CHEST
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Chestnet.org

July 13, 2026

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th St, NW
Washington, DC 20503

**Re: OMB-2026-0034, Proposed Revisions to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards**

Dear Director Vought:

The American College of Chest Physicians (CHEST) represents more than 19,000 physicians and allied health professionals dedicated to improving the prevention, diagnosis, and treatment of respiratory disease, critical illness, and sleep disorders. Through clinical practice guidelines, scientific exchange, clinical education, and support for biomedical research, CHEST helps translate scientific discovery into evidence-based care for patients worldwide.

Our members provide critical medical care to patients across the continuum of health, from preventing tobacco-related disease and managing chronic illnesses such as COPD, asthma, and interstitial lung disease, to treating life-threatening conditions including sepsis, respiratory failure, pulmonary embolism, and acute respiratory distress syndrome. Respiratory diseases remain among the leading causes of death, disability, and health care utilization in the United States. Our members care for patients living with some of the nation's most prevalent and preventable diseases, as well as those facing rare, rapidly evolving, and highly complex illnesses that demand continual scientific discovery and clinical innovation. During public health emergencies, pandemics, natural disasters, and humanitarian crises, these clinicians serve on the front lines.

CHEST shares the Administration's goal of ensuring that Federal investments are directed toward high-quality, reproducible, transparent science that delivers meaningful benefit to patients and responsible use of taxpayer funding. We strongly support efforts to strengthen scientific rigor, improve accountability, eliminate fraud and abuse, increase transparency, and most importantly, ensure that public investments generate measurable improvements in health.

We align on the importance of scientific rigor but differ on the mechanism by which it is protected and enhanced. Determining scientific merit, identifying methodological weaknesses, evaluating reproducibility, and deciding where Federal research investment will have the greatest long-term impact require deep scientific and clinical expertise. These judgments unfold over decades, as evidence accumulates, hypotheses are tested, and discoveries are translated into clinical practice. Scientific advancement cannot depend on cumbersome decision-making structures that shift focus in response to ever-changing governmental priorities.

Scientific instability is not an abstract governance concern for patients with respiratory disease and critical illness. It carries direct consequences for patient care. Delays in clinical trials postpone new therapies for pulmonary fibrosis, lung cancer, pulmonary hypertension, COPD, asthma, pediatric respiratory disease, and rare lung diseases. Interruptions to longitudinal studies diminish our ability to understand environmental exposures, occupational lung disease, and chronic respiratory illness. Restrictions that inadvertently discourage scientific collaboration impede the nation's preparedness for future pandemics, emerging respiratory pathogens, and other public health emergencies by by limiting the interdisciplinary collaboration needed to rapidly generate and apply new evidence. Every disruption to the biomedical research enterprise ultimately affects current and future patients through delayed diagnoses, fewer treatment options, and slower improvements in survival, quality of life, and population health.

**Patients depend on a scientific enterprise that is rigorous, stable, collaborative, and capable of generating evidence that improves care. To ensure the proposed rule strengthens that enterprise, CHEST recommends that the following principles guide the final rule.**

1. **Patients need scientific decisions grounded in expertise.**
   Federal research investments should be guided by independent scientific and clinical expertise, rigorous expert peer review, and objective evidence. Accountability is strengthened when the process is grounded in transparency, reproducibility, and methodological rigor as determined by scientific judgment.

2. **Patients need continuity in scientific discovery.**
   Many of the most important advances in pulmonary, critical care, and sleep medicine emerge from decades of sustained research. Stable investment and predictable oversight are essential to preserving clinical trials, longitudinal studies, surveillance systems, and research infrastructure that ultimately improve health outcomes.

3. **Patients need evidence that reflects the people medicine serves.**
   Clinicians can provide the best care only when research can examine clinically meaningful differences in disease burden, diagnosis, treatment response, and outcomes across patient populations. Federal policy should preserve the ability to generate evidence that improves care for all Americans, addresses preventable disparities in health outcomes, and ensures that historically understudied populations are not left behind by the evidence base that informs patient care.

4. **Patients need a scientific enterprise built on collaboration.**
   Medical discovery increasingly depends on collaboration across disciplines, institutions, health systems, government agencies, community organizations, and, when scientifically appropriate, international partners. Policies should strengthen the collaborative networks that accelerate innovation, improve preparedness, and address complex health challenges that no single institution can solve alone.

5. **Patients need discoveries translated into better care.**
   Scientific advances improve health only when they are disseminated, scrutinized, replicated, and incorporated into clinical practice. Policies governing publication, scientific exchange, and dissemination should maximize the public benefit of Federally funded research by ensuring discoveries reach the clinicians, health systems, and patients they are intended to serve.

CHEST offers the section-by-section recommendations following this letter to align the proposed rule with these principles. The decisions made through this rulemaking will shape

the future of the nation's biomedical research enterprise and, ultimately, the care available to millions of Americans. CHEST shares the Administration's commitment to ensuring that Federal research investments produce meaningful benefits for patients and taxpayers alike. We welcome continued dialogue as OMB considers these comments and would be pleased to contribute our members' expertise to help develop a final rule that advances scientific excellence, protects public trust, and improves patient care.

Sincerely,

Robert Musacchio, PhD
Chief Executive Officer & Executive Vice President
American College of Chest Physicians

## PRINCIPLE 1
## PATIENTS NEED SCIENTIFIC DECISIONS GROUNDED IN EXPERTISE

Federal research investments should be guided by independent scientific and clinical expertise, rigorous peer review, and objective evidence. Accountability is strengthened when the process is grounded in transparency, reproducibility, and methodological rigor as determined by scientific judgment.

### § 200.202(a) — Program planning and design

**Recommendation.** *Revise § 200.202(a) to remove the requirement that agencies design programs to align with current Administration priorities and instead require agencies to demonstrate that new programs are grounded in statutory authority, scientific evidence, documented public health need, and measurable outcomes.*

Program planning should emphasize:

- scientific evidence supporting the proposed approach;
- documented burden of disease or public health need;
- expected patient and public benefit;
- evaluation plans and performance measures; and
- consistency with congressional statutory authority.

**Rationale.** Scientific priorities frequently extend across multiple administrations. Program design should therefore be anchored in evidence and statutory purpose rather than policy priorities that may change during the life of a research program. Requiring alignment with current Administration priorities risks redirecting research investments away from the highest-impact scientific opportunities before their benefits can be realized.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Many of the most important advances in respiratory medicine, including therapies for pulmonary fibrosis, advances in lung cancer screening, and improvements in intensive care, resulted from sustained scientific investment spanning decades. Their eventual impact could not have been predicted based on short-term policy priorities but emerged through continued investigation and accumulation of evidence. This model of long-term investment has produced substantial public benefit: Analyses have found that nearly all drugs approved in the last two decades were supported by Federal research investments, often in partnership with private-sector development, with foundational discoveries and government investments in basic science generating knowledge that enabled multiple downstream therapies.

### § 200.205 — Federal agency review of merit of proposals

**Recommendation.** *Revise § 200.205 to preserve independent scientific merit review as the primary basis for discretionary award decisions and remove requirements for political appointee pre-issuance review and evaluation of proposals based on alignment with Presidential priorities.*

Instead, require agencies to:

- conduct merit review using reviewers with appropriate scientific, clinical, methodological, and statistical expertise;
- establish objective reviewer qualification standards;
- evaluate proposals based on scientific merit, methodological rigor, anticipated patient and public benefit, implementation feasibility, and statutory program objectives; and
- publicly document the rationale whenever funding decisions depart from peer-review recommendations.

**Rationale.** Determining whether a proposed study is scientifically rigorous, clinically meaningful, methodologically sound, and likely to improve patient care requires specialized expertise. Strengthening reviewer qualifications and transparency advances the Administration's stated goals of Gold Standard Science more effectively than inserting political review into scientific evaluation.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Clinical research increasingly depends on coordinated networks of hospitals, investigators, and research staff that require predictable, scientifically grounded funding decisions to maintain readiness. Distinguishing the most promising scientific opportunities already requires careful evaluation of methodological rigor, feasibility, clinical significance, and long-term potential. Introducing additional non-scientific decision criteria increases uncertainty and risks redirecting support away from the research most likely to improve patient care. Because many biomedical discoveries require years or even decades to translate into clinical benefit, research priorities should remain sufficiently stable to allow the scientific process, not shifting policy priorities, to determine which investments ultimately improve health outcomes.

**§ 200.206 — Federal agency review of risk posed by applicants**

**Recommendation.** *Revise § 200.206 to ensure that assessments of applicant risk rely on objective, documented evidence that is directly relevant to the responsible stewardship of Federal funds and the successful conduct of the proposed research. Scientific integrity should be evaluated through established research misconduct processes and documented findings rather than subjective assessments of "questionable practices" or organizational affiliations. Financial capacity and organizational stability should be assessed in a manner that supports appropriate oversight without disadvantaging scientifically meritorious applicants whose size, funding model, or institutional resources differ from more established organizations.*

**Rationale.** Existing Federal research integrity, misconduct, financial oversight, and suspension and debarment processes already provide objective mechanisms for protecting taxpayer investments. Risk assessment should distinguish between an organization's ability to responsibly administer Federal funds and the scientific merit of the proposed research. Smaller institutions, community-based organizations, and emerging research programs often contribute unique expertise, patient access, and innovation despite having fewer financial resources or less extensive Federal funding histories. Risk assessment should support appropriate oversight without unnecessarily limiting participation by scientifically meritorious applicants.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Pulmonary, critical care, and sleep medicine rely on scientists who routinely serve in multiple professional roles as investigators, clinicians, guideline developers, scientific advisors, leaders of professional societies, and participants in disease-specific research initiatives. These affiliations reflect scientific expertise and professional service, not scientific bias or research misconduct. Standards that permit funding decisions to be influenced by organizational affiliations rather than documented misconduct or objective evidence risk excluding the very experts whose experience is most critical to advancing patient care. Likewise, risk assessments that place disproportionate emphasis on an organization's financial size, prior funding history, or institutional resources may disadvantage smaller research programs and community-based organizations that contribute important scientific expertise and provide access to patient populations that are otherwise underrepresented in clinical research. Federal oversight should evaluate demonstrated conduct and stewardship of public funds without limiting scientifically meritorious research based on organizational characteristics unrelated to scientific quality.

## PRINCIPLE 2
## PATIENTS NEED CONTINUITY IN SCIENTIFIC DISCOVERY

Many of the most important advances in pulmonary, critical care, and sleep medicine emerge from decades of sustained research. Stable investment and predictable oversight are essential to preserving clinical trials, longitudinal studies, surveillance systems, and research infrastructure that ultimately improve health outcomes.

### § 200.340 — Termination and suspension

**Recommendation.** *Revise § 200.340 to preserve termination of Federal awards for documented noncompliance, fraud, or other established statutory or regulatory grounds, and remove provisions allowing discretionary termination or extended stop-work orders based on changing agency or administration priorities.*

If OMB retains expanded termination authority, it should require:

- written justification tied to objective regulatory or statutory criteria;
- an assessment of the scientific and patient impact of terminating ongoing research;
- an opportunity for recipient response or appeal; and
- reimbursement of reasonable wind-down costs necessary to protect research participants, preserve study integrity, and responsibly close active projects.

**Rationale.** Biomedical research is cumulative and often spans many years. Unlike many Federal programs, clinical research cannot simply pause and resume without consequence. Expanding discretionary termination authority and prolonged stop-work orders increases the risk that Federally funded studies will lose participants, disrupt data collection, dismantle research infrastructure, and diminish the scientific value of prior Federal investment. Predictable oversight protects both taxpayer investments and the integrity of the evidence patients depend upon.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Clinical research depends on maintaining studies that cannot simply be restarted after an interruption. Some studies enroll patients during brief windows of acute illness, where every missed patient is a lost opportunity. Others, particularly those involving rare pulmonary diseases or conditions requiring long-term follow-up, take years to recruit sufficient participants and generate meaningful evidence. Significant funding interruptions or prolonged stop-work orders can permanently compromise either, leaving years of research unable to answer the questions the studies were designed to address and negating the patient benefit the research was designed to create. The result is more than an administrative setback. It wastes prior Federal investment, diminishes the contributions of research participants to advance future care, and delays—or prevents altogether—the generation of evidence the medical community needs to improve outcomes.

### § 200.202(f) — Multi-year awards

**Recommendation.** *Revise § 200.202(f) to direct agencies to use multi-year awards whenever sustained funding is necessary to support long-term scientific discovery, clinical research, surveillance, or evidence generation.*

**Rationale.** Many of the conditions that most urgently require new therapies cannot be adequately studied within a single funding cycle. Research involving rare pulmonary diseases, chronic respiratory illnesses, sleep disorders, and recovery after critical illness often requires years to identify eligible patients, complete enrollment, and observe clinically

meaningful outcomes. Multi-year awards provide the continuity necessary to generate robust evidence while protecting the Federal investment already made in patients, investigators, and research infrastructure.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Research evaluating diseases such as pulmonary arterial hypertension, lymphangioleiomyomatosis (LAM), alpha-1 antitrypsin deficiency, rare interstitial lung diseases, cystic fibrosis, and other uncommon pulmonary conditions may require years to identify and enroll sufficient numbers of participants because these diseases affect relatively small patient populations. Likewise, studies of COPD progression, pulmonary fibrosis, post-intensive care syndrome, sleep disorders, and lung cancer screening depend on extended follow-up to measure meaningful clinical outcomes. Transformative advances often require decades of sustained investigation; for example, nearly twenty years elapsed between foundational research on anti-IL-5 therapy and the approval of mepolizumab for severe asthma. Multi-year awards provide the continuity necessary to ensure that these long-term investments yield evidence capable of improving future patient care.

## § 200.208 — Specific conditions

**Recommendation.** *Revise § 200.208 to ensure that specific award conditions remain proportionate to documented risk and are implemented in ways that preserve the continuity of Federally funded scientific research.*

Specifically, the final rule should:

- require agencies to document the specific financial, administrative, or programmatic risk that justifies imposing additional award conditions;
- encourage agencies to select the least burdensome oversight mechanisms necessary to address identified risks;
- avoid mid-award changes to payment mechanisms or administrative requirements unless supported by documented evidence that such changes are necessary to protect Federal funds or ensure compliance; and
- recognize the potential impact of additional award conditions on ongoing clinical research, including patient enrollment, study continuity, and long-term evidence generation.

**Rationale.** Appropriate financial oversight protects taxpayer investments, but oversight mechanisms should distinguish between managing financial risk and maintaining the continuity of scientific research. Mid-award changes to payment mechanisms, including transitions from advance payments to reimbursement, may create significant operational challenges for research institutions without improving scientific quality or accountability. When such changes disrupt staffing, patient enrollment, data collection, or study operations, they also delay the generation of evidence that Federal research investments are intended to produce.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Pulmonary, critical care, and sleep medicine research frequently depends on uninterrupted support for clinical research coordinators, laboratory personnel, data management, and patient follow-up. Smaller academic centers, community hospitals, and disease-specific research programs may have limited financial reserves to absorb prolonged reimbursement delays while maintaining ongoing studies. Abrupt changes to payment mechanisms during an active award may interrupt patient enrollment, delay follow-up, reduce research capacity, and ultimately slow the development of evidence needed to improve outcomes for patients with respiratory disease and critical illness.

## PRINCIPLE 3
## PATIENTS NEED EVIDENCE THAT REFLECTS THE PEOPLE MEDICINE SERVES

Clinicians can only provide the best care when research is able to examine clinically meaningful differences in disease burden, diagnosis, treatment response, and outcomes across patient populations. Federal policy should preserve the ability to generate evidence that improves care for all Americans, addresses preventable disparities in health outcomes, and ensures that historically understudied populations are not left behind by the evidence base that informs patient care.

Further, **CHEST is concerned that categorical restrictions on otherwise meritorious biomedical research are inconsistent with the proposed rule's stated objective of promoting objective, evidence-based science. Research should be evaluated on its scientific merit, methodological rigor, and potential to improve patient care as opposed to categorically excluded because of the populations studied or the subject matter being investigated**.

### § 200.218 — Prohibition of using Federal awards to promote or support theories of disparate-impact liability

**Recommendation.** *Revise § 200.218 to clarify that the provision should not be interpreted to prohibit or discourage scientifically appropriate biomedical research that examines clinically relevant differences in disease burden, diagnosis, treatment response, or health outcomes across patient populations.*

**Rationale.** Clear regulatory standards are essential to both scientific integrity and effective compliance. Ambiguous language may discourage institutions from supporting legitimate biomedical research because investigators and recipients cannot confidently distinguish prohibited conduct from scientifically appropriate inquiry. The final rule should clearly state that research designed to improve patient care through the study of clinically relevant differences remains permissible when conducted in accordance with established scientific and ethical standards.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Pulmonary, critical care, and sleep medicine research frequently examines differences in disease prevalence, environmental and occupational exposures, diagnostic performance, treatment response, and clinical outcomes across patient populations. These investigations are intended to improve evidence-based care, not to promote unlawful discrimination. Greater regulatory clarity would reduce uncertainty for research institutions and investigators while ensuring that scientifically appropriate studies addressing clinically important questions can continue to generate evidence that improves patient care.

### § 200.300(a)(2) — Prohibition on DEI activities

**Recommendation.** *Revise § 200.300(a)(2) to clarify that the prohibition on DEI activities does not restrict Federally funded biomedical, clinical, public health, or health services research that examines differences in disease burden, diagnosis, treatment response, access to care, or health outcomes across patient populations when scientifically appropriate.*

**Rationale.** Federal biomedical research must retain the ability to investigate clinically meaningful differences in disease presentation, treatment effectiveness, and health outcomes wherever they exist. Research designed to understand and reduce preventable differences in health outcomes is fundamental to evidence-based medicine and should not be prohibited.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Research examining racial differences in pulse oximeter performance, geographic disparities in COPD outcomes, occupational risk factors for lung disease, environmental contributors to asthma, and barriers to timely lung cancer treatment has improved diagnosis, treatment, patient safety, and care delivery. Importantly, research that investigates differences in outcomes for specific populations often generates improvements that benefit all patients. Preventing investigators from studying these clinically relevant questions would leave clinicians with less complete evidence and ultimately reduce their ability to deliver safe and effective care.

**§ 200.300(a)(3) — Prohibition on gender ideology**

**Recommendation.** *Revise § 200.300(a)(3) to clarify that the prohibition does not restrict research involving sex or gender when these variables are scientifically or clinically relevant to the research question or patient population under study.*

**Rationale.** Sex- and gender-related characteristics influence the epidemiology, diagnosis, presentation, treatment response, and outcomes of numerous pulmonary, critical care, and sleep disorders. Investigators should remain able to study these characteristics whenever necessary to answer clinically important scientific questions.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Sex and hormonal influences play an important role in the development, presentation, and treatment of many pulmonary diseases. Conditions such as lymphangioleiomyomatosis (LAM), catamenial pneumothorax, and the post-pubertal shift in asthma prevalence illustrate why these factors are clinically relevant. Likewise, studying respiratory physiology, sleep disorders, critical care outcomes, or thromboembolic risk in transgender patients may provide additional insights into these biological mechanisms, enabling greater understanding of the role of hormones and physiology in respiratory disease. Federal policy should preserve investigators' ability to pursue these questions so clinicians have the evidence needed to provide safe and effective care to all patients.

**§ 200.300(a)(4) — Disparate impact**

**Recommendation.** *Revise § 200.300(a)(4) to clarify that agencies may continue to support research evaluating differences in health outcomes, access to care, and disease burden across patient populations when necessary to fulfill statutory public health and biomedical research objectives.*

**Rationale.** Understanding why health outcomes differ across populations is a core function of biomedical and public health research. Evaluating disparate outcomes does not presume disparate treatment; it identifies opportunities to improve prevention, diagnosis, and treatment for patients who experience disproportionate burdens of disease. The resulting understanding of disease processes and pathophysiology can improve prevention and treatment, reduce mortality, and enhance quality of life for all patients.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Diseases such as COPD, tuberculosis, and asthma disproportionately affect certain communities because of differences in environmental exposures, occupational hazards, access to specialty care, smoking prevalence, and other factors that influence health. Research identifying these patterns has informed screening recommendations, preventive strategies, and clinical practice. Limiting investigators' ability to study these clinically relevant differences would reduce clinicians' ability to improve outcomes for the populations at greatest risk.

## PRINCIPLE 4
## PATIENTS NEED A SCIENTIFIC ENTERPRISE BUILT ON COLLABORATION

Medical discovery increasingly depends on collaboration across disciplines, institutions, health systems, government agencies, community organizations, and, when scientifically appropriate, international partners. Policies should strengthen the collaborative networks that accelerate innovation, improve preparedness, and address complex health challenges that no single institution can solve alone.

### § 200.202(e) — International elements

**Recommendation.** *Revise § 200.202(e) to clarify that Federal agencies should evaluate international collaborations using a risk-based framework rather than treating foreign collaboration as a negative factor in award design or review.*

Specifically, the final rule should:

- require agencies to consider the scientific necessity and public health value of proposed international collaborations;
- distinguish between documented national security or research security risks and the scientific merit of a proposed collaboration, evaluating both factors through a transparent, risk-based framework;
- recognize that international collaboration may be essential to achieving the purposes of certain Federally funded biomedical research programs;
- and preserve agency discretion to restrict collaborations when documented legal, security, or foreign policy concerns outweigh the scientific and public health benefits of the collaboration.

**Rationale.** CHEST supports appropriate safeguards to protect Federally funded research from inappropriate foreign influence and other research security threats. At the same time, international scientific collaboration is often essential to advancing biomedical discovery. A risk-based framework better aligns with the proposed rule's objectives by distinguishing collaborations that present legitimate security concerns from those that are scientifically appropriate to improve patient care.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** International scientific collaboration is often essential to answering questions that cannot be addressed within a single country. During the COVID-19 pandemic, international platform trials such as the United Kingdom's RECOVERY trial rapidly identified effective therapies and ruled out ineffective ones, allowing clinicians worldwide, including in the United States, to improve the care of hospitalized patients far more quickly than would have been possible through isolated national efforts. Likewise, pivotal clinical trials evaluating therapies for idiopathic pulmonary fibrosis and pulmonary arterial hypertension relied on multinational enrollment to generate sufficiently robust evidence. Preserving the ability to support scientifically appropriate international collaborations ensures that U.S. patients continue to benefit from high-quality evidence generated through global scientific partnerships.

### § 200.220 — Prohibition of using Federal funds for covered foreign collaborations

**Recommendation.** *Revise § 200.220 to replace the proposed categorical prohibition on covered foreign collaborations with a risk-based framework that permits scientifically appropriate collaborations when identified potential national security, legal, or research security risks can be appropriately managed.*

Specifically, CHEST recommends that the final rule:

- retain restrictions on collaborations involving documented national security risks, controlled technologies, or prohibited entities;
- preserve an exception process supported by transparent and objective evaluation criteria;
- permit collaborations necessary to accomplish the scientific objectives of Federally funded biomedical research when appropriate safeguards are in place; and
- evaluate proposed collaborations based on documented risk rather than categorical prohibitions.

**Rationale.** CHEST recognizes the importance of protecting Federal research investments and addressing legitimate national security concerns. However, categorical restrictions may unnecessarily limit biomedical research that presents little or no security risk while contributing substantially to scientific discovery and patient care. A targeted, risk-based approach more effectively balances research security with the continued advancement of high-quality biomedical science.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Many respiratory diseases require international scientific collaboration because the necessary patient populations, disease burden, or clinical experience do not exist within a single country. Research advancing the treatment of rare pulmonary diseases, including idiopathic pulmonary fibrosis and pulmonary arterial hypertension, has relied on multinational clinical trials to enroll sufficient patients and generate robust evidence. Modern approaches to multidrug-resistant tuberculosis have been informed by research conducted in regions where disease prevalence is substantially higher than in the United States. Likewise, international surveillance and collaborative research during outbreaks of SARS, MERS, influenza, and COVID-19 enabled clinicians to rapidly characterize emerging respiratory pathogens and evaluate effective approaches to diagnosis, treatment, and critical care. Broad restrictions on international collaboration may delay patient enrollment, limit access to specialized expertise and research infrastructure, and slow the generation of evidence needed to improve preparedness and health outcomes. A risk-based framework better preserves these scientifically essential collaborations while protecting U.S. national interests.

## PRINCIPLE 5
## PATIENTS NEED DISCOVERIES TRANSLATED INTO BETTER CARE

Scientific advances improve health only when they are disseminated, scrutinized, replicated, and incorporated into clinical practice. Policies governing publication, scientific exchange, and dissemination should maximize the public benefit of Federally funded research by ensuring discoveries reach the clinicians, health systems, and patients they are intended to serve.

### § 200.432 — Conferences

**Recommendation.** *Revise § 200.432 to permit recipients to budget reasonable conference attendance and presentation costs as part of approved awards without requiring project-specific advance approval for each scientific meeting.*

Specifically, CHEST recommends that the final rule:
- permit recipients to budget conference participation as a general category of allowable costs;
- continue evaluating costs for reasonableness and relevance to the award;
- avoid requiring investigators to identify specific future conferences before research findings are available; and

- recognize scientific meetings as an essential mechanism for dissemination and peer review.

**Rationale.** Scientific conferences provide an important forum for rapid dissemination, peer critique, collaboration, and refinement of Federally funded research before formal publication. Existing Federal cost principles already provide adequate safeguards to ensure conference-related expenses remain reasonable and directly related to the award.

**Impact on Pulmonary, Critical Care, and Sleep Medicine**. Rapid communication of emerging evidence is particularly important in pulmonary and critical care medicine, where new findings may immediately influence patient management during respiratory outbreaks or inform evolving standards of care. Scientific meetings hosted by organizations such as CHEST allow investigators to present preliminary findings, receive expert feedback, and accelerate translation of new evidence into clinical practice and future research.

**§ 200.450 — Lobbying**

**Recommendation.** *Revise § 200.450 to clarify that communicating scientifically supported research findings, evidence-based clinical recommendations, and public health information directly related to the objectives of a Federal award does not constitute prohibited advocacy or public messaging.*

**Rationale.** Scientific discovery improves health only when research findings are communicated to clinicians, patients, health systems, and public health partners. The final rule should clearly distinguish between issue advocacy unrelated to the objectives of a Federal award and evidence-based scientific communication that is necessary to translate federally funded research into improved patient care. Greater clarity would promote consistent implementation while reducing uncertainty for recipients regarding permissible dissemination activities.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Advances in pulmonary, critical care, and sleep medicine improve outcomes only when clinicians, health systems, and patients understand how to apply new evidence. Activities such as publishing clinical guidance, disseminating evidence-based recommendations, and communicating research findings to support implementation are essential components of translating federally funded research into better patient care. Clear regulatory language would help ensure these activities remain distinct from prohibited advocacy.

**§ 200.454 — Memberships, subscriptions, and professional activity costs**

**Recommendation.** *Revise § 200.454 to preserve the allowability of reasonable professional, academic, and technical journal subscriptions when they directly support the objectives of a Federally funded award.*

Specifically, CHEST recommends that the final rule:
- permit recipients to charge reasonable subscription costs that support award activities;
- continue applying existing standards for reasonableness and allocability; and
- avoid categorical prohibitions on resources necessary for evidence-based research.

**Rationale.** Access to the current scientific literature is a foundational input to high-quality research. Journal subscriptions enable investigators to design studies informed by existing evidence, identify knowledge gaps, interpret findings in the context of prior work, and avoid unnecessary duplication of Federally funded research. Existing Federal cost principles

already allow agencies to determine whether these costs are reasonable, allocable, and directly support the objectives of the award.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Pulmonary, critical care, and sleep medicine are rapidly evolving fields in which new evidence frequently changes standards of care. Investigators and clinicians rely on timely access to peer-reviewed literature to evaluate emerging therapies, recognize safety signals, incorporate corrections and retractions, and translate new discoveries into patient care. Restricting access to the scientific literature would weaken the ability of Federally funded researchers to build on existing evidence and ultimately slow improvements in diagnosis, treatment, and clinical outcomes.

**§ 200.461 — Publication and printing costs**

**Recommendation.** *Revise § 200.461 to permit recipients to budget and charge reasonable publication costs, including page charges, article processing charges, and open-access fees, when those costs directly support dissemination of Federally funded research.*

Specifically, CHEST recommends that the final rule:

- preserve publication as an allowable cost when directly related to award-funded work;
- permit applicants to budget anticipated publication costs during award development;
- continue evaluating costs under existing standards for reasonableness and allocability; and
- recognize publication as an integral component of the Federally funded research enterprise.

**Rationale.** Scientific discovery improves health only when research findings are communicated, scrutinized, replicated, and incorporated into clinical practice. Publication is not ancillary to biomedical research—it is the principal mechanism through which Federally funded discoveries become available to clinicians, health systems, guideline developers, and patients. The proposed rule characterizes publication as potentially serving "institutional, professional, or reputational interests" rather than programmatic objectives, yet acknowledges that publication may be required by statute or award terms. CHEST believes dissemination is itself a core public benefit of Federally funded biomedical research.

**Impact on Pulmonary, Critical Care, and Sleep Medicine.** Many of the most important advances in pulmonary, critical care, and sleep medicine, including lung-protective ventilation for acute respiratory distress syndrome, antifibrotic therapies for idiopathic pulmonary fibrosis, evidence-based management of severe asthma, and lung cancer screening, improved health outcomes only after their findings were published, independently evaluated, incorporated into clinical practice guidelines, and disseminated through clinical education. Professional societies such as CHEST play a critical role in translating these discoveries into evidence-based care. Restricting support for publication would delay that translation and diminish the return on Federal research investments.