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Genetic Alliance Opposes OMB-2026-0034

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Genetic Alliance is a national nonprofit organization focused on genetic disease, genomic medicine, and the responsible use of molecular information across the lifespan. We work with individuals, families, communities, clinicians, researchers, laboratories, and advocacy organizations to advance accurate diagnosis, appropriate care, research participation, data access, and participant control for people whose health depends on molecular understanding of disease.

Our work begins with genetic disease, but the implications of this proposed rule are far broader. Modern medicine increasingly depends on molecular diagnosis, molecular stratification, and targeted treatment. This is true for both rare and common genetic conditions. It is also true for cancer, infectious diseases, immune disorders, pharmacogenomics, newborn screening, reproductive health, neurologic diseases, cardiovascular diseases, and many other areas of care. In cancer, treatment decisions often depend on tumor genetics and molecular signatures. In infectious diseases, pathogen sequencing and molecular surveillance guide outbreak response, resistance monitoring, and treatment strategy. In pharmacogenomics, inherited variation can determine whether a medication is effective, ineffective, or dangerous. Across medicine, the ability to match the right diagnostic approach, surveillance strategy, treatment, or trial to the right person depends on stable research systems, open scientific exchange, international collaboration, and timely dissemination of evidence.

These are not abstract scientific preferences. They are the infrastructure of contemporary care. Without the ability to identify molecular subgroups, aggregate small populations, share variant and pathogen data, publish findings rapidly, attend scientific meetings, maintain longitudinal studies, and collaborate internationally, the practical application of modern biomedical research will be decimated. People will wait longer for answers. Clinicians will have less evidence. Researchers will lose continuity. Families and communities will lose trust. Treatments will be delayed or misapplied. The damage will fall hardest on people whose conditions are uncommon, complex, emerging, or poorly represented in existing datasets.

Genetic conditions affect infants, children, adolescents, adults, aging adults, and entire families across generations. Some genetic diseases are individually rare; others are common. Many

common diseases are now understood to include molecularly distinct subgroups that require different approaches to diagnosis, treatment, and follow-up. The same principle applies across oncology, infectious disease, immunology, neurology, cardiology, and other fields: disease categories that once appeared uniform are now known to contain biologically distinct subtypes. Progress depends on the ability to follow the evidence wherever it leads, not on forcing research to conform to political priorities that may change every election cycle.

Genetic Alliance has spent decades building systems that allow communities to participate meaningfully in research, including registries, biobanks, IRB-supported research pathways, participant-centered data systems, advocacy tools, and access to genomic results. Our programs are grounded in a simple principle: people must have access to accurate diagnosis, useful information, research opportunities, and control over their own health and genomic data. Genetic Alliance's RISE program demonstrates the practical importance of this work: clinical genome sequencing for underserved children with suspected genetic disease in low-resource communities has produced diagnostic yields approaching 50%, changed clinical management for many families, and supported patients across multiple countries and care settings.

For these reasons, Genetic Alliance strongly opposes the provisions in OMB-2026-0034 that would destabilize federally supported research, restrict dissemination of scientific findings, and obstruct international collaboration. These provisions are not neutral administrative changes. They threaten the core infrastructure that makes molecularly informed diagnosis, care, surveillance, treatment development, and public health response possible.

First, proposed §§ 200.202, 200.205, and 200.340 would make long-term research unstable by tying awards more directly to shifting federal policy priorities and discretionary termination. OMB states that § 200.205 would require senior appointee pre-issuance review to ensure that awards advance administration priorities, while also clarifying that peer review remains advisory and does not replace agency discretion. OMB also proposes revising § 200.340 to allow termination when an award no longer effectuates program goals, federal agency priorities, or the national interest "as they exist at the time of the termination."

That approach is incompatible with modern biomedical research. Longitudinal natural history studies, registries, biobanks, diagnostic networks, newborn screening follow-up, cancer cohorts, infectious disease surveillance, treatment-development programs, pharmacogenomic studies, and genotype-phenotype studies cannot be restarted every political cycle. Individuals and families enroll in these efforts because they are assured their participation matters over time. Researchers and clinicians build trust with communities over years. The biological needs of people do not change when administrations change. A child waiting for a diagnosis, an adult with cancer seeking a targeted therapy, a patient with an infection requiring resistance-informed treatment, a family contributing data to help others, or a community building a registry should not have their future determined by political review rather than scientific merit, clinical need, and public health value.

If federal awards can be re-reviewed, suspended, or terminated based on changing political priorities rather than the needs of affected people and the integrity of the science, the result will be interrupted studies, stranded participants, lost data continuity, delayed answers, and avoidable harm.

Second, proposed restrictions on conferences, subscriptions, and publication costs would directly impede the movement of knowledge needed to diagnose, treat, monitor, and prevent disease. OMB proposes that conference attendance costs would be allowable only when expressly approved by the agency and included in the award's terms and conditions. OMB also proposes prior approval requirements for memberships, subscriptions, and professional activity costs, and would make publication costs unallowable unless required by statute or approved in advance on a case-by-case basis.

For molecularly informed medicine, this is not a minor administrative inconvenience. Case reports, conference presentations, pre-publication discussions, expert meetings, journal access, open publication, data deposition, and rapid dissemination are often the routes by which a clinician recognizes a condition, a researcher finds a matching case, a laboratory identifies a variant pattern, a public health team tracks an emerging pathogen, a family receives an answer, or early clinical findings are translated into care. Many genetic conditions have only a small number of known patients. Many cancers are now divided into molecular subtypes that require specific therapies. Infectious disease response depends on rapid sharing of sequence data, resistance patterns, and clinical observations. Evidence is scattered across institutions, countries, languages, specialties, databases, and public health systems. Slowing access to publications, meetings, and scientific exchange will slow diagnosis, delay care, weaken surveillance, and reduce the likelihood that the right intervention reaches the right person at the right time.

Third, proposed § 200.220 is especially damaging. OMB proposes a new government-wide prohibition on using federal funds to support bilateral or multilateral collaborations, agreements, programs, or activities with covered foreign countries or covered foreign entities. The prohibition would apply not only to direct research activities, but also to technical assistance, travel, and indirect costs allocable to such collaborations.

This would be devastating. Modern biomedical research cannot be conducted effectively within national borders alone. Molecular diagnosis and care require sharing variant evidence, tumor markers, pathogen sequences, resistance data, ancestry-informed interpretation, clinical observations, functional data, longitudinal outcomes, therapeutic experience, and public health signals across many sectors and countries. Variant interpretation requires comparison across ancestries and populations. Cancer subtyping depends on evidence from distributed cohorts. Infectious disease preparedness depends on global surveillance. Rare and stratified patient populations require international case aggregation. Functional studies, natural history data, clinical expertise, and treatment-development capacity are often distributed across countries. For many conditions, there may be only a few recognized experts worldwide. For people with

unresolved disease, a match in another country may be the difference between no diagnosis and a medically actionable diagnosis.

A broad restriction on international collaboration would not merely reduce scientific convenience. It would make some research impossible. It would also exacerbate inequities by isolating U.S. research from populations underrepresented in genomic, clinical, cancer, infectious-disease, and pharmacogenomic datasets. It would cut off collaborations that build diagnostic, therapeutic, laboratory, and public health capacity in low- and middle-income settings. The science depends on global evidence. A rule that restricts the evidence base will make diagnosis, treatment, surveillance, and public health response less accurate, less equitable, and less useful.

The proposed rule is framed as improving oversight and accountability. Genetic Alliance supports responsible stewardship of federal funds. But responsible stewardship in biomedical research must begin with the needs of people, not the political priorities of the moment. It must protect continuity, scientific independence, timely dissemination, and the ability to collaborate where the patients, data, expertise, pathogens, variants, tumors, and evidence exist. Federal research policy should be accountable to the public good: better diagnosis, better care, better treatment options, stronger surveillance, more trustworthy research relationships, and faster translation of evidence into benefit.

These proposed provisions would move federal research policy in the opposite direction. They would place political review above scientific merit, administrative control above participant need, and national isolation above the global evidence base required to understand and treat disease.

On behalf of people and families living with genetic disease across the lifespan, and on behalf of all those whose care depends on molecular diagnosis, targeted treatment, pathogen surveillance, pharmacogenomic evidence, and biologically informed medicine, Genetic Alliance urges OMB not to finalize OMB-2026-0034 unless these provisions are removed or substantially revised. At a minimum, OMB should remove or narrow the proposed restrictions in §§ 200.202, 200.205, 200.220, 200.340, 200.432, 200.454, and 200.461 as applied to biomedical, genomic, genetic, cancer, infectious disease, pharmacogenomic, and public health research.

Federal research policy should accelerate diagnosis, care, treatment development, data sharing, public health response, and responsible collaboration. These provisions would do the opposite. They would delay answers, destabilize research, suppress dissemination, obstruct global evidence generation, and isolate the scientific and clinical communities that people depend on.

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