



IMPACT REPORT 2023

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LETTER FROM THE PRESIDENT

Dear Supporters,

I am happy to present to you the Institute for In Vitro Sciences' (IIVS) 2023 annual report, marking my first year serving as President. It has been an honor to lead the IIVS team through a period of growth and transformation, and I am excited to share with you the progress we have made in advancing new approach methodologies in toxicological research. In addition to my appointment, we welcomed Kristie Sullivan, MPH to our team as the Vice President of Education and Outreach. Under Kristie's leadership, we re-launched our Practical Methods training workshops and are able to offer it multiple times throughout the year to provide hands-on experience with case study discussions to help attendees gain familiarity and comfort with the assays.

IIVS has expanded our testing to offer ToxTracker, a stem-cell based assay to identify hazard and mode-of-action of potentially genotoxic materials. Using the Good In Vitro Method Practices (GIVIMP) guidance document as our quality system, we have standardized our process for preparing and characterizing human precision cut lung slices that are available for purchase and use in both US and international laboratories.

In closing, I extend my heartfelt gratitude to our dedicated staff, partners, and supporters who have contributed to the success of IIVS in the past year.

Together, we are making significant strides towards our shared vision of a day when methods based on humane, human-specific responses will be used by industry and regulatory agencies to determine the safety and efficacy of substances.

Looking Ahead

- Practical Methods trainings for 2024 and early 2025 are filling up fast, so [register soon](#) to reserve your spot.
- IIVS Study Directors are busy transferring new methods like the Reactive Oxygen Species (ROS) assay and nuclear receptor screening assays into our laboratories to offer as GLP-compliant testing services.
- Follow us on [LinkedIn](#) and sign up for our [newsletter](#) to see announcements of webinars, meetings, publications, and all of the latest news from our staff.

Amanda K. Ulrey, RQAP-GLP
President
February 2024

OPERATIONAL HIGHLIGHTS



IIVS's [certification program in Good In Vitro Method Practices \(GIVIMP\)](#) gained momentum in 2023 with 5 facilities currently enrolled in the program and 4 facilities successfully obtaining certification or verification.

IIVS hosted the 8th and 9th workshops in the In Vitro Workshop series focused on *in vitro* methodologies for genetic and other toxicity assessments of tobacco and nicotine products.

More information on this workshop series can be found in our [latest newsletter](#).

DRUG TESTING AND ANALYSIS

SPECIAL ISSUE - RESEARCH ARTICLE | [Open Access](#) | [CC](#) [BY](#) [NC](#) [ND](#)

Key challenges for in vitro testing of tobacco products for regulatory applications: Recommendations for dosimetry

Jacqueline Miller-Holt [✉](#), Holger Behrsing, Ian Crooks, Rodger Curren, Kubilay Demir, Jeremie Gafner, Gene Gillman, Michael Hollings, Robert Leverette, Michael Oldham, Liam Simms ... [See all authors](#)

Alternatives to Laboratory Animals

Impact Factor: 2.7
 5-Year Impact Factor: 2.2

[JOURNAL HOMEPAGE](#)
[SUBMIT PAPER](#)

Restricted access | Research article | First published online February 23, 2023

Key Challenges and Recommendations for *In Vitro* Testing of Tobacco Products for Regulatory Applications: Consideration of Test Materials and Exposure Parameters

Martha M. Moore, Irene Abraham [ORCID](#), and Rodger Curren [ORCID](#) [View all authors and affiliations](#)

Volume 51, Issue 1 | <https://doi.org/10.1177/02611929221146536>

The [EPIC webinar series](#) on the Use of NAMs in Risk Assessment was launched in partnership with the US Environmental Protection Agency, PETA Science Consortium International, and the California Department of Pesticide Regulation. These quarterly webinars consistently draw more than 250 participants.



Dr. Vivek Patel and Dr. Carlos Rodríguez successfully lead the effort for IIVS to become a certified provider of the ToxTracker and ACE methodologies, developed by Toxys.

EDUCATION AND OUTREACH

The word of the year in 2023 was confidence. How can we increase regulators' confidence in using non-animal methods? IIVS Education and Outreach activities are targeted to this need by providing training, expert advice, and leadership.

Practical Methods Trainings



Practical Methods
TRAINING IN NEW APPROACHES FOR RIGHT NOW

- Held 4-day, hands-on trainings in January, July, and September of 2023. Participants included reviewers and decision-makers from EPA, FDA, CPSC, and ANVISA as well as industry safety assessors and academics.



- Organized a 1-day seminar for approximately 80 safety assessors of cosmetics with the German Society for Cosmetic Science in Frankfurt, Germany.

“The IIVS practical methods training was tailored on my actual needs and learning objectives, beautifully linking the hands-on experience that I was lacking with the big-picture perspective on how to work together with different stakeholders towards good safety decisions.”

Legislative Panel and Media Event

In July IIVS partnered with the Humane Society of the United States to host Maryland state legislators and the media in support of a general assembly bill passed this year that will

provide grants to Maryland scientists who develop and optimize non-animal-based research methods. See the coverage of this first-of-its-kind legislation on [WBALTV](https://www.wbal.com/story/news/2023/07/20/maryland-lab-at-forefront-of-using-alternative-to-animal-testing-for-research/7048444002/).

Maryland lab at forefront of using alternative to animal testing for research

Institute for In Vitro Sciences conducts tests using human-relevant models for products, ingredients

Share   

WBALTV 

Updated: 5:35 PM EDT Jul 20, 2023

Webinars

- Study Director Allison Hilberer presented in a 2-part webinar series on [phototoxicity testing](#).
- Study Director Dr. Argel Islas-Robles presented in a 2-part series on the [derivation of a point of departure from in vitro methods for use in skin sensitization](#).
- Kristie Sullivan hosted the Dynamic Discussions webinar series with PCRM and Unilever.

International Outreach Highlights

Dr. Quanshun Zhang travel to China for two extended visits to promote the uptake of non-animal test methods by the government. Highlights include:

- Advising Zhejiang Key Lab for In Vitro Test Methods
- Facilitating progress on domestic production of 3D skin models for skin irritation
- Partnering with UniAsia cosmetics company on training initiatives
- Facilitating validation study of new in-country skin sensitization method EndoSENS
- Updating provincial IFDC agencies on progress in *in vitro* testing during COVID-19 pandemic
- Education on *in vitro* test methods for inhalation



REGULATORY ACCEPTANCE OF NAMS

IIVS outreach activities have direct impact on the regulatory acceptance of non-animal methods. We are often consulted by regulatory agencies to address data analysis challenges or share advances in *in vitro* methodologies.



Organisation for Economic Cooperation and Development

IIVS is particularly active at the OECD. Our experience on validation has led to our involvement in discussions to modernize OECD validation guidance. Our scientists are also serving as technical experts in groups working on new test guidelines for eye irritation, phototoxicity, and skin sensitization. In 2023, we co-led a project to advance non-animal methods for respiratory sensitization and a revision of the Defined Approach for Skin Sensitization guideline to include more test methods.

HESI Botanical Safety Consortium

Hans Raabe, Argel Islas-Robles, and Gertrude-Emilia Costin were invited to participate in the efforts of this consortium to support the advancement of *in vitro* methods botanical safety assessment.

Inaugural ISID Meeting

In May, IIVS Senior Toxicologist and Study Director, Allison Hilberer presented at the inaugural International Society for Investigative Dermatology (ISID) Meeting in Tokyo. There, Allison showcased a collaboration between IIVS, Shiseido and the Research Institute for Fragrance Materials which highlighted the use of New Approach Methodologies to evaluate skin sensitization, photoirritation, and photoallergy potential of test materials.

ICCS UV Filters Working Group

Kristie Sullivan is active in a new working group formed by the International Collaboration on Cosmetic Safety to facilitate acceptance of non-animal approaches to assess the safety of UV Filters.

Skin Irritation Methods for Pesticides

Hans Raabe, Gertrude-Emilia Costin, and Kristie Sullivan are leading an effort to outline the science behind skin irritation, to connect regulatory needs for pesticide formulation assessment to the evidence behind available *in vitro* methods.

TESTING SERVICES SUMMARY

Tradeshows

IIVS exhibited at several tradeshows in 2023 in an effort to connect with our community routinely using *in vitro* methods and those groups who might be new to using *in vitro* methods. Look for us at these and other meetings in the future: Society of Toxicology, Personal Care Products Council, EuroTox, World Congress, the American Society for Cellular and Computational Toxicology, American College of Toxicology, and the Household Cleaning Products Association.

DEA Schedule 1 Certification

Our laboratory has acquired the State and Federal licenses required to work with several materials and compounds listed on DEA schedule 1. Read our [newsletter](#) for further details.

List of Manuscripts from 2023

[Promoting New Approach Methodologies \(NAMs\) for research on skin color changes in response to environmental stress factors: tobacco and air pollution](#)

[Key Challenges and Recommendations for In Vitro Testing of Tobacco Products for Regulatory Applications: Consideration of Test Materials and Exposure Parameters](#)

[Key Challenges for In Vitro Testing of Tobacco Products for Regulatory applications: Recommendations for Dosimetry](#)

[Key Challenges for In Vitro Testing of Tobacco Products for Regulatory Applications: Recommendations for the In Vitro Mouse Lymphoma Assay](#)

[Cryopreserved human precision-cut lung slices provide an immune competent pulmonary test system for “on-demand” use and long-term cultures](#)

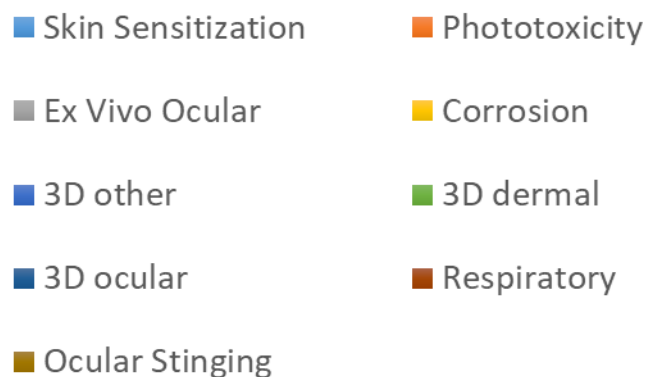
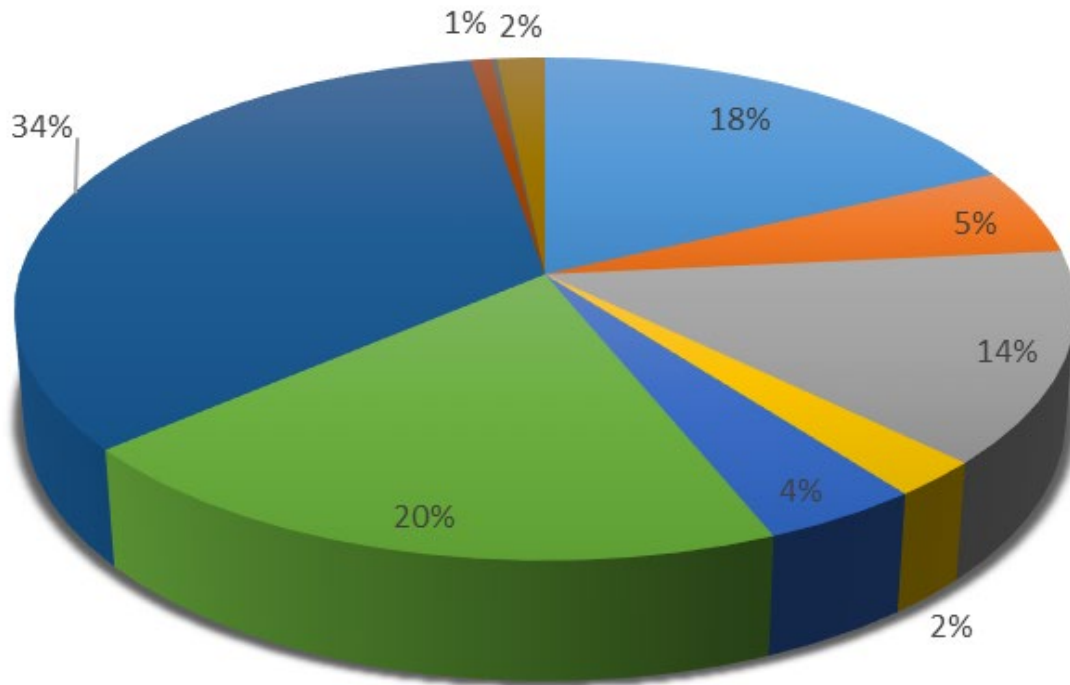
Posters from 2023

IIVS staff published several posters at meetings throughout 2023. Visit our [website](#) for access to all of our scientists' work.

TESTING SERVICES SUMMARY

2023 Research and Testing Program Summary

In 2023, over half of the studies performed in our laboratory used a 3-dimensional tissue construct as the test system. The pie chart below summarized the number of contract studies performed in each program. In addition to testing services, IIVS now also processes and characterizes [human precision-cut lung slices](#). This program saw excellent growth in 2023 as more groups utilized them to perform testing in their own laboratories, preventing the use of animals.



2022 AUDITED FINANCIAL REPORT

** PUBLIC DISCLOSURE COPY **

Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except private foundations)

Do not enter social security numbers on this form as it may be made public.

Go to www.irs.gov/Form990 for instructions and the latest information.

OMB No. 1545-0047

2022

Open to Public Inspection

A For the 2022 calendar year, or tax year beginning and ending

B Check if applicable:	C Name of organization INSTITUTE FOR IN VITRO SCIENCES, INC. Doing business as Number and street (or P.O. box if mail is not delivered to street address) Room/suite 30 W WATKINS MILL RD 100 City or town, state or province, country, and ZIP or foreign postal code GAITHERSBURG, MD 20878 F Name and address of principal officer: AMANDA K. ULREY SAME AS C ABOVE	D Employer identification number 52-2029668 E Telephone number (301) 947-6523 G Gross receipts \$ 6,861,123. H(a) Is this a group return for subordinates? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> H(b) Are all subordinates included? Yes <input type="checkbox"/> No <input type="checkbox"/> If "No," attach a list. See instructions H(c) Group exemption number
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I Tax-exempt status: ☒ 501(c)(3) 501(c) () (insert no.) 4947(a)(1) or 527

J Website: WWW.IIVS.ORG

K Form of organization: ☒ Corporation Trust Association Other **L Year of formation:** 1997 **M State of legal domicile:** MD

Part I Summary

Activities & Governance	1 Briefly describe the organization's mission or most significant activities: TO INCREASE THE USE AND ACCEPTANCE OF NON-ANIMAL TEST METHODS WORLDWIDE. 2 Check this box <input type="checkbox"/> if the organization discontinued its operations or disposed of more than 25% of its net assets. 3 Number of voting members of the governing body (Part VI, line 1a) 3 8 4 Number of independent voting members of the governing body (Part VI, line 1b) 4 5 5 Total number of individuals employed in calendar year 2022 (Part V, line 2a) 5 60 6 Total number of volunteers (estimate if necessary) 6 5 7a Total unrelated business revenue from Part VIII, column (C), line 12 7a 0. 7b Net unrelated business taxable income from Form 990-T, Part I, line 11 7b 0.																									
Revenue		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Prior Year</th> <th>Current Year</th> </tr> </thead> <tbody> <tr> <td>8 Contributions and grants (Part VIII, line 1h)</td> <td>1,949,651.</td> <td>1,077,048.</td> </tr> <tr> <td>9 Program service revenue (Part VIII, line 2g)</td> <td>4,553,806.</td> <td>5,782,738.</td> </tr> <tr> <td>10 Investment income (Part VIII, column (A), lines 3, 4, and 7d)</td> <td>13.</td> <td>83.</td> </tr> <tr> <td>11 Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)</td> <td>0.</td> <td>897.</td> </tr> <tr> <td>12 Total revenue - add lines 8 through 11 (must equal Part VIII, column (A), line 12)</td> <td>6,503,470.</td> <td>6,860,766.</td> </tr> </tbody> </table>		Prior Year	Current Year	8 Contributions and grants (Part VIII, line 1h)	1,949,651.	1,077,048.	9 Program service revenue (Part VIII, line 2g)	4,553,806.	5,782,738.	10 Investment income (Part VIII, column (A), lines 3, 4, and 7d)	13.	83.	11 Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)	0.	897.	12 Total revenue - add lines 8 through 11 (must equal Part VIII, column (A), line 12)	6,503,470.	6,860,766.						
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Part II Signature Block

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than officer) is based on all information of which preparer has any knowledge.

Sign Here	Signature of officer AMANDA K. ULREY, PRESIDENT Type or print name and title	Date
Paid Preparer Use Only	Print/Type preparer's name AMANDA E. WATERHOUSE Preparer's signature <i>Amanda E. Waterhouse</i> Date 11/01/23 Check if self-employed <input type="checkbox"/> PTIN P02014004 Firm's name RSM US LLP Firm's EIN 42-0714325 Firm's address 230 N ELM ST, STE 1100 GREENSBORO, NC 27401 Phone no. 336-272-4551	

May the IRS discuss this return with the preparer shown above? See instructions ☒ Yes ☐ No

232001 12-13-22 LHA For Paperwork Reduction Act Notice, see the separate instructions. Form 990 (2022)

Electronic Filing and Payment Authorization



Taxpayer Name: INSTITUTE FOR IN VITRO SCIENCES, INC. Tax Period Ending: 12/31/22
 Tax ID No: 52-2029668 Return ☒ Extension ☐
 Tax Type Income / Franchise ☐ Composite ☐ Nonresident Withholding ☐ Information Returns ☐
 Excise ☐ Sales / Use ☐ Property ☐ Other ☒ specify: 990

Jurisdiction(s) where tax return(s) or request(s) for extension will be filed electronically:

Fed <input checked="" type="checkbox"/>	DC <input type="checkbox"/>	IA <input type="checkbox"/>	MN <input type="checkbox"/>	NM <input type="checkbox"/>	RI <input type="checkbox"/>	WA <input type="checkbox"/>
AL <input type="checkbox"/>	DE <input type="checkbox"/>	KS <input type="checkbox"/>	MS <input type="checkbox"/>	NY <input type="checkbox"/>	SC <input type="checkbox"/>	WV <input type="checkbox"/>
AK <input type="checkbox"/>	FL <input type="checkbox"/>	KY <input type="checkbox"/>	MO <input type="checkbox"/>	NC <input type="checkbox"/>	SD <input type="checkbox"/>	WI <input type="checkbox"/>
AZ <input type="checkbox"/>	GA <input type="checkbox"/>	LA <input type="checkbox"/>	MT <input type="checkbox"/>	ND <input type="checkbox"/>	TN <input type="checkbox"/>	WY <input type="checkbox"/>
AR <input type="checkbox"/>	HI <input type="checkbox"/>	ME <input type="checkbox"/>	NE <input type="checkbox"/>	OH <input type="checkbox"/>	TX <input type="checkbox"/>	
CA <input type="checkbox"/>	ID <input type="checkbox"/>	MD <input type="checkbox"/>	NV <input type="checkbox"/>	OK <input type="checkbox"/>	UT <input type="checkbox"/>	
CO <input type="checkbox"/>	IL <input type="checkbox"/>	MA <input type="checkbox"/>	NH <input type="checkbox"/>	OR <input type="checkbox"/>	VT <input type="checkbox"/>	
CT <input type="checkbox"/>	IN <input type="checkbox"/>	MI <input type="checkbox"/>	NJ <input type="checkbox"/>	PA <input type="checkbox"/>	VA <input type="checkbox"/>	

Jurisdiction(s) (please list):

Declaration and Signature Authorization of Taxpayer's Authorized Representative

Under penalties of perjury, I declare with respect to the returns, forms and instructions prepared by RSM on 11/1/23 (i) I am the taxpayer or an officer, partner, member, manager, or other authorized representative of the above named taxpayer, (ii) I am authorized to sign and file the tax return(s) on behalf of the taxpayer, (iii) I have reviewed the tax return(s), including accompanying schedules and statements, estimated tax forms and required payment amounts, or request(s) for an extension to file the tax return(s), and each of them is true, correct and complete to the best of my knowledge and belief and (iv) I hereby authorize RSM US LLP to electronically file the tax return(s) or request(s) for an extension to file the tax return(s). On behalf of the above-named taxpayer:

- I consent to RSM and its authorized transmitters or intermediate service providers sending the return(s) or request(s) for an extension to the appropriate taxing authorities and receiving from those authorities (a) an acknowledgement of receipt or reason for rejection of the transmission, and (b) any other communication relating to such request(s).
- To the extent the information has been entered on the filing instructions and respective tax filing(s), I authorize and direct RSM to provide to said tax authorities the taxpayer's bank routing and account information for the purpose of making an electronic funds transfer for the payment of the taxpayer's tax liabilities in connection with the electronic filing of any return or request for an extension of the time to file.
- I consent to RSM creating an online account with the applicable taxing authorities on behalf of the taxpayer to enable the transmission and filing of the return(s) and tax form(s).

I understand that RSM may in some cases be required to include the taxpayer's identification number (e.g., social security number or tax identification number) as part of the electronic file to e-file certain tax return or extensions for the above-named taxpayer in certain jurisdictions. If the taxpayer's identification number is required, I hereby authorize RSM to include the number for that purpose.

DocuSigned by: 	November 2, 2023	Amanda Ulrey	President
SIGNATURE	DATE	NAME (PRINT)	TITLE

Form 8879-TE Department of the Treasury Internal Revenue Service	IRS e-file Signature Authorization for a Tax Exempt Entity For calendar year 2022, or fiscal year beginning _____, 2022, and ending _____, 20____ Do not send to the IRS. Keep for your records. Go to www.irs.gov/Form8879TE for the latest information.	OMB No. 1545-0047 <div style="font-size: 2em; font-weight: bold;">2022</div>
Name of filer INSTITUTE FOR IN VITRO SCIENCES, INC.		EIN or SSN 52-2029668
Name and title of officer or person subject to tax AMANDA K. ULREY PRESIDENT		

Part I Type of Return and Return Information

Check the box for the return for which you are using this Form 8879-TE and enter the applicable amount, if any, from the return. Form 8038-CP and Form 5330 filers may enter dollars and cents. For all other forms, enter whole dollars only. If you check the box on line 1a, 2a, 3a, 4a, 5a, 6a, 7a, 8a, 9a, or 10a below, and the amount on that line for the return being filed with this form was blank, then leave line 1b, 2b, 3b, 4b, 5b, 6b, 7b, 8b, 9b, or 10b, whichever is applicable, blank (do not enter -0-). But, if you entered -0- on the return, then enter -0- on the applicable line below. Do not complete more than one line in Part I.

1a Form 990 check here <input checked="" type="checkbox"/>	b Total revenue, if any (Form 990, Part VIII, column (A), line 12) _____	1b <u>6,860,766.</u>
2a Form 990-EZ check here <input type="checkbox"/>	b Total revenue, if any (Form 990-EZ, line 9) _____	2b _____
3a Form 1120-POL check here <input type="checkbox"/>	b Total tax (Form 1120-POL, line 22) _____	3b _____
4a Form 990-PF check here <input type="checkbox"/>	b Tax based on investment income (Form 990-PF, Part V, line 5) _____	4b _____
5a Form 8868 check here <input type="checkbox"/>	b Balance due (Form 8868, line 3c) _____	5b _____
6a Form 990-T check here <input type="checkbox"/>	b Total tax (Form 990-T, Part III, line 4) _____	6b _____
7a Form 4720 check here <input type="checkbox"/>	b Total tax (Form 4720, Part III, line 1) _____	7b _____
8a Form 5227 check here <input type="checkbox"/>	b FMV of assets at end of tax year (Form 5227, Item D) _____	8b _____
9a Form 5330 check here <input type="checkbox"/>	b Tax due (Form 5330, Part II, line 19) _____	9b _____
10a Form 8038-CP check here <input type="checkbox"/>	b Amount of credit payment requested (Form 8038-CP, Part III, line 22) _____	10b _____

Part II Declaration and Signature Authorization of Officer or Person Subject to Tax

Under penalties of perjury, I declare that ☒ I am an officer of the above entity or ☐ I am a person subject to tax with respect to (name of entity) _____, (EIN) _____ and that I have examined a copy of the 2022 electronic return and accompanying schedules and statements, and, to the best of my knowledge and belief, they are true, correct, and complete. I further declare that the amount in Part I above is the amount shown on the copy of the electronic return. I consent to allow my intermediate service provider, transmitter, or electronic return originator (ERO) to send the return to the IRS and to receive from the IRS (a) an acknowledgement of receipt or reason for rejection of the transmission, (b) the reason for any delay in processing the return or refund, and (c) the date of any refund. If applicable, I authorize the U.S. Treasury and its designated Financial Agent to initiate an electronic funds withdrawal (direct debit) entry to the financial institution account indicated in the tax preparation software for payment of the federal taxes owed on this return, and the financial institution to debit the entry to this account. To revoke a payment, I must contact the U.S. Treasury Financial Agent at 1-888-353-4537 no later than 2 business days prior to the payment (settlement) date. I also authorize the financial institutions involved in the processing of the electronic payment of taxes to receive confidential information necessary to answer inquiries and resolve issues related to the payment. I have selected a personal identification number (PIN) as my signature for the electronic return and, if applicable, the consent to electronic funds withdrawal.

PIN: check one box only

☒ I authorize RSM US LLP

ERO firm name

to enter my PIN

20878

Enter five numbers, but do not enter all zeros

as my signature on the tax year 2022 electronically filed return. If I have indicated within this return that a copy of the return is being filed with a state agency(ies) regulating charities as part of the IRS Fed/State program, I also authorize the aforementioned ERO to enter my PIN on the return's disclosure consent screen.

☐ As an officer or person subject to tax with respect to the entity, I will enter my PIN as my signature on the tax year 2022 electronically filed return. If I have indicated within this return that a copy of the return is being filed with a state agency(ies) regulating charities as part of the IRS Fed/State program, I will enter my PIN on the return's disclosure consent screen.

Signature of officer or person subject to tax

Amanda Ulrey

Date

November 2, 2023

Part III Certification and Authentication

ERO's EFIN/PIN. Enter your six-digit electronic filing identification number (EFIN) followed by your five-digit self-selected PIN.

69398820814

Do not enter all zeros

I certify that the above numeric entry is my PIN, which is my signature on the 2022 electronically filed return indicated above. I confirm that I am submitting this return in accordance with the requirements of Pub. 4163, Modernized e-File (MeF) Information for Authorized IRS e-file Providers for Business Returns.

ERO's signature RSM US LLP

Date

11/01/23

**ERO Must Retain This Form - See Instructions
Do Not Submit This Form to the IRS Unless Requested To Do So**

LHA For Privacy Act and Paperwork Reduction Act Notice, see instructions.

Form 8879-TE (2022)