NIH Update Panel Topics

**Introductions**

- Each panelist introduces themselves (name, position in OPERA)

**GPS Update Highlights (Slide 2)**

Can you tell us about some of the areas that are being updated this year?

- Some of the updates include:
  - HFT sections
  - OS language
  - ORCID ID requirements
  - Research Misconduct language
  - SBIR/STTR levels, IP, and life-cycle certifications

Usually we post our significant changes online each year. Will we be doing that this year?

Yes.

**Forms/Application instructions timelines (Slide 3)**

Not only will the GPS be updated, but we are also working on updates to our NIH forms. We’ll be moving from our Forms E package to Forms F. When will those changes be happening, and what’s going to change?

Forms F coming for due dates on or after May 25, 2020. Guide Notice announcement coming soon!

- What forms are changing?
  - PHS 398 Cover Page Supplement- New HFT section with a new question and 2 attachment fields
  - PHS 398 Career Development Award Supplemental Form- Added new attachment field
  - PHS Fellowship Supplemental Form- Added new attachment field
  - PHS Human Subjects and Clinical Trials Information Form- Some form wording changes, some new title fields, removed attachment field and a new ACT question
  - PHS Assignment Request Form- Remove some fields, added a text field, and some field label changes.

Where will new forms and instructions be posted?

The new forms will be available in grant submission systems (Grants.gov Workspace, ASSIST, and other Systems-to-Systems) in the Spring. The application guide and instructions will be available on the OER website.

I’ve heard there are also some Forms E changes coming. How are those different from Forms F and what’s the rationale?
There are no changes to Forms E. We will be issuing an updated Forms E application guide that incorporates some of the recent policy changes including HFT and ORCID ID requirements.

**HFT (Slides 4-5)**

There have been a few policy notices issued lately applications for research involving human fetal tissue. Mainly, that NIH is now requiring applicants to submit additional information about HFT in their grant applications. Can you all tell me a bit more about what will be required, and when this goes into effect?

Background on slide.

How does this affect active awards versus competitive renewals/new applications?

The policy applies to active awards when they have their annual non-competitive renewal and immediately for new applications/comp. renewals.

How do I determine if the research I’m proposing is subject to these requirements?

Refer to the guide notice on what constitutes HFT EA and consult with program staff at the IC(s) to which you are applying.

I’ve applied with HFT but have not heard any updates. What should I be expecting?

Adam: NIH is in the process of establish the EABs and their review process. Applications are being held until they can be reviewed by the EAB.

Where can applicants go if they still have questions? Are there FAQs available?

Additional FAQs are available on the OER website, and questions can also be sent to the grants policy inbox. We frequently update our FAQs based on the questions we receive.

**Other Support (Slides 6-8)**

Earlier this summer NIH issued a guide notice clarifying the requirements for submitting other support and reminding recipients of the requirements for foreign components and FCOI. Kristin – what were the areas that the notice clarified, can you give us some background?

Background on slide.

Right now, the format page doesn’t match the guide notice – will it be updated?

NIH is currently working on updating the Other Support format page, instructions and other relevant resources, to align with the guide notice.

What is NIH going to do with the information collected in Other Support?

The NIH’s interests are in assuring the needed transparency and fairness to enable the agency to make the best-informed decisions and avoid over-commitment and overlap. In order to fully review applicant’s other support, NIH needs to be able to review all resources supporting an applicants’ research endeavors.
Do recipients have to report all in-kind resources?

Applicants/recipients should report only those resources that are uniquely available to a specific researcher, as opposed to an institution-wide resource such as the institution’s core facilities or shared equipment that is made broadly available.

A lot of time when people talk about Other Support, they also talk about Financial Conflicts of Interest. Have there been any changes to the FCOI policy?

No, there hasn’t been any change to the FCOI policy. Give an overview of FCOI using the slide.

Another area where we have received a lot of questions is foreign components. Kristin, has the definition of a foreign component changed?

No, the definition of foreign components is still the same. Give overview of the questions to identify a foreign component using the slide.

So, would something like buying materials possibly considered to be a foreign component?

No. Walk through the two questions. Conducted outside US? Significant portion of the project? If this is a vendor providing supplies or materials, then they would not be conducting a significant element of the project, even if they are foreign.

So, if I have determined that I do have a foreign component in my grant, how would I request that prior approval?

You would follow the standard process for prior approval requests, which is to submit the request through your Authorized Organization Representative to the Grants Management Specialist listed on the Notice of Award.

Question to Michelle: Is NIH working with other agencies to harmonize these requirements across the government?

Give high-level overview of our efforts to collaborate/harmonize

**ORCID ID requirements** (Slide 9)

ORCID IDs are unique identifiers for individual investigators that can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. Over the past few years NIH has been working with ORCID to see how we can use these identifiers as a tool for NIH applicants and recipients. As part of this, NIH will now be requiring some applicants to have ORCID IDs.

Are individual fellowship and career development applicants expected to put both their Commons ID and their ORCID ID in their applications?

No, the ORCID ID must be linked in their eRA Commons Personal Profile (i.e. linked to their Commons ID).
The requirement for ORCID identifiers will be enforced at the time of application for individual fellowship and career development awards. The application itself will continue to only require the input of the Commons ID.

In the case of institutional research training, career development, and research education awards that require appointments through the xTrain system. The requirement is to have an ORCID ID linked in their eRA commons account. The ORCID ID requirement check will be check in X train via the eRA Commons Personal Profile.

When do these requirements go into effect?

This requirement is in effect for institutional research training, career development, and research education awards.

This requirement takes effect for individual fellowship and career development awards beginning with receipt dates on or after January 25, 2020.

**Unfunded application notifications** (Slide 10)

A few months ago, NIH announced a new process where applicant organizations will receive a centralized notification of applications that NIH will not be funding. Avery can you tell us some more about that process? Who gets the notification?

Overview on slide.

- The notification is sent to the authorized organization representative and signing official listed in the grant application, as well as the Notice of Award email address listed in the applicant’s Institutional Profile File.
- It’s never a bad idea to revisit your institutional profile file to ensure that this email is accurate and up-to-date by having a signing official go to the eRA Manage Your Institution Profile webpage.

Can PIs see the information?

Authorized eRA Commons users- PIs, SOs, and delegated Assistants- will be able to see if an unfunded application notification has been sent for a specific application by viewing the Status Information in eRA Commons, which will also show the date the unfunded notification was sent. However, external users will only be able to view the application status, rather than the content of the notification. The eRA Online Help webpage has more specific information for navigating the ERA profile, and can be accessed

- As a reminder, FAQs on this topic are linked within the guide notice and available on www.grants.nih.gov.

**ESI Extension System** (Slide 11)

I heard there is a new system for requesting ESI extensions for our early-stage investigators. Kasima, can you tell us some more about how that works?

Brief overview on slide

Does the investigator enter the request? Or does the institutional official?
The investigator will enter the request via an ESI Extension Request button in the Education section of their personal profile.

Are there any changes to the ESI policy, aside from the new system?

No

- As a reminder, Investigators must contact the NIH eRA Service Desk if the ESI status contained in his/her eRA Commons Profile is incorrect.

**Unique Entity Identifier (UEI) (Slide 12)**

I hear there are also some changes coming for recipients on the use of a new Unique Entity Identifier instead of the DUNS. Kasima, what is that going to look like, do organizations need to do anything to initiate this change?

Brief overview on slide.

- Still awaiting guidance from GSA
- Institutions already registered in SAM.gov will not need to initiate any changes. These registrations will automatically receive a new SAM.gov UEI.
  - Any new institutions not currently registered will need to complete the registration process. New registrants will be assigned a SAM.gov UEI as part of registration.

What’s the timeline for this change?

- Full implementation by Dec 2020
  - Implementation schedule guidance is pending from GSA

Organizations have to annually update/renew its SAM.gov registration, will the new SAM.gov UEI have to be changed annually?

The SAM.gov will be assigned once. The organization is still required to update/renew its registration annually. You will not receive different SAM.gov UEIs as part of the renewal.

What happens to my old DUNS number?

It is maintained for historical purposes.

**RGM initiatives**

NIH has been working on several initiatives as part of the HHS Reinvent Grants Management initiative. Background on Slide.

- **NOA Page One**
  - Timeline? Oct 2020
- **FFR Single submission**
  - Timeline? FY21
  - What are the advantages for recipients?
Since PMS is the financial system, can leverage the real data available.

**Lastly, Avery has a policy reminder based on questions we’ve received from several grantees over the past few months.**

Reminder – SBIR checkbox for eligibility [based on frequent questions to the policy inbox]

- As a reminder, for SBIR applications, the signing official needs to go into the company institutional eRA Commons profile to make sure that you check the checkbox that says you state you are eligible to apply. This checkbox needs to be checked annually.

- If your institution has checked the eligibility box in the institutional eRA commons profile and this issue has persisted, some additional resources that may be useful for addressing SBIR concerns can be found at [https://sbir.nih.gov/](https://sbir.nih.gov/). This site specifically addresses SBIR eligibility criteria, as well as many other resources regarding recipients that are new to SBIR/STTR.

We also have a few additional policy reminders, which we’ve included in the slide deck for your reference.

Questions?