

INVOICING FOR IRB FEES

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

1

Major Changes

- Instead of using iLab to create and distribute invoices for IRB fees, HRPP will begin utilizing DISCOVER-e.
- DISCOVER-e will notify the study team when invoices are ready for review.
- The study team will log into DISCOVER-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.

2

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.



Billing Contact / Grants Manager has been moved to the KSP tab.

CLARIFICATION:

Users can only be listed as **1** role:

- Principal Investigator,
- Study Coordinator,
- Billing Contact / Grants Manager, **OR**
- Key Study Personnel (Sub-I, Research – Clinical, Research – Non-Clinical)

VUUserID	First Name	Last Name	Department	Credentials	Phone	Pager	Role in Project	Accessing PIR (IRPAA)?	Training Expire
JOHNDM	Dena	Johnson	Human Research	jhj	(615) 322-2922		Principal Investigator	YES	10-24-2019

3

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 DISCOVER-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.

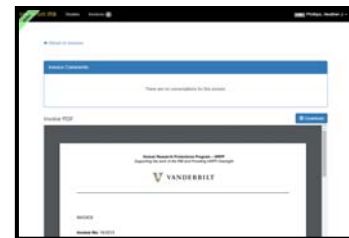
VUUserID	First Name	Last Name	Department	Credentials	Phone	Pager	Role in Project	Accessing PIR (IRPAA)?	Training Expire
JOHNDM	Dena	Johnson	Human Research	jhj	(615) 322-2922		Principal Investigator	YES	10-24-2019

4

Invoicing Process

- 1) DISCOVER-e will generate an invoice for a billable submission when it is assigned to a final agenda.
 - DISCOVER-e email is sent to PI, Study Contact, & Billing Contact/Grant Manager
 - Notifications will come from a Vanderbilt IRB DISCOVER-e noreply@vumc.org email
- 2) Recipient will log into DISCOVER-e (<https://irb.mc.vanderbilt.edu/login>) and access the invoice to assess for accuracy and completeness.

Invoice ID	Status	SIB #	PI	Cost Center	Approval Date	Submission ID	Submission Type	Review Type
19-0216	Paid	190217	Johnson, Denis M	fcd	2019-02-19 12:54:00	JOHN0605312019120540	New Study	Full Committee



5

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.

Invoice ID	Status	SIB #	PI	Cost Center	Approval Date	Submission ID	Submission Type	Review Type
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Approved Documents Submissions **Funding** Performance Sites

Funding Questions

Study Involves:

External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry Yes No

VICTR funding support or use of VICTR facilities No Yes

Internal Funds No Yes

No Funds No Yes

Other Questions:

Is there a grant application or proposal required for the external support? Yes No

Will the external support require the signing of a written letter/MOU/agreement/contract? Yes No

Does the study involve the use of Vanderbilt hospital facilities or assays related to human samples/tissue? Yes No

Does this study have an associated billing plan? Yes No

Center Number

Funding Sources

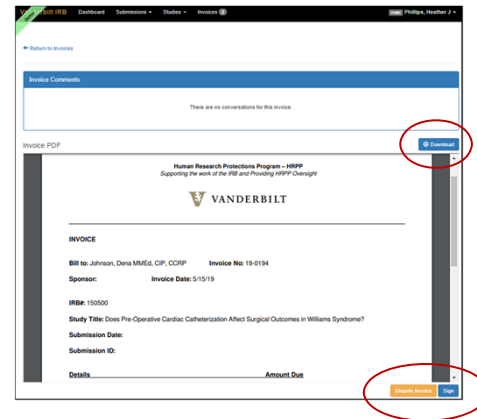
Federal

NIH

6

Invoicing Process

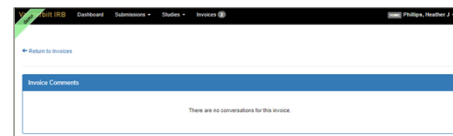
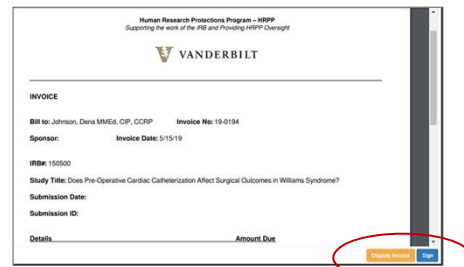
- 4) Click on an invoice ID to open the invoice.
Take action on the invoice within 5 business days.
- Sign (approval)
 - Dispute
- Look: You can also download an invoice from here!
- **Sign:** The invoice has the appropriate center number and is approved to be billed.
 - Only one study member's e-signature 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.



7

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.



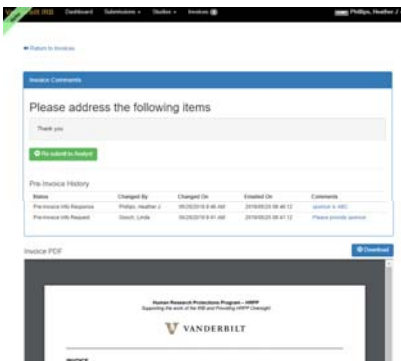
8

Communications

- After an invoice has been disputed by the study team, a VHRPP Invoicing administrator will communicate via DISCOVER-e to resolve the dispute.
- The communication process is modeled after the pre-review communication process:
 - DISCOVER-e will send an email notification of pre-invoice information requested.
 - Study staff will log into DISCOVER-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.

IRB #190007 Pre-Invoice information requested

VI Vanderbilt IRB DISCOVER-e <noreply@vumc.org>
To Phillips, Heather J

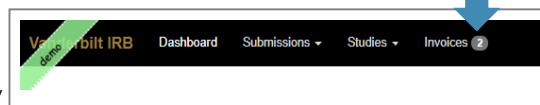


9

Invoice Management

- Access all Invoices for all studies from the black bar in DISCOVER-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.

The number next to Invoices indicates the number of invoices that require action.



Invoice ID	Status	IRB #	PI	Cost Center	Approval Date	Submission ID	Submission Type	Review Type
19-0216	Paid	190027	Johnson, Dena M	tbd		JOHNDM05312019125540	New Study	Full Committee
19-0196	Waived	190023	Johnson, Dena M	1-04-123-1234	5/13/2019	JOHNDM05132019082449	Amendment	Full Committee
19-0195	Paid	190024	Johnson, Dena M		5/15/2019	JOHNDM05142019120009	Continuing Review	Full Committee
19-0194	Sent	150500	Johnson, Dena M		2/9/2016	JOHNDM05062019112547	Continuing Review	Full Committee

10

Invoice Status Types

The screenshot shows the 'Invoices' section of the VUMC Invoicing System. The table below lists various invoices with their statuses. The 'Status' column is highlighted with a red box.

Invoice ID	Status	IRB #	PI	Cost Center	Approval Date	Submission ID	Submission Type	Review Type
19-0196	Waived	190023	Johnson, Dena M	1-04-123-1234	5/13/2019	JOHNDM05132019082449	Amendment	Full Committee
19-0195	Paid	190024	Johnson, Dena M		5/15/2019	JOHNDM05142019120009	Continuing Review	Full Committee
19-0194	Disputed	150500	Johnson, Dena M		2/9/2016	JOHNDM05062019112547	Continuing Review	Full Committee
19-0168	Sent	180041	Ozier, Julie		4/16/2019	OZIERJA02282017082648	New Study	Expedited

- **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.

11

Questions?

Please direct invoicing questions to VHRPPinvoicing@vumc.org.

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

12