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NIH Recipients Conducting Biospecimen Research: Gaps in Emergency Planning and Reporting

REPORT HIGHLIGHTS

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NIH Recipients Conducting Biospecimen Research: Gaps in Emergency Planning and Reporting

Why OIG Did This Review

- As emergencies (e.g., hurricanes, flooding) become more frequent, important medical research using biospecimens and NIH funds may be at risk. Each year, NIH invests billions of dollars in extramural cancer research, which is often dependent on high-quality biospecimens (e.g., blood, tissue).
- In emergencies, biospecimens can be damaged or ruined if, for example, freezers unexpectedly shut down due to power outages. Biospecimens often have specific temperature storage requirements, and even small temperature fluctuations can damage or ruin sensitive samples.
- NIH recipients are not required to have emergency plans. However, NIH directs recipients to guidance on how to plan for emergencies. NIH also has some requirements and guidance for recipients on how to report negative effects of emergencies on their research.

What OIG Found

All 23 recipients in our review were located in areas that were higher risk for emergencies, and all recipients reported having emergency plans. However, most (16) recipients' efforts were not informed by risk assessments, which could result in ineffective planning or wasted resources.

Recipients that experience an emergency may not be submitting timely or complete information to NIH. Five out of six recipients that experienced negative effects of an emergency may not have reported them to NIH in a timely manner, and the completeness of the reports could also be a concern. This could hinder NIH's ability to (1) assist recipients after an emergency; and (2) estimate and report the financial and programmatic impacts of emergencies to stakeholders.

What OIG Concludes

While our sample size was small, our findings identify gaps in recipients' emergency planning and reporting that may apply beyond our sample. Additional planning guidance could help recipients better protect their biospecimens and the important NIH-funded research that relies on them. More specific guidance for recipients on how and when to report negative effects from emergencies could also help ensure that NIH has timely and complete data to assist recipients' recovery efforts and report accurate information to stakeholders (e.g., Congress, the public).

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BACKGROUND

OBJECTIVES

To determine whether and how:

1. Extramural recipients that conduct biospecimen research funded by the National Institutes of Health (NIH) have planned for emergencies.
2. NIH is receiving timely and complete information from recipients whose research is negatively affected by emergencies.

Each year, NIH invests billions of dollars in extramural cancer research that often relies on biospecimens.[1] The quality and integrity of these biospecimens – and the important medical research that relies on them – are at risk during emergencies.

Damaged or lost biospecimens can result in costly delays and replacement expenses.[2, 3] As natural disasters and other public health emergencies become more frequent, these risks and costs increase, and emergency plans that protect NIH-funded research become increasingly important.[4, 5] To prepare for these disasters, recipients' emergency planning and response efforts can be supported by NIH funding, either directly or indirectly.[6]

When recipients experience negative effects from emergencies, it is important for NIH to be informed of damages and delays. This allows NIH to assist recipients in recovering from an emergency and to report accurate financial and programmatic impacts of the emergencies to relevant stakeholders.

Biospecimens help advance important NIH extramural research

Biospecimens help biomedical researchers understand the risks, outcomes, and treatments of cancer and many other diseases.[7, 8] They are biological materials, such as blood or tissue, that are commonly used in clinical and research settings because they contain cellular, genetic, or molecular information.[9, 10] Biospecimens can be collected and used for a specific study or stored as legacy specimens.[11]

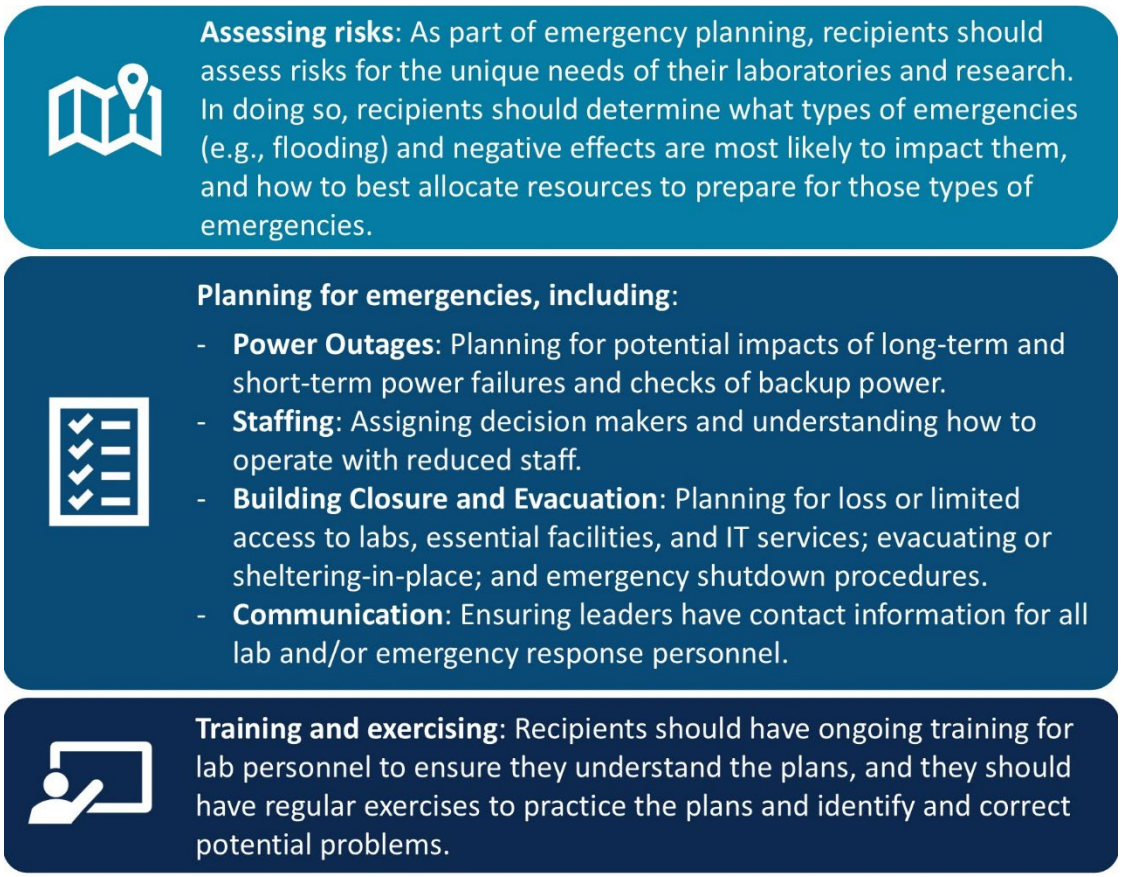
To be effective for research, biospecimens must be properly preserved. Biospecimens have strict storage requirements to ensure they remain as close as possible to the original subject's biology.[12] Many biospecimens must be stored at ultralow temperatures (negative 80 degrees Celsius in liquid nitrogen or a freezer) to prevent degrading and, if stored properly, can be preserved for many years.[13]

NIH has stated that the lack of standardized, high-quality biospecimens is widely recognized as a significant roadblock to progress in cancer research.[14] If biospecimens are destroyed or compromised, the important biomedical research and medical advancements that depend on them could be lost or delayed.

Emergency planning guidance for NIH extramural recipients

NIH does not require recipients to have emergency plans.[15] However, NIH does recommend that its recipients follow guidance on emergency planning. The guidance that NIH directs recipients to is largely created by third parties. The most comprehensive source is the National Research Council's *Prudent Practices in the Laboratory*.[16, 17]

The emergency planning guidance that NIH recommends addresses three main areas:



Source: OIG analysis of NIH-recommended guidance, *Prudent Practices in the Laboratory*.

NIH's recommended guidance applies to all recipients, regardless of whether they use biospecimens. In addition, NIH's National Cancer Institute has developed best practices specific to biospecimens for its recipients. The emergency planning aspects of this guidance largely coincide with the three main areas above. The best practices also contain guidance on using monitoring and alarm systems for biospecimen storage equipment if temperatures fluctuate, which could also be helpful during an emergency.[18]

NIH requirements and guidance for reporting the negative effects of emergencies on recipients' research

NIH's Grants Policy Statement contains some requirements and guidance to recipients on reporting negative effects of emergencies on their research. Recipients are required to notify NIH of developments that have a significant impact on NIH-funded research, including negative effects caused by emergencies.[19] Section 8.1 of the Grants Policy Statement requires recipients to inform NIH of problems, delays, or adverse conditions that impair their ability to meet the award objectives. The information submitted to NIH should describe the effects; any actions that the recipient has taken or considered; and any assistance that the recipient needs to recover from or resolve the situation. NIH requires recipients to report significant effects of an emergency as soon as they become known.

Additionally, NIH reports information to stakeholders on the effects of emergencies. For example, Congress may request information about the impact of an emergency, and in some cases, provide additional appropriations to help recipients recover.

NIH assists extramural recipients recovering from an emergency

Once NIH receives a report from a recipient, it can take a variety of actions to assess recipients' needs and determine appropriate next steps. This can include conducting calls or site visits to recipients in regions affected by emergencies to evaluate the impact on NIH-funded projects. It can also include waiving certain prior-approval requirements and providing extensions of time for financial or other reporting.[20]

NIH has an emergency and natural disasters response website for the biomedical research community, including its extramural recipients.[21] This website provides NIH and other (e.g., CDC) resources to recipients that have experienced an emergency. The website includes links to guidance for specific emergency situations, frequently asked questions, and trainings.

Methodology

We surveyed a simple random sample of 150 recipients that received funding from NIH to conduct research using human biospecimens. We selected recipients residing in counties with a "relatively moderate" or higher FEMA risk index score to capture recipients at higher risk for emergencies.[22] We sent an anonymous, web-based survey to these 150 recipients.[23] See the Detailed Methodology for more information on our population and sample selection.

We asked recipients to confirm that they conducted research using human biospecimens and, if so, we posed additional questions:

- We asked all recipients if they had emergency plans that protect human biospecimens. For recipients that answered affirmatively, we posed additional questions about training and exercising those plans. For recipients that did not answer affirmatively, we asked if they had general emergency plans.

- We asked recipients with emergency plans for details about the contents of their plans, such as whether they conducted risk assessments and addressed power outages; staffing; building closure and evacuation; and communication in their plans.
- Finally, we asked all recipients about whether they experienced emergencies (between January 2019 and February 2024) and, if so, whether they experienced any negative effects from those emergencies.[24] We asked recipients how, if at all, they reported those negative effects to NIH.

A total of 58 recipients responded to our survey. Of these, 35 recipients reported that they did not conduct research using human biospecimens.[25, 26] Removing these recipients from our sample yielded a total of 23 recipients.[27]

We then analyzed recipients' survey responses. We performed both qualitative analysis of respondents' open-ended responses and quantitative analysis of closed-ended responses.

We also collected and analyzed data from NIH. We reviewed NIH policies and procedures regarding emergency planning and reporting, as well as existing guidance. Additionally, we sent NIH written questions to understand recipients' reporting procedures, NIH officials' roles, and NIH's technical assistance after emergencies.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

All 23 recipients in our review reported emergency planning, and some included training and exercising, but only 7 recipients' efforts were informed by risk assessments

Recipients in our review were all located in higher-risk areas for emergencies, and all recipients reported having emergency plans. In addition, most recipients (17 of 23) reported having emergency plans that protect human biospecimens.[28] Some (11 of 17) of these recipients also reported training and exercising their plans.

NIH-recommended guidance outlines the importance of assessing risks for the unique needs of recipients' laboratories and research. Risk assessment allows recipients to determine the most likely emergencies, understand potential negative effects, and best allocate limited resources.[29] Despite this guidance, about two-thirds of recipients in our review did not conduct a risk assessment (16 of 23). This gap in emergency planning could result in recipients not having fully planned for emergencies and/or having wasted resources planning for unlikely scenarios.

In addition, several recipients in our review had suggestions for additional resources that could improve their emergency planning.

Seven recipients in our review reported assessing risks before emergency planning

Most (16) recipients in our review did not report conducting a risk assessment. Those that did not assess risks sometimes reported doing other activities prior to developing plans, such as reviewing guidance documents. Only two recipients did not report conducting any activities prior to planning.

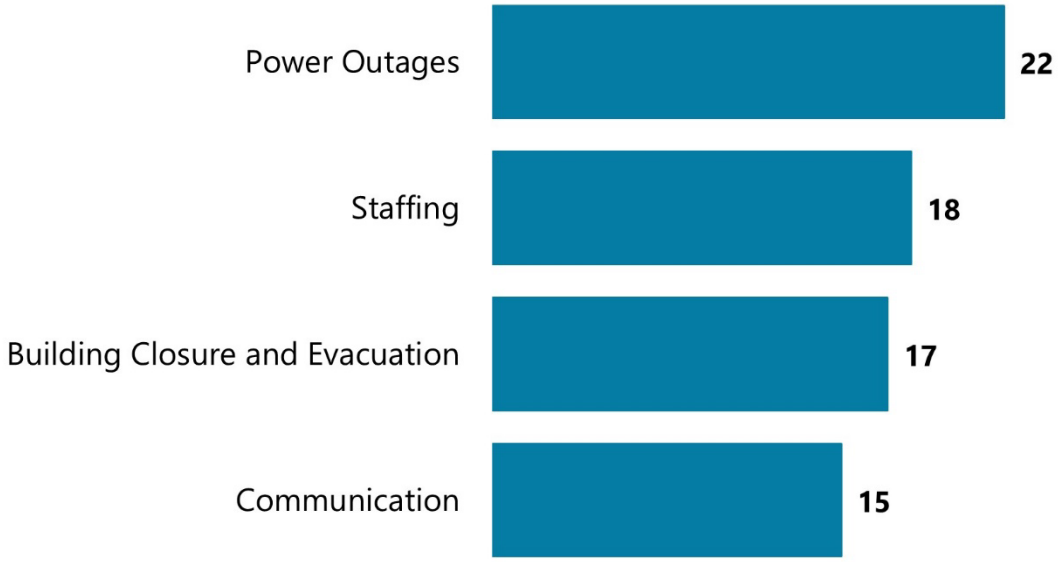
Some (8) recipients that did not report assessing risk also reported only using or modifying plans provided by their institutions. These recipients may not have department- or laboratory-specific emergency plans that account for the unique needs of the research or laboratory. These planning gaps could put biospecimens at risk of damage or loss due to an emergency.

Most recipients reported routinely updating plans to reflect current threats. For emergency plans that protect human biospecimens, most, but not all, recipients reported updating their plans (14 of 17). These recipients reported updating their plans as needed or after an event (9), annually (3), every 2-5 years (1), or only when they have active biospecimen projects (1). The remaining recipients reported that they do not update their plans (1), did not know when the plans were last updated (1), or did not respond to the question (1).

Twenty-two recipients in our review reported having plans that covered, at a minimum, power outages

Nearly all recipients in our review reported planning for power outages, and they least often had plans for communication during an emergency. NIH's recommended emergency planning guidance suggests that recipients develop plans that incorporate power outages; staffing; building closure and evacuation; and communication.

Exhibit 1: While nearly all recipients planned for power outages, they less often had plans for communication.



Source: OIG analysis of recipient survey responses.

While all recipients reported having some type of plan, the contents of the plans varied. Thirteen recipients had planned for all four of these areas, and four recipients planned for three of these areas. Fewer recipients planned for two or one of these areas (three and two recipients, respectively). One recipient did not indicate whether it had conducted planning in any of the four areas.

Some recipients (9) also reported including contents of their plans that went beyond the four planning areas outlined in NIH-recommended guidance. These recipients all reported using monitoring or alarm systems on storage equipment to alert laboratory personnel if temperatures fluctuated.[30]

Additionally, nine recipients experienced emergencies between January 2019 and February 2024 but reported not losing any human biospecimens during these emergencies; they attributed this to following their emergency plans. [31, 32]

See the Appendix for the emergencies that recipients in our review reported experiencing.

Eleven recipients in our review reported training personnel on and exercising their emergency plans that protect human biospecimens

Of the 17 recipients in our review with emergency plans that protect human biospecimens, most (14) reported training personnel on the plans and nearly the same number (13) reported exercising their plans. Eleven recipients reported both training personnel on and exercising their emergency plans.

Ongoing training of emergency plans is essential to ensure that recipients and laboratory personnel understand the plans.[33, 34] For the 14 recipients that reported training personnel, only half (7) reported conducting training annually. The remaining recipients reported training only during onboarding or orientation (5), after an event or as needed (1), or only when they have active biospecimen projects (1). The remaining 3 of 17 recipients either reported that they do not train their personnel (2) or did not respond to the question (1).

Regular exercising of emergency plans allows recipients to practice them and identify and correct potential problems.[35] Similar to training, for the 13 recipients that reported exercising plans, 7 reported conducting exercises annually. The remaining recipients reported conducting exercises after an event or as needed (5) or only when they have active biospecimen projects (1). The remaining 4 of 17 recipients either reported that they do not exercise their plans (3) or did not respond to the question (1).

Some recipients suggested additional resources that could help them improve emergency planning

Some recipients in our review suggested additional resources that could improve their emergency planning. Six recipients reported that they would benefit from receiving examples of emergency plans or other resources, such as guidelines, webinars, or online tools. These materials would allow recipients to save time and resources when planning, which means more resources could be focused on their research. Additionally, three recipients reported wanting more involvement or guidance from NIH officials, such as more information on available resources, but they did not provide specifics.

Five out of six recipients that experienced negative effects of an emergency may not have reported them to NIH in a timely manner, and the completeness of the reports could also be a concern

NIH uses recipients' reports on the effects of emergencies to assess their needs and determine appropriate next steps. Without this information, NIH may not have a clear

understanding of the negative effects on recipients' research or be able to provide additional support to help them recover. Gaps in information, through delays or incomplete reporting, could also limit NIH's ability to accurately report the negative financial and/or programmatic effects of emergencies on NIH-funded research to Congress or the public.[36]

Our data, from a limited sample of recipients that experienced an emergency, show that NIH may not be receiving timely information about the negative effects of emergencies on recipients' research. Six recipients reported to us that they experienced an emergency that negatively affected their research.[37] Five of these six recipients waited until the annual reporting process to notify NIH.[38] Using the annual reporting process to report this information may not afford NIH the ability to receive the information as soon as it is known. The remaining recipient reported meeting with NIH officials and also using the annual reporting process to notify NIH.

NIH may also not be receiving complete information from recipients about the effects of emergencies on their research. NIH does not have a standardized way to collect this type of information from recipients; recipients may use various methods to report damages. For example, recipients may use administrative supplement applications, which request additional funding to help cover unforeseen costs.[39] Recipients may also report damages to NIH via annual reports or meetings with NIH officials.

NIH does not prompt recipients on what to include in these damage reports. For example, NIH does not prompt recipients to consistently include the types of damage (e.g., lost samples, lost research); the extent of the impact of the damage (e.g., delays); the costs due to damaged or lost samples or research; or the financial effects of any lost productivity. Rather, NIH allows recipients to determine what to report. When NIH requires additional details not immediately provided, NIH will specify to the recipient the needed information and the manner for its submission. Without prompts or standardization, though, NIH may not be aware of the information it is not receiving, which limits its potential for followup.

NIH also does not have structured data fields in its systems to query or identify submitted damage reports. As a result, NIH would struggle to aggregate data specific to each emergency and report accurate information to stakeholders. NIH estimated that COVID-19 cost $16 billion in delays and/or losses to the research it funds.[40] NIH did not consistently collect across awards the information used to calculate this figure (e.g., productivity losses such as studies halted, animals culled, staff diverted, and resources to recover from the months of losses). Instead, to calculate this figure, NIH reported to us, it applied blanket estimates across projects and Institutes and Centers.

CONCLUSION

NIH is the largest funder of biomedical research in the world, awarding billions of dollars each year for extramural cancer research that often relies on biospecimens.

The quality, integrity, and protection of biospecimens is crucial to ensure that biomedical research progresses in a timely, high-quality, and cost-effective manner. Natural disasters and other emergencies are a threat to this research, as biospecimens often have specific and extreme storage requirements. As emergencies become more frequent, this important medical research and the associated NIH funding may be at risk if recipients are not prepared.

Our review of 23 recipients that reported conducting human biospecimen research found several gaps and concerns in recipient emergency planning and reporting. Most of these recipients did not engage in risk assessments and, therefore, may be conducting ineffective planning or wasting resources. Additionally, NIH may not be receiving timely or complete information from recipients that experience negative effects from emergencies. It is important that NIH understand the damages and delays recipients experience due to emergencies to best support their recovery and to accurately report this type of information to stakeholders.

Despite the small sample size, identified gaps and concerns can be useful to recipients in learning how to conduct emergency planning efficiently and effectively, such as by using risk assessments. Additionally, our findings can help NIH identify opportunities to improve formal or informal, written or verbal guidance to recipients on emergency planning and reporting that might help recipients avoid damages resulting from emergencies. For example, NIH may wish to explore the following:

- Strengthening guidance on risk assessments to ensure that recipients' limited resources are invested in planning efficiently and effectively. Developing effective emergency plans could mitigate the negative effects of emergencies on valuable research and potentially reduce the dollar amount NIH would otherwise use to assist recipients in recovering from an emergency.
- Taking steps to ensure that the information it receives from recipients affected by emergencies is more timely and complete. NIH could do this by providing more specific guidance to recipients on when to report damages and what to include in these reports. Consistent, complete reporting from recipients would help NIH better assist recipients in recovering after an emergency and would improve NIH's ability to report information to relevant stakeholders.

DETAILED METHODOLOGY

We first established a population of extramural recipients that received funding from NIH to conduct research using human biospecimens. Because NIH does not maintain a field to search its data to identify which recipients use biospecimens, we conducted keyword searches of NIH study descriptions (i.e., abstracts) of recipients' research to identify them. We used the following keywords to determine our population: blood, human tissue, plasma, tissue samples, biopsy sample, histological samples, histology samples, human fetal sample. We included in our population domestic recipients that received NIH funding between July 2020 and June 2022. This date range was the most recent 24-month period at the time we obtained the data. We excluded foreign recipients, as they could experience different types of emergencies and have different response infrastructures, and therefore have different emergency planning needs and resources. This yielded approximately 23,000 studies.

We then removed duplicates and performed other data cleaning steps, including narrowing this pool to recipients in areas with "relatively moderate" or greater FEMA risk index scores or recipients that were located in Puerto Rico. The resulting final population comprised approximately 8,400 recipients.

From this population, we selected a simple random sample of 150 recipients. We sent surveys via email and confirmed that 141 recipients received the email. The remaining nine recipients had undeliverable email addresses. We found phone numbers for five of these nine recipients and attempted followup calls with them. However, we were unable to connect with recipients via phone calls. We could not find additional contact information for the remaining recipients. We conducted two rounds of email followup with recipients, unless they informed us that they completed the survey, or their address was undeliverable.

Limitations

We cannot confirm that the keyword searches we used to identify our population were sufficient. While we used questions at the beginning of the survey to screen out recipients that should not be in our sample (i.e., because they did not conduct research using human biospecimens), we are unable to determine whether the keyword searches potentially omitted recipients from our population that should have been included.

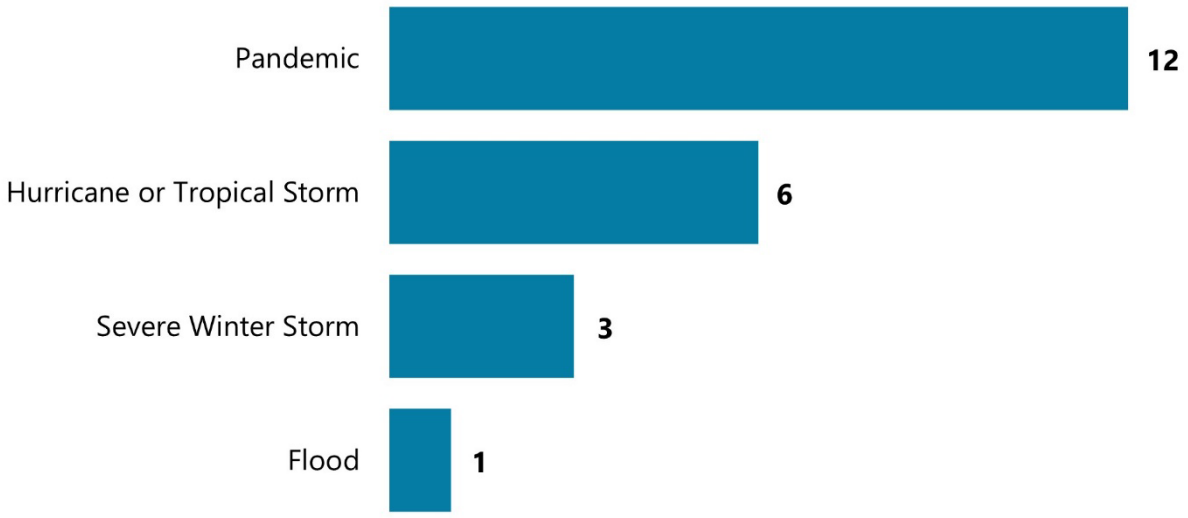
Our survey relied on self-reported data. Because of this, we were not able to independently verify survey responses for most respondents. Recipients were given the option to provide supporting documentation, such as their emergency plans. Two respondents provided supporting documentation. We attempted to use this supporting documentation to better understand these two recipients' survey responses. However, the majority of one of the recipients' plans were behind a

university firewall. The other recipient's documentation did not fully support its survey responses, and we could not verify that the documentation submitted was complete.

We attempted to identify if respondents completed the survey more than once by reviewing surveys for similar answers that could indicate duplication. We also reviewed the contact information some recipients voluntarily provided. Through these methods, we did not identify any duplication of survey responses. However, because the survey was anonymous, we cannot completely eliminate the possibility of recipients completing the survey multiple times.

Finally, due to the low survey response rate, we do not generalize our findings to the survey sample or the broader population of NIH recipients. We also cannot conduct a nonresponse analysis due to the anonymous nature of the survey.

Appendix: Emergencies that recipients reported experiencing



Note: Thirteen recipients in our review reported experiencing at least one emergency.

Source: OIG analysis of recipient survey responses.

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ENDNOTES

[1] NIH Reporter, *Estimates of Funding for Various Research, Conditions, and Disease Categories*. Accessed on March 7, 2025.

[2] National Academies of Sciences, Engineering, and Medicine, *Impacts of Prior Disasters on the Academic Biomedical Research Community – Strengthening the Disaster Resilience of the Academic Biomedical Research Community*. Accessed on February 15, 2023.

[3] Paul Elias and Alicia Chang, "Cane Disrupts Scientific Research," *CBS News*. Accessed on February 15, 2023.

[4] Bedford et al., "A New Twenty-First Century Science for Effective Epidemic Response," *Nature*. Accessed on November 14, 2024.

[5] National Centers for Environmental Information, National Oceanic and Atmospheric Administration, *Billion-Dollar Weather and Climate Disasters Overview*. Accessed on February 25, 2025.

[6] Direct costs support the research itself (e.g., salaries, materials, supplies, equipment). Indirect costs are often referred to as "overhead expenses" and support overall research activities not associated with a specific project (e.g., facility costs such as building or laboratory maintenance, administrative costs such as accounting expenses). NIH, *Indirect Cost: Definition and Example*. Accessed on September 9, 2024.

[7] Carrick et al., "The Use of Biospecimens in Population-Based Research: A Review of the National Cancer Institute's Division of Cancer Control and Population Sciences Grant Portfolio," *Biopreservation and Biobanking*. Accessed on September 20, 2024.

[8] Grady et al., "Broad Consent For Research With Biological Samples: Workshop Conclusions," *The American Journal of Bioethics*. Accessed on September 20, 2024.

[9] NIH, *Policy Manual Section 3008 – NIH Human Biospecimen Program*. Accessed on October 10, 2024.

[10] National Cancer Institute, *Biospecimen and Biorepository Basics*. Accessed on November 14, 2024.

[11] A legacy specimen is one that remains after all study-specific goals have been completed. These remaining biospecimens are available for other studies (subject to application, scientific review, and approval). National Cancer Institute, *NCI Best Practices for Biospecimen Resources*. Accessed on October 10, 2024.

[12] NIH, *Biospecimen Collection, Processing, Storage, Retrieval and Dissemination*. Accessed on September 12, 2024.

[13] NIH, *Biospecimen Collection, Processing, Storage, Retrieval and Dissemination*. Accessed on September 12, 2024.

[14] National Cancer Institute, *NCI Best Practices for Biospecimen Resources*. Accessed on February 15, 2023.

[15] NIH requires recipients to adhere to several regulations around laboratory safety. Recipients must be in compliance with the NIH Grants Policy Statement, which is provided to recipients when they receive their notice of award. NIH's Grants Policy Statement is intended to provide recipients, in a single document, all the policy requirements that serve as the terms and conditions of an NIH grant award. The Grants Policy Statement outlines that recipients must meet applicable Federal, State, and local health and safety standards. NIH, *Grants Policy Statement Sections 4.1.12 and 8.1*. Accessed on November 11, 2024.

[16] National Research Council, *Prudent Practices in the Laboratory*. Accessed on April 9, 2024.

[17] NIH also directs recipients to *Biosafety in Microbiological and Biomedical Laboratories, 6th Edition*, by the Centers for Disease Control and Prevention.

[18] National Cancer Institute, *NCI Best Practices for Biospecimen Resources*. Accessed on February 15, 2023.

[19] NIH, *Grants Policy Statement Section 8.1*. Accessed on June 17, 2024.

[20] NIH, *NIH Extramural Response to Natural Disasters and Other Emergencies*. Accessed on June 16, 2023.

[21] NIH, *NIH Extramural Response to Natural Disasters and Other Emergencies*. Accessed on June 16, 2023.

[22] FEMA's risk index scores represent a community's relative ranking among all other communities. The FEMA risk index contains, by county, a score from 0 to 100 that reflects the risk for 18 hazard types (e.g., hurricanes, wildfires). Scores are national percentiles, not absolute measurements, and are expected to change over time either because a community's risks have changed or because its position has changed relative to risks in other communities. For more information, see *FEMA National Risk Index Technical Documentation*. Additionally, although data for Puerto Rico are not collected in the FEMA risk index, we included recipients in Puerto Rico because communities there are regularly impacted by emergencies (e.g., hurricanes).

[23] We used an anonymous survey in an effort to increase our response rate. In the anonymous survey, recipients had the option to provide their names and contact information and to provide emergency plans or other relevant documentation. Eleven recipients provided their names and contact information. One recipient provided additional documentation, and one other recipient provide a link to its institution's emergency resource page.

[24] We defined emergencies as natural disasters (e.g., hurricanes, earthquakes, floods), public health emergencies (e.g., pandemics), and human-made events (e.g., terrorist or cyber-attacks). We specified that this definition did not include isolated spills or exposures within a specific laboratory or facility.

[25] We distinguished between recipients that conducted research using human versus animal biospecimens due to the existing requirements on research that includes animals. Recipients that conduct research using animals must abide by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and the Guide for the Care and Use of Laboratory Animals. There is also a specific committee, the Institutional Animal Care and Use Committee, charged with oversight of animal care and use in research. NIH, *The Institutional Animal Care and Use Committee*. Accessed on October 17, 2024.

[26] We use the term "biospecimen" in this report when the information is generally applicable to all biospecimens, such as in the background and certain findings. We use the term "human biospecimen" when referring to specific data points or information relevant to only human biospecimens.

[27] We also asked recipients whether they have used or currently use select agents as part of the Federal Select Agents Program, and 2 of these 23 respondents answered affirmatively to this question. The Federal Select Agents Program is jointly overseen by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture. As part of their oversight, these agencies assess recipients' emergency plans.

[28] Six of the 23 recipients reported at least partially addressing all three of the main areas of emergency planning included in NIH-recommended guidance: assessing risks; developing plans; and training and exercising. An additional 11 reported addressing two of the three main areas.

[29] National Research Council, *Prudent Practices in the Laboratory*. Accessed on April 9, 2024.

[30] NCI's Best Practices for Biospecimen Resources include monitoring and alarm systems. However, we did not prompt recipients to indicate which NIH Institutes and Centers (e.g., NCI) fund their research. Therefore, we cannot determine if these recipients' emergency plans were informed by NCI's guidance.

[31] Three of these nine recipients also reported using monitoring or alarm systems on storage equipment to alert laboratory personnel if temperatures fluctuated.

[32] Four additional recipients experienced emergencies during our review period and reported not losing any human biospecimens during these emergencies, but they attributed this to the emergencies not impacting their buildings or labs.

[33] FEMA, *The Importance of Local Damage Assessment Lesson 4: Training and Exercising*. Accessed on February 21, 2025.

[34] National Research Council, *Prudent Practices in the Laboratory*. Accessed on April 9, 2024.

[35] National Research Council, *Prudent Practices in the Laboratory*. Accessed on April 9, 2024.

[36] Congressional funding for research is sometimes tied to emergencies. For example, NIH received $4.8 billion for COVID-19-related activities. U.S. Public Health Service, *COVID-19 Supplemental Appropriations in the 116th Congress*. Accessed on October 10, 2024.

[37] Seven recipients experienced an emergency but did not report any negative effects to us.

[38] The annual reporting process is also called the Research Performance Progress Report (RPPR). Recipients are required to submit this report and have it approved annually for each grant to continue their funding. A required section gives recipients the opportunity to describe any challenges or delays encountered during the reporting period and describe plans to resolve those challenges or delays. This section is among many others in RPPRs, such as accomplishments, budget, and outcomes.

[39] NIH, *Administrative Supplements.* Accessed on February 21, 2025.

[40] Jeannie Baumann, "Pandemic Cost NIH $16 Billion in Delayed, Lost Medical Research," *Bloomberg Law*. Accessed on February 15, 2023.

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Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

How Does It Help?

Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

Who Is Protected?

Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

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