

SCHOOL OF DENTAL MEDICINE

ASE WESTERN RESERVE NIVERSITY

New Campus Fringe Rate Approved

The DHHS has approved a (3) three year F&A rate of 60.0% for CWRU, which is a 1.5 percentage point change from our previous rate of 58.5%. This rate will be effective through June 2020. Effective July 1, 2020, the rate will increase to 61.0%.

Period	On-Campus Research	Off-Campus Research
07/01/2016- 06/30/2017	58.5%	26.0%
07/01/2017- 06/30/2020	60.0%	26.0%
07/01/2020- 06/30/2021	61.0.%	26.0%

In addition, CWRU's federally negotiated fringe rate will increase from 27.5% to 30.0% for awards effective July 1, 2017. This is for all federally-funded research, including research conducted at the MetroHealth System, Cleveland Clinic Lerner College of Medicine and University Hospitals. Effective immediately, all new proposals being submitted should use this new fringe rate. Please note that the new non-federal fringe rate will be 32% effective 7/1/17. Effective immediately, all new proposals being submitted should use this new fringe rate.

Period	Full Time Faculty and Staff	Term, Temp and Early Ret.
07/01/2017-06/30/2018	32.0%	17.5%

This notification also serves as an immediate notice of the new F&A rates that should be used when preparing proposal budgets for awards with an anticipated start date of July 1, 2017 or after. Please refer to the following chart to further determine which rates to apply based on the type of proposal:

Type of Proposal	Applicable F&A Rate
New proposal submitted on or after 03/06/2017	New rate-60.0%
Renewal (competing continuation) proposal submitted on or after 03/06/2017	New rate-60.0%
Non-Competing Continuation proposal on existing Federal award	Use the F&A rate at which it was originally awarded throughout the life of the competitive segment. Unless it is an NIH P or U grant which is negotiated annually (Per NIH Policy Part II Section 7.4 Page IIA-58)
Non-Competing Continuation proposal on existing Non-Federal award	Use the F&A rate at which it was originally awarded throughout the life of the competitive segment.
Supplemental proposal on existing Federal award	For NIH supplements please utilize the new rate. If the awarded rate differs from the parent rate, the supplement must be set up in a separate account.
Supplemental proposal on existing Non- Federal award	New rate-60.0%

Sparta Process

Sparta will be updated shortly to reflect this change however in the interim, any new funding proposals will need to be manually updated to reflect these new rates. The fringe rate change is completed on the Personnel Budget Grids for each individual. The F&A rate is completed on the Budget Grid smart form. If you need assistance with this, please contact sparta@case.edu.

Implementation Guidance for Awards

The application of F&A rates to federal awards is governed by 2 CFR 200 (Uniform Guidance). The higher rates will apply only to new and renewal awards with a start date on or after July 1, 2017. If a Federal award is received with the old (58.5%) rate, the appropriate PreAward Office will work with the sponsor to ensure grants awarded on or after July 1, 2017 are either awarded with the new F&A rate or are subsequently revised to incorporate the new rate.

New and Renewal Proposals Submitted but not Yet Awarded:

To ensure that direct costs available to Principal Investigators are not adversely impacted by this rate change, awards received in response to previously submitted new or competing renewal proposals will, when necessary, be accepted using the F&A rate contained in the submitted proposal. PreAward Offices will, however, work with agencies to increase F&A costs to the new rates wherever possible. Whichever F&A rate is finally awarded will subsequently be used throughout the competitive segment of that award.

Existing Awards and their Non-Competitive Proposals:

All existing awards and their associated non-competitive continuation proposals will continue to use the F&A rate in effect at the time of their initial award (or most recent renewal) throughout the remainder of their competitive segment. 2 CFR 200 (Uniform Guidance) requires a fixed rate over the life of a sponsored agreement and defines "life" as each new competitive segment.

The new rate agreement can be found at the Office of Research Administration's website on our <u>Commonly Requested Information sheet</u> which will be updated shortly.

Who is Eligible to Submit an Application Under NIH's Continuous Submission Policy

By NIH Staff

Appointed members of standing NIH study sections, NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, or NIH Program Advisory Committees are all eligible for continuous submission (submitting R01, R21, and R34 applications at any time in response to active funding opportunity announcements (FOAs) that have standard due dates).

Reviewers who have served on at least 6 qualifying NIH study sections during an 18-month period starting January 1 of one year and ending June 30 of the following year are also eligible for continuous submission under the "recent substantial service" option.

NIH recently published consolidated guidance on continuous submission. For more information, read NIH Guide Notice <u>NOT-OD-17-042</u>.

Compliance Corner- Summary of Major Changes in the Final Common Rule

The final rule differs in important ways from the NPRM. Most significantly, several proposals are not being adopted:

- The final rule does not adopt the proposal to require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research.
- To the extent some of the NPRM proposals relied on standards that had not yet been proposed, the final rule either does not adopt those proposals or includes revisions to eliminate such reliance.
- The final rule does not expand the policy to cover clinical trials that are not federally funded.
- The final rule does not adopt the proposed new concept of "excluded" activities. Generally, activities proposed to be excluded are now either described as not satisfying the definition of what constitutes research under the regulations or are classified as exempt.
- The proposed revisions to the exemption categories have been modified to better align with the longstanding ordering in the final rule. The final rule does not include the proposed requirement that exemption determinations need to be made in specified ways.
- The final rule does not include the proposed standardized privacy safeguards for identifiable private information and identifiable biospecimens. Aspects of proposals that relied on those safeguards have been modified or are not being adopted.
- The final rule does not adopt the most restrictive proposed criteria for obtaining a waiver of the consent requirements relating to research with identifiable biospecimens.

The final rule makes the following significant changes to the Common Rule:

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.
- Establishes new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.
- Creates a requirement for U.S.- based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the United States, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule.
- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

To read the full 126 page version of the Common Rule, please click here. *Update: February 2, 2017*

Relevant Grant Opportunities for the SoDM

Whitehall Foundation - Bioscience Research Projects

The Whitehall Foundation assists scholarly research in the life sciences through its research grants and grants-in-aid programs. It is the foundation's policy to support those dynamic areas of basic biological research that are not heavily supported by federal agencies or other foundations with specialized

missions. The foundation emphasizes the support of young scientists at the beginning of their careers and productive senior scientists who wish to move into new fields of interest.

1) Research: Research grants of up to \$225,000 over three years will be awarded to established scientists of all ages working at an accredited institution in the United States. Grants will not be awarded to investigators who have already received, or expect to receive, substantial support from other sources, even if it is for an unrelated purpose.

2) Grants-in-Aid: One-year grants of up to \$30,000 will be awarded to researchers at the assistant professor level who experience difficulty in competing for research funds because they have not yet become firmly established. Grants-in-Aid can also be made to senior scientists.

To be eligible, applicants must hold the position of assistant professor or higher; have Principal Investigator status; and be considered an "independent investigator" with his/her own dedicated lab space or have lab space independent of another investigator.

LOI Deadline: April 15, 2017 Invited Applications Deadline: September 01, 2017 For more information visit the Whitehall Foundation webpage.

Limited Submission Reminder: Edward Mallinckrodt, Jr. Foundation: Mallinckrodt Grants Applications

Key Deadlines: April 21, 2017, 5:00pm (CWRU Letter of Intent), August 1, 2017, 5:00pm EST (external application).

The **Edward Mallinckrodt**, **Jr. Foundation** is a private foundation that funds basic biomedical research in St Louis and throughout the United States. Mallinckrodt Grants are competitively provided to investigators based on their proposals, selected from applicants on an annual basis. These awards are usually \$60,000 per year for three years, provided an annual progress report is submitted and approved. The mission of the Foundation is to support early stage investigators engaged in basic biomedical research that has the potential to significantly advance the understanding, diagnosis or treatment of disease.

Number of Applications Allowed: One

For more information on this limited submission opportunity, visit the Office of Research Administration website.

NIH: Neoantigen-Based Therapeutic Targeting of Head and Neck Cancers (R01)

The purpose of this Funding Opportunity Announcement (FOA) is to support basic and preclinical research aimed at developing novel immunotherapeutic targets for head and neck cancers (HNC), including salivary gland cancers. Research supported by this FOA will identify human HNC-specific neoantigens, and will test the utility of these neoantigens as targets for eliciting anti-tumor immune responses in affected patient populations.

Application deadline is July 19, 2017.

For more information visit the NIH website.

Pediatric Dentistry Master Clinician Program American Academy of Pediatric Dentistry (AAPD) Healthy Smiles, Healthy Children (HSHC)	March 17, 2017 Application Confirmed	see record
new Neuroskeletal Biology of the Dental and Craniofacial	August 28, 2017 Letter of	\$200,000

Skeletal System (R21) United States Department of Health and Human Services (HHS) NIH & NIDCR	Intent Confirmed	
new Neuroskeletal Biology of the Dental and Craniofacial Skeletal System (R01) United States Department of Health and Human Services (HHS) NIH & NIDCR	August 28, 2017 Letter of Intent Confirmed	\$250,000
Institutional Training for a Dental, Oral and Craniofacial Research Workforce (T90/R90) United States Department of Health and Human Services (HHS) NIH & NIDCR	September 25, 2017 Application Confirmed	\$550,000
UICC Technical Fellowships (UICC-TF) [previously Global Education and Training Initiative (GETI): International Cancer Technology Transfer Fellowships (ICRETT)] International Union Against Cancer - Union Internationale Contre le Cancer (UICC)	Continuous Application Anticipated	see record