

# TERASAKI INSTITUTE FOR BIOMEDICAL INNOVATION

## INTERNAL CONTROL AND COMPLIANCE REPORTS

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December 31, 2021

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**INDEPENDENT AUDITORS' REPORT ON INTERNAL CONTROL OVER  
FINANCIAL REPORTING AND ON COMPLIANCE AND OTHER MATTERS  
BASED ON AN AUDIT OF FINANCIAL STATEMENTS PERFORMED IN  
ACCORDANCE WITH *GOVERNMENT AUDITING STANDARDS***

To the Board of Directors of  
Terasaki Institute for Biomedical Innovation

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of Terasaki Institute for Biomedical Innovation (a nonprofit organization), which comprise the statements of financial position as of December 31, 2021 and 2020, the related statements of activities, functional expenses, and cash flows for the year then ended, and the related notes to the financial statements, and have issued our report thereon dated September 27, 2022.

**Report on Internal Control Over Financial Reporting**

In planning and performing our audit of the financial statements, we considered Terasaki Institute for Biomedical Innovation's internal control over financial reporting (internal control) as a basis for designing the audit procedures that are appropriate in the circumstances for the purpose of expressing an opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of Terasaki Institute for Biomedical Innovation's internal control. Accordingly, we do not express an opinion on the effectiveness of Terasaki Institute for Biomedical Innovation's internal control.

*A deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. *A material weakness* is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis. *A significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

## **Report on Compliance and Other Matters**

As part of obtaining reasonable assurance about whether Terasaki Institute for Biomedical Innovation's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the financial statements. However, providing an opinion on compliance with those provisions was not an objective of our audit and, accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

### **Purpose of this Report**

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the organization's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the organization's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

A handwritten signature in cursive script that reads "Windes, Inc.".

Long Beach, California  
September 27, 2022

**INDEPENDENT AUDITORS' REPORT ON COMPLIANCE FOR EACH MAJOR PROGRAM AND ON INTERNAL CONTROL OVER COMPLIANCE REQUIRED BY THE UNIFORM GUIDANCE**

To the Board of Directors of  
Terasaki Institute for Biomedical Innovation

**Report on Compliance for Each Major Federal Program**

**Opinion on Each Major Federal Program**

We have audited Terasaki Institute for Biomedical Innovation's compliance with the types of compliance requirements identified as subject to audit in the *OMB Compliance Supplement* that could have a direct and material effect on each of Terasaki Institute for Biomedical Innovation's major federal programs for the year ended December 31, 2021. Terasaki Institute for Biomedical Innovation's major federal programs are identified in the summary of auditors' results section of the accompanying schedule of findings and questioned costs.

In our opinion, Terasaki Institute for Biomedical Innovation complied, in all material respects, with the types of compliance requirements referred to above that could have a direct and material effect on each of its major federal programs for the year ended December 31, 2021.

**Basis for Opinion on Each Major Federal Program**

We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and the audit requirements of Title 2 U.S. *Code of Federal Regulations Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Our responsibilities under those standards and the Uniform Guidance are further described in the Auditors' Responsibilities for the Audit of Compliance section of our report.

We are required to be independent of Terasaki Institute for Biomedical Innovation and to meet our other ethical responsibilities, in accordance with relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion on compliance for each major federal program. Our audit does not provide a legal determination of Terasaki Institute for Biomedical Innovation's compliance with the compliance requirements referred to above.

## **Responsibilities of Management for Compliance**

Management is responsible for compliance with the requirements referred to above and for the design, implementation, and maintenance of effective internal control over compliance with the requirements of laws, statutes, regulations, rules, and provisions of contracts or grant agreements applicable to Terasaki Institute for Biomedical Innovation's federal programs.

## **Auditors' Responsibilities for the Audit of Compliance**

Our objectives are to obtain reasonable assurance about whether material noncompliance with the compliance requirements referred to above occurred, whether due to fraud or error, and express an opinion on Terasaki Institute for Biomedical Innovation's compliance based on our audit. Reasonable assurance is a high level of assurance but is not absolute assurance and, therefore, is not a guarantee that an audit conducted in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance will always detect material noncompliance when it exists. The risk of not detecting material noncompliance resulting from fraud is higher than for that resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Noncompliance with the compliance requirements referred to above is considered material if there is a substantial likelihood that, individually or in the aggregate, it would influence the judgment made by a reasonable user of the report on compliance about Terasaki Institute for Biomedical Innovation's compliance with the requirements of each major federal program as a whole.

In performing an audit in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material noncompliance, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding Terasaki Institute for Biomedical Innovation's compliance with the compliance requirements referred to above and performing such other procedures as we considered necessary in the circumstances.
- Obtain an understanding of Terasaki Institute for Biomedical Innovation's internal control over compliance relevant to the audit in order to design audit procedures that are appropriate in the circumstances and to test and report on internal control over compliance in accordance with the Uniform Guidance, but not for the purpose of expressing an opinion on the effectiveness of Terasaki Institute for Biomedical Innovation's internal control over compliance. Accordingly, no such opinion is expressed.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and any significant deficiencies and material weaknesses in internal control over compliance that we identified during the audit.

## **Report on Internal Control Over Compliance**

*A deficiency in internal control over compliance* exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. *A material weakness in internal control over compliance* is a deficiency, or combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. *A significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of internal control over compliance was for the limited purpose described in the Auditors' Responsibilities for the Audit of Compliance section above and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies in internal control over compliance. Given these limitations, during our audit we did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses, as defined above. However, material weaknesses or significant deficiencies in internal control over compliance may exist that were not identified.

Our audit was not designed for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, no such opinion is expressed.

## **Report on Schedule of Expenditures of Federal Awards Required by the Uniform Guidance**

We have audited the financial statements of Terasaki Institute for Biomedical Innovation as of and for the year ended December 31, 2021 and 2020, and have issued our report thereon dated September 27, 2022, which contained an unmodified opinion on those financial statements. Our audit was performed for the purpose of forming an opinion on the financial statements as a whole. The accompanying schedule of expenditures of federal awards is presented for purposes of additional analysis as required by the Uniform Guidance and is not a required part of the financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the financial statements. The information has been subjected to the auditing procedures applied in the audit of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the schedule of expenditures of federal awards is fairly stated in all material respects in relation to the financial statements as a whole.

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of the Uniform Guidance. Accordingly, this report is not suitable for any other purpose.

*Winder, Inc.*

Long Beach, California  
September 27, 2022



**TERASAKI INSTITUTE FOR BIOMEDICAL INNOVATION**

**SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS  
FOR THE YEAR ENDED DECEMBER 31, 2021**

<u>Federal Grantor/Pass-Through Grantor/Program or Cluster Title</u>	<u>Federal Assistance Listing Number</u>	<u>Federal Expenditures</u>	<u>Amounts Provided to Subrecipients</u>
<b>RESEARCH AND DEVELOPMENT - CLUSTER:</b>			
<b>U. S. Department of Health and Human Services</b>			
National Institute of Health			
National Institute of General Medical Sciences	93.859	\$ 422,036	\$ 218,342
Pass Through:			
Univeristy of Connecticut Health Center	93.859	<u>166,325</u>	<u>-</u>
		<u>588,361</u>	<u>218,342</u>
National Institute of Arthritis and Musculoskeletal and Skin Diseases	93.846	703,727	456,283
Pass Through:			
The Board of Trustees of the University of Illinois	93.846	133,155	-
The Brigham and Women's Hospital, Inc.	93.846	<u>93,700</u>	<u>-</u>
		<u>930,582</u>	<u>456,283</u>
National Heart, Lung, and Blood Institute			
Pass Through:			
The Regents of University of California, Los Angeles	93.837	143,853	-
Mayo Clinic Arizona	93.837	<u>550,805</u>	<u>-</u>
		<u>694,658</u>	<u>-</u>
National Institute of Biomedical Imaging and Bioengineering			
Pass Through:			
The Regents of University of California, Los Angeles	93.286	141,854	-
Mayo Clinic Arizona	93.286	<u>53,458</u>	<u>-</u>
		<u>195,312</u>	<u>-</u>
National Cancer Institute	93.394	213,062	-
Pass Through:			
The Brigham and Women's Hospital, Inc.	93.396	216,537	-
	93.394	<u>203,642</u>	<u>-</u>
		<u>633,241</u>	<u>-</u>
National Center for Advancing Translational Sciences			
Pass Through:			
The Regents of University of California, Los Angeles	93.350	<u>163,236</u>	<u>-</u>
		<u>163,236</u>	<u>-</u>
<b>TOTAL U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES</b>		<u>3,205,390</u>	<u>674,625</u>
<b>U.S. Department of Defense</b>			
Basic Applied Research in Science and Technology			
Pass Through:			
Advanced Regenerative Manufacturing Institute, Inc.	12.630	<u>242,322</u>	<u>-</u>
<b>TOTAL EXPENDITURES OF FEDERAL AWARDS</b>		<u>\$ 3,447,712</u>	<u>\$ 674,625</u>

**TERASAKI INSTITUTE FOR BIOMEDICAL INNOVATION**

**NOTES TO THE SCHEDULE OF EXPENDITURES OF FEDERAL AWARDS  
FOR THE YEAR ENDED DECEMBER 31, 2021**

**NOTE 1 – Basis of Presentation**

The accompanying schedule of expenditures of federal awards (the Schedule) includes the federal award activity of Terasaki Institute for Biomedical Innovation under programs of the federal government for the year ended December 31, 2021. The information in the Schedule is presented in accordance with the requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Because the Schedule presents only a selected portion of the operations of Terasaki Institute for Biomedical Innovation, it is not intended to and does not present the financial position, changes in net assets, or cash flows of Terasaki Institute for Biomedical Innovation.

**NOTE 2 – Summary of Significant Accounting Policies**

Expenditures reported on the Schedule are reported on the accrual basis of accounting. Such expenditures are recognized following the cost principles contained in the Uniform Guidance, wherein certain types of expenditures are not allowable or are limited as to reimbursement.

Terasaki Institute for Biomedical Innovation has elected not to use the 10 percent de minimis indirect cost rate as allowed under the Uniform Guidance.

**TERASAKI INSTITUTE FOR BIOMEDICAL INNOVATION**

**SCHEDULE OF FINDINGS AND QUESTIONED COSTS  
FOR THE YEAR ENDED DECEMBER 31, 2021**

**SUMMARY OF AUDITORS' RESULTS**

**Financial Statements**

The auditors' report expresses an unmodified opinion on whether the financial statements of Terasaki Institute for Biomedical Innovation were prepared in accordance with generally accepted accounting principles.

***Internal control over financial reporting***

1. Material weakness(es) identified? – No
2. Significant deficiencies identified? – None reported
3. Noncompliance material to financial statements noted? – No

**Federal awards**

***Internal control over major programs***

1. Material weakness(es) identified? – No
2. Significant deficiencies identified? – None reported
3. Type of auditors' report issued on compliance for major programs – Unmodified
4. Any audit findings disclosed that are required to be reported in accordance with 2 CFR Section 200.516(a)? – No
5. Identification of major programs: Research and Development - Cluster, AL No. Various
6. Dollar threshold used to distinguish between type A and type B programs was \$750,000.
7. Auditee qualified as low-risk auditee? – No

**FINDINGS – FINANCIAL STATEMENTS AUDIT**

None

**FINDINGS AND QUESTIONS COSTS – MAJOR FEDERAL AWARD PROGRAMS AUDIT**

None