



**MEDICAL SCHOOL**  
UNIVERSITY OF MICHIGAN

# GRANT SERVICES & ANALYSIS



# 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 it’s 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](mailto: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

