TISSUE IR

There are two primary differences between a tissue protocol in 3.6.4 and 4.0:

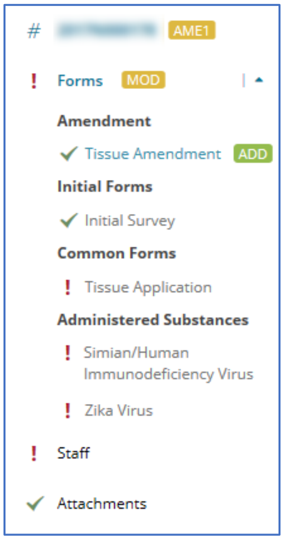
1) the Tissue application is slightly more detailed in the information required
2) the approved Tissue protocol can be amended for study staff, tissue source(s), and sponsor(s).

TISSUE APPLICATION COMPARISON

TISSUE APPLICATION 4.0 FIELD	TISSUE APPLICATION 3.6.4 FIELD	NOTE
A. Purpose of tissue study	B. Purpose	
B. Tissue origin (species)	C. Species	
		• If origin is “sheep,” must choose “SPF sheep” or “Non-SPF sheep”
C. Animal donation-treatment		Options are: • Treated with a biological agent regardless of their pathogenicity to humans • Treated with a select biological toxin • Treated/altered using recombinant and synthetic nucleic acid molecules • None of the above
D. Tissue requested	D. Type	Options are: • Blood, serum, or plasma • Other body fluids • Whole or partial organ, or other tissue • Whole body
E. Source of tissue	E. Source	Options are: • Currently approved IACUC protocol at your institution • External collaborator (academic, hospital, industry, etc.) • Licensed biological supply house • Other
Source of tissue = “Currently approved IACUC protocol at your institution”	Internal IACUC protocol number	Must supply • Protocol number • PI name
Source of tissue = “External collaborator”	External collaborator	Must supply • Contact name • Email • Institution
		• Copy of outside IACUC approval
Source of tissue = “Licensed biological supply house”	Biological Supply House	Must supply 1) Name of company providing tissue
Source of tissue = “Other”	Other source	Must supply 2) A description of other source

Bridging-the-Gaps

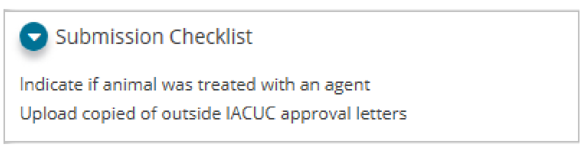
1) The tissue application data is mapped from 3.6.4 to 4.0 as shown in the table above
2) The first time the Submitter clicks **Create Amendment**, the gaps in the protocol – resulting from the migration from 3.6.4 to 4.0 will display (**!**) in the left pane as seen in the screenshot below



3) Complete the Tissue Amendment application description and click [Save]

! Forms

4) Click on the **! Forms** hyperlink in the left pane
5) Click on the hyperlink for any form with a red exclamation mark (**!**) next to it, (i.e., **Tissue Application**, **Simian/Human Immunodeficiency Virus**, and **Zika Virus** as shown in the screenshot above)
6) With the form open, the Submission Checklist – in the right pane – will highlight the question(s) on the form with unfilled validation



7) Answer any unanswered questions on the form and save the form
8) Repeat the steps above until all forms have been completed[1]

! Staff

9) Click on the **! Staff** hyperlink in the left pane; in the center workspace the list of Study Staff will display
10) Click on **Personnel Activity** if the line item has a red exclamation mark (**!**) next to it
    a) Ensure one checkbox option for QUALIFICATIONS AND EXPERIENCE (bottom section of window) has been checked and a training description entered, as required, for the Study Staff

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[1] If a red exclamation point (**!**) continues to display at the **Forms** group level (in the left pane), but only green checkmarks display at the form item level, check the Tissue Amendment form to ensure all questions have been answered.

b) Ensure the checkbox – for the applicable Procedure form – is checked for every form the staff member will be involved in *Note: Each form must have at least one study staff assigned to it to fulfill validation.*

c) Save, then close, the form

11) Repeat the above three steps 10a, 10b, and 10c for each Study Staff member

AMENDING THE PROTOCOL

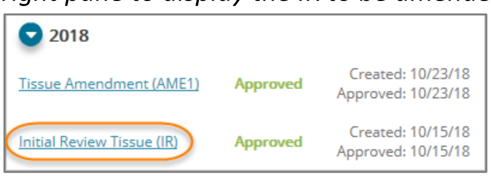
Once all the gaps have been bridged in the protocol you can make the necessary additions to:

- Study staff – Staff / Study Staff or Non-study staff
- Tissue source – Form / Tissue Application
- Sponsor – Related Records / Funding Source

Amending study staff

1) Log into Insight; navigate to Tissue protocols

2) Search for the Tissue IR submission and open it
Note: Approved Tissue IRs have an Overall Status of "Exempt". If the Tissue IR has approved, pending or draft Amendments, click the Initial Review Tissue (IR) hyperlink in the right pane to display the IR to be amended



3) Click the **Create Amendment** action in the left pane to start the Amendment

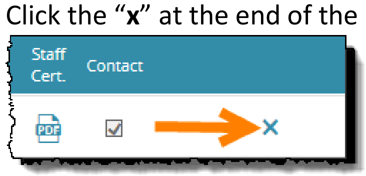
4) In the Tissue Amendment, briefly describe the proposed change(s) to the tissue protocol in the text box; click **[Save]**

5) Click the **Staff** hyperlink in the left pane

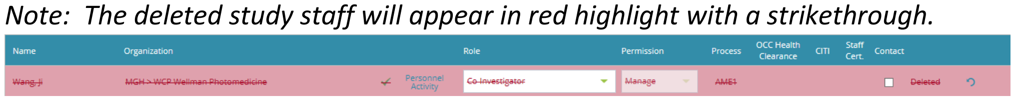
Removing Study Staff

a) Click **Close Panel** in center workspace to expand the area

b) Click the "**x**" at the end of the row of the staff member you wish to remove



c) Click **[OK]** in response to the prompt, "Are you sure you want to delete Lastname, Firstname?"
Note: The deleted study staff will appear in red highlight with a strikethrough.



d) If you wish to **Undo** the deletion, click the ↺ at the end of the row

Adding Study Staff

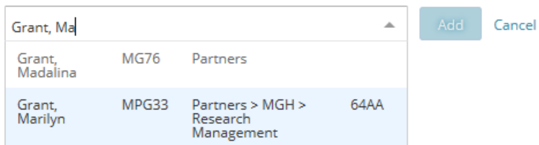
a) Click **Close Panel** in center workspace to expand the area

b) Click the **+ New study Staff** hyperlink

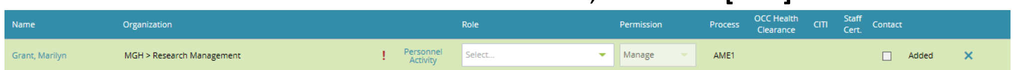
+ New study Staff

c) Begin typing the name of the individual in the search box in *Lastname*, *Firstname* format

Note: As matches are found, they will display in blue highlight below the search box.



d) Click on the desired name to select the individual; then click **[Add]**



e) Select a **Role** for the individual

f) Click on Personnel Activity and select the appropriate description of the individual's Qualifications and Experience

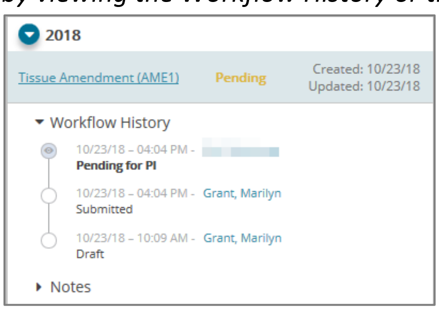
Note: All options, except "extensive experience", require a description.

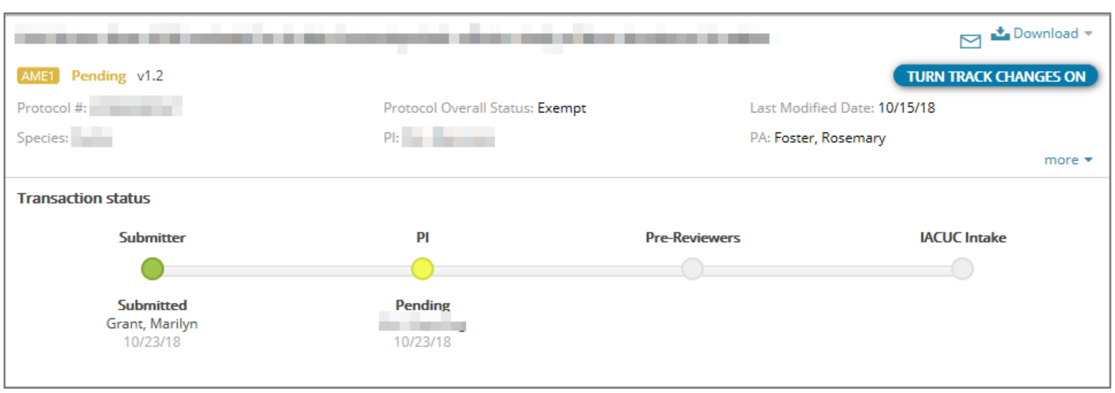
g) Click **[Save]** and then **[Close]**

6) Click **Open Panel** to display the right pane

7) Click the **[Submit]** button under Submitter Actions in the right pane

Note: If the PI is the Submitter, the PI must complete the ***Principal Investigator Certification*** *before submitting. Otherwise, the transaction is submitted for review and must then be signed off by the PI. The submission will go through review and approval; it can be tracked by viewing the Workflow History or the Transaction Status.*





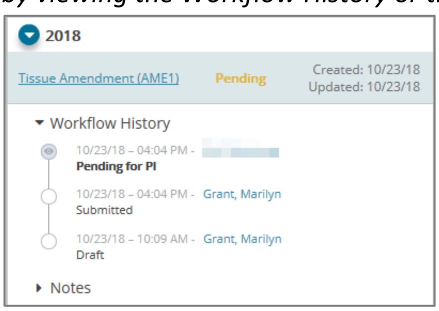
> ***Note:*** *Staff Updates can be used to modify Personnel Activities, Permissions, and Contacts. Additionally, Staff Updates can be used to add new study staff or remove existing staff; these will follow the Study Staff Amendment workflow path.*

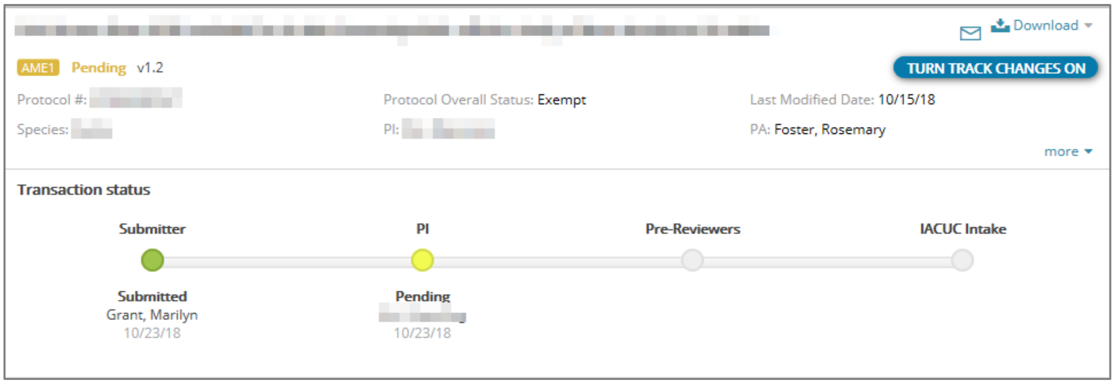
Amending tissue source

1) Log into Insight; navigate to Tissue protocols

2) Search for the Tissue IR submission and open it
Note: Approved Tissue IRs have an Overall Status of "Exempt". If the Tissue IR has approved, pending or draft Amendments, click the <u>Initial Review Tissue (IR)</u> hyperlink in the right pane to display the IR to be amended

3) Click the **Create Amendment** action in the left pane to start the Amendment
4) In the Tissue Amendment, briefly describe the proposed change(s) to the tissue protocol in the text box; click **[Save]**
5) Click the **Forms** hyperlink in the left pane
6) Click the **<u>Tissue</u>** form to open it
7) Provide the appropriate information in **E. Indicate the source of the tissues to be used**; provide all required information related to the tissue source
8) Click **[Save]** then **[Submit]**
9) *Note: If the PI is the Submitter, the PI must complete the **Principal Investigator Certification** before submitting. Otherwise, the transaction is submitted for review and must then be signed off by the PI. The submission will go through review and approval; it can be tracked by viewing the Workflow History or the Transaction Status.*



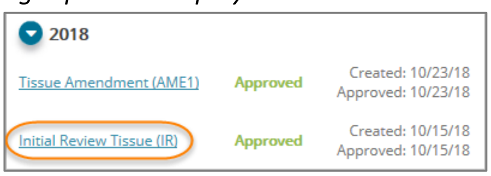


Amending sponsor

1) Log into Insight; navigate to Tissue protocols

   View: Active Inactive **Tissue Only**

2) Search for the Tissue IR submission and open it
   Note: Approved Tissue IRs have an Overall Status of "Exempt". If the Tissue IR has approved, pending or draft Amendments, click the Initial Review Tissue (IR) hyperlink in the right pane to display the IR to be amended

3) Click the **Create Amendment** action in the left pane to start the Amendment
4) In the Tissue Amendment, briefly describe the proposed change(s) to the tissue protocol in the text box; click **[Save]**
   Note: Submitter Actions may indicate, "Your application is complete and ready to be submitted" but there are additional steps that need to be taken.
5) Click the **Related Record** hyperlink in the left pane
6) Click the **+ Add Funding Source** hyperlink
7) Search for a funding source by either Agreement #, fund #, or PI Name; check the box next to the desired funding source(s)
   Note: Sponsors requiring Annual Reviews (i.e., DOD funded sponsors) cannot be added to Tissue protocols – the checkbox to add is disabled – as the annual review is not a viable process for a Tissue IR.
8) Click **[Add]**; if the sponsor(s) is successfully added the confirmation message, "Relationship was successfully created" will appear temporarily in the right pane
9) Click **[Submit]**
10) *Note: If the PI is the Submitter, the PI must complete the **Principal Investigator Certification** before submitting. Otherwise, the transaction is submitted for review and must then be signed off by the PI. SUNDRY funds will be automatically approved. Funds requiring congruency will go through review and approval, which can be tracked by viewing the Workflow History or the Transaction Status.*