NIH FORMS-F and Other Policy Changes

Agenda

Proposal considerations

Policy changes

Review of Human Subjects/Clinical Trial Determinations and Selecting an FOA

Forms Changes

Latest on Late Application Policies

- The general NIH Late Application Policy is in effect
- NOT-OD-15-039:
- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html

- Additional Late Application Policies
  - Mainly Institute-specific/FOA-specific
    - NIGMS, NIAID, NIA, NCI (R25 program), Parent FOA T32/T35

NIH Guide to Grants & Contracts

https://grants.nih.gov/grants/guide/listserv_dev.htm

NIH Guide to Grants and Contracts

Track the release of new funding opportunity announcements and notices that we publish in the NIH Guide for Grants and Contracts:

Weekly E-mail Listserv

Receive weekly emails (usually on Friday afternoon) with with the Current Weekly Table of Contents (TOC) from the NIH Guide to Grants and Contracts including direct links to all funding opportunities and notices published during the week.

Subscribe/unsubscribe

RSS Feed

View NIH Guide information using your RSS reader. RSS is an XML-based format for content distribution. To view this information in your RSS news reader:

- Copy or click on the URL of the feed
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grants.nih.gov/grants/guide/newsfeed/fundingopps.xml

Twitter

Get immediate updates on new funding opportunities and notices by following us on Twitter

@NIHFunding

Customize Saved Search Notifications

Save your search and get daily, weekly or monthly notifications when we publish a funding opportunity or notice that matches your search in the future.

Example – *Related Notices* in FOA

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute on Aging (NIA)
Funding Opportunity Title	Mechanisms of Rejuvenation and Age-Acceleration in Heterochronic Blood Exchange (R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	**May 14, 2020** - NIA Late Application Policy for NIA-Specific FOAs with Application Due Dates in May, June, and July 2020. See Notice NOT-AG-20-033. July 26, 2019- Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128 August 23, 2019- Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137

Which Forms do I use?

The **DUE DATE** drives the form selections:

- FORMS-E - due dates before May 25, 2020
  - Example, FOA due date is May 18, a late application policy allowed submission until June 30.

- FORMS-F - due dates on/after May 25, 2020
  - Example, you prepared application early, plan to submit May 20, but FOA due date is May 25.

If your due date is …	You must use …
On or before May 24, 2020, including: Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before May 24, 2020 Applications submitted by June 1, 2020 under NIH Continuous Submission Policy for the May 7, 2020 AIDS intended due date	*FORMS-E* application forms and instructions Parent Announcements posted prior to 2020 (if applying to a parent FOA)
On or after May 25, 2020, including: All application types (New, Resubmission, Renewal, Revision) Applications submitted early for intended due dates on or after May 25, 2020 Applications submitted after June 1, 2020 under NIH Continuous Submission Policy	*FORMS-F* application forms and instructions Parent Announcements posted in spring 2020 (if applying to a parent FOA)

Continuous Submission Policy

- Change in Submission Deadlines and End of Recent Substantial Service Option (NOT-OD-20-060):
- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-060.html

- Discontinuing "**recent substantial service**", earned for **temporary or ad hoc service** on a qualifying NIH study section at least 6 times in an 18 month period.

  - Reviewers who are currently eligible for continuous submission through their **recent substantial service** will remain eligible through the end of their term on **September 30, 2020**.

  - Reviewers who earn eligibility for service through June 30, 2020 will receive continuous submission eligibility from **August 1, 2020 through September 30, 2021**.

- Continuous submission privileges for **appointed regular members** of NIH committees are unchanged.

- CSR.cont.sub.comm@mail.nih.gov

- See their FAQs: https://grants.nih.gov/faqs#/continuous-submission.htm

Continuous Submission Receipt Dates

For the Advisory Council Round:	Non-AIDS Standard Application Due Dates		Continuous Submission Non-AIDS Application Receipt Period Ends
	R01	*R21, R34*	*R01, R21, R34*
May	October 5 November 5	October 16 November 16	December 10
October	February 5 March 5	February 16 March 16	April 10
January	June 5 July 5	June 16 July 16	August 10

For the Advisory Council Round:	AIDS Application Due Dates	Continuous Submission AIDS Application Receipt Period Ends
	R01, R21, R34	*R01, R21, R34*
May	January 7	February 1
October	May 7	June 1
January	September 7	October 1

- Direct any submission issues, including Grants.gov rejection messages indicating the opportunity is closed, to the eRA Service Desk.

Continuous Submission/Late Application Policy

- Temporary or ad hoc reviewers who are not eligible for continuous submission may be eligible to use the late submission window as described in the NIH Late Policy.

- ***How does Continuous Submission relate to the NIH Late Policy?***

- Continuous Submission applies to R01, R21, and R34 applications submitted by continuous submission eligible PD/PIs and MPIs to FOAs with standard due dates, including standard AIDS due dates.
- The NIH Late Policy applies to
  - All other types of applications submitted by continuous submission eligible PD/PIs and MPIs.
  - All applications submitted by all other PD/PIs and MPIs.

COVID-19: Proposal Considerations

- Should I address impact of COVID-19 in my NIH/AHRQ proposal?

- Guidance for NIH Peer Reviewers:
- https://grants.nih.gov/grants/files/Coronavirus-update-Guidance-for-Peer-Reviewers.pdf

- "Assume that issues resulting from the coronavirus pandemic will be resolved prior to award, and not allow concerns about temporary, emergency situations to affect their scores."

Budgeting Guidance

Cost principles:

- Reasonableness (including necessity)
- Allocability
- Consistency
- Allowability/Conformance

NIH Grants Policy Statement, section 7.9, *Allowability of Costs/Activities*:

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm

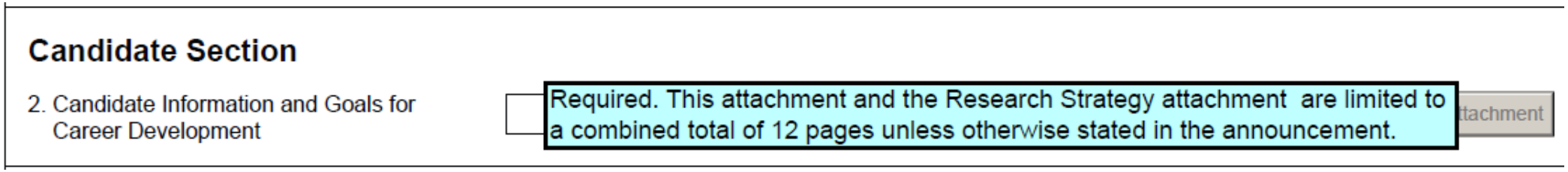
Develop your Budget:

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm

Policy Change/FORMS-F
NIH/AHRQ: Career Development Awards

- NOT-OD-20-090 - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-090.html
- Added instructions about rigor, experimental design, and quantitative approaches to the "Candidate Information and Goals for Career Development" section.

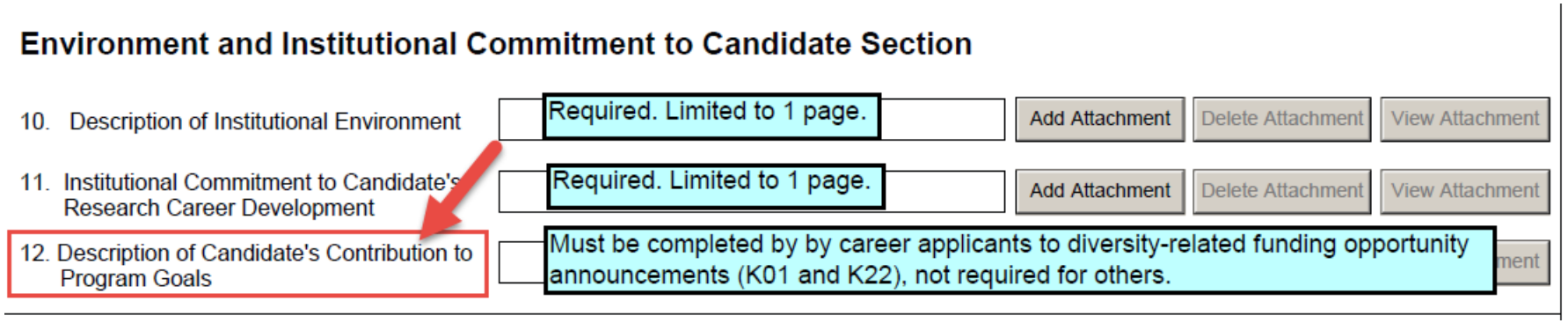
- "Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches and data analysis and interpretation."



Policy Change/FORMS-F
NIH/AHRQ: Career Development Awards

- Applicants to **diversity-related** FOAs (e.g., diversity-related K01) will be required to **include an attachment** describing how the candidate's participation would further the goals of the program.

- Added new "Description of Candidate's Contribution to Program Goals" attachment.



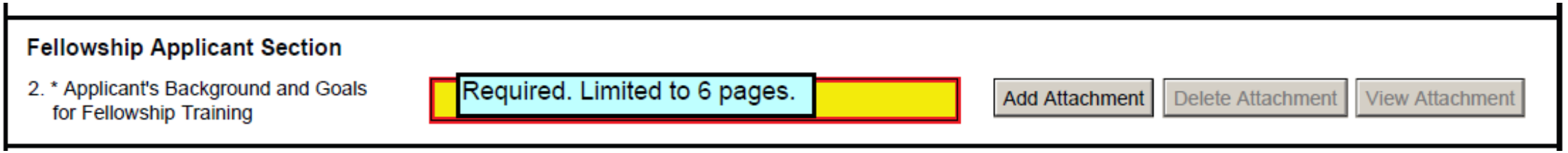
New “Description of Candidate’s Contribution to Program Goals” attachment

- The sponsoring institution must provide a document on institutional letterhead that explains how the candidate’s participation will further the goals of the career development program to promote diversity in health-related research.

- Must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department.

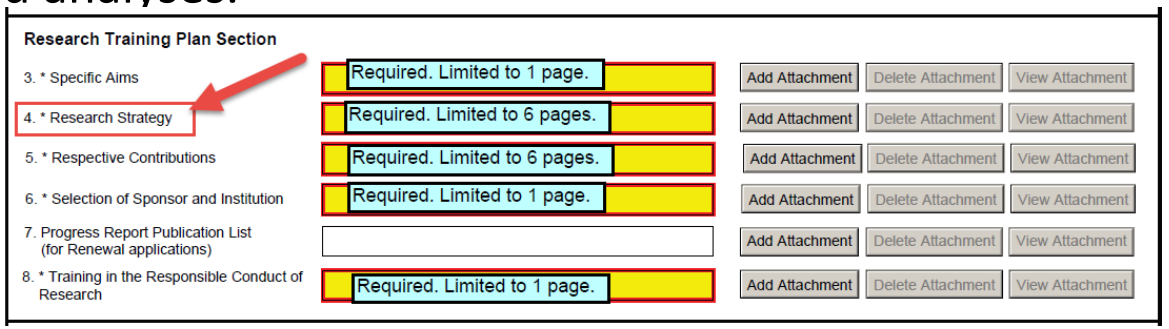
Policy Change/FORMS-F
NIH/AHRQ: Individual Fellowships (F's)

- NOT-OD-20-090 - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-090.html
- **Applicant's Background and Goals for Fellowship Training**
- **Training Goals and Objectives**
- Identify the skills, theories, conceptual approaches, etc., to be learned or enhanced during the award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation, as applicable.

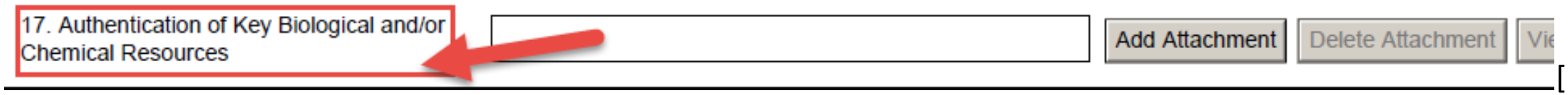


Policy Change/FORMS-F
NIH/AHRQ: Individual Fellowships (F's)

- In the Research Strategy section, fellowship candidates will be expected to describe (a) the strengths and weaknesses in the rigor of the prior research that serves as the key support for the proposed project, (b) plans to address any weaknesses in the rigor of the prior research, (c) how the experimental objectives proposed will achieve robust and unbiased results, and (d) how relevant biological variables are factored into research designs and analyses.



- If applicable, fellowship candidates will be required to include an attachment describing how they will authenticate key biological and/or chemical resources.



Discussion Guide for K and F-applicants

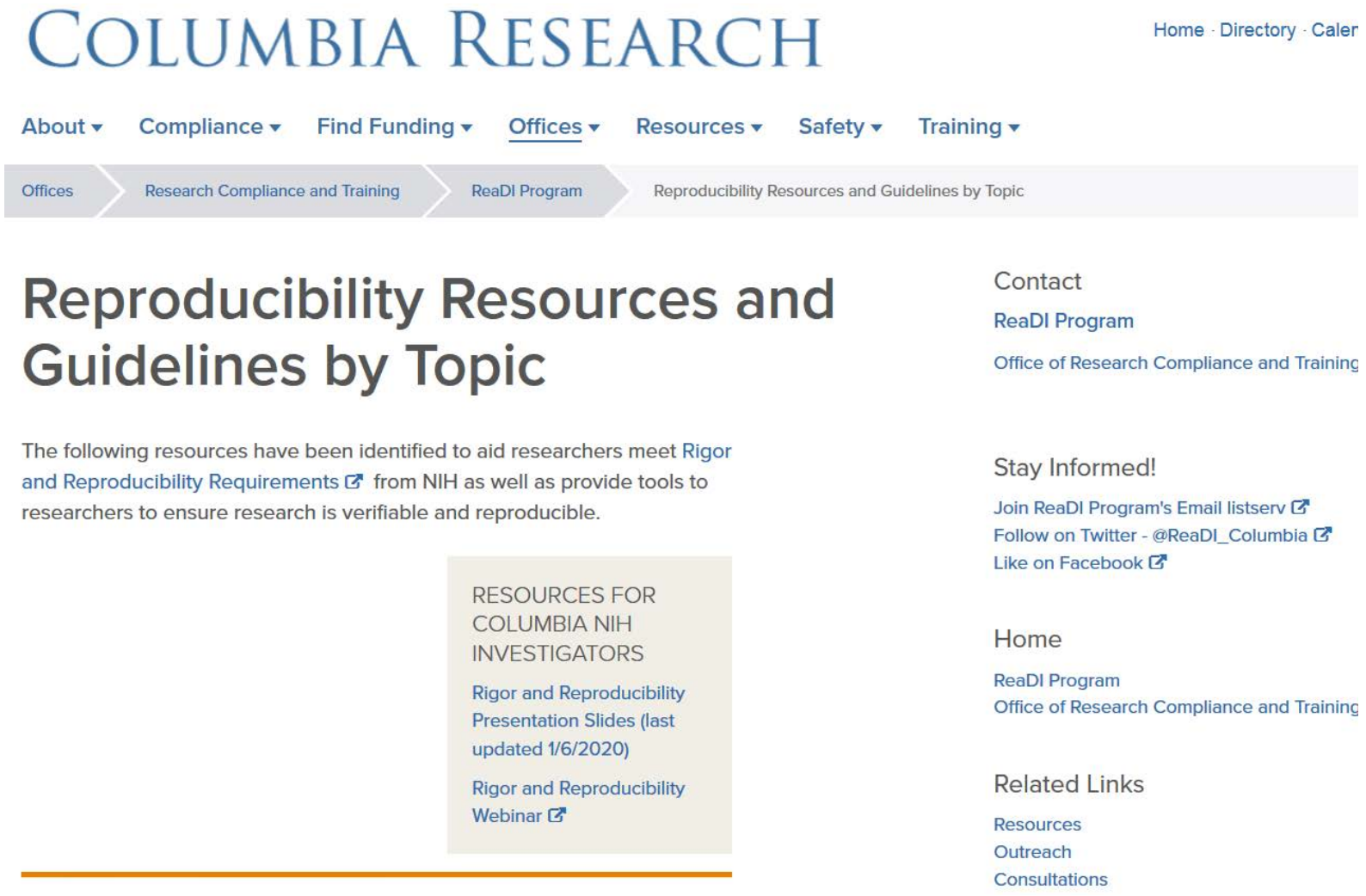
Let's Talk About Rigor and Reproducibility!

This discussion guide is intended for fellows and early-career researchers initiating conversations with mentors and others on addressing NIH's Rigor and Reproducibility requirements for career development and training goals. For more information on NIH's Rigor and Reproducibility including webinars and presentations, see the ReaDI Program's Reproducibility webpage.

Applicants are expected to address any new research skills planned to acquire in areas of rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation. For each of the areas below, list what research skills you will require to learn and further develop to carry-out the research project?

Rigorous Research Design (Review Planning a Rigorous Experiment checklist)	
Experimental Methods	

ReaDI Program

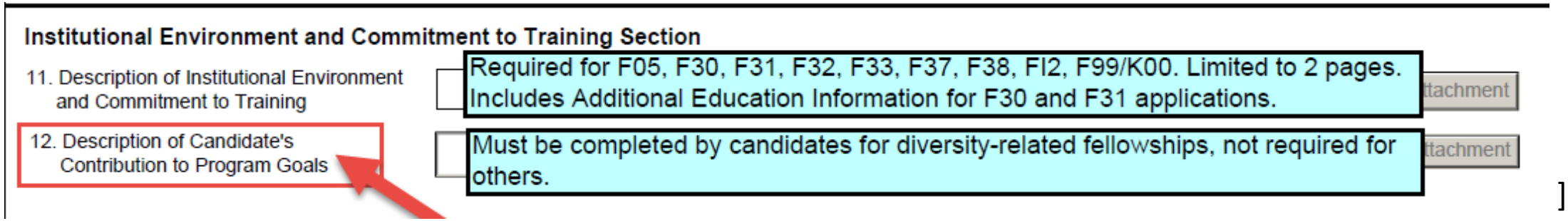


https://research.columbia.edu/ReaDI-Program

Policy Change/FORMS-F
NIH/AHRQ: Individual Fellowships (F's)

- The sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the fellowship program to promote diversity in health-related research.

- Must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department.



Single IRB

- **For NIH applicants, the single IRB plan is no longer required.** Do not provide an attachment. The applicant must provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.

- Still required for AHRQ

- Career Development and Fellowship Applications are now subject to Single IRB Policy. – must select Yes or No in section 3.2 of Study Record

- Still need to budget for Single IRB costs

Single IRB

- See HRPO site: https://research.columbia.edu/single-irb-review-multi-site-research

- If you are conducting non-exempt human subjects research and research will be conducted at multiple domestic sites:
  - Immediately complete the CU sIRB Request Form
  - Email it to irboffice@columbia.edu

- Process the same for when Columbia is the PTE, or when Columbia is the subrecipient.

- **Single IRB is mandatory for all federal agencies** (with the exception of FDA)

Am I doing Human Subjects (HS) Research?

Use the Human Subjects Decision Tree:

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

Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Examples of human subjects research include:

- Collecting blood
- Conducting a survey
- Changing participants' environment
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique

Included in the NIH application:

✓ Protection of Human Subjects attachment

If funded, grantees will need:

✓ An Institutional Federal-Wide Assurance (FWA) with OHRP

✓ IRB approval or determination of exemption

✓ Human Subjects education* even for exemptions

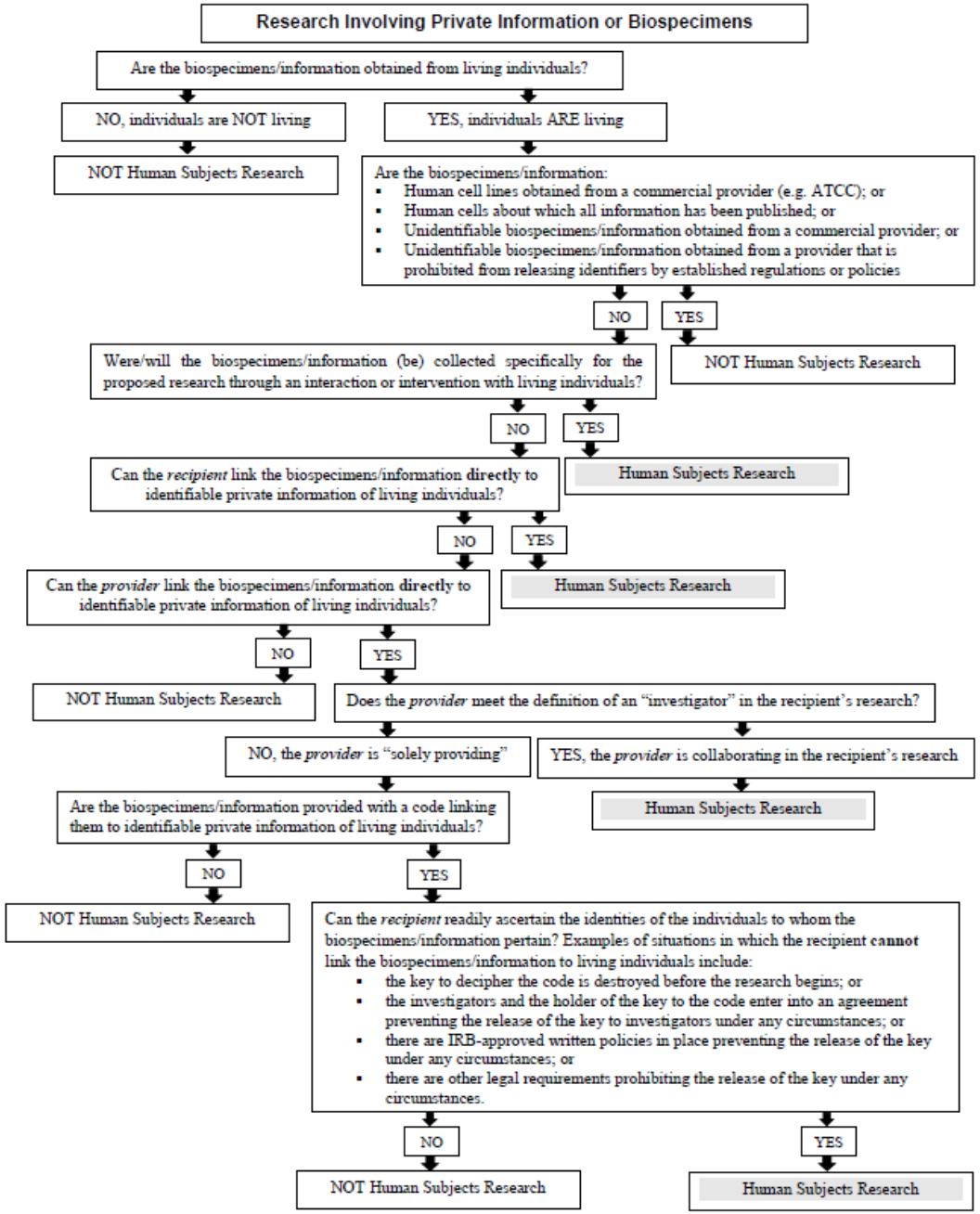
If research meets the criteria for one of the eight categories of activities that are **exempt** from the federal regulations, not all of the above may apply. Some of the exemptions require a limited IRB review (7 and 8, and some designs under 2 and 3).

Exemptions:

Exemption 1 Conducted in an educational setting involving normal education practices	**Exemption 2** Use of educational tests, surveys, interviews, or observations of public behavior	**Exemption 3** Use of benign behavioral interventions in adults	**Exemption 4** Collection/study of data or specimens if publicly available or recorded such that subjects cannot be identified* *May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)
Exemption 5 Public service program research or demonstration projects	**Exemption 6** Taste and food quality evaluations	**Exemption 7** Storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.	**Exemption 8** Secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required.

Questions/comments? Contact OER-HS@nih.gov

https://grants.nih.gov/sites/default/files/human-subjects-research-infographic.pdf



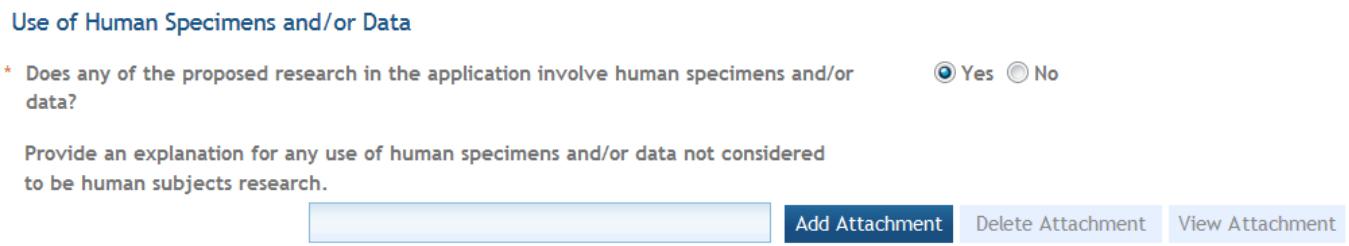
Please note: this document is intended to be a resource only. Final decisions should be made in accordance with 45 CFR 46.

NIH Office of Extramural Research - June 25, 2019

Research Involving Private Information or Biospecimens may also be considered Human Subjects Research. See flowchart:

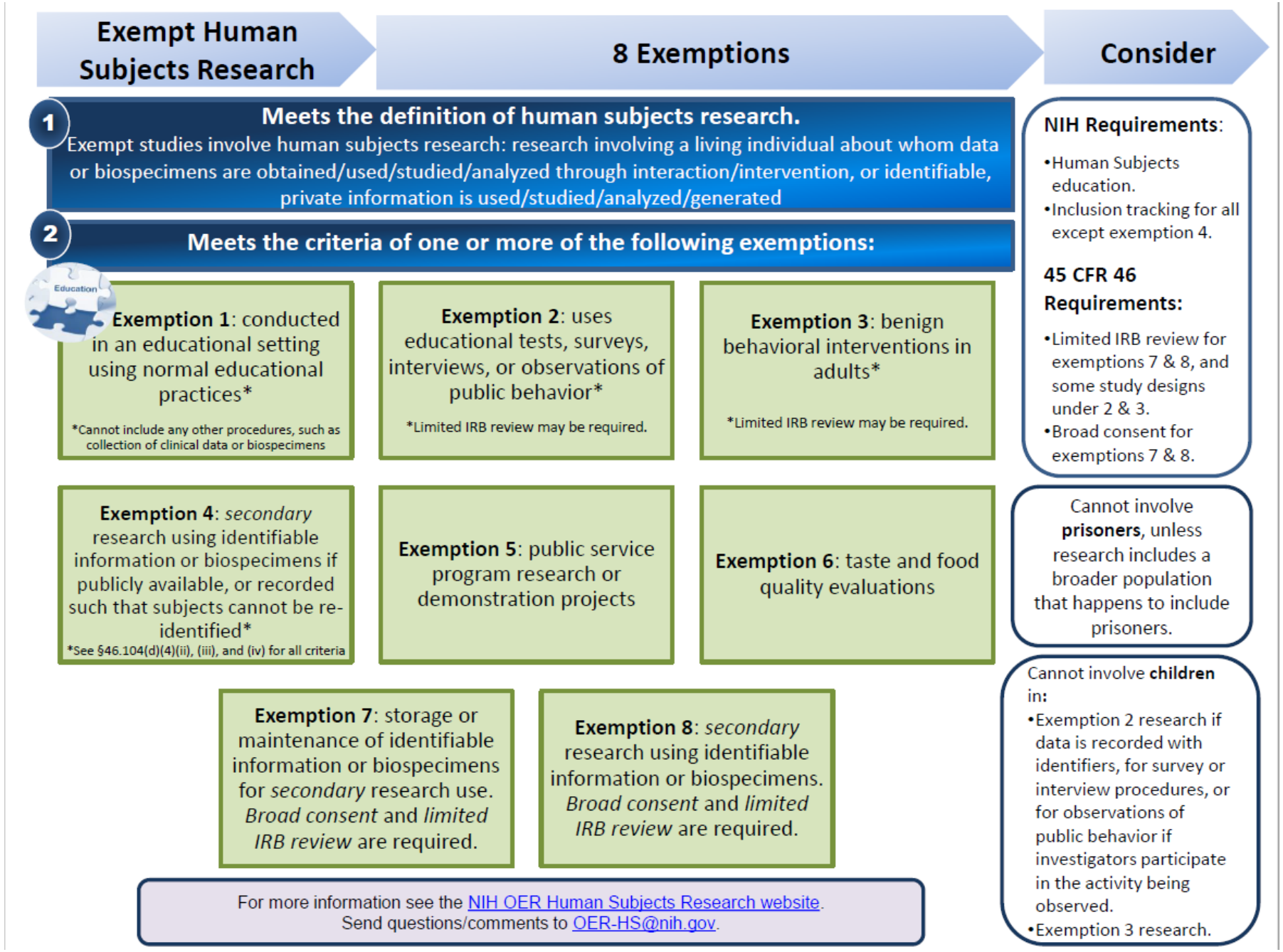
https://grants.nih.gov/grants/policy/hs/private-information-biospecimens-flowchart.pdf

We come back to this later on in this presentation:



If YES, is it Exempt of Non-Exempt?

- Contact the IRB to discuss and clarify.
- Has an impact on the sections you complete in the PHS Human Subjects/Clinical Trial form and study records.
- Impact on Single IRB if multiple sites are involved.
- IRB doesn't designate Exemptions 7 and 8.
- The IRB makes the *final* determination when a protocol is submitted during JIT.



https://grants.nih.gov/sites/default/files/exemption_infographic_v8_508c_1-15-2020.pdf

If non-exempt, is it an NIH-defined Clinical Trial?

Use the Clinical Trial Decision Tool:

- https://grants.nih.gov/ct-decision/index.htm

The four 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 being evaluated a health-related biomedical or behavioral outcome?

Also see NIH Protocol Templates and e-Protocol Writing Tool:

https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

- Phase 2 or 3 clinical trials that require Investigational New Drug applications (IND) or Investigational Device Exemption (IDE) applications
- Behavioral and social sciences research involving humans

ReaDI Program Resources: https://research.columbia.edu/clinical-and-health-sciences

Select the Appropriate FOA

Understanding FOAs:

- https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm
- Applications that include **clinical trials** must be submitted in response to an FOA that allows clinical trials (even if other studies on the same application are not clinical trials).
- Make sure that the NIH Institute or Center that might be interested in your research **is listed as a participating organization** in the FOA.
- Notices of special interest (NOSIs) may identify NIH Institutes or Centers participating in the notice initiative that are not listed in the FOA used for submission.
- Return to the FOA to check the **Related Notices** section before submission to ensure you are in line with the most recent guidance.
  - Don't turn the FOAs into PDFs! Updated in real-time.

Example: New PA-20-183 for FORMS-F

Research Project Grant (Parent R01 Clinical Trial Required) (PA-20-183)

Contacts and Special Interests

Release Date: May 05, 2020
Expiration Date: May 8, 2023

R01 Clinical Trial Required Participating Institutes and Centers:

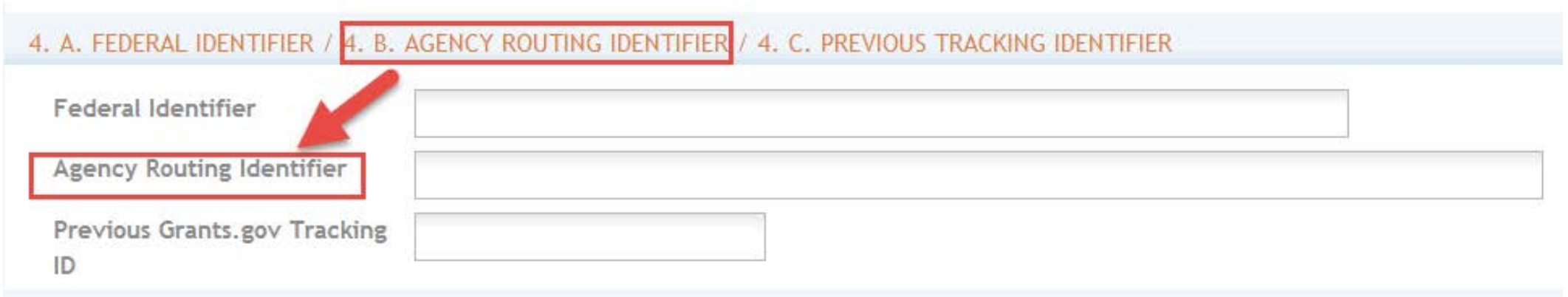
- **NIH Institutes and Centers that accept Investigator-Initiated R01 applications in response to the Parent R01 Clinical Trial Required Announcement - (PA-20-NNN):** NHGRI, NEI, NIA, NIAAA, NIAID, NIDA, NIDCD, NIEHS, NIGMS, NIMHD, NINR
- **NIH Institutes and Centers that only accept Investigator-Initiated R01 applications proposing mechanistic clinical trials in response to the Parent R01 Clinical Trial Required Announcement (PA-20-NNN):** NCCIH, NHLBI, NIAMS, NIMH, NINDS
- **NIH Institutes and Centers that DO NOT ACCEPT applications in response to the Parent R01 Clinical Trial Required Announcement but ONLY accept R01 applications proposing clinical trial(s) in response to their specific funding opportunity announcements: NCI, NIBIB, NICHD, NIDCR, NIDDK (PA-18-330), NLM, FIC, NCATS**

When in doubt, talk to the Scientific/Research Contact at the specific Institute named in the FOA.

Notices of Special Interest (NOSIs)

- Video on NOSIs: https://youtu.be/LhXW67LNbIc

- NOSI, you **must** include the NOSI number in Box 4B (the Applicant Routing Identifier) on the proposal SF 424 cover page.



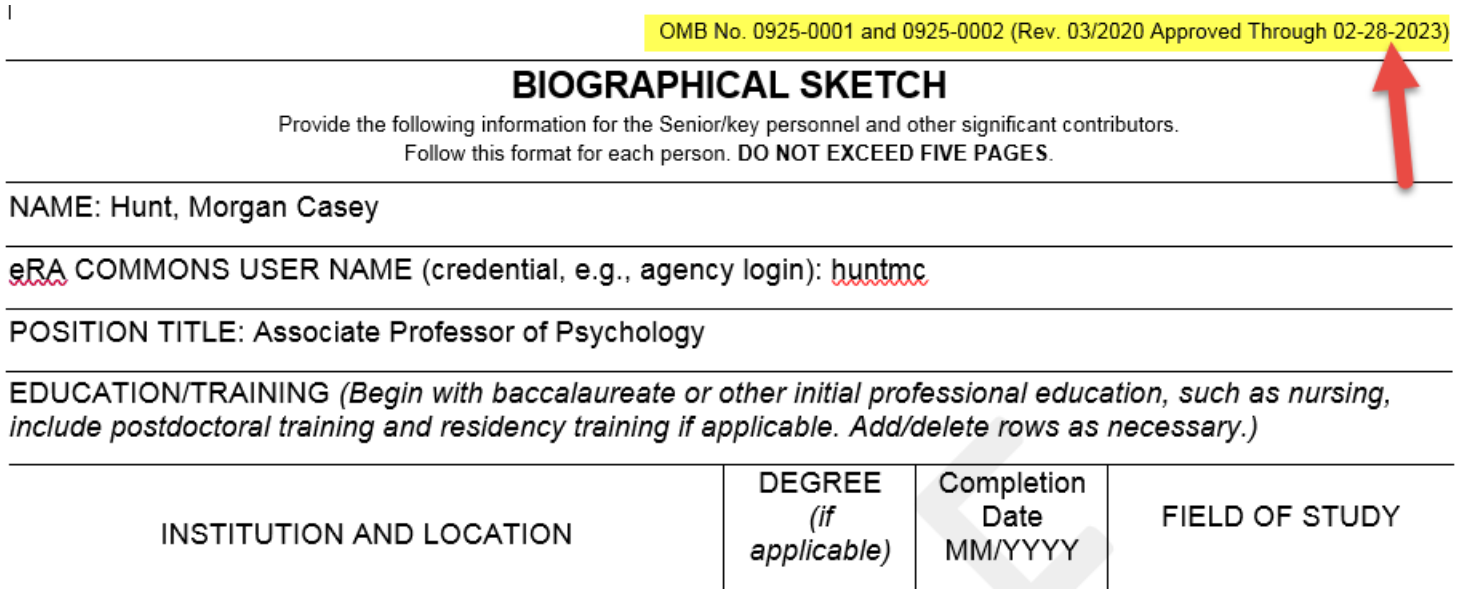
FORMS-F Proposal Checklists

- Courtesy of VP&S Office for Research:
- https://research.ps.columbia.edu/content/checklists

- Grant Starter Kit:
- https://research.ps.columbia.edu/content/grant-starter-kit

Resubmission?

- Careful to switch to FORMS-F
- Make sure to use the latest Biosketch format, new expiration date: https://grants.nih.gov/grants/forms/biosketch.htm
- Tried SciENcv? https://www.ncbi.nlm.nih.gov/sciencv/



OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02-28-2023)

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: Hunt, Morgan Casey

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

POSITION TITLE: Associate Professor of Psychology

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

New Expiration Dates

Expiration Date: old (FORMS-E) 03/31/2020;

New (FORMS-F) date 02/28/2023

New Question: Human Fetal Tissue (HFT)

New on Cover Page Supplement

- If Yes, go to application instructions for specific information about these two attachments:
- https://grants.nih.gov/grants/how-to-apply-application-guide.html

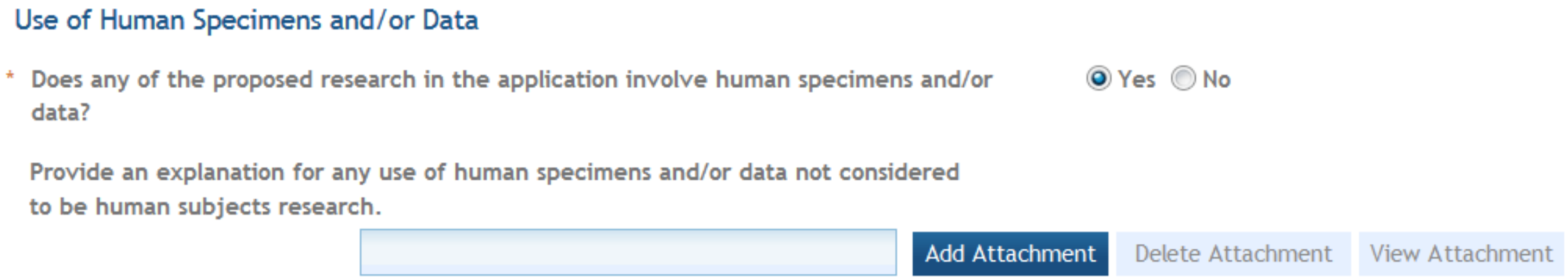
PHS Human Subjects/Clinical Trial Information Form and Study Records

- Updated Expiration Date
- Reworked landing page to require an answer and supporting explanation (if applicable) for the question "Does any of the proposed research in the application involve human specimens and/or data?" for all applications

Study record changes

- Defaulted Clinical Trial Questionnaire question "1.4.a Does the study involve human participants?" to Yes, since study records are only available when the answer to the "Are Human Subjects Involved?" question on the R&R Other Project Information form is Yes
- Separated "Inclusion of Women, Minorities, and Children" attachment into two attachments – "Inclusion of Individuals Across the Lifespan" and "Inclusion of Women and Minorities"
- Renamed "Enrollment of First Subject" field to "Enrollment of First Participant"
- Added "Inclusion Enrollment Report Title" field to the Inclusion Enrollment Report
- Removed "Brief Summary" attachment
- Renamed "Narrative Study Description" attachment to "Detailed Description"
- Added new question and checkbox – "Is this an applicable clinical trial under FDAAA?"
- Renumbered form fields, as needed

Human Specimens and/or Data



All applicants are required to answer this question. The explanation attachment is now always available. Previously, the question and attachment were only available when Human Subjects was NO, which didn't allow for scenarios where an application involved both human subjects and human specimens and/or data.

Attachment – if not human subjects research

Remember that flowchart? Slide 25: **Research Involving Private Information or Biological Specimens**.

- You must provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

This explanation should include:

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects' identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.

Study Record: 1.4.a. defaults to YES

* 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

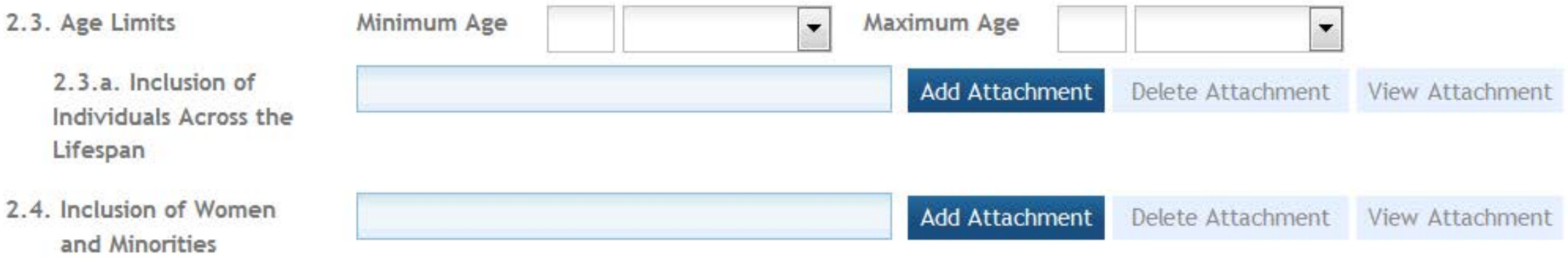
If you answered "Yes" to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial.

Refer to the table below for information about what sections of this form are required, based on your answers to Question 1.4 "Clinical Trial Questionnaire."

Form Section	If you answered "yes" to all the questions in the Clinical Trial Questionnaire	If you answered "no" to any of the questions in the Clinical Trial Questionnaire
Section 2 - Study Population Characteristics	Required	Required
Section 3 - Protection and Monitoring Plans	Required	Required
Section 4 - Protocol Synopsis	Required	Do not complete
Section 5 - Other Clinical Trial-related Attachments	Required if specified in the FOA	Do not complete

Section 2 – Study Population Characteristics

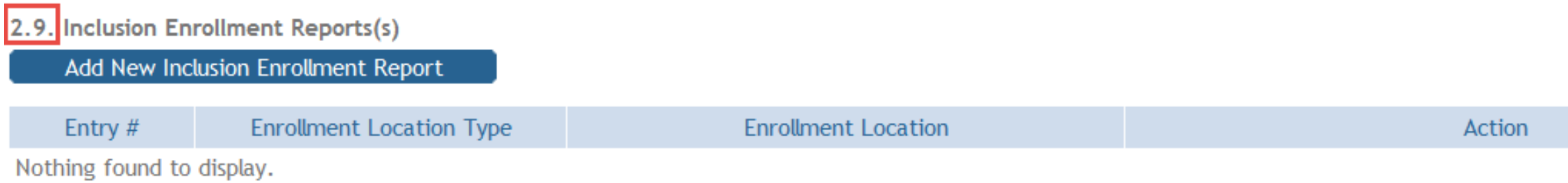
- Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments
  - “Inclusion of Individuals Across the Lifespan”
  - “Inclusion of Women and Minorities”



Enrollment of First Participant

- Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”

Inclusion Enrollment Reports (IERs)



Added a field number.

IERs continued

- Added a TITLE field in the IER.

Let's Talk IERs

- Each proposed study, unless it falls under Exemption 4, must contain at least one IER.
- Max. 20 IERs per Study Record
- **More than one site?**
  - May create one IER or separate, multiple IERs to enable reporting by study or by site, depending on the scientific goals of the study and whether **monitoring of inclusion enrollment would benefit from being combined or separated**.
- Non-U.S. sites must be reported separately from participants enrolled at U.S. sites, even if they are part of the same study.
- Please review the FOA to determine whether there are any other specific requirements about how to complete the IER.

Human Subjects System (HSS)

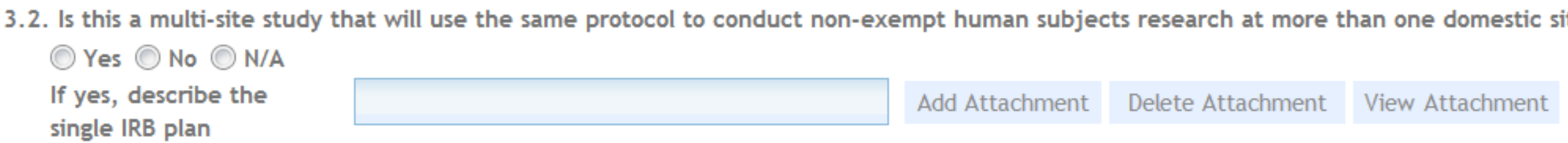
- The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects and clinical trials to NIH; and for NIH agency staff to monitor and manage the data.

- The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator (PI) on the ***Human Subjects and Clinical Trial Information*** **form**.

- This data is then made available to PIs and signing officials (SO) through a link that will be available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR).

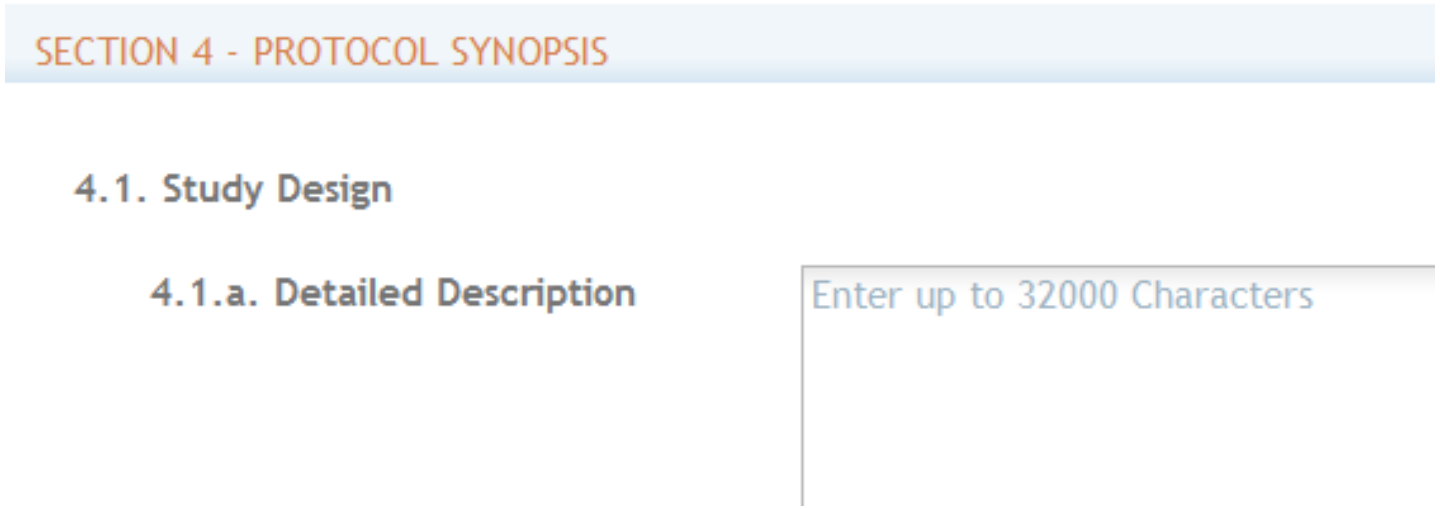
Section 3.2 - Single IRB

- Must answer Yes or No.
- N/A not an option
- AHRQ, must upload the Single IRB Plan
- NIH applications – nothing to upload



Section 4 – Protocol Synopsis (Clinical Trials only)

- Removed “Brief Summary” attachment.
- Renamed “Narrative Study Description” attachment to “Detailed Description”
  - To reduce overlap of requested information, and align with clinicaltrials.gov.



Section 4 continued

- Added new question and checkbox – “Is this an applicable clinical trial under the Food and Drug Administration Amendments Act (FDAAA)?”
- For more information, see https://clinicaltrials.gov/ct2/manage-recs/faq#act

Optional PHS Assignment Request Form

- The PHS Assignment Request Form was reworked to improve usability.
  - Clarified instructional text
  - Improved field labels
  - And a new “Rationale for assignment suggestions” text box.

- Removed fields
  - Do Not Assign to Awarding Components
  - Do Not Assign to Study Sections

In order to prepare the application:

- Parent Announcements
- Application Instructions
- FORMS-F Annotated Form Sets
- Biosketch Format Pages

Questions?

- Contact your SPA Project Officer
- We're here to help!