INVOICING FOR IRB FEES

Transition from iLab to DISCOVR-e
Effective date: 08/01/2019 (Industry Sponsored)

Major Changes

• Instead of using iLab to create and distribute invoices for IRB fees, HRPP will begin utilizing DISCOVR-e.

• DISCOVR-e will notify the study team when invoices are ready for review.

• The study team will log into DISCOVR-e and either approve (e-Sign) or dispute the invoice.

• This process is being applied to industry sponsored studies on 8/1/19 and will be expanded to federally funded studies at a later date.
Who is notified of new invoices?

- Invoice notifications will be sent to the Principal Investigator and Study Coordinator and also the Billing Contact/Grant Manager if identified in the study.

CLARIFICATION:
Users can only be listed as 1 role:
- Principal Investigator,
- Study Coordinator,
- Billing Contact / Grants Manager,
- Key Study Personnel (Sub-I, Research – Clinical, Research – Non-Clinical)

Billing Contact / Grants Manager role

- Can be assigned at initial study creation and then changed like KSP.
- Provides view only access to study documents – this role does not allow submission creation.
- Does not require human subjects training credit in DISCOVR-e.
- Billing Manager Dashboard provides access to
  - Approved study documents
  - Final Approval Letters (FALs)
  - Committee Action Letters (CALs)
  - Invoices
- Can be changed by without an IRB submission.
Invoicing Process

1) DISCOVR-e will generate an invoice for a billable submission when it is assigned to a final agenda.
   - DISCOVR-e email is sent to PI, Study Contact, & Billing Contact/Grant Manager
   - Notifications will come from a Vanderbilt IRB DISCOVR-e noreply@vumc.org email

2) Recipient will log into DISCOVR-e (https://irb.mc.vanderbilt.edu/login) and access the invoice to assess for accuracy and completeness.

Invoicing Process

3) Review the invoice information and verify the center number & funding from the study's Funding page.
   - From the Invoices dashboard, you can hyperlink to the IRB study or the specific submission.
   - Center number is an editable field on the Funding tab.
   - Changes to funding information must be submitted as an amendment.
Invoicing Process

4) Click on an invoice ID to open the invoice. Take action on the invoice within 5 business days.
   • Sign (approval)
   • Dispute
   • Look: You can also download an invoice from here!
   • Sign: The invoice has the appropriate center number and is approved to be billed.
     • Only one study member's e-signature is required
   • Dispute: The invoice is not approved to be billed.
     • The center number has not been assigned.
     • The funding information is inaccurate.
     • The invoice was created in error.

Actions

• Signed invoices
  • Will be paid by internal cost transfer through the Department of Finance and a journal entry to the general ledger from VHRPP.

• Disputed invoices
  • Will be returned to VHRPP Invoicing for resolution.
  • The communication process will function much like the pre-review communication process.
  • Only the VHRPP Invoicing administrator can initiate communication.
Communications

- After an invoice has been disputed by the study team, a VHRPP Invoicing administrator will communicate via DISCOVR-e to resolve the dispute.

- The communication process is modeled after the pre-review communication process:
  - DISCOVR-e will send an email notification of pre-invoice information requested.
  - Study staff will log into DISCOVR-e to access the comments.
  - Study staff will click the green re-submit to analyst button to include response text to the billing analyst.
  - Upon review of the comments, VHRPP may waive the invoice fee, defer the invoice until a center number is provided, or send a final invoice.
  - Request for waiver must be approved by VHRPP.

Invoice Management

- Access all Invoices for all studies from the black bar in DISCOVR-e
- You will only see invoices for studies on which you are listed as either the Principal Investigator, Study Coordinator, or Billing Contact/Grants Manager
  - The Billing Contact / Grants Manager will automatically land on this dashboard when they log in.
Invoice Status Types

- **Status Types:**
  - **Sent:** A billable submission has been invoiced and sent to the study team for review and action.
  - **Disputed:** The invoice preview does not contain correct information (e.g. cost center) or the invoice has been generated in error.
  - **Waived:** The submission is not billable or the HRPP Director has waived fees for the study/submission.
  - **Paid:** The invoice has been signed by the study team (PI, SC, Billing Contact/Grants Manager) AND has been sent to Finance for general ledger upload.

Questions?

Please direct invoicing questions to VHRPP invoicing@vumc.org.

Please note that regulatory analysts are not responsible resolving Invoicing issues.