NIH
Update
Clinical Trials

- Enhancing Clinical Trial Stewardship & Transparency
- NIH invests more than $3 billion each year to fund clinical trials.
- Therefore, in order to improve its stewardship of clinical trials, NIH recently announced the following reforms, which are crucial first steps in achieving its goal:
  - Expectation that all NIH–funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in Good Clinical Practice (GCP). – Effective January 1, 2017
  - Expectation that all NIH–funded clinical trials are registered and that results are submitted to ClinicalTrials.gov whether or not subject to FDAAA. – Applies to grants, contracts, and intramural clinical trials submitted on or after January 18, 2017.
  - Requires all applications involving one or more clinical trials to be submitted in response to a clinical–trial specific FOA. – Effective for receipt dates on or after September 27, 2017.

  - See NOT–OD–16–148; NOT–OD–16–149; and NOT–OD–16–147 for additional information
Kirschstein National Research Service Awards (NRSA)

NIH announced the following projected stipend levels for NRSA postdoctoral trainees and fellows in FY 2017:

NRSA stipends in FY17 will ensure that all postdoctoral NRSA recipients are above the $47,476 FLSA exemption threshold in order to have parity with postdoc associates.

See NOT-OD-16-134 for details.

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<th>Yrs</th>
<th>Stipend for FY 2016</th>
<th>FY2017</th>
<th>Monthly Stipend</th>
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RPPR – REMINDERS

- Timely Reporting using RPPR format
- Non–SNAP – Due 60 days before budget period ends
- SNAP – Due 45 days before budget period ends
- Multi–year funded progress reports due on the anniversary of the budget/project period start date of the award
Effective Jan 30, 2017
This is the NSF Bible so bookmark the site and select html and/or pdf
No longer “two” documents → Chapters numbered I–XII
Webinars on Nov 7 & Jan 19.
    ◦ Registration required: https://www.eiseverywhere.com/ereg/newreg.php?eventid=208602&
PAPPG – Significant Changes

- Several! Check out the NSF summary. The focus is on increased clarity.
- Collaborator & Other Affiliations Information
  - Thesis Advisor and Postgraduate Scholar Sponsor replaced with PhD Advisor.
  - Instructions added for placement of this section in separately submitted collaborative proposals.
- Cost Sharing
  - Reference added to 200.99, voluntary committed CS.
  - Voluntary committed vs voluntary uncommitted.
Separate section developed for Types of Proposals (RAPID, EAGER, etc.)

International Travel Grants have been expanded to address support for both domestic and international travel

REMINDER – Automated Checks
- Project Summary (PS): 1 pg w/3 sections: Overview, Intellectual Merit and Broader Impacts
- A PS with special characters may still be submitted as a supplementary doc
Fair Labor Standards Act (FLSA)

• Exempt Criteria
  – salaried, (paid a predetermined and fixed salary not subject to reduction because of variations in the quality or quantity of work performed (the "salary basis test");
  – paid more than a specified weekly salary level, which, effective 12/1/16 is $913 per week (the equivalent of $47,476 annually for a full-year worker) under this Final Rule (the "salary level test"); and
  – primarily perform executive, administrative, or professional duties, as defined in the Department's regulations (the "duties test").

• Non-Exempt and Overtime eligible
Generally, full-time research titles at NYU are considered exempt:

- Junior Research scientists and Scholars
- Assistant Scientists and Scholars
- Associate research scientists and Scholars
- Senior Research Scientists and Scholars
- Postdoctoral associates*

Effective December 1, 2016 will be increased to the new threshold of $47,476

*excludes postdoc fellows who receive stipends, not salaries
Part–time Researchers

Effective December 1, 2016 Part–Time Researchers will be considered non-exempt

Current Part–time Exempt Researchers will be converted to non-exempt.

• Assistant Research Scientist: minimum hourly rate:  $18 per hour
• Associate Research Scientist minimum hourly rate:  $26 per hour

Part–time non-exempt research staff are eligible for overtime when they work over 40 hours.
Single IRB

- Policy issued by NIH, effective 5/25/16
- Mandates a single IRB for multi-site projects
- Goal is speed and efficiency of IRB reviews, but
  - Can overwhelm the IRB of record if large no. of sites
  - Can be outsourced to commercial IRB (which NYU is likely to do)
  - Can be charged as a direct cost, but no estimates of costs yet
  - IRB software systems will have to be revised to accommodate
  - NIH has promised guidance on 7 related issues, but only one has issued
- COGR and AAU have requested a one-year extension
Charges to grants for graduate students will remain as they have been:
- Non-union RAs will be charged tuition remission at 37% or 51% of salary, depending on the unit
- Union RAs will be charged the fringe benefits rate of 29.5% of salary

Charges from 9/1 – present will be rolled back