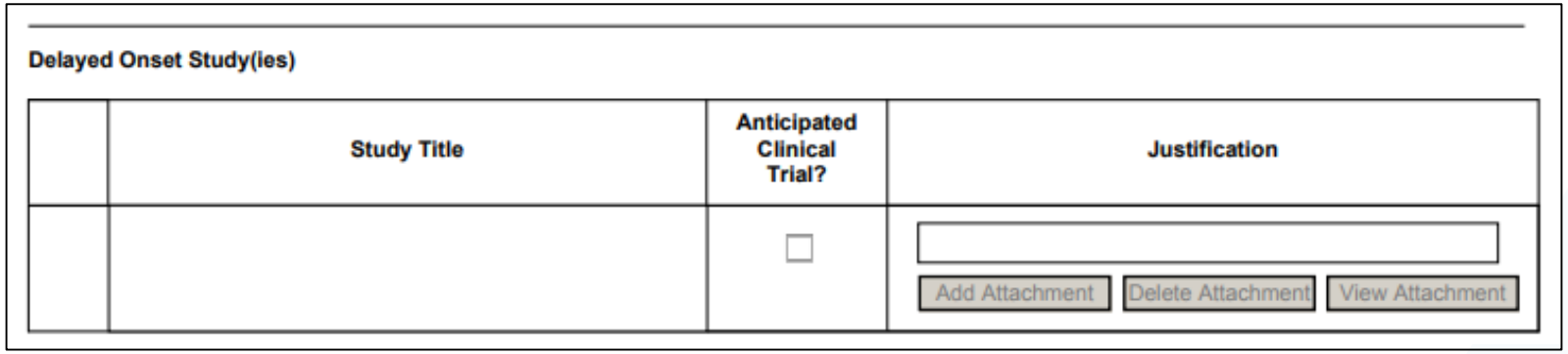
Delayed Onset

Delayed Onset: Human subjects research anticipated but specific plans cannot be described at time of application

Delayed Start: Research plans can be described at time of application, but research will not immediately begin (will occur later in the funding period)

Creating a Delayed Onset Record

- Provide a justification for delayed onset
- Indicate whether a clinical trial is anticipated
- Complete information (e.g. Human Subjects and Clinical Trials Information Form, FWA, IRB approval) required before study begins

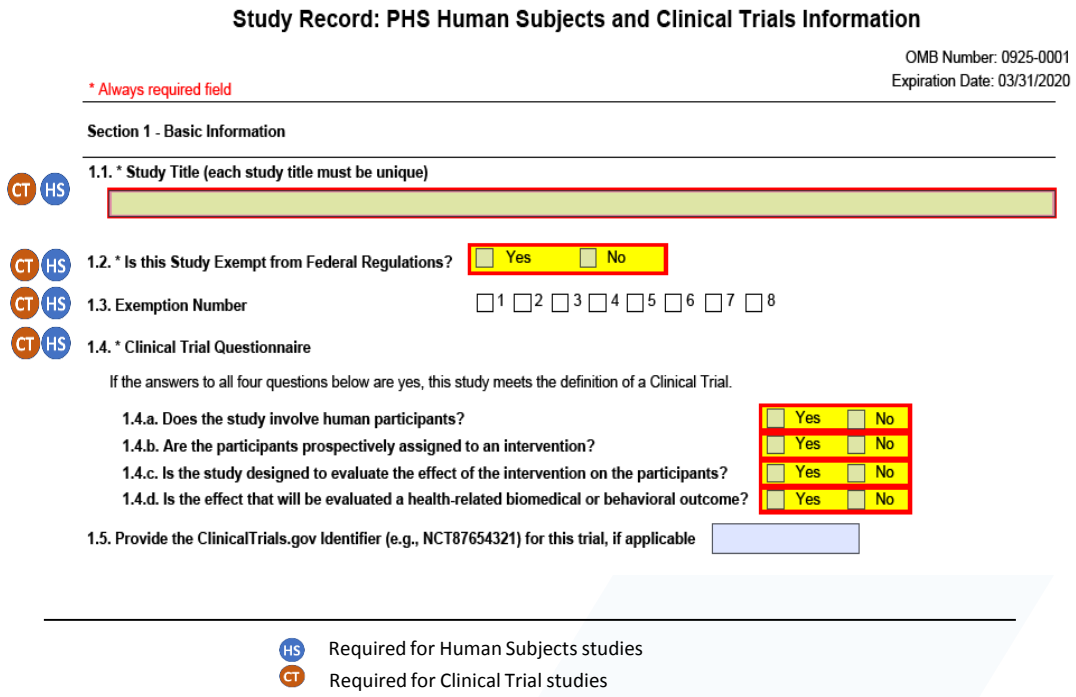


Multiple delayed onset studies may be included on one record

PHS Human Subjects and Clinical Trials Information Form

Study Record(s)

1. Basic information
2. Study Population Characteristics
3. Protection and Monitoring Plans
4. Protocol Synopsis
5. Other Clinical Trial-related Attachments



Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* 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

HS Required for Human Subjects studies

CT Required for Clinical Trial studies

See the Application Guide for detailed instructions

How Many Studies Should My Application Have?

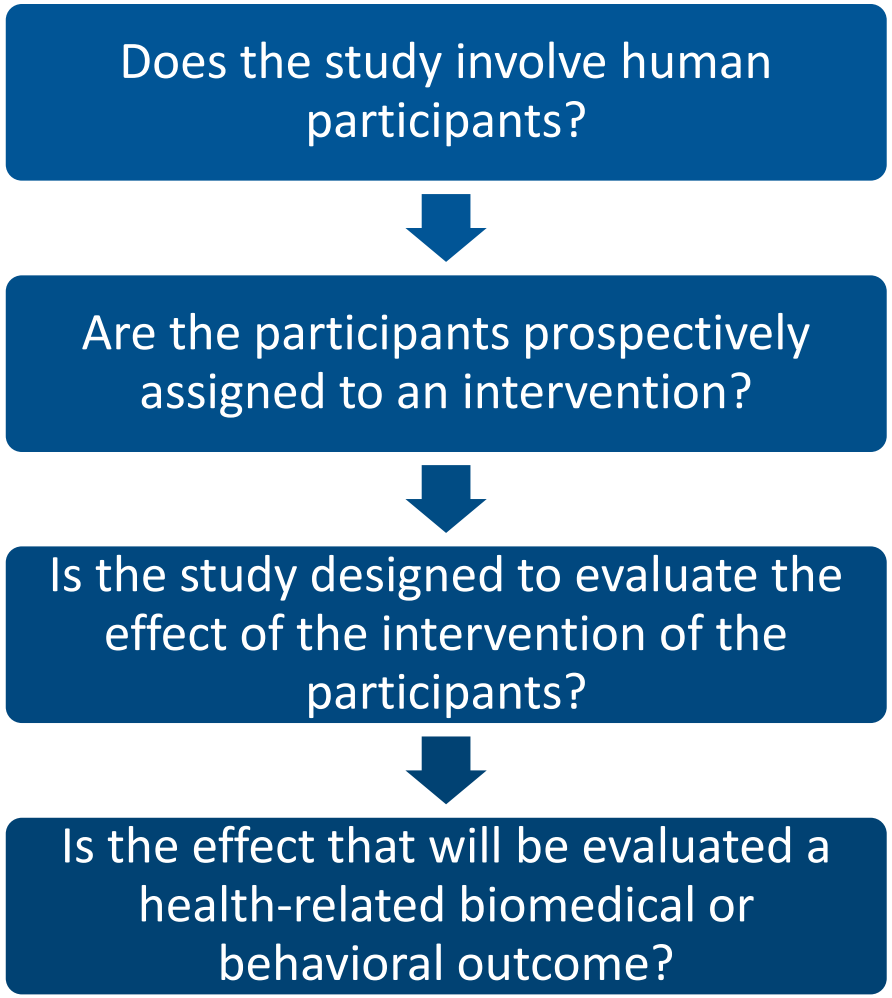
- In some cases how to group or split studies is a judgement call
- Consider:
  - What will be most clear for reviewers
  - Not necessarily based on how aims are separated
  - May be best to group studies if many of the study details are the same between studies

Use a unique (non-numeric) title for each study

Exemptions

- About 10% of NIH-funded studies involving human subjects are exempt
  - Most common exemptions are currently 1, 2, and 4
- Understand the upcoming changes to the Common Rule when selecting exemptions
  - Applications submitted for due dates on or after January 25, 2019 may select exemptions 7 and 8

Clinical Trial Questionnaire



Answers determine:

- ✓ Appropriate FOA type
- ✓ Application form requirements
- ✓ Review criteria for evaluation
- ✓ Requirement for registration and results reporting
- ✓ Requirement for GCP training

If YES to all questions, study is a clinical trial

Funding Opportunity Announcement (FOA) Policy

- Applications involving clinical trials must be submitted to clinical-trial specific FOAs

- Purpose is to:
  - Improve NIH's ability to identify proposed clinical trials
  - Ensure key pieces of trial-specific information are submitted with each application
  - Uniformly apply trial-specific review criteria

https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm

Using the Human Subjects and Clinical Trial Form

Form Section	If answered "No" to any questions in Clinical Trial Questionnaire	If answered "Yes" to all questions in Clinical Trial Questionnaire
Section 1 Basic Information	Required	Required
Section 2 Study Population Characteristics	Required; some fields optional if exemption 4	Required
Section 3 Protection and Monitoring Plans	Some fields required; some fields optional	Required
Section 4 Protocol Synopsis	Not permitted	Required
Section 5 Other Clinical Trial-related Attachments	Not permitted	Required *only* if specified in FOA

Inclusion of Women and Minorities in NIH Research

Public Law (42 U.S. Code § 289a–2) requires:

- Women and minorities be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion
- NIH-defined Phase III clinical trials be designed to permit analysis by sex/gender, race and ethnicity
  - Applicable* NIH-defined Phase III trials awarded December 13, 2017 or later must report results of "valid" analyses to Clinicaltrials.gov. See NOT-OD-18-104
- NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations

*Applicable clinical trials are drug and device trials subject to Clinicaltrials.gov registration and results reporting requirements under Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007

Some Clarifications

NIH-Defined Phase III Clinical Trial

- Studies that evaluate an intervention in large groups of people by comparing the intervention to other standard or experimental interventions.
- Includes drug, device, behavioral interventions, community trials, etc.

Valid Analysis

- Investigators generally stratify primary outcome by sex/gender and/or race ethnicity
  - Example: Report overall risk ratio, as well as corresponding risk ratios in subgroups
- In most cases, high statistical power not necessary
- Intent is to inform future studies (e.g. use in meta-analysis)

Full definitions in OER Glossary at https://grants.nih.gov/grants/glossary.htm

Inclusion of Children in NIH Research

- Policy applies to applications submitted prior to January 25, 2019
- Children must be included in clinical research studies unless there are scientific or ethical reasons not to do so
- “Children” are currently defined by the NIH as individuals <18 years

Inclusion Across the Lifespan

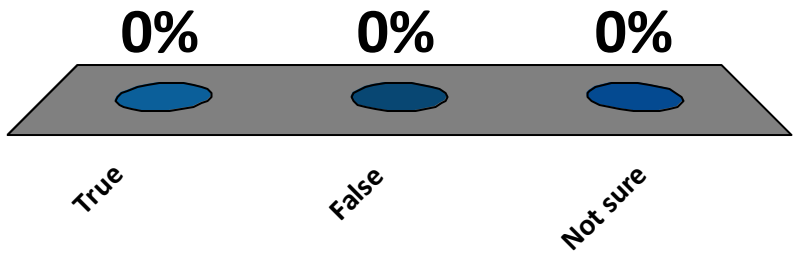
- Revision to Inclusion of Children Policy; effective for applications submitted for due dates on or after January 25, 2019 (and for contract solicitations and intramural studies issued after that date).
  - See NOT-OD-18-116
- Requires individuals of all ages be included in NIH human subjects research unless there are scientific or ethical reasons not to do so
- Requires submission of individual-level data on participant age at enrollment in progress reports

Your study is determined to be an Exemption 1 (research on educational practices). You must still target and monitor inclusion of women, minorities, and children.

✔A. True

B. False

C. Not sure



Plans for Inclusion of Women, Minorities, and Children

- Make sure you can justify your minimum and maximum age range (enter N/A if none)
- Inclusion should be scientifically appropriate and realistic
  - Consider external validity
  - Every study does not necessarily need to include every group

Protection of Human Subjects Plan

For non-exempt human subjects research address:

1. Risks

- Human subjects involvement and characteristics; meets reg requirements for vulnerable populations
- Sources of materials – what, how, access to identifiers
- Potential Risks for ALL research interventions: physical, psychological, social, legal

2. Adequacy of Protection Against Risks

- Recruitment; consent
- Procedures to minimize identified risks
- Additional protections for vulnerable subjects

Protection of Human Subjects Plan

3. Potential Benefits of Research to Human Subjects and Others

- Discuss risks in relation to anticipated benefits
- In some cases, there is no direct benefit to subjects
- Do not discuss monetary compensation here

4. Importance of Knowledge to be Gained

- Discuss in relation to risks

- **For exempt research, include justification for exemption**

Protection of Human Subjects Plan

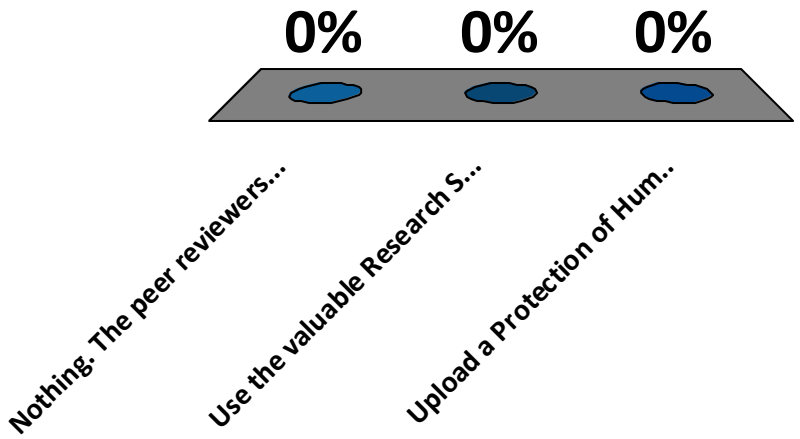
- Protection of Human Subjects Plan
  - Don’t assume reviewers will understand what you mean
    - Explain how, what, when, where, why and who
  - Common issues identified in peer review:
    - Vague terminology and/or descriptions: de-identified, anonymized, provider’s role
    - Investigator was involved in original data collection or has direct association w/ source
    - Incidental findings not addressed
    - Physical or psychological risks not adequately addressed

I will use human tissue from 5 different repositories however that's a lot to explain in the Research Strategy of my application. What should I do?

A. Nothing. The peer reviewers should figure it out.

B. Use the valuable Research Strategy section and leave something out if I run out of space.

✓ C. Upload a Protection of Human Subjects section and explain all of the sources of my human materials. Refer to this section in the research strategy



Avoiding Duplicate Information

Human Subjects/Clinical Trial Form

- **Detailed** study information (e.g., eligibility, inclusion, protection and monitoring plans)

Research Strategy

- **Overall** strategy, methodology, and analyses of your proposed research
- Encouraged to refer to information from the Human Subjects/Clinical Trial Form
- Do not duplicate information presented in the Human Subjects/Clinical Trial Form

Single IRB Plan

- Multi-site domestic studies which involve non-exempt human subjects research must use a single Institutional Review Board (siRB)
    - Some exceptions apply (e.g. foreign/tribal sites, Ks, Ts, Fs)
- In this section, explain if you plan to use an sIRB or are requesting an exception
    - Consider sIRB of record, which sites will sign reliance agreement
    - Make sure to consider any potential sIRB costs in budget (even if requesting an exception)

Data Safety and Monitoring Plans

- Clinical Trials
  - Include data safety and monitoring plan
    - Describe overall framework for safety monitoring including:
      - Responsible entity for monitoring (PI, independent safety monitor, etc.)
      - Procedures for reporting adverse events/unanticipated problems
    - Plan should be commensurate with risks
    - Institutes and Centers may have their own policies: https://humansubjects.nih.gov/datasafety

Data Safety and Monitoring Board

- Generally required for:
  - Multisite trials with > minimal risk
  - NIH-defined Phase III clinical trials
- Refer to IC policies
  - https://humansubjects.nih.gov/datasafety

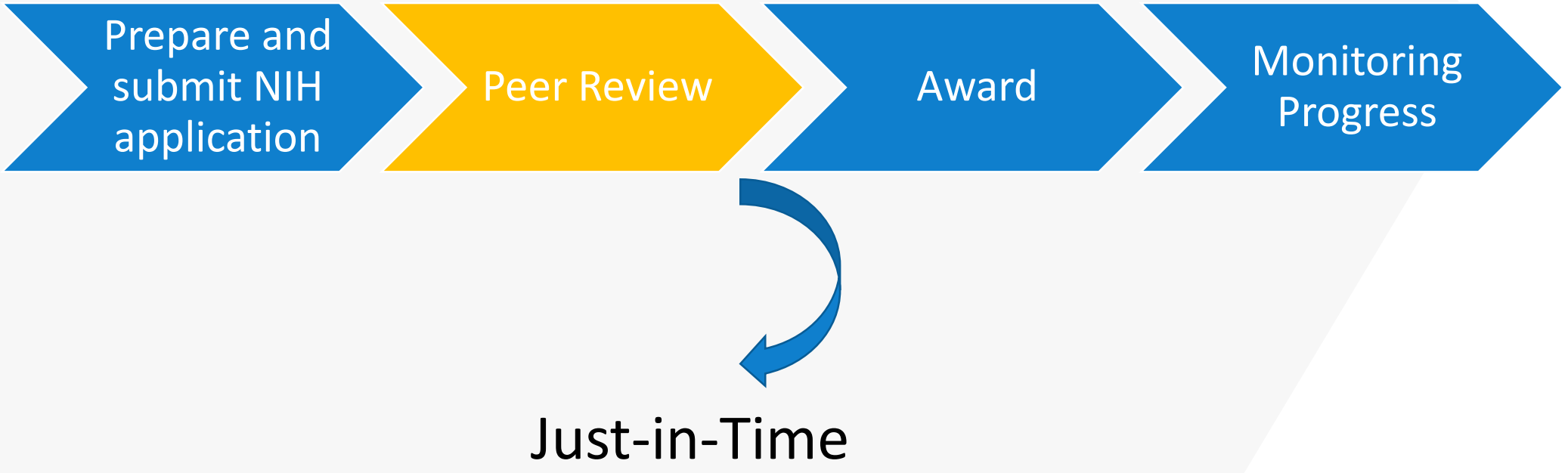
Protocol Synopsis

- Required for clinical trials; aligns with Clinicaltrials.gov
- 4.2.d Study Phase
  - Study Phase question uses ClinicalTrials.gov definition of phase
    - Trials involving devices or behavioral interventions should select “Other”
  - NIH-defined Phase III question uses NIH definitions of phase
    - Includes drug and non-drug studies
  - Possible to have a study phase of “Other”, and still answers “Yes” to the NIH-defined Phase III question
- 4.7 Dissemination Plan
  - Brief description of plans to meet expectations of NIH policy

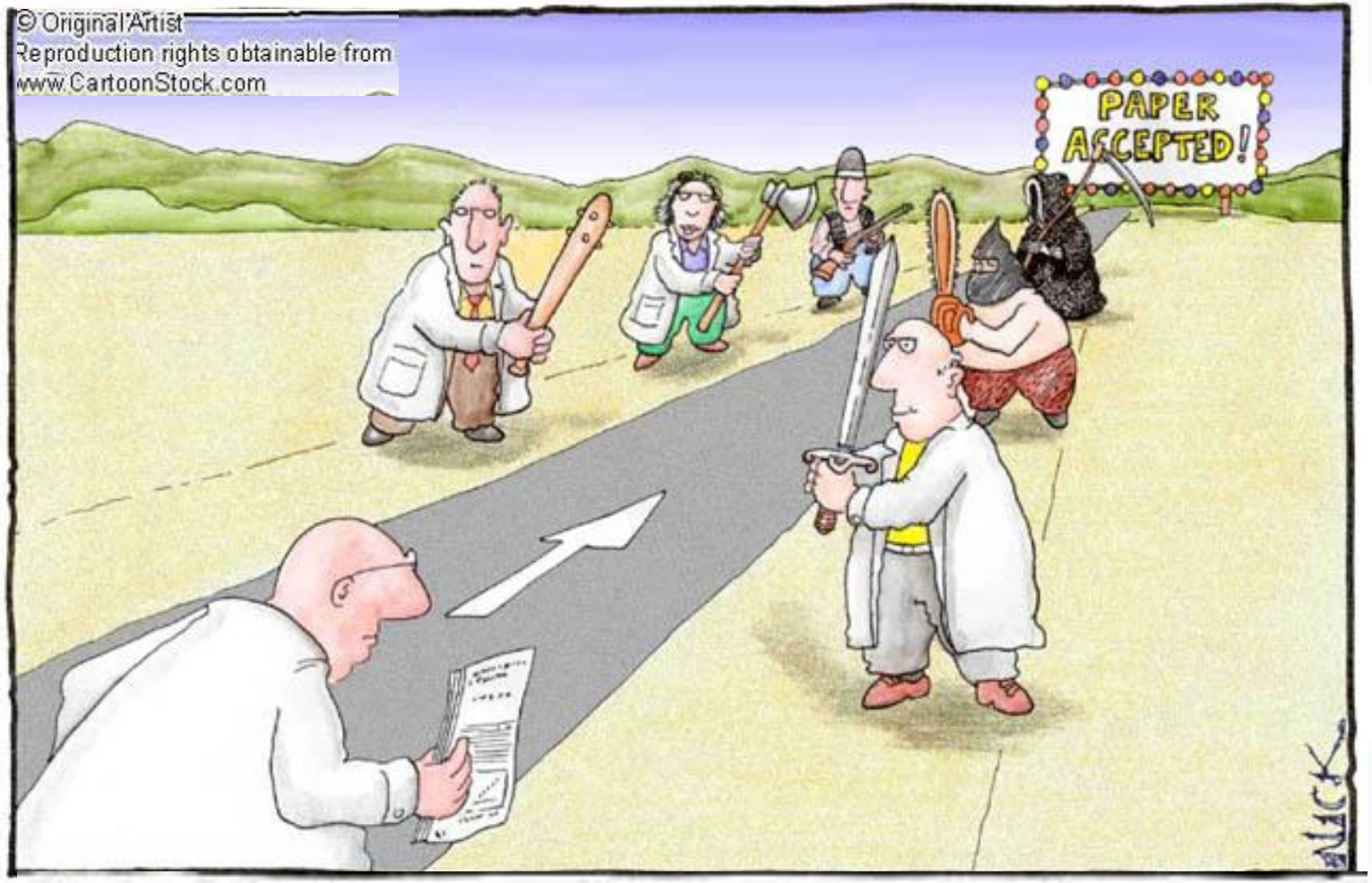
Trainees & Fellows Proposing “Clinical Trial Research Experience”

- Answer ‘Yes’ to all 4 questions in Clinical Trial Questionnaire
- Complete form Sections 1-3
  - Not permitted to complete Section 4 or 5
- Statement from Mentor or Sponsor:
  - Role of fellow/trainee in proposed clinical trial
  - Source of funding for the trial
  - Mentor’s relevant experience
  - Assurance that the mentor/sponsor will be responsible for the clinical trial

Lifecycle of NIH Award



Review of Your Application



Most scientists regarded the new streamlined peer-review process as 'quite an improvement.'

Peer Review

- Evaluate scientific & technical merit of the application
- Considered in the overall score:
  - Human subjects section (including DSMP)
    - Reviewers identify any concerns
  - Inclusion of Women, Minorities, and Children/Individuals Across the Lifespan
    - Acceptable or Unacceptable rating for Gender, Minority and Children/Age plans
- sIRB plan not considered in overall score

How is Human Subjects Section Evaluated?

- Each reviewer will assess human subjects protections
  - Is the designation correct?
  - Are 4 points addressed?
  - For clinical trial: appropriate DSMP?
  - Written comments in summary statement
- Peer review group will discuss and include comments about any concerns
- Administrative codes in Summary Statement

Common Inclusion Concerns

- Inadequate information describing the sex/gender, race, ethnicity, and/or age(s) of the sample
- Inadequate justification for proposed sample
  - Sex/gender, race, ethnicity, and/or age(s) breakdown not appropriate for the scientific goals of the study or not adequately justified
- Unrealistic sampling
  - Appropriate from scientific perspective but not realistic
    - Collaborations and outreach plans may help

SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:***
08/11/2016
Ann Hardy
240 111-5555
hardyan@od.nih.gov

Application Number: **1 R01 IC12345-01**

Principal Investigator
DOE, JOHN

Applicant Organization: ABC SCHOOL OF MEDICINE

Review Group: **ZRG1 ABC-D(50)**
Center for Scientific Review Special Emphasis Panel
US-Canada Program for Collaborative Biomedical Research

Meeting Date: **07/20/2016**
Council: **OCT 2016**
Requested Start: **12/01/2016**

RFA/PA: **IC16-006**
PCC: **M51B B**

Project Title: **An Excellent Research Project**

SRG Action: **Impact Score: 24**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: 30- Human subjects involved – no SRG concerns
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted
Gender: 1A-Both Genders, scientifically acceptable
Minority: 5A-Only foreign subjects, scientifically acceptable
Children: 1A-Both Children and adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

HS Code	Meaning
10	No HS
30	Non-exempt HS
48	SRG concerns
E1-E7	Exemption

SUMMARY STATEMENT

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Ann Hardy
240 111-5555
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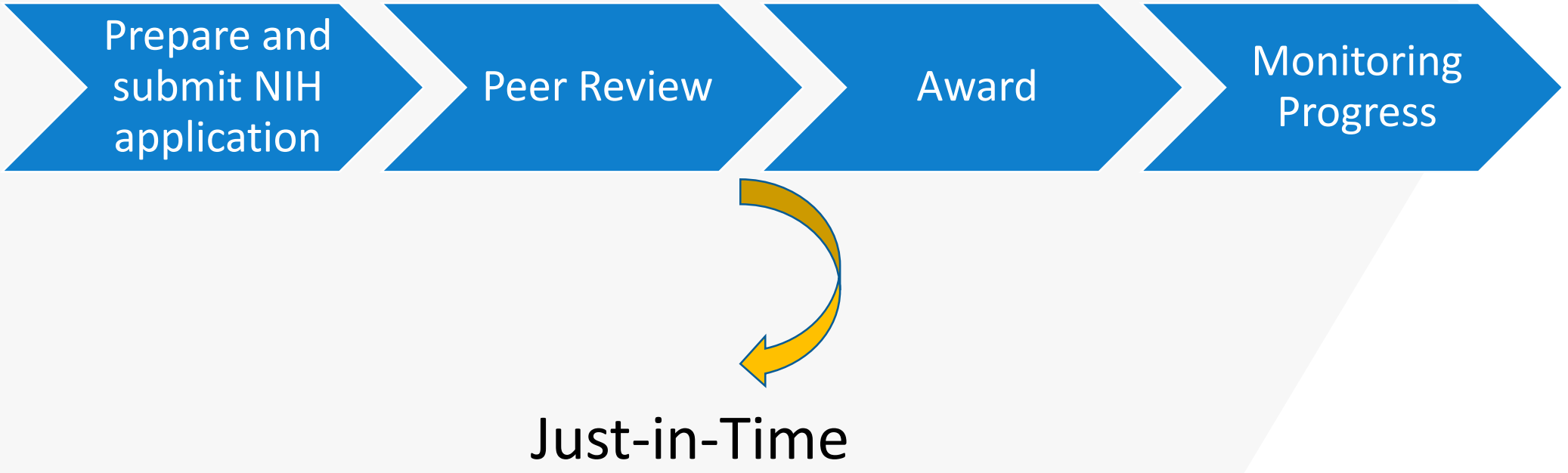
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted
Gender: 4U-Gender representation unknown, scientifically unacceptable
Minority: 5A-Only foreign subjects, scientifically acceptable
Children: 4U-Child representation unknown scientifically unacceptable
Clinical Research - not NIH-defined Phase III Trial

Lifecycle of NIH Award



Just-in-Time Requirements

After peer review, during just-in-time period:

- Provide Institution's OHRP Federal-wide Assurance Number (FWA)
- Certify:
  - IRB approval (or exemption)
  - Human subjects education for key personnel
  - GCP training for clinical trials
    - https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx

Good Clinical Practice Training (GCP)

- All NIH-funded clinical investigators and clinical trial staff involved in the design, conduct, oversight, or management of clinical trials should be trained in GCP
- GCP training can be achieved through :
  - ✓class or course
  - ✓academic training program
  - ✓certification from a recognized clinical research professional organization
- Training should be refreshed every 3 years

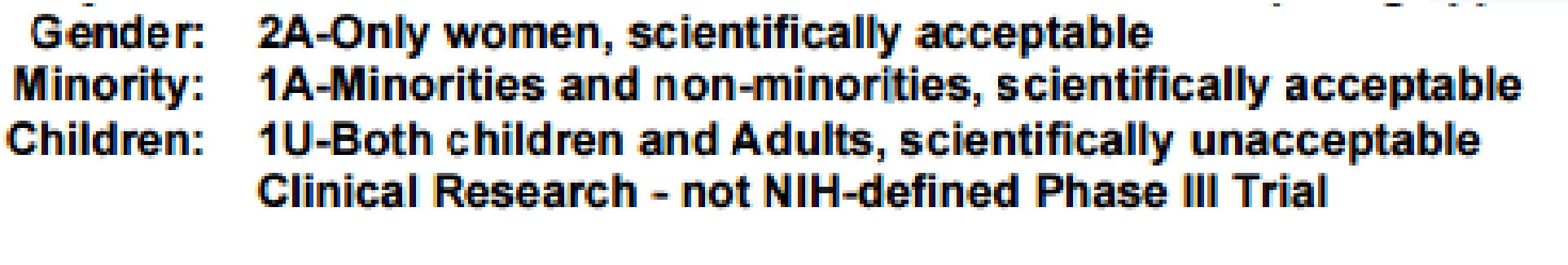
Learn more at https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

Multi-site Study Considerations

- Generally funding recipient is considered to be engaged in HS research
- All engaged sites must have:
  - FWA (can be covered under recipient's FWA)
    - http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html
  - IRB Approval
    - Sites to rely on one IRB
      - Written agreement http://www.hhs.gov/ohrp/assurances/forms/irbauthagree.html

Just-in-Time Requirements

- Work with Institute/Center staff to resolve unacceptable inclusion concerns

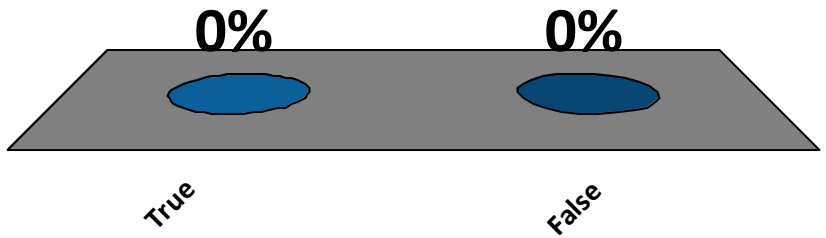


- Provide inclusion enrollment report(s) if missing or needs updated as a result of peer review and/or programmatic adjustments

IRB Approval is Required before an NIH Grant Can be Funded

✔ A. True

B. False

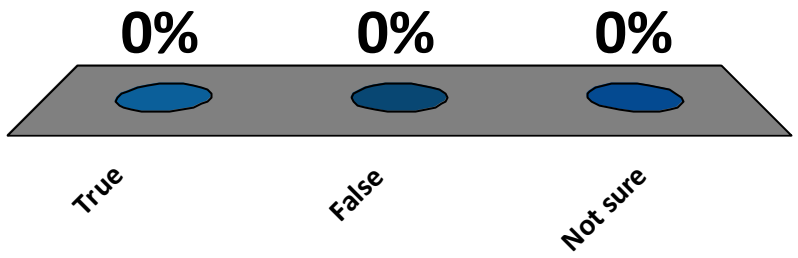


A Phase I clinical trial will need a Data and Safety Monitoring Plan (DSMP).

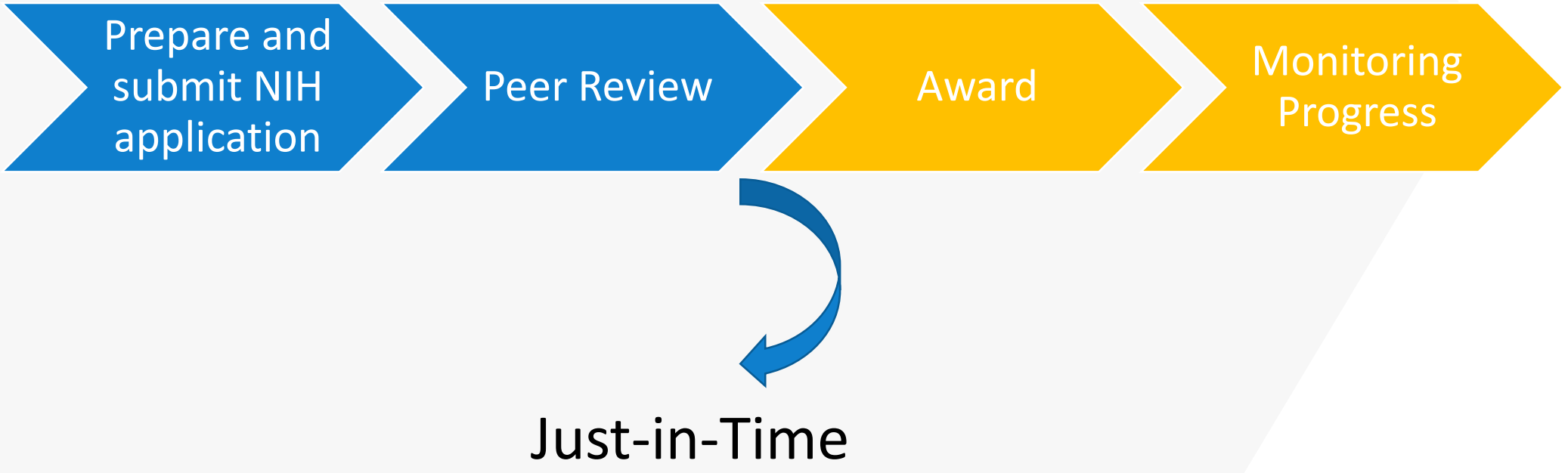
✔ A. True

B. False

C. Not sure



Lifecycle of NIH Award



After the Award… Now What?

- Comply with DHHS/institutional requirements for:
  - Annual IRB approval
  - Adverse Event/Unanticipated Problem Reports – within specified time frame
- Keep in mind you are expected to follow NIH single IRB policy if site is added

After the Award… Now What?

- **Prior NIH Approval for changes in human subjects research that increase risk**
  - **Changes from no to yes for HS or increase risks**
  - **Discuss plans with NIH PO *before starting***
  - **Provide required information on Human Subjects and Clinical Trial Information Form**
- **Discuss any planned changes w/ funding IC prior to start NOT-OD-15-128**

After the Award…Now What?

- Provide **actual inclusion enrollment data** in progress reports
  - If application submitted for due dates on or after January 25, 2019, provide participant-level data on sex/gender, race, ethnicity and age at enrollment
- For NIH-defined Phase III Clinical Trials – **report status/results of analyses** by sex/gender, race, and ethnicity
  - For applicable NIH-defined Phase III Clinical Trials, report results by sex/gender and/or race/ethnicity in Clinicaltrials.gov within 1 year of primary completion date

Certificates of Confidentiality (CoC)

- What is a Certificate of Confidentiality?
  - Prohibits disclosure of names or information, documents, or biospecimens containing identifiable sensitive information
    As a result of 21st Century Cures Act:
    - To persons not connected to the research
    - In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, (unless with participants' consent)
    - For any other purpose, with some exceptions

- See (NOT-OD-17-109) published September 7, 2017

Key Changes to Certificates of Confidentiality

Issue	Previous Authority	Current Authority
How to get one	Issued upon approval of application	• NIH-funded – **automatic**
Disclosure	PI/ Institution could voluntarily disclose	Disclosure is prohibited unless specifically allowed by statute or with consent
Admissibility as evidence	Information protected by a CoC could be used in a legal proceeding if disclosed	Protected information cannot be used in a legal proceeding even if it is disclosed elsewhere
Copies of information	Unclear; typically advised to amend or extend	All information, including copies, is protected

Applies to ongoing research as of December 13, 2016

What Makes a Good Human Subjects Section?

One that follows the applicable instructions and provides the required information ☺

Useful Resources: Human Subjects Protections and Inclusion

- **NIH OER Human Subjects Website**
  https://humansubjects.nih.gov
- **Certificates of Confidentiality**
  https://humansubjects.nih.gov/coc/index
- **Single IRB Policy** https://osp.od.nih.gov/clinical-research/irb-review/
- **Inclusion of Women and Minorities**
  https://grants.nih.gov/grants/funding/women_min/women_min.htm
- **Inclusion Across the Lifespan**
  https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

Useful Resources: Clinical Trials

- **Clinical Trials Requirements website:** https://grants.nih.gov/policy/clinical-trials.htm
- **Clinical Trial FAQs:** https://grants.nih.gov/policy/clinical-trials/faq-list.htm
- **Video overview of Human Subjects and Clinical Trials form:** https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1

Questions