When to use Forms-E or Forms-F

- **NOT-OD-20-026** – FORMS Set based on *Intended* due date
  - Both forms can be found on the NIH *How to Apply* site.

- FORMS-E: *Intended* due date on or before May 24, includes
  - Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before May 24
  - Applications submitted by June 1 under NIH Continuous Submission Policy for May 7 AIDS intended due dates

- FORMS-F: *Intended* due date on or after May 25, includes
  - All application types (New, Resub, Renewal, Revision)
  - Applications submitted early for intended due dates on or after May 25

- Where are the new forms? Extramural Nexus
  - *Parent announcements* will be replaced 30 to 60 days prior to first submission date
  - FORMS-F are now available in non-parent announcements
New FORMS-F Checklist

• Cover Letter
• Human Fetal Tissue
• Single IRB (sIRB)
• Human Subjects & Clinical Trials
• ORCID IDs
• Training Program Plan (Ts) – Letters of Support
• PHS Fellowship Supplemental Form
Cover Letter

• SF424 (R&R) Form, page 2

• May no longer include assignment request preferences
  • Information has to be represented in Assignment Request Form

• If using Human Fetal Tissue obtained from elective abortions (HFT)
  • Required to include a statement – even if no human subjects or costs
Human Fetal Tissue Section

- PHS 398 Cover Page Supplement, Part II
  - If yes, see NOT-OD-19-137 for HFT clarification
  - HFT Sample IRB Consent Form – blank sample
  - HFT Compliance Assurance (letter signed by PD/PI)

- R&R budget required – may not use modular
  - Include “Human Fetal Costs” in section F. 8-10 Other on its own specific line item – if no costs, enter 0

- Justification to be clearly labeled as HFT – includes
  - Quantity, types(s), source(s) of the HFT, stage of fetal development

- Research Strategy
  - must include specific information in the Approach section for applications proposing HFT
Single IRB (sIRB)

• NIH:
  • Single IRB plan no longer required for applications submitted to NIH.
  • A statement naming the sIRB of record will be provided at Just-In Time.

• AHRQ:
  • Single IRB plan is required at time of submission.
Human Subjects & Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

• The “Inclusion of Women, Minorities and Children” attachment separated into two attachments:
  • Inclusion of Individuals Across the Lifespan
  • Inclusion of Women and Minorities

• ClinicalTrials.gov Identifier: -Optional.
  • Enter NCT # for the study if available. Newly proposed studies do not need to be in ClinicalTrials.gov at time of application.

• Is this an applicable clinical trial under FDAAA? – New field and checkbox

• “Data and Safety Monitoring Plan” attachment – required for CT study; optional for HS study
ORCID iD

• ORCID identifiers are now REQUIRED (effective 1/25/2020) at the time of application for individual fellowship and career development awards. [NOT-OD-19-109](#)

• eRA system validations will check whether applicants have ORCID iDs and applications will not be accepted unless an ORCID iD is linked to the PD/PI's eRA Commons Personal Profile.
Training Program Plan – Letters of Support

• Letters of Support
  • If letters contain extraneous information such as preliminary data, methods and background, applications may be withdrawn.

PHS Fellowship Supplemental Form

• New attachment: “Description of Candidate’s Contribution to Program Goals” to the Institutional Environment and Commitment to Training Section
  • This attachment is only for applicants to diversity-related FOAs. All other fellowship applications should skip this section.
  • Not required as part of the Admin shell, but needs to be uploaded prior to submission.
Processing COVID-19 Proposals

• Medical School and ORSP are working hard to process these as quickly as possible.

• Aware of a proposal?
  • Send msgrants@umich.edu an email us as soon as you are aware
  • Make sure the PAF Project Title starts with “COVID-19”
  • And again, once signed by the dept and on to our office

• We will keep an eye out for it and process as soon as we can