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U.S. Department of Health and Human Services (HHS)

Title

UC Comments in Response to NOT-OD-26-112 "Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards"

Permalink

<https://escholarship.org/uc/item/5t52r4mg>

Journal

N/A

Author

UC Office of President

Publication Date

2026-10-16

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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Submitted through: <https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/>

October 16, 2026

Office of The Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

RE: UC Comments in Response to NOT-OD-26-112, “[Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards](#)”

Dear Sir or Madam:

We write on behalf of the University of California (UC) with regard to the Request for Comment on the Draft National Institutes of Health Biosafety Policy for Research Involving Biohazards issued on August 19, 2026 (Draft NIH Biosafety Policy). The UC is comprised of ten campuses, six academic health centers, an Agriculture and Natural Resources division, 21 health professional schools, and three affiliated U.S. Department of Energy national laboratories.

UC stands at the forefront of cutting-edge research and technology development. As a system, UC receives approximately \$7.5 billion annually of extramural awards to support research conducted throughout all UC locations. UC is awarded more NIH and National Science Foundation (NSF) funding than any other institution in the country.

While UC welcomes several aspects of the Draft NIH Biosafety Policy, including a simplified review structure and terminology, greater transparency through a public incident database, and the addition of delegated review, there are several concerns that need to be addressed before full implementation. As the Policy is refined, we encourage NIH to promote consistent interpretation across institutions and ensure that communication and review requirements do not unnecessarily delay research. Given the longstanding role of the NIH Guidelines for Recombinant and Synthetic Nucleic Acids in institutional biosafety programs, clear and practical requirements will be essential for successful implementation of the new Policy.

UC recognizes that the Policy is intended to be less prescriptive, however, it is too ambiguous and lacks detail for consistent application across institutions. NIH should provide examples as well as optional implementation tools and supplemental guidance documents that institutions may choose

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to use. In addition to the specific comments provided below, UC supports and endorses the comment letter submitted by Campus Safety, Health, and Environmental Management Association (CSHEMA) on October 12, 2026 in response to this request for comment.

1. Define and narrow policy scope to apply oversight proportionate to the risk.

Scope Ambiguity: The Policy requires significant clarification regarding its scope and applicability before it can be implemented consistently and effectively across institutions. As currently written, shown below, the scope is ambiguous about which activities fall under the Policy:

The NIH Biosafety Policy covers all biomedical research, in laboratory settings, involving biohazards.

For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:

1. *Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;*
2. *Cells, viruses, or organisms, other than plants, that have been genetically modified;*
3. *Toxins, prions, and other self-aggregating proteins; or*
4. *Cells or organisms, other than plants, containing 1, 2, or 3 above.*

It is unclear whether the Policy is intended to focus solely on research involving biological agents that pose a direct risk to human health, or whether it broadly applies to all biological materials and research activities, with the sole exclusion of plants. NIH should provide examples illustrating how the scope applies to common categories of research, including synthetic biology, computational or *in silico* design, plants, arthropods, animal pathogens, toxins, and non-infectious or non-replicating materials.

Risk-Proportionate Thresholds: If the intent is to include all biomedical research involving biological agents, the Policy would represent a substantial expansion of oversight into many research activities that are historically considered low risk. Expanding oversight would significantly increase administrative burden without a demonstrated improvement in biosafety outcomes. A limiting threshold should be added such that covered work must present a credible, scientifically plausible risk of causing disease in healthy adult humans under reasonably foreseeable laboratory exposure routes and quantities. Consideration should be given to reduce the scope of the Policy by removing oversight of toxins, self-aggregating proteins, genetically modified Risk Group 1 organisms, and other low risk activities that were exempt under the previous version of the NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules.

Non-Human Health Risks: If NIH intends the Policy to address risks beyond human health, it should establish a separate and clearly defined threshold for credible environmental,

agricultural, ecological, or animal-health consequences. Those risks should not be incorporated into the Policy through undefined or open-ended references to “biohazards”.

Applicability to Non-NIH Funded Research: Because this Policy functions as an institution-wide regulation, it may impose significant compliance obligations on non-NIH funded research. The Policy should either limit applicability to NIH-supported research, or define clear boundary conditions for affiliates, tenants, leased space, and core facilities.

2. Clarify and standardize definitions and terminology throughout the Policy.

The Policy contains numerous terms that are either undefined, inconsistently defined, or insufficiently detailed for reliable implementation across institutions. Given the Policy’s flexible structure, NIH should provide resources explaining key terms that are likely to produce inconsistent institutional interpretations. These resources should include examples and, where appropriate, criteria for determining when an activity falls within or outside a defined category.

Undefined Terms: The Draft Policy contains numerous undefined terms, which is problematic because the lack of a definition is cause for inconsistent interpretation across institutions. Accordingly, the following terms must be defined in the final Policy: “authorized organizational representative,” “biohazard,” “biohazardous,” “biological toxin protein,” “biosafety officer,” “GDMO,” “primary cells that may be contaminated by adventitious agents,” and “well-characterized cell lines.” For clinical research, additional terms requiring definitions include “shedding,” “replicating,” “integrating,” “higher risk manipulations,” and “product.”

Inconsistent Use: The term “biological agent” is used inconsistently throughout the Policy. For example, the definition describing biological agents as “bacterial, viruses, fungi, or parasites that cause human disease” does not encompass all biological agents addressed by the Policy, including “gene drive modified biological agent” and “RG1 wild-type biological agents.” Because not all biological agents cause human disease, “human pathogenic agent” may be a more accurate term where the Policy specifically intends to refer to agents capable of causing human disease.

Definitions that Require Clarity: The definition of “toxin” is overbroad and, as written, does not accurately describe a toxin. Unlike other biological agents, toxins do not replicate and may be more appropriately considered analogous to chemical hazards. The definition should clarify the characteristics of toxins, such as toxicity (LD₅₀ or LC₅₀) and if small molecule toxins are intended to be included. The definition of “laboratory research” should also be revised to encompass research activities and settings that may require biosafety oversight but do not neatly fit within a BSL/ABSL 1-4 designation. Examples include arthropod containment, clinical research activities, and research with plants expressing toxins that affect humans.

3. Broaden the reference framework for risk assessment and containment standards.

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Limitations of Reliance on the Biosafety in Microbiological and Biomedical Laboratories (BMBL): The Draft Policy relies heavily on the BMBL for agent-specific containment requirements. However, the BMBL does not provide Risk Group classification for agents and lags behind emerging or rapidly evolving research. Institutions have historically relied on the NIH Guidelines for Recombinant and Synthetic Nucleic Acids, World Health Organization, the Public Health Agency of Canada, or other recognized national and international authorities to assist in determining the agent Risk Group. The Policy should provide the risk-based rationale for prescribed minimum biosafety levels and clarify how its requirements apply outside conventional benchtop laboratories, including clinical, animal, large-scale, and other research settings where appropriate containment may depend on site-specific engineering, administrative, and procedural controls.

National Risk Group Classification and Institutional Authority: NIH should maintain an authoritative, regularly updated Risk Group classification resource, similar to the agent classification framework included in earlier versions of the NIH Guidelines for Recombinant and Synthetic Nucleic Acids. NIH should establish a defined process and frequency for reviewing and updating agent classifications and containment recommendations. NIH should establish nationally consistent Risk Group classifications, while institutions retain authority to determine appropriate biosafety level, containment requirements, and oversight based on local IBC risk assessments, available controls, and the specific research being conducted.

NIH should also clarify the relationship between Risk Group classification and Containment Levels. Risk Group classification generally describes the hazard associated with an agent or activity, while Containment Level describes the controls and containment measures appropriate for a particular operation. The final Policy or accompanying guidance should not treat these concepts as interchangeable. NIH may establish national minimum expectations or reference points, but the institutional IBC should retain the authority to assign or approve the appropriate containment level for a specific activity based on the institution's risk assessment, available engineering and administrative controls, institutional risk acceptance, and applicable internal standards. Institutions should also be permitted to impose more stringent containment or oversight requirements when warranted by site-specific conditions.

NIH Review Process and Timelines: The Policy should clarify what constitutes an "initial request," when NIH approval is required, and whether determinations apply to individual experiments or more broadly to an agent or category of research. NIH determinations and their rationale should be publicly available and applicable across institutions when appropriate, reducing duplicative submissions and unnecessary delays. NIH should define what constitutes a "timely" review by establishing target turnaround times, completeness criteria, a process for additional information requests, and an expedited pathway for urgent public health research. NIH should provide decision trees, a searchable repository of prior determinations, and pre-authorized categories for well-characterized agents, attenuated strains, and replication-defective vectors to further reduce unnecessary case-by-case review.

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UC supports the proposed streamlined process under which an NIH-approved containment reduction is publicly posted and may subsequently be relied upon by other IBCs without separate NIH approval. NIH should clarify whether each determination applies to a particular agent, strain, construct, or activity; the information institutions must retain; the circumstances requiring renewed review; and the extent to which IBCs may impose more stringent controls based on site-specific conditions.

4. Preserve Institutional Biosafety Committee (IBC) authority and institutional-based risk assessment.

IBC as Primary Oversight Body: The proposed Policy should preserve the longstanding role of Institutional Biosafety Committees as the primary bodies responsible for conducting research-specific risk assessments and determining appropriate containment. Multiple provisions appear to shift decision-making authority from the institutions to NIH while simultaneously emphasizing risk-based oversight. Consistent with the Policy's focus on human health, IBC expertise requirements should be strengthened to include expertise in biosafety, public health, and infectious diseases. Animal research expertise should be included, as applicable, without specifying the animal model type, to allow institutions to evaluate the relevant expertise needed. The Policy should retain the requirement for a BSO for large-scale biological research.

Full Review versus Delegated Review Requirements: The Policy should clearly distinguish activities that require full IBC review from those eligible for delegated review. Requiring review of all genetically modified cells, viruses, or organisms could create substantial burden for routine low-risk research. This is particularly relevant for genetically modified arthropods and animals. The apparent inconsistency between delegated review for transgenic organisms at BSL-1/ABSL-1 and the BSL-2 minimum containment requirement for GDMOs should be resolved. NIH should provide a tiered decision framework, with examples of activities that may be handled through full IBC review, delegated review, or exemption. The framework should identify escalation triggers, while preserving institutional authority to impose additional review based on site-specific circumstances.

Expand Delegated Review Criteria: The defined delegated review criteria may be too narrow given the expanded scope, producing net added burden for low-risk work. These criteria should be expanded for routine low-risk research such as replication-incompetent or non-integrating vectors, reporter-only constructs, cell lines, primary materials, transgenic animals, low-risk genetically modified organisms, with clear criteria for when elevation to full IBC review is required. A full committee review of these research materials would be overly burdensome and would fall more in line with the delegated IBC review tasks based on risk.

Exemptions from the Policy: NIH should clearly explain how exemptions are intended to operate under the new Policy, including whether existing institutional practices may continue, whether exempt determinations require IBC review or documentation, and what circumstances

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require escalation to delegated or full IBC review. NIH should address transition expectations for exempt research activities that may not have been historically reviewed by the IBC.

NIH should distinguish between activities that are outside the scope of the Policy, activities that are exempt from formal IBC review but remain subject to institutional documentation or oversight, and activities eligible for delegated review. This distinction should be reflected in the Policy's definitions, decision tools, and implementation guidance.

Occupational Health and Safety Plan Clarification: Additional clarification is needed regarding the Occupational Health and Safety Plan (OHSP), including when such plan is required, the elements NIH expects institutions to maintain, and the scope of NIH oversight or authority in this area.

5. **Revise public disclosure requirements for Institutional Assurances, meeting minutes and incident reports that balance transparency with privacy, biosecurity and reporting integrity.**

Redaction and Security Standards: Public posting of IBC meeting minutes, incident reports, and Institutional Assurances without uniform standards for disclosure and redaction may create security, privacy, proprietary, and reputational risks and could discourage timely and complete reporting. The Policy states that “appropriate and allowable redactions” can be made. To promote consistency across institutions, NIH should establish and publish a standardized redaction framework that clearly identifies information that should be withheld, including sensitive facility or inventory information, security vulnerabilities, proprietary methods, titles, and personal identifiers. Public disclosure requirements should account for incidents involving ongoing investigations, litigation, privacy restrictions, or oversight by another federal or state agency. For BSL-3, BSL-4, GDMO, “other pertinent information,” or other potentially security-sensitive research, NIH should not require public disclosure of information that could compromise broader federal biosecurity objectives, reveal protected intellectual property or proprietary information, or create material financial, competitive, privacy, or security harms. The Policy should clearly define the minimum information that must be publicly available and establish consistent standards for withholding or redacting protected information.

Incident Reporting Thresholds and Timeline: NIH should replace institution-by-institution public posting of all incident reports with a two-tier reporting framework. NIH-reportable and high-consequence incidents should be reported to NIH and summarized publicly using standardized redactions. Lower-risk incidents, near misses, and anomalies should be maintained through institutional systems and aggregated in a centralized, de-identified database. Further, NIH should establish clear reporting thresholds that distinguish events involving a credible exposure or release pathway from contained anomalies in which redundant controls remained effective. The Policy should clarify the relationship among incident reports, IBC meeting minutes, and Institutional Assurances, including how confidentiality, retention, and disclosure requirements apply when an incident involves multiple protocols or grant funding periods.

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Additional time beyond the 24-hour requirement or alternative disclosure procedures should be available for security-sensitive incidents or those subject to active investigation.

Centralized Incident Database: Given NIH's proposal to establish a centralized capability to aggregate, de-identify, and analyze biosafety incidents, near misses, and anomalies, NIH should consider using this mechanism to provide a centralized, anonymized public database rather than requiring institutions to publish individual reports on their website. This approach could provide meaningful transparency and opportunities for shared learning while preserving the culture of trust necessary for robust internal incident and near-miss reporting.

Continuity Mechanism: The Policy should include a continuity mechanism, such as an extension while an Institutional Assurance renewal is under NIH review, to ensure that administrative processing delays do not unnecessarily interrupt otherwise compliant research.

6. Clarify containment and oversight standards for gene drive modified organisms and address environmental, agricultural, animal and arthropod risks more comprehensively.

Oversight of Genetically Modified Plants: NIH should clarify whether another federal agency will have oversight authority for genetically modified plants and provide justification for their exclusion from this Policy. Genetically modified plants may express toxins, have the potential to contaminate native plant varieties through pollen or seed flow, and may impact associated arthropod communities or soil microbiota.

Arthropod Oversight and Containment Levels: While gene drives in animals, including arthropods, require increased containment levels under this Policy, similar requirements for plants have been removed from IBC oversight. The Policy should clarify if gene drive modified organisms that do not impact human health are within the scope of this policy. The requirement for research with gene drive modified organisms to be conducted at a minimum of BSL-2 containment is a poor fit for genetically modified insects such as mosquitoes, flies, or other arthropods, as the biosafety level terminology primarily focuses on infectious-agent risk. For many gene-drive or genetically modified arthropods, the principal hazard is environmental escape and establishment, not infection of laboratory personnel. As such, the appropriate terminology would be arthropod containment levels (ACL). The Policy should distinguish between human health biocontainment and environmental containment of genetically modified organisms.

Environmental, Agricultural, and Animal Health Risk: More broadly, environmental risk and consideration is captured in multiple sections of the Policy, but only human health is noted in the scope of this Policy. The Policy should clarify if environmental, agricultural, and animal health risk should be considered under the scope of this Policy. Any environmental, agricultural, ecological, or animal-health risks included within the Policy should be governed by the separate threshold described in Section 1 and should not expand the Policy's scope through open-ended interpretation of "biohazard".

7. Reduce administrative burden and eliminate regulatory redundancy.

Extend Implementation Timeline: The implementation timeline should be extended from “6 months from publication of final Policy” to a minimum of 12 months to allow institutions sufficient time to develop and validate systems necessary to comply with the new Policy. NIH should clarify how the proposed institutional biosafety assurance is intended to complement existing compliance certifications associated with NIH funding to ensure the process avoids duplicative administrative requirements. Each assurance requirement should be revised to express each statement as a complete, clearly defined institutional responsibility or submission element. Model templates and electronic resources should be made available ahead of the Policy effective date, including risk assessment tools, delegated review templates, incident reporting template, redaction guidelines, and public meeting minute formats.

Records Retention: Records-retention requirements should be specific to IBC oversight rather than directly tied to award financial-record retention periods. IBC oversight is based on active institutional research and does not necessarily align with grant submission or financial-reporting cycles. Accordingly, the Policy should define the categories of records subject to the retention requirement and distinguish institutional IBC records from grant records. IBC protocols are often living documents that evolve with active research and institutional controls and may not correspond directly to the scope of an individual grant proposal.

IBC Submission Timeline: Requiring a *de novo* IBC registration submission every 3 years can present a significant administrative burden on both the Principal Investigator and the IBC. NIH should allow institutions to establish periodic review intervals based on the nature and the risk level of the research.

Meeting Minutes Documentation and Public Posting: Public-posting requirements should be limited to information necessary to promote meaningful transparency and accountability. The requirement to post approved minutes immediately following approval, or by the next convened meeting, should be modified to provide institutions reasonable flexibility based on meeting frequency and administrative capacity.

Meeting Minutes and Incident Report Templates: Mandatory NIH templates for meeting minutes and incident reports may be overly prescriptive for institutions with established electronic systems and may increase administrative burden without improving safety outcomes. NIH should consider permitting substantially equivalent formats, including exports from institutional electronic systems, provided all required data elements are captured. NIH should publish a machine-readable list of required fields to standardize content while minimizing duplicative work. Additionally, NIH should consider removing training information from the meeting minutes template. Personnel training records are dynamic in nature and may contain personnel-identifying information that institutions would otherwise need to redact prior to making records available to the public. Training documentation is more appropriately maintained through separate institutional tracking mechanisms.

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Standardized IBC Training: NIH should create and publish standardized IBC member training to outline the roles and responsibilities of IBC membership and include information about the review process. This would ensure that local IBCs are analyzing and assessing research activities with consistency instead of relying on third party or institution-created training for their IBC members.

Coordination with Existing Federal Oversight: Additional clarification is needed regarding the relationship between this Policy and other existing federal oversight. Several areas appear to overlap with established requirements administered by Occupational Safety and Health Administration (OSHA), Federal Select Agent Program (FSAP), Food and Drug Administration (FDA), Animal and Plant Health Inspection Service (APHIS), and the recently issued July 2016 United States Government Policy for Stopping High-Risk Life Sciences Research. The Policy should clearly identify which agency has primary oversight responsibility when multiple regulatory requirements apply and explain how overlapping requirements will be coordinated to avoid duplication or conflicting determinations. NIH should define which specific requirements outlined in the Policy are applicable when research may fall under the purview of multiple agencies or federal policies.

8. Establish a clear biosafety oversight framework for clinical research.

IBC Role in Clinical Research: The Policy does not adequately define the IBC's role in overseeing clinical research. IBC oversight of clinical research should complement, rather than duplicate, other federally required review and applicable human-subject protections. Where FDA and other regulatory processes already address product safety, shedding, or related risks, the Policy should clearly define the specific biosafety issues that remain within IBC oversight and establish clear endpoints for that oversight, such as last administration of an investigational product and a defined, evidence-based shedding monitoring window. This gap can create duplicative oversight, administrative confusion, and unnecessary delays for clinical research programs. The clinical research provisions should be reconciled with the 21st Century Cures Act, the Common Rule under 45 CFR 46, and existing FDA oversight frameworks.

Clinical Definitions and Terminology: As noted in our definitional comments, the absence of definitions for "shedding," "replicating," "integrating," "higher risk manipulations," and "product" creates significant challenges for institutions to apply effective clinical biosafety oversight.

Hierarchy of Controls and Tiered Risk Management: The Policy's risk assessment considerations for clinical research should take a layered approach to safety and focus on the hierarchy of controls. While the Policy acknowledges that clinical laboratories do not use traditional biosafety levels, the only risk mitigation guidance provided for clinical personnel is the use of universal precautions. This significantly understates the appropriate approach to clinical biosafety. Standard precautions should serve as the established baseline, with transmission-based precautions implemented based on the hazard characteristics and routes of

transmission specific to the investigational product or procedure. The Policy should reflect a tiered model of risk management.

9. Provide guidance for synthetic biology and artificial-intelligence assisted research.

Emerging Technology Oversight Gap: The rapid advancement of synthetic biology and artificial intelligence-assisted research design represents a growing category of biosafety concern that the Policy does not address. Both technologies have the capacity to substantially accelerate research workflows, lower barriers to the design and synthesis of novel biological agents and produce outcomes that existing oversight frameworks were not designed to evaluate. NIH should provide implementation guidance and institutional review tools for these areas, either in the final Policy or in accompanying guidance.

Synthetic Biology: With respect to synthetic biology, the Policy should provide guidance on the oversight of research involving the *de novo* synthesis of genetic sequences, the creation of novel biological constructs without natural counterparts, and the application of standardized biological parts in ways that may confer new or enhanced properties on organisms or agents. NIH should provide criteria and examples identifying which categories of synthetic biology work require IBC review, delegated review, or no additional biosafety review.

Artificial Intelligence and Large Language Model-Assisted Biological Design: With respect to artificial intelligence (AI) and large language model-assisted biological design, the Policy should establish review triggers and minimum institutional safeguards applicable when AI tools are used to propose, optimize, or select biological designs tied to high-consequence properties, including enhanced transmissibility, expanded host range, immune evasion, antimicrobial resistance, environmental stability, or increased toxicity. These safeguards should be narrowly and precisely defined so as not to impede general computational research, bioinformatics, or routine AI-assisted data analysis, while ensuring that AI-facilitated pathways toward potentially dangerous agent characteristics are subject to appropriate institutional and federal oversight.

10. Required Guidance Documents and Implementation Resources

To support consistent implementation while preserving institutional flexibility, NIH should make the following guidance documents, templates, decision tools, and reference resources available before the effective date of the final Policy.

- Examples of research activities and determinations to assess if the work falls within the scope of the Policy
- Guidance confirming institutional IBC authority to assign or approve containment and oversight based on research-specific risk assessment, institutional risk acceptance, available controls, and internal standards
- Risk group classifications
- Template to request NIH determination for risk group assessment and biosafety level reduction

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- Guidance on reliance upon posted NIH containment-reduction determinations, including the scope and applicability of each determination, criteria for when a new NIH request is required, and documentation and recordkeeping requirements for IBCs relying on a prior determination
- Searchable repository of prior NIH determinations on Risk Group classification and Biosafety Level or containment reduction
- Incident report template
- Incident reporting decision tree on what is required to be submitted to NIH and publicly posted
- Guidance on incident-reporting timelines, redactions, active investigations, and alternative disclosure procedures
- Machine-readable list of required fields for public meeting minutes
- Risk assessment template with references beyond the BMBL
- Guidance on environmental, agricultural, ecological, animal-health, and arthropod risks
- Decision tree distinguishing activities outside the scope of the Policy, activities exempt from formal IBC review but subject to institutional documentation or oversight, activities eligible for delegated review, and activities requiring full IBC review.
- Delegated review template
- Standardized redaction reference
- Standardized IBC member training
- Occupational health and safety plan template
- AI and LLM research examples with determinations if they are within the scope of Policy
- Synthetic biology risk assessment template

Thank you for the opportunity to comment. We look forward to continued engagement on this important Policy.

Sincerely,

DocuSigned by:

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Kevin Confetti

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