Human Subjects Research: What SBIR & STTR Applicants Need to Know

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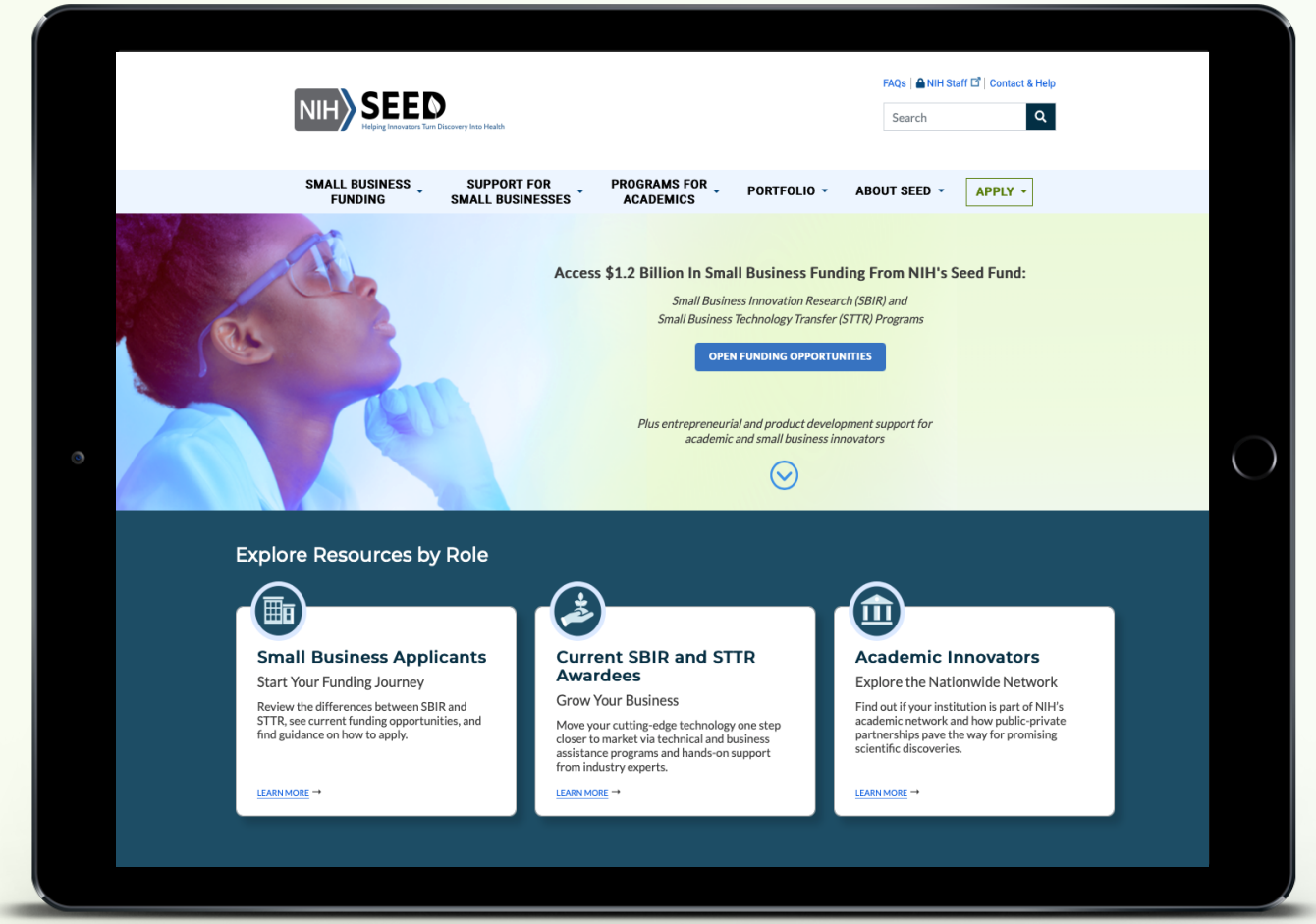
OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

NIH SEED

Small Business Program Website



http://seed.nih.gov

NIH Mission

National Institutes of Health
Turning Discovery Into Health

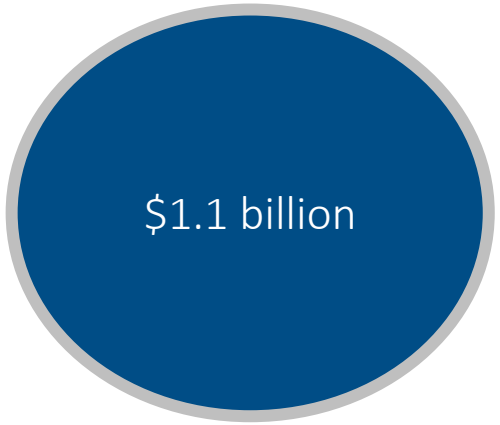



To seek fundamental knowledge about the nature and behavior of living systems and the ***application of that knowledge to enhance health, lengthen life, and reduce illness and disability****.*

The Small Business Program helps NIH accelerate discoveries from bench to bedside

Congressionally Mandated Programs

$1.2 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

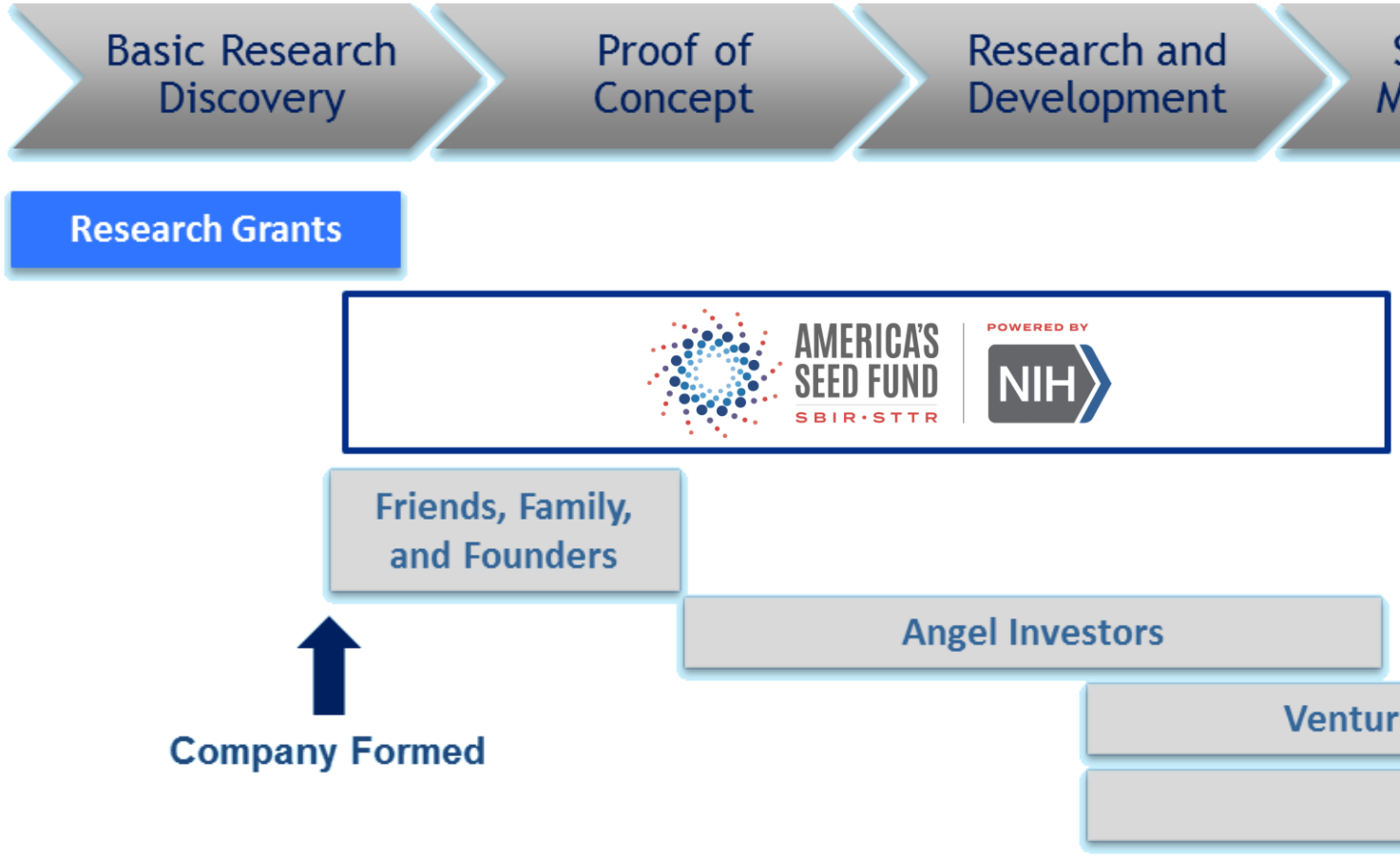
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Benefits of NIH Funding

The largest sources of early-stage capital for life sciences in the US



- **"Free Money"-** Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Small Business Success Stories

Kansas Biomedical Company Advances Brain Disorder Research

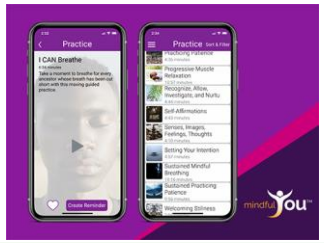
PINNACLE TECHNOLOGY INC

Rural Maine Company Goes Deep in the Brain to Treat Movement Disorders

FHC
Neural microTargeting™ Worldwide

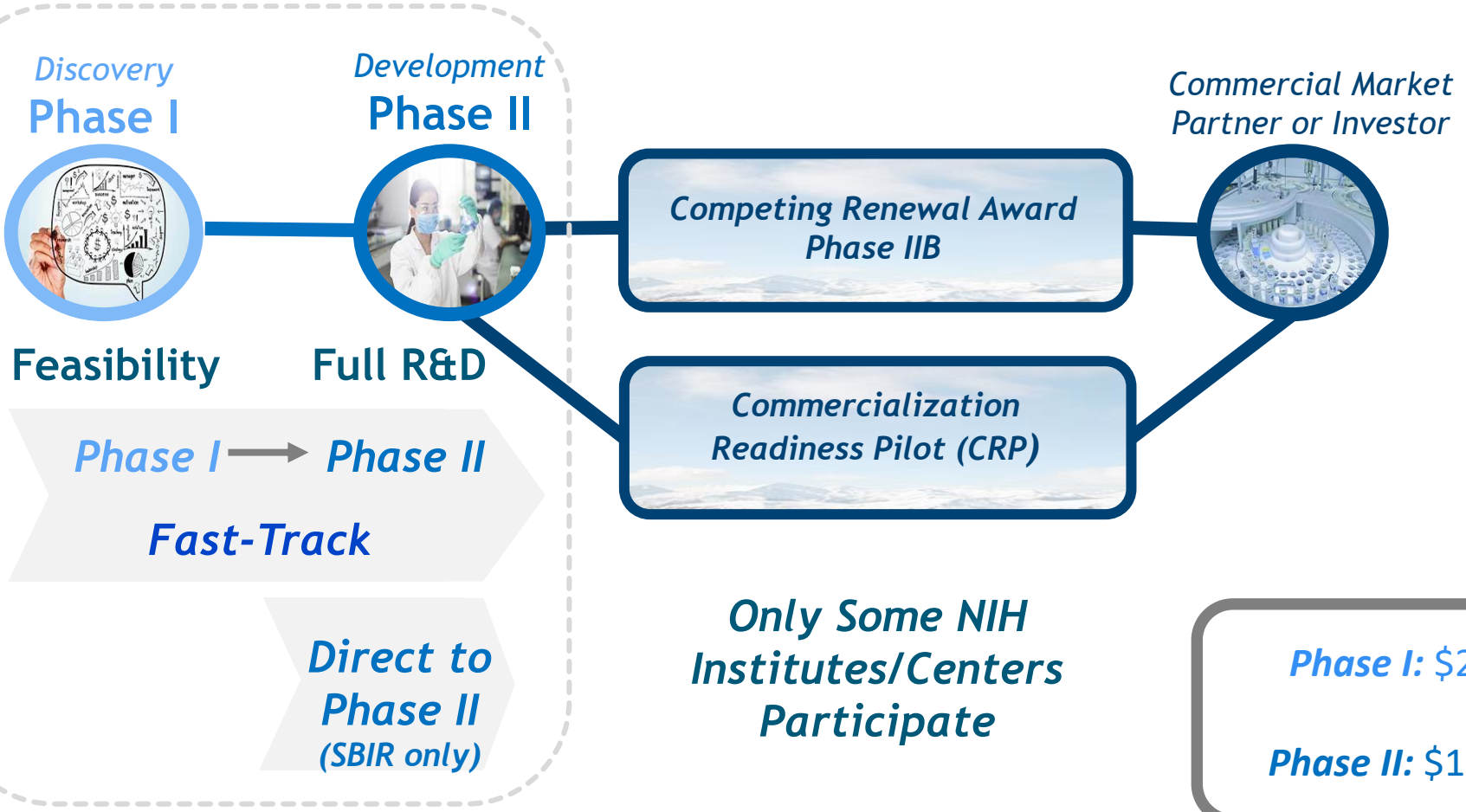
Digital Learning Company Supports Parents, Teachers, and Underserved Communities

trifoia®



https://seed.nih.gov/portfolio/stories

Phased Programs



Only Some NIH Institutes/Centers Participate

Phase I: $275,766/1-2 years*

Phase II: $1,838,436/1-3 years*

***NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected topics**

Funding Opportunities

https://seed.nih.gov

Majority of the funding goes to investigator-initiated grant applications

Standard receipt dates: September 5, January 5, April 5

Open Funding Opportunities

General Grant Omnibus Solicitations

Clinical Trial Not Allowed:
SBIR (PA-22-176) and STTR (PA-22-178)

Clinical Trials Required:
SBIR (PA-22-177) and STTR (PA-22-179)

Read the "Program Descriptions and Research Topics" Section in the Solicitation

Targeted Solicitations

Specific Grant Solicitations:
https://seed.nih.gov/small-business-funding/

SBIR Contract Solicitation: **Deadline Nov 4**
https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

READ CAREFULLY!

Not all Institutes/Centers participate

Not all targeted solicitations have specific set-asides or review

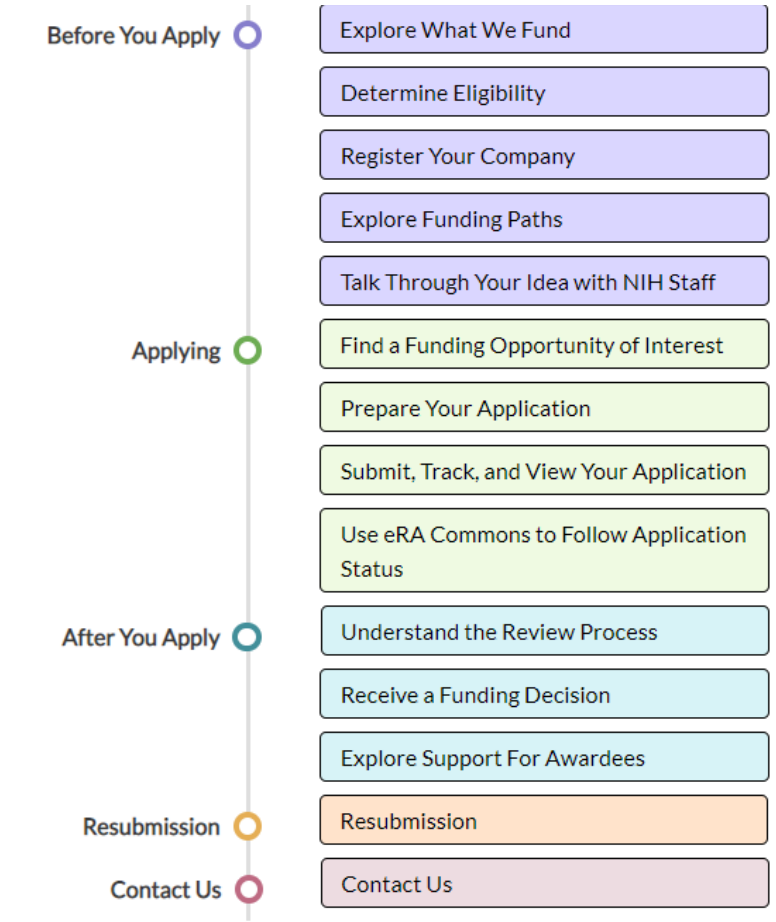
Resources

SMALL BUSINESS FUNDING

HOW TO APPLY

Find step-by-step instructions to apply for SBIR and STTR grants along with contact touchpoints at each step.

https://seed.nih.gov/small-business-funding/how-to-apply



Links to:

Application Instructions

Annotated Form Set

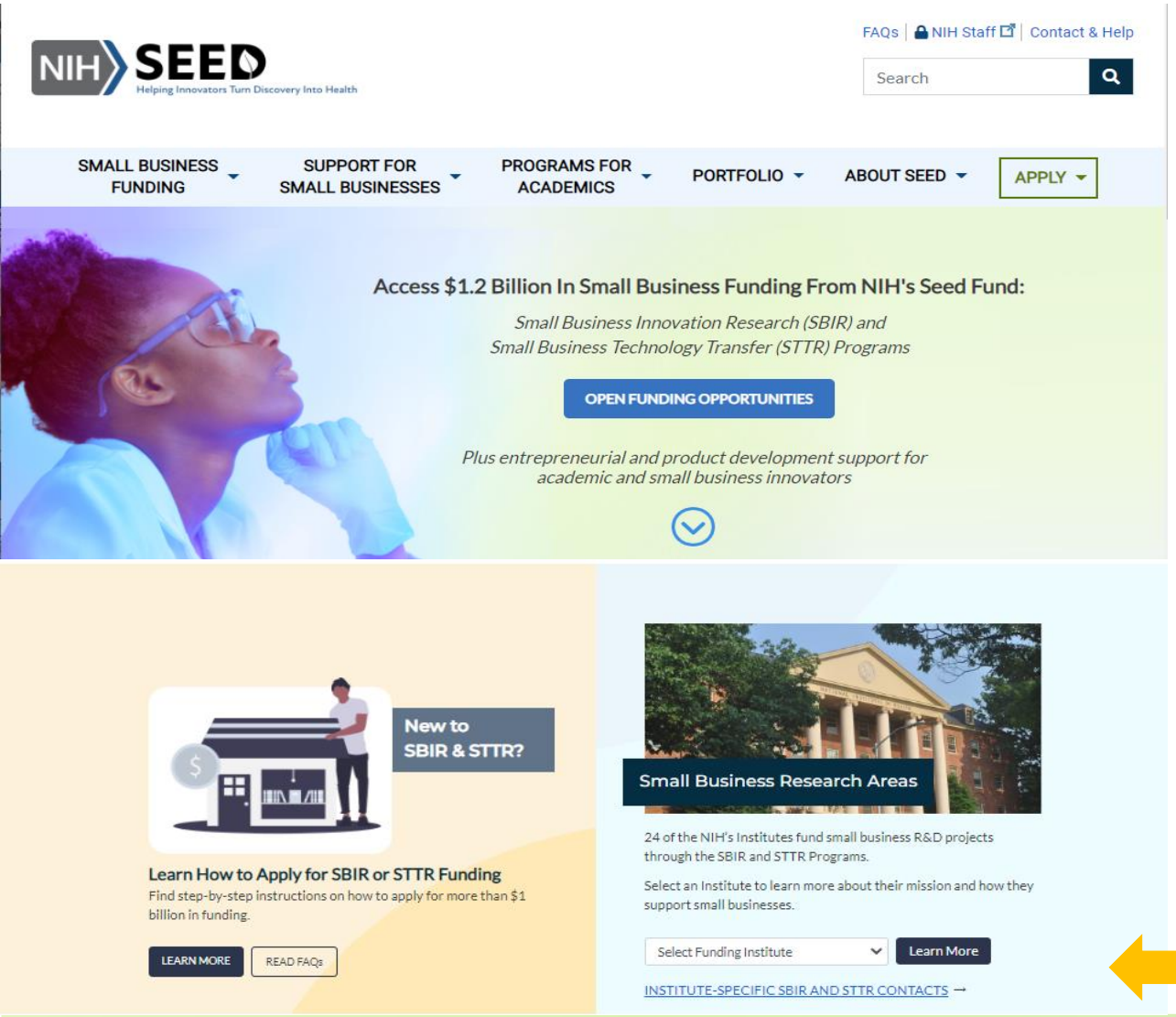
Sample Applications

Programs for Applicants:

- **NIH Applicant Assistance Program**
- **Health Disparities Pre-Application (HDPreAPP) Program**

https://seed.nih.gov/aboutseed/diversify-entrepreneurial-workforce

Most Important Piece of Advice



Talk to a Program Officer at least a month before the application deadline!

List of SBIR Program Managers: https://seed.nih.gov

Research Portfolio Online Reporting Tools (RePORT): https://report.nih.gov/

Not sure who to contact?
https://public.era.nih.gov/commons/public/servicedesk/initseed.era
or
Email: SEEDinfo@nih.gov

Connect with SEED

Online
http://seed.nih.gov/

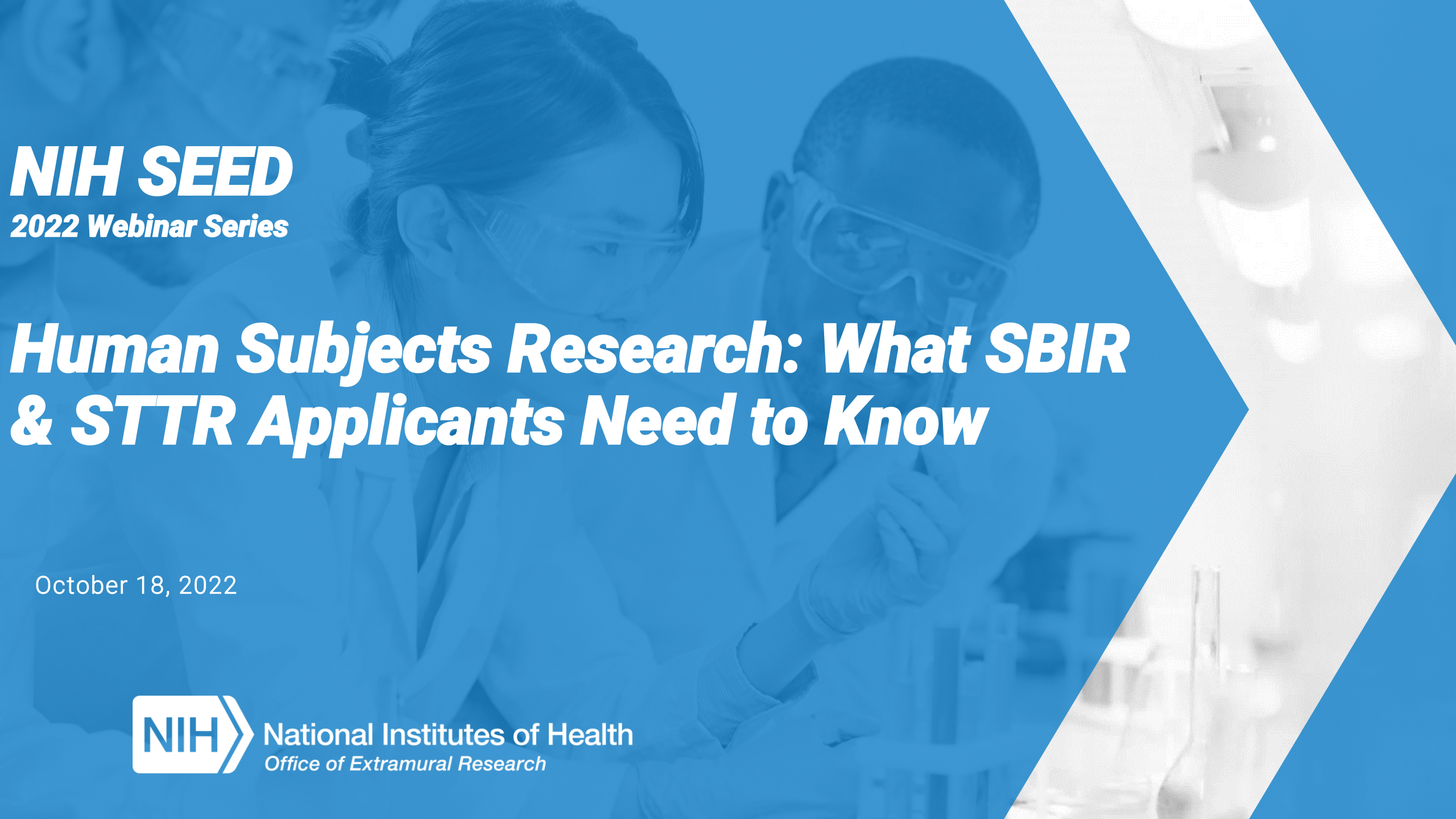
Email us
SEEDinfo@nih.gov

@nihseed
https://twitter.com/nihseed

NIH SEED
https://www.linkedin.com/company/nihseed

Sign up for NIH and SEED updates:
https://seed.nih.gov/subscribe

The NIH Guide for Grants and Contracts:
http://grants.nih.gov/grants/guide/listserv.htm



NIH SEED

2022 Webinar Series

Human Subjects Research: What SBIR & STTR Applicants Need to Know

October 18, 2022

National Institutes of Health
Office of Extramural Research

Research Involving Human Subjects

Lyndi Lahl, RN, MS
Human Subjects Officer, OER/DHSR

National Institutes of Health
Office of Extramural Research

45 CFR 46 Subpart A: The Common Rule and Subparts B, C, and D

- Harmonizes protection of human subjects among different U.S. Federal departments and agencies
- Outlines regulations for:
  - IRB review and approval
  - Informed consent
  - Federalwide assurance
- *Subpart B* – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- *Subpart C* – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- *Subpart D* – Additional Protections for Children Involved as Subjects in Research

Determining if a Proposed Activity is Non-Exempt, Human Subjects Research

Is the activity **research**?

Does the research activity involve **human subjects**?

Is the human subjects research **exempt**?

1. Determine if the Activity Is Research

Research is a **systematic investigation**, including research development, testing, and evaluation, designed to **develop or contribute to generalizable knowledge**

45 CFR 46.102(l)

Is the Activity Research?

- Is the activity a systematic investigation?
  - Are there plans using a methodical approach?
    - Is there a hypothesis? A research question? Plans to systematically collect and analyze data?
- Is the activity designed to develop or contribute to generalizable knowledge?
  - Will the activity add information and contribute to generalizable knowledge?
  - Note- plans to share results with the larger community does not determine if the evaluation is designed to develop or contribute to generalizable knowledge.

2. Determine if the Research Activity Involves Human Subjects

Human subject are a living individual about whom an investigator conducting research

(1) Obtains information or biospecimens through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**

45 CFR 46.102(e)(1)

Are Human Subjects Involved in the Research?

- Identify who is the subject
  - Human subject is the person that the information is about or from whom the specimen was taken
- Is there an interaction or intervention? *OR*
- Does the investigator have
  - Identifiable, private information about the subject or
  - Identifiable biospecimens?

Resource:
Research Involving Private Information or Biospecimens

3. Determine if the Human Subjects Research Activity is Exempt

- Research activities that meet the conditions for an exemption category are exempt from the typical requirements of the Common Rule (i.e., IRB review and approval according to the regulations)
- Institutions generally designate experienced individuals (IRB member or in the IRB office) to make exemption determinations
- NOTE: If the proposed human subjects research activity is exempt under one or more categories, **STOP.** The activity is ***not*** nonexempt human subjects research.

45 CFR 46.104

Resource:

Exempt Human Subjects Research Infographic

Exempt Categories of Research

Exemption 1: Normal educational practices in established or commonly accepted settings*

Exemption 2: Interactions involving educational tests, surveys, interviews, or observations of public behavior

Exemption 3: Benign behavioral interventions in adults if information is sensitive and identifiable*

Exemption 4: Secondary research use of identifiable, private information or identifiable biospecimens

Exemption 5: research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program*

Exemption 6: taste and food quality*

Exemption 7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

Exemption 8: Secondary research using identifiable private information or identifiable biospecimens

**Exempt categories that may include an NIH-defined clinical trial*

See Common Rule Exempt Research and NIH OER Definition of Human Subjects Research websites

Determine if the Activity Is Non-Exempt, Human Subjects Research

When the answer to the first two questions is yes, and the answer to the third question is no, the activity ***is*** non-exempt human subjects research and requires IRB review and approval.

1. Is the activity research?
2. Does the research activity involve human subjects?
3. Is the human subjects research exempt?

Resources:

- NIH Human Subjects Research Infographic
- NIH Decision Tool: Am I Doing Human Subjects Research?
- OHRP Human Subject Regulations Decision Charts

HHS Regulatory Requirements for Non-exempt Human Subjects Research

Institutions **engaged** in NIH conducted or supported non-exempt human subject research must

- Provide **written assurance** that it will comply with the regulatory requirements
  - OHRP-approved Federalwide Assurance (FWA) *and*
- Certify to NIH that research was reviewed and approved by an **IRB** and that the research will be subject to continuing review by an IRB

45 CFR 46.103

Engagement in Human Subjects Research

In general, institutions are considered engaged in an NIH conducted or supported non-exempt human subjects research project when:

The institution's employees or agents obtain, for research purposes:

- data about the human subjects through intervention or interaction; or
- identifiable private information about the subjects
- Informed consent

Note- Prime recipients of an NIH award (e.g., grant, contract, cooperative agreement) for non-exempt human subjects research are considered engaged in the research project, even when all activities involving human subjects are carried out by employees or agents of another institution.

Resource:
OHRP Guidance document, Engagement of Institutions in Human Subjects Research

Required Education In the Protection of Human Research Participants

- **All key personnel** must have education on the protection of human research participants:
  - Individuals responsible for design and conduct of the research
  - Also applies to key personnel at performance sites
- One-time training
- See NIH Guide Notice
  - NOT-OD-00-039 and
  - NOT-OD-11-061

  Resource: NIH website, Training & Resources- Human Subjects

Certificates of Confidentiality (CoC)

- **Prohibits** disclosure of names or information, documents, or biospecimens containing identifiable, sensitive information
  - 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
- Deemed issued to all NIH-funded research that collects or uses identifiable, sensitive information as of December 13, 2016
- Copies of research protected
- Covered information protected in perpetuity

See Guide Notice NOT-OD-17-109

Resource: NIH website, Certificates of Confidentiality

Single IRB Requirements

- NIH Single IRB Policy
  - Multi-site domestic studies where each site will conduct the same protocol involving non-exempt human subjects research must use a single Institutional Review Board
  - See Guide Notice NOT-OD-16-094
- Common Rule Cooperative Research
  - Any institution located in the United States that is *engaged* in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States
  - See HHS Regulations at 45 CFR 46.114(a)

Resource: NIH website, Single IRB for Multi-Site or Cooperative Research

Clinical Trial Requirements
What SBIR & STTR applicants need to know

Pamela Kearney, MD
Director, DHSR

October 18, 2022

National Institutes of Health
Office of Extramural Research

GOALS

- Understand the NIH definition of Clinical Trial
- Review how to decide if your study is a CT
- High level overview of clinical trial policies and regulations
- Review of relevant resources

Human Subjects

Mechanistic

Other experimental

Independent variable

Biomedical outcome

Pilot/feasibility

Exploratory

Applied

WHAT IS A CLINICAL TRIAL?

Behavioral

Basic Research

Intervention

Developmental

Effect

Prospectively assigned

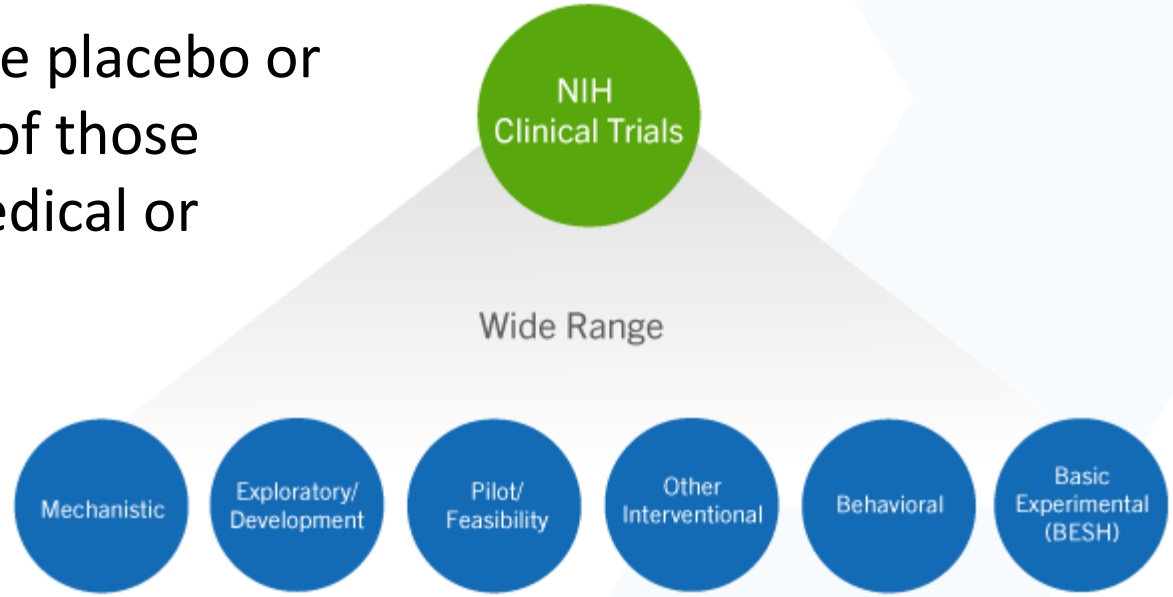
Behavioral outcome

NIH CT definition covers many types of CTs

NIH Definition of Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

NOT-OD-15-015



Are you doing an NIH Defined CT?

The 4 CT Questions

- Does the study involve **human participants**?
- Are the participants **prospectively assigned** to an **intervention**?
- Is the study designed to **evaluate the effect** of the intervention on the participants?
- Is the effect that will be evaluated a **health-related biomedical or behavioral outcome**?

If "Yes" to ALL of these questions, the study is considered a clinical trial

NOTE!!!

1. “Prospective” only means assignment to the intervention is **arranged in advance**
2. “Assigned” **does not mean** “random” - participants could be assigned to pick their own group. There can even be just one group!
3. “Intervention” can be a “manipulation”
4. Biomedical outcomes can “increase in knowledge” or be an “intent to change behavior”

Basic Experimental Studies with Humans (BESH)

Are BOTH

1. **Basic Research:** Systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.
2. **NIH Defined Clinical Trial**

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

CT Example -1

***Very FICTIONAL CASE!!!**

Some investigators interested in narcolepsy are testing the concept that electronic signals on the skin can affect alpha waves of early sleep. They will deliver electronic signals to the wrist of HVs who are drifting off to sleep and use EEG to measure what happens to the alpha waves.

CT Example - 2

***Very FICTIONAL CASE!!!

Some investigators interested in narcolepsy are testing the concept that electronic signals on the skin can affect alpha waves of early sleep. They will deliver electronic signals to the wrist of HVs who are drifting off to sleep and use EEG to measure what happens to the alpha waves.

1. Does the study involve **human participants**?
   YES, Healthy Volunteers
2. Are the participants **prospectively assigned** to an **intervention**?
   YES, Electronic signals to the wrist
3. Is the study designed to **evaluate the effect** of the intervention on the participants?
   YES, EEG will be used to measure the effect of the electrical signals on alpha brain waves
4. Is the effect that will be evaluated a **health-related biomedical or behavioral outcome**?
   YES – changes in alpha brain waves are a health-related biomedical outcome

This is an NIH Defined Clinical Trial!!!!

What if you are not sure?

1. Clinical Trial Interactive Decision Tree
2. Talk with your Program Official or Contract Officer. Don't have one yet? Try: NIH Matchmaker
3. REMEMBER! NIH defined CTs often don't look like a "classic randomized drug study"
4. Consult the resources on the NIH Grants CT Website

Why do we care?

- **CT Specific FOAs** (NIH-OD-18-106)
- **Misclassified CT may be withdrawn** prior to review
- **Clinical Trials specific requirements** (regulations and NIH policies)
  - **CT review criteria**
  - **Registration/Results reporting** (NIH-OD-16-149)
  - **GCP training** for staff (NIH-OD-16-148)
  - **Consent posting** (45CFR46.116(h))
  - **CT monitoring**:
    - **DSMP**: Data and Safety Monitoring Plans (NOT-98-084)
    - **DSMB**: Data and Safety Monitoring Boards:
      - Multisite study (NOT-98-084, NIH policy for Data and Safety Monitoring)
      - Phase III (NOT-98-084) and (NOT-00-038 Further guidance on Data and Safety Monitoring for Phase I and Phase II Trial)

CTs Must Be Compliant

- Part of the terms and conditions of your award!
- Be familiar with requirements
- Get help if you need it
- Be organized: spreadsheets, calendar reminders, etc

Funding Opportunity Announcement (FOA) Policy

- Applications involving clinical trials must be submitted to clinical-trial specific FOAs
- Applications submitted to incorrect FOA **will be administratively withdrawn**
- 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

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 is to be refreshed every 3 years

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

Data and Safety Monitoring

- Clinical trials must submit a **Data and Safety Monitoring Plan (DSMP)**
  - Address overall data and safety monitoring framework
  - Describe procedures for adverse event reporting
  - Identify the monitor (e.g. PI, independent safety monitor, DSMB, etc.)
- **Data and Safety Monitoring Board (DSMB)** generally required:
  - Multisite studies
  - NIH-defined phase III trials

Review IC-Specific Guidelines at https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm

Dissemination of NIH-Funded Clinical Trial Information

Policy Requires **Registration and Reporting**:

- **SUBMIT** - a plan in the application outlining compliance with the policy
- **REGISTER** - the clinical trial in ClinicalTrials.gov no later than 21 days after enrolling the first participant
- **REPORT** - Submit summary results in ClinicalTrials.gov no later than one year after primary completion date

Learn more at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Consent Posting

- Consent posting on a designated federal public website
- Required by the revised Common Rule 45CFR46.116(h)
- After recruitment closes and no later than 60 days after last study visit

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

NOW YOU:

- Are familiar with the **NIH definition of CT**
- Have looked at **an example** in order to think beyond the “classic” CT definition
- Have **reviewed the different policies and regulations**
- Have reviewed **resources** to go to for help

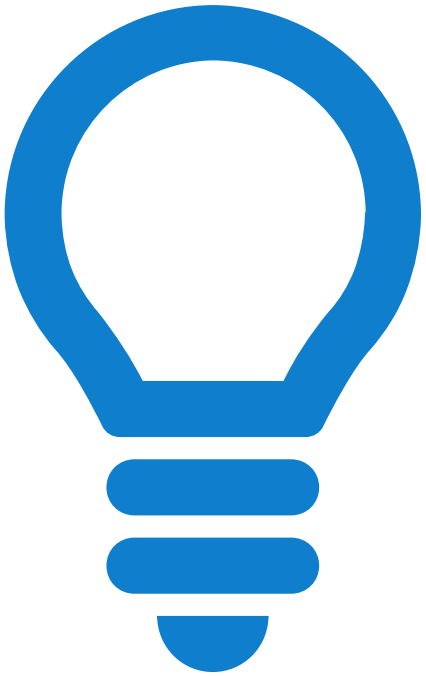
Links and Resources - Useful Websites -1

- **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
- **Basic Science Clinical Trials (BESH):**https://grants.nih.gov/policy/clinical-trials/besh.htm
- **Clinicaltrials.gov Registration and Reporting**
  - **Information:** https://grants.nih.gov/policy/clinical-trials/reporting/index.htm
  - **Registration Help:** https://clinicaltrials.gov/ct2/manage-recs/how-register
  - **Results Reporting Help:** https://clinicaltrials.gov/ct2/manage-recs/how-report

Links and Resources - Useful Websites -2

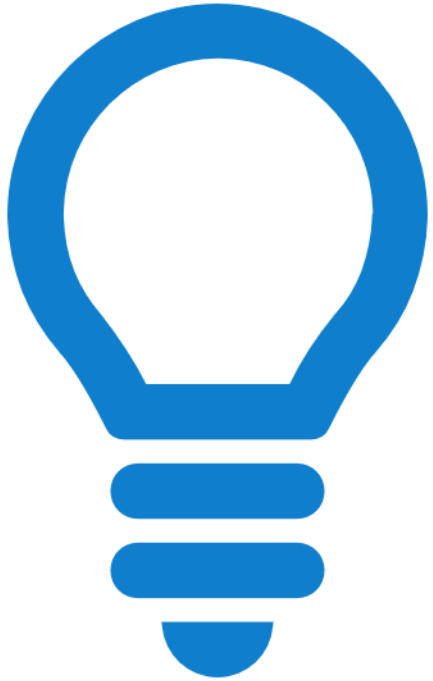
- **GCP Training:** https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm
- **CT Informed Consent Posting:** https://grants.nih.gov/policy/clinical-trials/informedconsent.htm
- **Data and Safety Monitoring:** https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm
- **CT Specific Funding Opportunity Announcements:** https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm
- **Clinical Trials Review Criteria:** https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

Links and Resources - Tools



- **NIH Matchmaker:** https://reporter.nih.gov/matchmaker
- **Clinical Trial Interactive Decision Tool:** https://grants.nih.gov/ct-decision/index.htm
- **Protocol Writing:**
  - **Information:** https://grants.nih.gov/policy/clinical-trials/protocol-template.htm
  - **e-Protocol Writing Tool**: https://e-protocol.od.nih.gov/#/home

Links and Resources – Policies and Regulations



- **NIH Definition of Clinical Trial:** (NOT-OD-15-015)
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QUESTIONS?

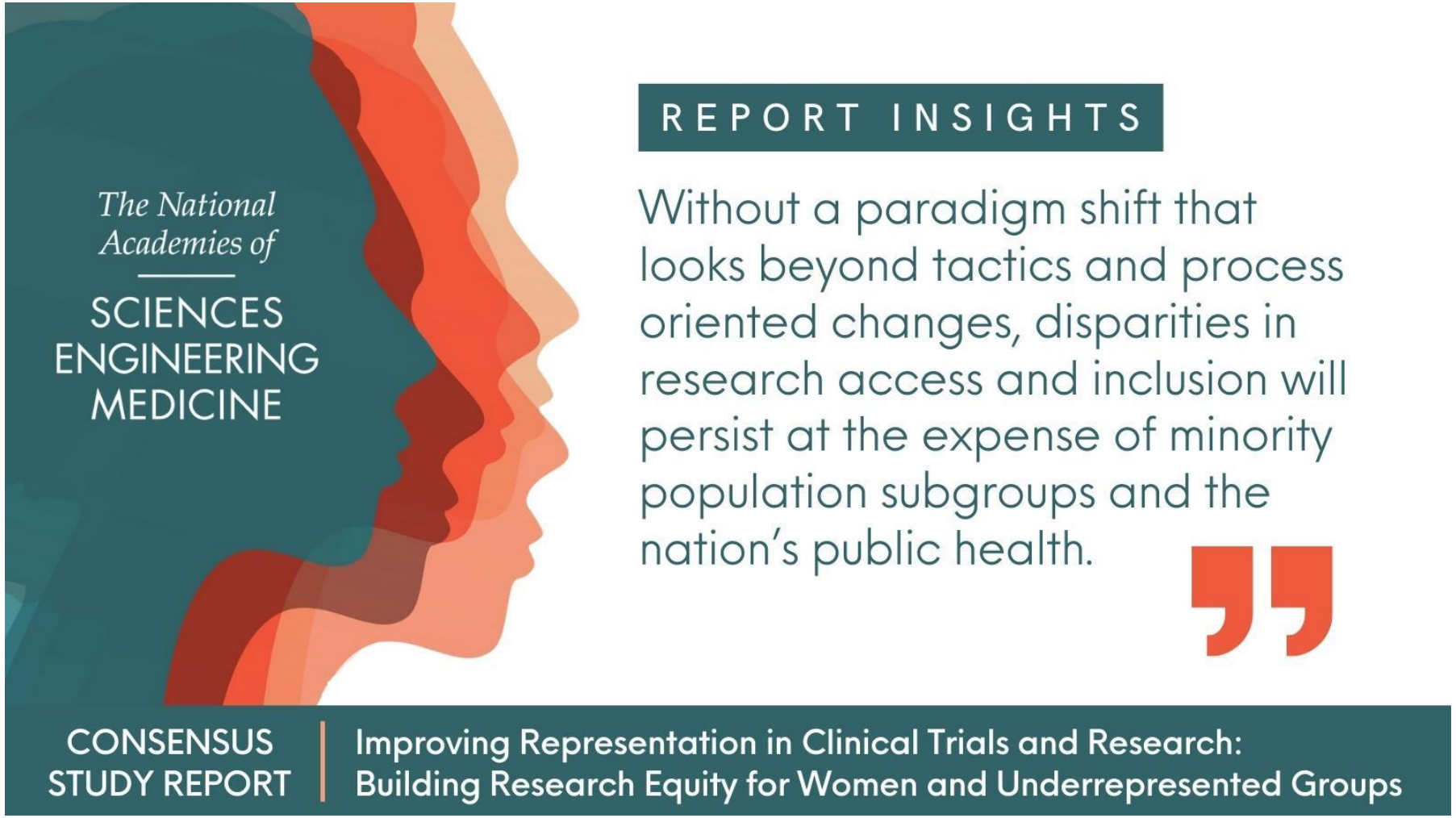
Including Diverse Populations in NIH-funded Clinical Research

Dawn Corbett, MPH
NIH Inclusion Policy Officer
Division of Human Subjects Research, Office of Extramural Research

October 18, 2022

National Institutes of Health
Office of Extramural Research

NASEM Report on Improving Representation in Clinical Trials Research



National Institutes of Health
Office of Extramural Research

Full report at https://nap.nationalacademies.org/read/26479/chapter/1

Inclusion of Women and Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion
- Additional requirements for NIH-defined phase 3 clinical trials
  - Analysis of primary outcome by sex/gender, race and ethnicity
    - Status/results reported in progress reports/RPPR Project Outcomes
    - If applicable clinical trial (ACT) must report results of analyses in Clinicaltrials.gov

National Institutes of Health
Office of Extramural Research

Policy Notice: NOT-OD-18-014

Inclusion Across the Lifespan

- Individuals of all ages must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so

- Requires submission of individual-level participant data in progress reports
  - –Sex or Gender
  - –Race
  - –Ethnicity
  - –Age at Enrollment

National Institutes of Health
Office of Extramural Research

Policy Notice: NOT-OD-18-116

Inclusion in the NIH Funding Process

- Inclusion plans
- Inclusion enrollment report

- Information requested by NIH staff

- Cumulative enrollment progress
- Progress/reporting on valid analyses

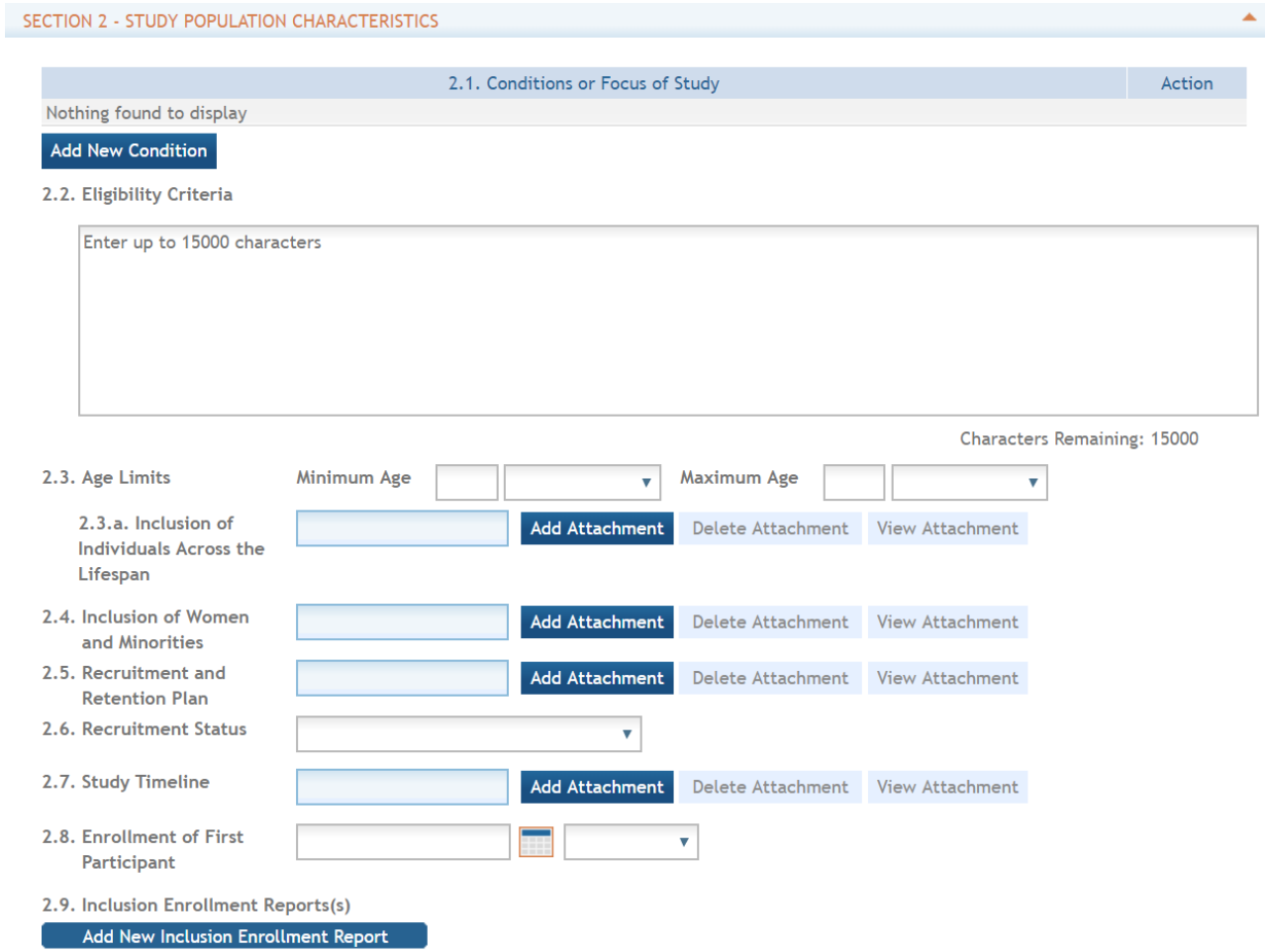
What's Required When Applying for Funding?

- Inclusion Plans
  - Women and Racial and Ethnic Minorities
  - Individuals Across the Lifespan
- Min/Max Age Limits
- Inclusion enrollment report

PHS Human Subjects and Clinical Trials Form

See the **Application Guide** for detailed information

- **PHS HS/CT Information Form**
- Study Record
  1. Basic information
  2. **Study Population Characteristics**
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments



What's Included in the Inclusion of Women and Minorities Plan?

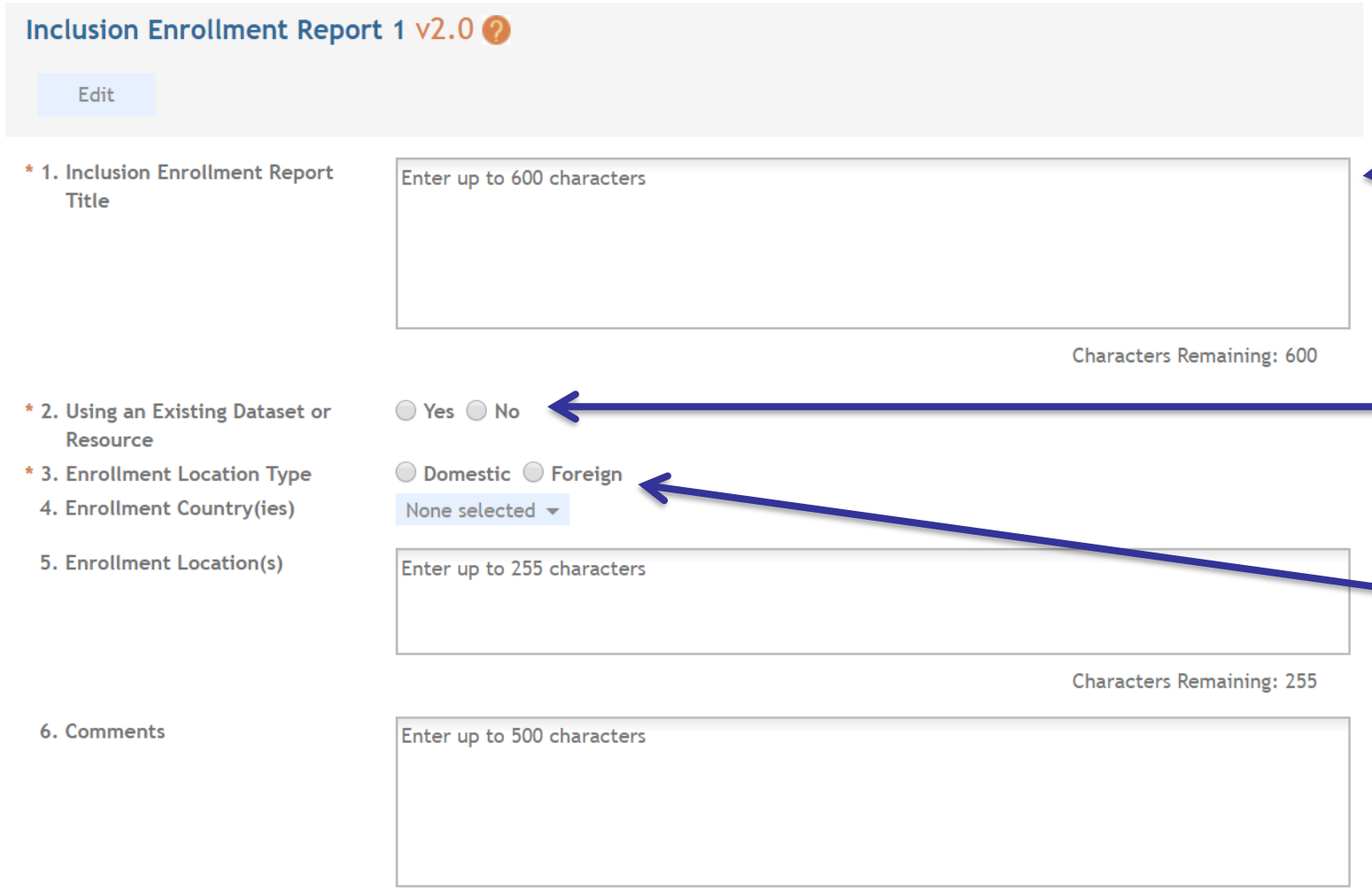
- Description of planned distribution by sex or gender, race, and ethnicity
  - Rationale for the selection
  - Justification for any exclusions
- Proposed outreach programs for recruitment
- For NIH-defined Phase 3 trials, plans for analysis by sex or gender, race, and ethnicity

What's Included in the Inclusion Across the Lifespan Plan?

- Rationale for age distribution, including how it will contribute to analysis
  - Justification for any exclusions

- Description of study team expertise and appropriateness of facilities for included age groups

Inclusion Enrollment Report



Inclusion Enrollment Report Title

Specify whether **Existing Dataset or Resource** will be Used

Include Separate Tables for Domestic/Foreign Populations

Inclusion Enrollment Reports

Planned

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

Cumulative (Actual)

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

Peer Review of Inclusion

National Institutes of Health

NIH Peer Review

Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research

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Revision Notes – March 2019

- Added guidance for considering plans for inclusion of individuals across the lifespan, including:
  - Consideration of age-appropriate inclusion and justification for age-based exclusions (including children and older adults)
  - Addition of definition of older adult
- Clarified language on requirements for valid analysis by sex/gender and race/ethnicity for NIH-defined Phase IIII clinical trials

Requirements and Responsibilities

As required by federal law (42 USC 289a-2) and NIH policy (NOT-OD-18-014 and NOT-OD-18-

National Institutes of Health
Office of Extramural Research

Guidelines available at
https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_Inclusion.pdf

Summary Statement

SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:*** **08/11/2020**
Jane Doe
240 111-5555
janesmith@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
Program for Collaborative Biomedical Research

Meeting Date: **07/20/2020** ***RFA/PA:*** **IC 20-006**
Council: **OCT 2020** ***PCC:*** **M51B B**
Requested Start: **12/01/2020**

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
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Gender: 1A-Both Genders, scientifically acceptable
Minority: 5A-Only foreign subjects, scientifically acceptable
Age: 3U-No children (only adults and older adults), scientifically unacceptable.
Clinical Research - not NIH-defined Phase III Trial

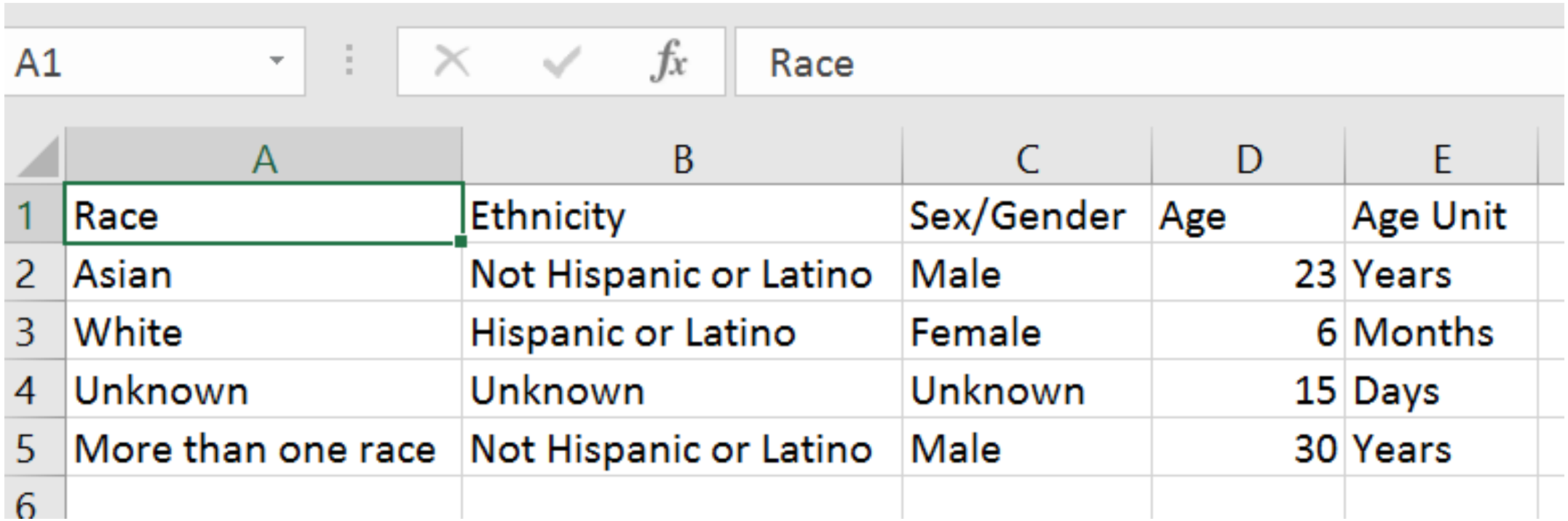
National Institutes of Health
Office of Extramural Research

Just-in-Time Requirements

- Unacceptable applications must resolve inclusion concerns prior to funding
  - Work with Institute/Center staff
- Provide requested documents or revisions
  - Missing/corrected inclusion enrollment report
  - Revisions due to peer review and/or programmatic adjustments

- Cumulative **actual inclusion enrollment data** in progress reports
- For NIH-defined Phase III Clinical Trials – **report status/results of analyses** by sex/gender, race, and ethnicity
  - For ACTs, report results by sex/gender and/or race/ethnicity in Clinicaltrials.gov
- Delayed onset studies
  - Provide full PHS Human Subjects and Clinical Trials Information Form once study can be described

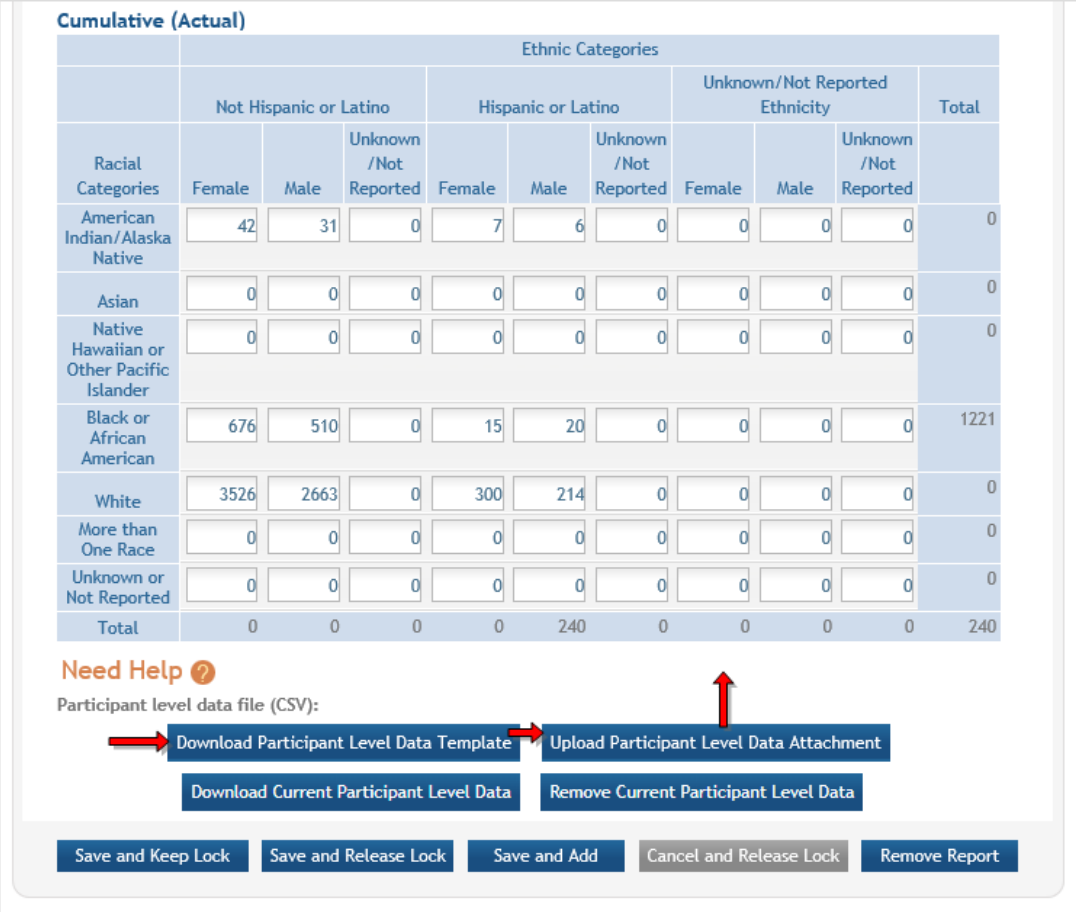
Individual-level Participant Data



A1 | Race

	A	B	C	D	E
1	Race	Ethnicity	Sex/Gender	Age	Age Unit
2	Asian	Not Hispanic or Latino	Male	23	Years
3	White	Hispanic or Latino	Female	6	Months
4	Unknown	Unknown	Unknown	15	Days
5	More than one race	Not Hispanic or Latino	Male	30	Years
6					

Uploading Participant-Level Data in HSS



Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	
American Indian/Alaska Native	42	31	0	7	6	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	676	510	0	15	20	0	0	0	0	1221
White	3526	2663	0	300	214	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	240	0	0	0	0	240

Need Help

Participant level data file (CSV):

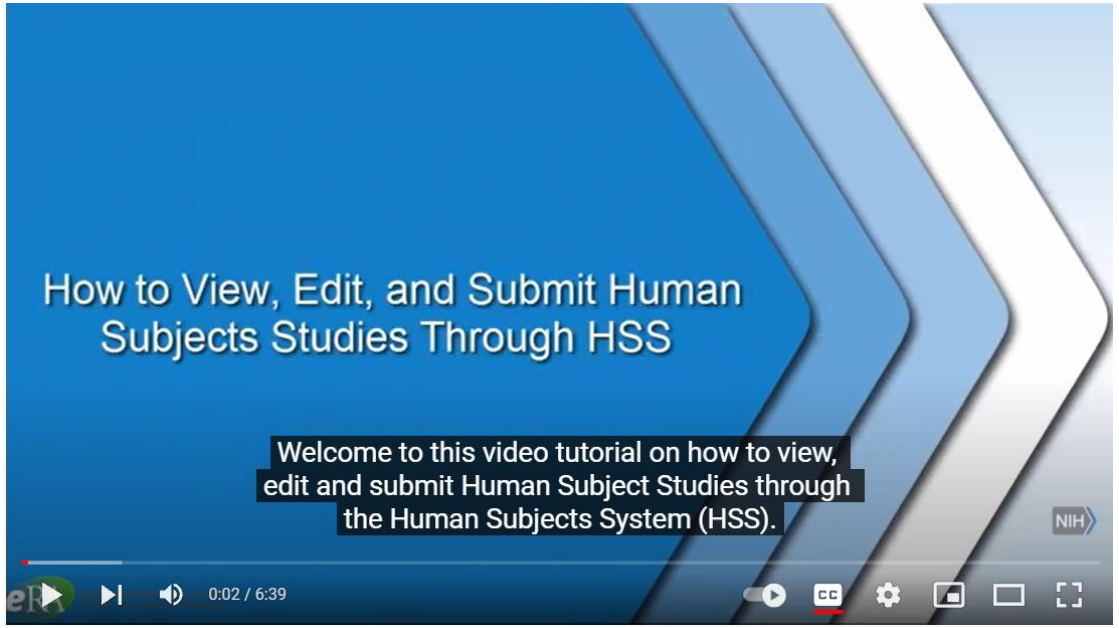
Download Participant Level Data Template | Upload Participant Level Data Attachment

Download Current Participant Level Data | Remove Current Participant Level Data

Save and Keep Lock | Save and Release Lock | Save and Add | Cancel and Release Lock | Remove Report

Videos, Templates, and Other Resources on HSS Training Site!

https://era.nih.gov/help-tutorials/era-training-hss.htm



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Knowledge Check

Cost is an acceptable reason to exclude women from an NIH clinical research study

FALSE

Case Study #1

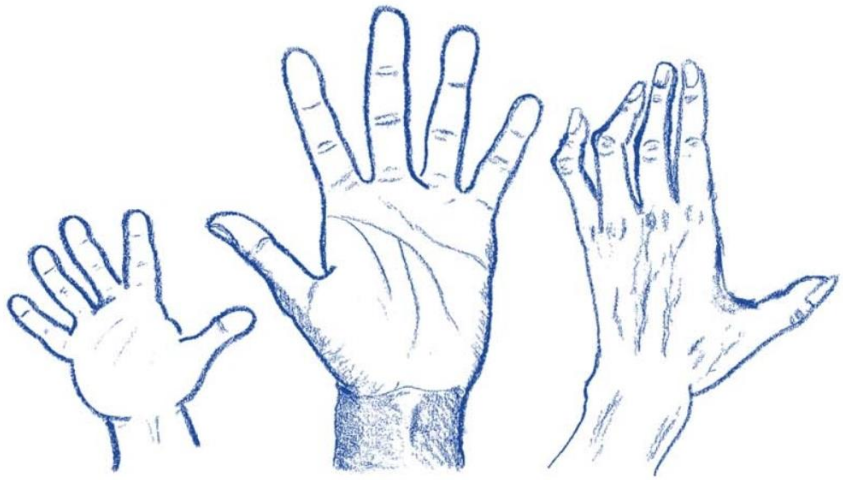
A researcher proposes a study to examine use of a smartphone app to improve glycemic control in diabetic individuals. The study excludes individuals who do not speak English because the consent form is available only in English.

Case Study #2

A researcher proposes a study for a new drug that will exclude individuals over 60 because of the likelihood of co-morbidities in this group.

Inclusion Across the Lifespan II Workshop

NIH Inclusion Across the Lifespan II



September 2, 2020

Report available on Inclusion Across the Lifespan website https://grants.nih.gov/policy/inclusion/lifespan.htm

Recurrent Themes

- Limiting inclusion/exclusion criteria
- Weighing risks of exclusion vs. participation
- Minimizing participant and caregiver burden
- Considering diversity within populations
- Assessment and adjustment of recruitment/retention
- Researcher training and resources

NIH Inclusion Data

NIH RCDC Inclusion Statistics Report

Summary | Detail | RISR FAQs | Contact Us

This report displays the typical representation of participants in human subject studies enrolled in NIH clinical research projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

Adjust the filters to view characteristics by race or ethnicity or to exclude single population studies. Drill down to explore more detailed statistics.

****Notes:** Research, condition, and disease categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project's studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

Example: R01 IC12345 enrolled 300 participants and is associated with the Basic Behavioral and Social Science and Prevention categories. All 300 participants will appear in both the Basic Behavioral and Social Science and Prevention category totals for that IC.

See the RCDC Inclusion Statistics Report (RISR) FAQs for more details about these data.

Human Subjects System (HSS) Enrollments by Age Groups in Research, Condition, and Disease Categorization (RCDC) Categories Inclusion Record Year 2021 are available in Excel format only.

Filter RCDC Categories | Total, NIH | 2021 | Sex/Gender | Exclude Single Sex/Gender Studies | Clear Filters | Export

RCDC Category	Median % Female Participants	Median % Male Participants	Median % Participants of Unknown or Unreported Sex/Gender
ALS	51%	49%	<1%
Acquired Cognitive Impairment	58%	41%	<1%
Acute Respiratory Distress Syndrome	44%	55%	<1%
Adolescent Sexual Activity	50%	46%	<1%
Agent Orange & Dioxin	51%	49%	<1%
Aging	55%	43%	<1%
Alcoholism, Alcohol Use and Health	50%	49%	<1%

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Data available on the RePORT website at https://report.nih.gov/RISR/#/

Resources

WEB

Inclusion of Women and Racial and Ethnic 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