

Click® IACUC 7.2

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| Context Help Text |

December 2014

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Page-Level Help

Procedure Pages

Administration of Substances Page

Use this page to add the substances that will be used in the procedure. If the substance already exists in the system, click Add and then select the appropriate substance. If not, you can create a new substance using the Create Substance link.

**Tip:** If you create a new substance, be sure to add it to the procedure.

Protocol Pages

Experiments Page

Use this page to add all your experiments to the protocol. When you add an experiment, you will select the procedures that apply and identify the variations to the selected procedures. You will also specify the number of animals used in the experiment and their pain categories.

**Tip:** If your experiments are similar, speed up the process by adding the first one, then copying and making changes to the copy:

1. Click Copy to the right of the experiment you want to copy.
2. Click the experiment name ending in "- Copy" and make the appropriate changes.
3. Click OK.

Once you have added experiments and related procedures, the experiments table includes links so you can edit the experiment and view procedure details.

Procedure Personnel Assignment Page

Use this page to assign protocol team members to the procedures used in the experiments. You must assign at least one member to each procedure.

**Note:** Review the training information below to ensure protocol team members have the necessary training before assigning them to a procedure.

Animal Justification Page

Use this page to explain why you require the number and types of species used in this protocol.

As you justify the animal usage in this protocol, ensure you have applied the 3Rs of experimentation where possible:

* Reduce animal numbers used
* Refine animal procedures to minimize discomfort as much as possible
* Replace animals in research, teaching, and testing when possible

Alternatives Page

Use this page to record what you have done to find alternatives for procedures causing high pain levels (category D or E).

Using alternatives is one way to apply the 3Rs of experimentation:

* Reduce animal numbers used
* Refine animal procedures to minimize discomfort as much as possible
* Replace animals in research, teaching, and testing when possible

Duplication Page

Use this page to record what you have done to ensure the same research has not already been performed.

Avoiding duplicate research is one way to apply the 3Rs of experimentation:

* Reduce animal numbers used
* Refine animal procedures to minimize discomfort as much as possible
* Replace animals in research, teaching, and testing when possible

Supporting Documents Page

Add any information that you did not include on other pages, for example:

* Flowcharts outlining the flow of research or proposed experiments
* Detailed explanations of science, including scientific notations or graphics
* Clinical trials documents related to the submission
* Other information relevant to the protocol that is not attached elsewhere (e.g., breeding or restraint device details, safety information, or departures from the *Guide*)

These documents will list on the Documents tab of the protocol workspace.

Activity Pages

Add Comment Page

Anyone who can view this submission can see your comment. This includes the protocol team, IACUC staff, and committee members. It may also include ancillary reviewers and other individuals that the protocol team adds to the submission's guest list.

Add Private Comment Page

Private comments only appear in the history log for IACUC staff and committee members. Protocol team members will not see them.

Assign Primary Contact Page

Select the person who will act as the protocol's main point of contact for communications with the IACUC. The primary contact receives notifications, in addition to the Principal Investigator, when the IACUC communicates a decision or requires the protocol team to take action.

**Note:** If the primary contact is engaged in the research, be sure to add that person to the protocol team.

Close Protocol (Admin) Page

Use this activity to close protocols for which active research has ceased, for example, the PI requested closure or the PI has left the institution.

Discard Page

Discarding your submission will permanently remove the submission from the review process. If you wish to remove the submission from the IACUC review process and resubmit it later, use the Withdraw activity instead. Doing so will return the submission to the Pre-Submission state and return it to your inbox.

**Tip:** You can find discarded submissions on the Archived tab of the IACUC Submissions workspace. Archived submissions are read-only, however, you can copy them.


Edit Pre-Review Page

Update information previously provided about this submission. IACUC staff can update pre-review information any time before the committee or designated member review decision is submitted.

Manage Related Safety Protocols Page

Associate safety protocols to the submission, for example, Institutional Biosafety Committee (IBC) or Occupational Health and Safety protocols.

Withdraw Page

Withdrawing your submission removes it from the IACUC review process so you can resubmit it later. The submission will appear in your inbox in the Pre-Submission state.

**Tip:** Use the Discard activity if you wish to permanently remove the submission from the review process. Doing so will move the submission to the Archived tab of the IACUC Submissions workspace. Archived submissions are read-only, however, you can copy them.



Field-Level Help

Research Team Information Page

Team Members

If you are not the PI on the research team, ensure you add yourself as a research team member, if appropriate, so you can create and edit that research team's substances and procedures.

Research team members can create and edit all procedures and substances created by the research team, however, they can only edit submissions (that are in an editable state) for which they are also members of that protocol's team.

Team Default Species

Select the species that will appear by default when research team members create a new procedure or experiment in a protocol. This can save time if the team often works with a particular species.

Substance Information Page

Supporting Documents

Add any substance-related documents, for example:

* Material Safety Data Sheets (MSDS)
* Chemical characteristics and the intended effects and/or side effects of the substance
* Detailed steps for administering the substance

These documents will list on the Documents tab of the substance workspace.

Procedure Pages

Procedure Identification Page

Select Procedure Type

Select the option that reflects the type of procedure. What you select here will affect the remaining pages that appear for this procedure.

Identify Expected Symptoms from Administering This Procedure

List any symptoms you expect as a result of performing this procedure. For example:

* Animals lose weight
* Animals develop lesions due to an open tumor

Identify Criteria under Which Animals Will Be Removed from Research

List any criteria you will use to determine if animals are removed from research. For example:

* Animals are no longer able to move to get food or water
* Animals are lifeless, unresponsive, etc.

Substance Administration Pages

Administration of Substances Page

Description of the Administration Procedure

Describe the procedure for administering the substance to the animal, for example:

If by injection, provide the step-by-step procedure

If supplied in the food, describe the quantities provided and the steps taken to ensure enough food is always present

Add Substance for Procedure Page

Route

Specify where the substance will be introduced into the animal (e.g., oral, intravenous, and subcutaneous).

Survival Surgery Page

Surgery Type

Select whether the surgery is major or minor according to the definitions contained in the *Guide for the Care and Use of Laboratory Animals*. Examples of major and minor surgery include:

* **Major:** Laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation
* **Minor:** Wound suturing, peripheral vessel cannulation, percutaneous biopsy, and most routine procedures performed in a veterinary clinic

Describe how Postoperative Pain and Distress will be Assessed

Include the clinical signs you will use to determine if veterinary care, euthanasia, or another procedure or treatment is needed.

Procedure Documents Page

Supporting Documents

Add any information related to the procedures, for example:

* Pictures or diagrams of procedures
* Detailed steps for performing the procedure

These files will list on the Documents tab of the procedure workspace.

Protocol Pages

Basic Information Page

Select Research Team

If you are on more than one research team, select it in the list. If the research team does not appear in the list, you will need to create it first before creating the protocol. Return to My Inbox and use the Create Research Team activity on the left.

Select Admin Office

Select the admin office within your institution that should oversee or review the protocol.

Short Title

Type a short title for your protocol. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters.

The short title identifies the protocol throughout the IACUC system, for example, in My Inbox.

Summary of Research

Type a short, high-level overview of the research. Include:

* The central question the research is intended to answer
* The primary objectives
* The methods or approach used

For example: This research uses mouse models to study the effects of drug X on early childhood. The general approach is to ...

What is the Intention of the Animal Protocol

Select the option that reflects the nature of the protocol. What you select here will affect the remaining pages that appear for this protocol.

**Important:** If you are doing experimental research with breeding, select **Experimental Research**. On the next page, you can indicate that the research includes breeding.

Experimental Research Protocol Addition Page

Will the Protocol Include Breeding

Indicate if the protocol will include breeding. The answer you specify here will affect the remaining pages that appear for this protocol.

Protocol Team Members Page

Identify Each Additional Person Involved in the Design, Conduct, or Reporting of the Research

When creating the protocol, the research team will list by default, but you can add and delete protocol team members.

**Notes:**

* The PI is specified on the Basic Information page. Do not add that person again here.
* Only the PI, PI proxy, and people on the protocol team can view and edit the protocol. If a research team member is not a protocol team member, that person will not be able to access the protocol.
* If the primary contact is engaged in the research, be sure to add that person to the protocol team.

External Team Member Information

Attach information about protocol team members that are not in the IACUC system (the person is not available for selection in the previous question). External members could be people outside your institution or students or other groups your institution doesn't include in the system.

Important! Do not attach information about team members you were able to select in the previous field. For people listed in the system, member information should be added to their profiles instead.

If you are unsure how to proceed, contact your IACUC staff for assistance.

Funding Sources Pages

Identify Each Organization Supplying Funding for the Protocol

Identify all external funding sources, such as industry sponsors and government agencies. The main purpose is to help the IACUC identify all protocols associated with particular grants. If funding comes from a specific internal funding program, also identify that funding source.

Details about specific questions:

Select the Funding Organization

Sponsor's Funding ID

Grants Office ID

Indicate the Protocol Team Members who Have a Financial Interest in this Research

A protocol team member (including PI) has a financial interest in the research if the person or their immediate family has received anything of value from a funding source, such as:

* Salary or payment for services
* Equity interest (e.g., stocks, stock options, other ownership interest)
* Income related to intellectual property (e.g., patents, copyrights)
* Reimbursed travel expenses

Add Funding Source Page

Select the Funding Organization

If your funding source is new and does not appear in the list, contact the IACUC staff to add it.

Sponsor's Funding ID

Type the ID assigned by the funding organization to identify the award, for example, DAMD17-01-1-0461 or G12AP20082.

Grants Office ID

Type the ID assigned by the internal organization (such as Sponsored Programs Office or Central Office) that manages the proposal/award.

Scientific Aims Page

Scientific Aims of the Research

Type the goals or objectives of the research.

Significance and Benefits of the Research

Explain why the research is important and how society will benefit from the research (e.g., improvement to human or animal health, advancement of knowledge, etc.)

Experiments: Edit Experiment Page

Species

Select the species used in your experiment. The species list indicates if the species is a USDA-covered species. Refer to *Animal Welfare Act Regulations* for the definition of USDA-covered species.

If your research team has a default species set up, that species will already be selected. You can choose a different species if appropriate.

Select Common Procedures

Add the procedures that will be conducted on all animals in the experiment. The list of procedures that appears contains only those procedures for the animals in the experiment.

**Tip:** You can start typing text and the system will list all procedures that contain the typed text.

If a procedure does not appear in the list, go back to the Experiments page and use the Create Procedure link at the top to add it.

Select Variable Procedures

Add the procedures that will be conducted on some animals or conducted differently across animals in the experiment. For example, you might use a substance administration procedure in the experiment, but the doses, routes, or concentrations may vary across animals in the experiment.

The list of procedures that appears contains only those procedures for the species in the experiment.

**Tip:** You can start typing text and the system will list all procedures that contain the typed text.

If a procedure does not appear in the list, go back to the Experiments page and use the Create Procedure link at the top to add it.

Describe the Variables of the Experiment

List and explain the variables (the items that will change) in the variable procedures. Examples include agents (substances), dosages, concentrations, routes, and frequency.

Describe Any Variations to the Procedures Selected

List and explain the variations applied to the procedures. For example, in a substance administration procedure where the dose (variable) will differ across animals, list the dose along with the number of animals that will receive each dose.

Procedure Timing

Specify the order procedures will occur and the interval between performing them.

For example: Perform the following procedures in the order listed. Each procedure is performed immediately after the previous one is completed. Repeat for each animal in the experiment.

* Procedure #1. Aerosol administration of agents
* Procedure #2. Non-invasive Plethysmography (Pulmonary Function Testing)
* Procedure #3. Invasive pulmonary function testing

Number of Animals by Pain Category

Type the number of animals in each USDA pain category. Include each animal in only one pain category, the highest pain category applicable. The numbers must add up to the total number of animals in the experiment.

* **Pain Category B:** Animals are those that are being "bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes." These animals have not been used for any research procedure, however minor.
* **Pain Category C:** Animals are not subjected to procedures that involve pain or distress or would require the use of pain-relieving drugs. Routine procedures such as injections and blood sampling from veins that produce only mild, transient pain or discomfort are reported in this category.
* **Pain Category D:** Animals are those subjected to potentially painful procedures for which anesthetics, analgesics, or tranquilizers will be used. The important concept is that animals are given appropriate anesthesia and/or pain relief to limit their pain and distress as much as possible.
* **Pain Category E:** Animals are those that are subjected to painful or stressful procedures without the use of anesthetics, analgesics, or tranquilizers. Withholding of anesthetics, analgesics, or tranquilizers can only be allowed if it is scientifically justified in writing and approved by the IACUC.

Supporting Documents

Add any information related to the experiments, for example:

* Methods of alleviating pain and distress, monitoring criteria, and schedules
* Details about husbandry exceptions, exception schedules, monitoring criteria, or weight loss justification

These documents will list on the Documents tab of the protocol workspace.

Procedure Personnel Assignment Page

Select the Team Members Who Will Be Performing This Procedure

Review the training information on the Procedure Personnel Assignment page to ensure protocol team members have the necessary training before assigning them to a procedure.

Animal Justification Page

Click Update to Indicate the Actual Number of Animals to be Used or Produced

The table shows the total number of animals reported across experiments for each pain category, by species. If you will be producing more animals than the number to be used in your experiments or reusing animals across experiments, then update the actual animal count for the highest pain category.

For example: Two experiments will use the same five animals. In the first experiment, the animals will be in pain category B. In the next experiment, the same animals will be in pain category C. Type 0 for the actual animal count for pain category B and 5 for pain category C.

Supporting Documents

Add any information that helps justify the numbers and/or types of species used in the protocol. These documents may elaborate on how you have applied the 3Rs of experimentation:

* Reduce animal numbers used
* Refine animal procedures to minimize discomfort as much as possible
* Replace animals in research, teaching, and testing when possible

Edit Animal Count Page

Indicate the Actual Number of Animals to be Used or Produced

Type the actual number to be used or produced under the highest pain category.

For example: If the same animals are used in multiple experiments with different pain categories, count these animals only once under the highest pain category. If all the animals are accounted for in their highest pain category, type 0 in the remaining pain categories.

Holding Details Page

Describe the Holding Duration and the Reasons for Holding the Animals

Explain how long the animals will be held and why the holding protocol is required. You may wish to reference your institution's standard operating procedures (SOPs) or explain any departures from the SOPs.

For example, "Animals are being transferred to this holding protocol while a renewal is being processed. Animals will be housed only; no research will take place. It is anticipated that the holding protocol will only be required for 14 days.”

Annual and Triennial Review Pages

Describe any Unanticipated Results Involving Animal Health

Examples of unanticipated results are:

* The number of animals required was higher than initially anticipated
* Actual experiment results were different than expected

You could also list a summary of amendments submitted during the current review period and reasons for them.

Amendment Pages

Amendment Short Title

Type a short title that identifies the amendment, for example, protocol team changes or increase in pain categories. As a guideline, keep it shorter than 50 characters.

The short title identifies the amendment throughout the IACUC system.

Select the Type of Amendment

Select one or both amendment types to reflect the changes you are making to the protocol..

Examples of amendment types include:

* **Significant:** Major changes to a protocol, such as, changes to the following items:
* Scientific aims (purpose/objectives) of the protocol
* Principal Investigator (PI)
* Degree of invasiveness of a procedure or pain/distress to an animal
* Species to be studied
* Methods of euthanasia
* Duration, frequency, or number of procedures performed on an animal
* Anesthetics or analgesics
* **All Other:** Minor changes to a protocol, such as changes to the protocol title, funding sources, or personnel (except PI).

Describe the Changes

Write only a brief overview of the changes here. On subsequent pages, you can change the protocol document as necessary.

Concern Pages

Basic Information Page

Name

Type a name that will distinguish this concern from others in the system, for example, "Animals screeching loudly several nights" or "Swine cages not cleaned for days." As a guideline, keep it shorter than 50 characters.

The name identifies the concern throughout the IACUC system.

Select the Category

Choose the category that describes the concern. Administration refers to anything that does not affect the animal's well-being, for example, missing information on cage cards or paint peeling in a lab. Animal welfare refers to anything that may affect the animal's well-being, for example, overcrowding of animals in cages.

Select the Source

Select the source of this concern. Concerns can arise as a result of facility inspections, IACUC program reviews, or audits of approved protocols. Additionally, a user can submit a concern at any time that is not related to a specific IACUC event (ad hoc).

Is This a Deficiency

Refer to your institution's policies for determining if a concern is actually a deficiency.

Identification Page

Describe the Concern

Provide specific and verifiable details that will help the IACUC investigate your concern. Include the following information if available:

Personnel involved

Protocol details

Location and time of concern

Animals affected

Deficiency Details Page

Identify the Severity

A significant deficiency is one that may or does cause harm to the animal's health or safety. Refer to your institution's policies for determining if a deficiency is minor or significant.

Is This a Repeat Deficiency

Refer to your institution's policies for determining if a deficiency is a repeat deficiency.

Inspection Pages

Inspection Information Page

Name

Type a name that will distinguish this inspection from others in the system, for example, "2014 June - Lab East Inspection". As a guideline, keep it shorter than 50 characters.

The name identifies the inspection throughout the IACUC system.

Select Inspection Locations

To find a particular location, filter the list by the building name to see the rooms for that building.

For examples and a list of operators you can use, click the Help icon.



Select Inspectors

Select IACUC committee members to perform the inspection. For facility inspections, if the facility houses USDA-covered species, then two inspectors are required. If not, then only one inspector is required.

Supporting Documents

Add any inspection document, for example:

Completed checklists

Images or photos of areas or items inspected

These documents will list on the Documents tab of the inspection workspace.

PAM Audit Page

Select Protocols to Be Audited

Select from the list of approved protocols that you want to audit.

Activity Pages

Concern Activity Pages

Submit Page

Select the Committee

Select the IACUC committee that should review the concern.

Submit Response Page

Clarification Response

Text added here does not become part of the concern but rather the concern history.

Clarification Response Documents

Documents added here do not become part of the concern but rather the concern history.

Submit Committee Determination Page

Is This a Deficiency

Refer to your institution's policies for determining if a concern is actually a deficiency.

Severity

A significant deficiency is one that may or does cause harm to the animal's health or safety. Refer to your institution's policies for determining if a deficiency is minor or significant.

Category

Choose the category that describes the concern. Administration refers to anything that does not affect the animal's well being, for example, missing information on cage cards or paint peeling in a lab. Animal welfare refers to anything that may affect the animal's well being, for example, overcrowding of animals in cages.

Comments

Comments added here do not become part of the concern but rather the concern history.

Supporting Documents

Documents added here do not become part of the concern but rather the concern history.

Inspections Activity Page

Inspection Documents

Documents added here do not become part of the inspection but rather the inspection findings. You can view these documents on the inspection's Findings tab.

Protocol Activity Pages

Manage Departures: Add Departure Page

Type

Select the item or area that departs from the Guide for the Care and Use of Laboratory Animals.

Submit Committee and Designated Review Pages

Last Day of Annual Review Period

Specify the last day of the annual review period. Typically, this is: Date of Approval + 1 Year - 1 Day

**Note:** If the next review for a submission is a triennial review, then set the last day of the annual review to be in the year after the last day of the triennial review period. The last day of the annual review period should not be in the same year as the triennial review.

If your institution does not require an annual review for all protocols, leave this field blank for protocols without USDA-covered species.

Last Day of Triennial Approval Period

Specify the last day of the triennial approval period. Typically, this is: Date of Approval + 3 Years - 1 Day

**Note:** If your institution requires an annual review, then set the last day of the annual review to be in the year after the last day of the triennial review period. The last day of the annual review period should not be in the same year as the triennial review.

Approval Date

Specify the date the IACUC decision was made. If you are submitting a committee review, select the date the committee made the decision, not the date that you are submitting the committee review.

Identify the Modifications Required or the Reasons for Withholding Approval

If the determination selected was the following, then:

**Approval Withheld:** Type the reasons the IACUC committee withheld approval

**Modifications Required...:** Type the changes required to the submission before it can be approved

Your description will be used:

In the determination letter sent to the investigator

In the protocol history that is visible to protocol team members

By an IACUC coordinator or other reviewer to verify the necessary changes were made to the submission

If Modifications are Required, Enter Them

If the determination selected was "Modifications Required...", then the information you include here will be used:

In the determination letter sent to the investigator

In the protocol history that is visible to protocol team members

By an IACUC coordinator or other reviewer after changes are made to verify that the changes meet your requirements

Submit Pre-Review Page

Forward Directly to Full Committee Review

Implications of this choice:

**Yes:** Moves the submission to the Meeting Assignment state so the IACUC coordinator can assign it to an IACUC meeting for review.

**No:** If the submission will not be forwarded directly to a full committee review, it will move to the Grace Period state so IACUC committee members can review it and determine whether it should go to full committee review.

Pre-Review Documents

Documents added here do not become part of the submission but rather the submission review. You can view these documents on the submission's Reviews tab.

Are You Ready to Submit This Pre-Review

Implications of this choice:

**Yes:** If this submission will be forwarded directly to a full committee review, then submitting the pre-review will move the submission to the Meeting Assignment state so the IACUC coordinator can assign it to an IACUC meeting for review. If the submission will not be forwarded directly to a full committee review, it will move to the Grace Period state so IACUC committee members can review it and determine whether it should go to full committee review.

**No:** Enables you to return and finish the review at another time (by clicking the activity again).

**Note:** After submitting the pre-review, an IACUC coordinator can change some of the pre-review information by clicking Edit Pre-Review. This is possible until the decision from a designated member or committee review is submitted.

Comments

Comments added here do not become part of the submission but rather the submission history.

Supporting Documents

Documents added here do not become part of the submission but rather the submission history.

File Mappings to Topic IDs

The following entries show the mapping of files to topic IDs. The file names should be reasonably easy to associate with topics shown earlier in this document. The topic IDs are used in the product to map a view or attribute to a help topic using the ClickIACUCHelpMap custom data type (CDT). You can override the current help topic using the ClickCustomHelpMap CDT. For more details, see the *IACUC Deployment Guide*.

**Tip:** Some help topics are mapped to multiple views, so make sure you check the ClickIACUCHelpMap CDT for IDs that are used more than once.

<Map Name="AddCommentPage" Link="PageLevelHelp/ActivityPages/AddCommentPage.htm" Skin="HTML5fieldHelp" ResolvedId="4038" />

<Map Name="AddPrivateCommentPage" Link="PageLevelHelp/ActivityPages/AddPrivateCommentPage.htm" Skin="HTML5fieldHelp" ResolvedId="4041" />

<Map Name="AdministrationOfSubstancesPage" Link="PageLevelHelp/ProcedurePages/AdministrationOfSubstancesPage.htm" Skin="HTML5fieldHelp" ResolvedId="4022" />

<Map Name="AlternativesPage" Link="PageLevelHelp/ProtocolPages/AlternativesPage.htm" Skin="HTML5fieldHelp" ResolvedId="4051" />

<Map Name="AmendmentShortTitleField" Link="FieldLevelHelp/Amendments/AmendmentShortTitleField.htm" Skin="HTML5fieldHelp" ResolvedId="4059" />

<Map Name="AnimalJustificationPage" Link="PageLevelHelp/ProtocolPages/AnimalJustificationPage.htm" Skin="HTML5fieldHelp" ResolvedId="4045" />

<Map Name="AnimalJustificationSupportingFilesField" Link="FieldLevelHelp/Protocols/AnimalJustification/SupportingDocsAnimalJustificationField.htm" Skin="HTML5fieldHelp" ResolvedId="4043" />

<Map Name="AntibodyProductionSupportingDocumentsField" Link="FieldLevelHelp/Protocols/AntibodyProduction/SupportingDocumentsAntibodyField.htm" Skin="HTML5fieldHelp" ResolvedId="4048" />

<Map Name="ApprovalDateField" Link="FieldLevelHelp/Activities/SubmitCommitteeAndDesignatedReview/ApprovalDateField.htm" Skin="HTML5fieldHelp" ResolvedId="4055" />

<Map Name="AssignPrimaryContactPage" Link="PageLevelHelp/ActivityPages/AssignPrimaryContactPage.htm" Skin="HTML5fieldHelp" ResolvedId="4040" />

<Map Name="ClickUpdateToIndicateActualNumbersField" Link="FieldLevelHelp/Protocols/AnimalJustification/ClickUpdateToIndicateActualNumberOfAnimalsField.htm" Skin="HTML5fieldHelp" ResolvedId="4062" />

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Published by Huron Technologies Inc.
1925 NW AmberGlen Pkwy

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