NIH Update

Federal Demonstration Partnership

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NIH FY 2018 Budget News

- NIH is funded under the Consolidated Appropriations Act, 2018 (P.L. 115-141) signed on March 23, 2018.
- NIHs FY 2018 budget amount is $37.3 billion which represents a $3 billion increase over FY 2017.
- 2018 Legislative Mandates posted NOT-OD-18-181

Simplified Acquisition and Micro-purchase Thresholds

- On June 20, 2018, the Office of Management and Budget (OMB) issued a memorandum raising the threshold for
  - **micro-purchases to $10,000, and**
  - **simplified acquisitions to $250,000**
- Applies to all recipients of federal financial assistance
- The memo also implements an approval process for certain institutions that wish to request micro-purchase thresholds higher than $10,000.
- NIH has updated its policy to reflect the new thresholds.
- This change is effective immediately

See NOT-OD-18-129

Federal Policy for The Protection of Human Subjects

The Final Rule (45 CFR part 46) is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs)

HHS has issued a Final Rule delaying the implementation until January 21, 2019

Recipients have the *option* of implementing 3 burden-reducing provisions during the delay period:

- The 2018 Requirements' definition of "research", which deems some activities not to be research
- Removal of the requirement for annual review for certain categories of research
- Removal of the requirement for IRBs to review grant applications related to the research

Note: The NIH policy on the use of single IRBs in multi-site studies took effect in January 2018.

See NOT-OD-18-211

Inclusion Policy Changes

Individuals of all ages, including children, must be included in all human subjects research conducted or supported by NIH, unless there are ethical reasons not to include them.

- Applies to all competing grant applications for due dates on or after January 25, 2019.
- Policy has been expanded to include individuals across the lifespan.
- Clinical research studies are expected to submit de-identified individual level data on sex/gender, race, ethnicity and age at enrollment with annual progress reports.

See NOT-OD-18-116

RPPR -Institutional Delegations and Decimal in Effort Reporting

Institutional delegations for Interim and Final RPPRs now align with delegations for annual RPPRs

- PD/PI may delegate initiation to a program assistant
- SO may delegate authority to PD/PI to submit an RPPR*

Data fields for effort reporting will be modified to enable use of decimals rather than a whole number.

*if consistent with institutional policy

See NOT-OD-18-202

Prospective Basic Science Studies Involving Human Participants

Studies that meet the NIH-definition of clinical trials and the Federal definition of basic science

- Delayed enforcement of registration and reporting in ClinicalTrials.gov for prospective basic science studies involving human participants.
- New FOAs specifically for prospective basic science studies involving human participants.
- Leniency for incorrect FOA submission.
- Request for Information has been released. Requests input from stakeholders on how best to implement the NIH CT policy for this subset of trials.

See NOT-OD-18-212 and NOT-OD-18-217

Protecting Human Research Participants (PHRP) Online Tutorial

- **NIH Office of Extramural Research (OER) will no longer offer the Protecting Human Research Participants course as of September 26, 2018.**
  - Users should complete any in-progress courses and/or print their course certificate before this date.

- **Investigators are still required to comply with all aspects of the NIH policy Required Education in the Protection of Human Research Participants.**
  - NIH does not specify or endorse any specific educational programs.

See NOT-OD-18-221 and FAQs

Clarification: Fixed Amount Award Definition and Implementation For Clinical Trials

NIH is acknowledging that no changes have been made to our current capitation funding model and recipients can continue to distribute capitation funding consistent with their current institutional policies.

- Recipient have questioned whether they are required to use fixed amount subawards to distribute capitation funds.

Fixed Amount Subaward:

- The total value of the award is negotiated upfront.
- Requires the pass-through entity to know both the unit price and the total number of units that will be provided.

Fixed-rate agreement:

- While there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study) the total amount of the award may be unknown when the agreement is created.
- Agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 45 CFR 75.201.
- Prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with NIHGPS, section 8.1.1.4

PARTICIPATION IN FEDERAL-WIDE EFFORTS

- **NIH participates in the Research Business Models (RBM) Working Group**
- **In 2017 the American Innovation and Competitiveness Act (AICA) directed the working group to review regulations and recommend ways to minimize burden in four areas**
  - Establishment of a centralized assurances repository;
  - Establishment of a centralized researcher profile database;
  - Development of a simplified, uniform grant application format and associated processes to streamline grant application and review; and
  - Simplification of mandatory progress reports, with an emphasis on performance outcomes
- **In May 2018 RBM issued a report on their efforts to date**
- **NIH will continue to participate in RBM as they highlight additional ways we can continue to reduce administrative burden across the Federal research enterprise.**

Save the Date:
2018 NIH Regional Seminars

Fall Regional Seminar

San Francisco, CA

October 17th – 19th

See NOT-OD-18-192

QUESTIONS?