The George Washington University
Standard Operating Procedures
Forte Participant Payments System
Human Subject Payments
Dated May 2024

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Overview

This manual provides the operating procedure to be used when using the Advarra (Forte) Participant Payments system at The George Washington University.

Advarra Participant Payments (commonly referred to as "Payments") is a system that administers payments to participants in an efficient and effective manner. A participant is enrolled in the system once and can then be assigned to one or many protocols operating across the campus (this may happen directly in Payments, or indirectly in OnCore for a protocol that has enabled the integration between the two systems). Research personnel with access to the system can search for the participant, assign them to their study and pay the participant depending on the roles assigned to the user. The system provides reports that will allow each protocol to review its participant payments and allow for consolidated university-wide reporting when necessary, such as for 1099 purposes.

Advarra Payments eliminates the need for preloaded gift cards and the approval and expense reporting processes associated with purchasing those gift cards. A consolidated report in the system will allow the Finance Division to record the participant payments to the appropriate protocol or study without further approval.

The use of this system is not intended to interfere with the IRB approval process.

Access to the information within Payments will be controlled as follows:

GW Single sign-on (SSO) technology will be utilized for accessing the system.

Roles defined for each user will determine what a user can see or act upon. Roles can provide global access to data or restrict access to specific protocols or studies.

Assignment of users to specific protocols (studies) will restrict the user to information within those protocols.

Accordingly, a user must have a role and be assigned to a protocol to see any data in Payments.

The GW Cancer Center's Applications Administrator, Clinical Research Programs will be responsible for providing the user's role within the system.

Once the IRB approval is received, study administrators will either create the study protocol in OnCore and turn on the integration with Payments to enable the creation of the protocol record in Payments, or create the study protocol directly in Payments (if the protocol will not be entered into OnCore). The Protocol Detail screen will contain the Protocol Number, the National Clinical Trial (NCT) Number, the study's Name and IRB Number. The NCT Number, Study Name and IRB Number are only visible to uses with access to the study. They do not appear on any reports.

The Protocol Detail screen will also contain the Financial Reference Number (Banner Alias) and the Internal Reference Number (Project/Task Award Number). These two items will be used by the Finance Division to record the participant payments to each award each week.

Finally, the Protocol Detail screen is where the periodic "stipends" are defined, whether the Protocol or award permits participant reimbursement for travel or other out of pocket expenses and which users have access to the Protocol data based on each user's defined role.

A participant will be enrolled in Participant Payments either through coming over from a synced OnCore study or by being created directly in Payments by the protocol administrator. Once enrolled in Payments, the participant can be enrolled in a Protocol (this association will be automatic if they have come over from OnCore) and receive payments on a single re-loadable credit card or via direct deposit into their bank account. Once a non-OnCore-associated participant is enrolled in Payments they are available for enrollment in other Protocols operating across the university. The payment method will be the same for every Protocol in which the participant is enrolled.

For the time being, the GW Cancer Center will maintain the inventory of available credit cards and will distribute them upon request to the study administrators. On a weekly basis, the Finance Division will produce reports from Payments that will support the amounts due Advarra. These reports will serve as an invoice and will be used to record the participant payments as award expenses and the fees for Payments as a Finance Division expense.

The IRB Process

The IRB approval process will not change with the implementation of Participant Payments. In general terms, we hope all studies will use Payments to pay their participants. Researchers who will use Payments should describe their use of the Participant Payments system when creating an IRB application and include language about Forte Participant Payments in the informed consent form (template language is provided on the OHR website under "research tools"). When circumstances exist that warrant an exception to the general rule, the Finance Division will work with the research team to determine the payment method to be utilized, and that information should be included in the study IRB application.

<u>Access Control (Project Plan 8.1)</u>

GW Information Technology (GWIT) has integrated Payments with the university's single sign-on protocol. Accordingly, a user's access to the system will be their GW NetID. Users will be created in the system by the Applications Administrator, Clinical Research Programs.

The system also includes non-GW users such as MFA employees that do not have a GW NetID. The non-GWU users must be established as a university "affiliate" in the HRIS system, effectively providing them with a GW NetID and password.

The Applications Administrator will assign user roles to individual users.

Users will be able to log in to Forte Participant Payments using their NetID. Without an assigned role the home screen is blank and the menu section displays no options.

When a user has a defined role in the system the landing page will be the first system functionality assigned to that role. The menu section will display only the functions assigned to that role.

The following are typical roles GW intends to use:

1. Protocol Administrator = Has the ability to create Protocols. Has the ability to edit Protocols created by this user or assigned to this user by others.
2. Financial Review without PHI (Protocol) = Has the ability to review and pay stipends and reimbursements for the assigned Protocols. Has the ability to run reports for Protocols assigned to the user.
3. Participant Check-In and Pay = Has the ability to view limited information on all participant in the system (Name, email address (if provided), participant identifier and the last four digits of the SSN if collected). Has the ability to add participants and to assign them to Protocols assigned to the user. Has the ability to check participants in for visits and to pay the participants.
4. Payment Card Replace = Has the ability to view limited information on all participants in the system (Name, email address if provided) and can issue a replacement card to any participant.
5. Payment Reports Global = reserved for Finance (Procure-to-Pay). Has the ability to run payment reports to pay Advarra weekly and to review 1099 requirements on participants.
6. Contact Administrator = Reserved for Applications Administrator. Has the ability to add or edit user information, assign roles and reset passwords.
7. Org Administrator = Reserved for Applications Administrator. Has the global access to all functionality.

Access for new users or revised access for existing users will be communicated to the Applications Administrator via email to: P2P@gwu.edu. These requests include addition of new users or changing the roles assigned to an existing user. The Protocol Administrator should submit these requests.   Likewise, the Protocol Administrator must communicate to the Applications Administrator when an "affiliate" user (non-GWU employees) leaves their position so all of their access can be removed.

The Applications Administrator will select Contacts from the main menu and Add a new Contact from the following screen:

The Applications Administrator will complete the user's information and select CREATE

Assigning a user to a specific protocol will also be the responsibility of the Applications Administrator. See Adding Users to Protocol under the next section.

Building a Protocol (Project plan 8.2 -8.5)

Once the IRB has provided its approval, the first step in utilizing Participant Payments is the creation of a Protocol (for studies that will not be in OnCore). This access is available to users with a Protocol Administrator Assigned role.

The source information for creating a Protocol will be the award documents or the IRB documents. If required information cannot be found within these documents, the university's standard policies would apply.

Note: for studies in OnCore that do not already exist in Payments, the integration between OnCore and Payments will move the initial Protocol creation step to that system. The user will set the Enable Payments Integration field on the Management tab of PC Console to Yes in order to sync basic Protocol information from OnCore to Payments. The user will then navigate to Payments to finish setting up the Protocol. Protocols that will be synced to Payments from OnCore should *not* be created directly in the Payments system.

Step 1

Under Menu – Payments – Protocol, the user will see a list of Protocols in the system. The user will also find a button "+New Protocol" on the righthand side of the screen:

The Protocol creation screen appears below:

The Protocol Number (for a non-OnCore Protocol) is the IRB Number plus a research team-provided identifier such as IRB # - G10001, for example. The IRB # will cause this number to be unique throughout the system while the research provided number will be easily identifiable by the research team. The Protocol Number for an OnCore study will come over automatically from OnCore.

This number will be used throughout the system (reports and screens) to identify the protocol / study.

The NCT Number is the National Clinic Trial Number. The entry is informational. This information is only visible to users with access to the Protocol. This information does not appear on any reports. The entry must start with the letters NCT followed by 8 numbers. Entry of this number is optional when creating a study directly in Payments (because the study won't be in OnCore). The NCT Number will come over automatically from OnCore for synced studies.

The Protocol Name is also informational. This information is only visible to users with access to this Protocol. This information does not appear on any reports. The Protocol Name will come over automatically from OnCore for synced studies.

In our example we established a new Protocol with a Protocol Number of GW0987Test.

When the user selects "Create" the following screen appears:

The Protocol template is created with the current user (Protocol Administrator) assigned to it.

Note: for studies that have been synced from OnCore, Protocol Users will have to be assigned by the Applications Administrator. Reach out to P2P@gwu.edu with the Protocol Number in order to be added as a user.

Step 2

By selecting "Edit" above the user can populate the remaining items to define the Protocol. Regardless of whether a Protocol comes over from OnCore or is created directly in Payments, this information will need to be filled out.

The IRB Number should be a provided with your IRB Approval. This is informational data only and is only viewable by users with access to the Protocol. Note: the IRB Number will not come over from OnCore and will have to be added manually in Payments.

The Financial Reference Number is the Banner Alias used when recording expenses to the study.

The Internal Reference Number is the Protocol / Study's PTA number. For non-sponsored Protocols/studies, the GL Natural account is used.

The Financial Reference Number and The Internal Reference Number are used on various reports and are very important for recording the participants' payments to the appropriate study.

The Keyword is a user defined field.

The Business Units will define the school / Division awarded the study.

Step 3

Under "Visits," by selecting "+ New Visit" the user can define the task the participant needs to complete, the stipend amount to be paid, which reimbursable expenses apply to the visit and whether the visit is active in the system.   This is a very important step as setting up these visits (tasks) for the duration of the study defines the next available visit and payment due to the participant.

 Under "Unscheduled Visits," by selecting "+ New Visit" the user can define the stipend amount to be paid and whether reimbursable expenses apply to the unscheduled visit.

Any payment due to a participant must be defined on this screen.

The system does not provide functionality for undefined payments.

The "Allow Reimbursement" flag (Yes vs No) defines whether a participant will be reimbursed for out of pocket costs associated with completing tasks.

When the flag is turned to "Yes" a new section opens on the screen to allow the user to define what types of reimbursements are permitted and if there are any limits to each reimbursement type (See below).

The Active Protocol flag makes the Protocol available for use within the system (to add, assign and pay participants).

The Visit table allows the user to define each task a participant must complete and the amount of stipend to be paid upon completion.

The Unscheduled Visit section allows the user to define a planned but unscheduled visit and stipend to be paid.

Defining Visits and Stipend Amounts

Expense Reimbursement

The screenshot below appears at the bottom of the Protocol page when the "Allow Reimbursement" flag has been changed to Yes:

Reimbursement Rules (Optional)

Guidelines	
Maximum Hotel Reimbursement	$
Maximum Parking Reimbursement	$
Mileage Rate per Mile	$
Minimum miles for reimbursement	
Maximum miles for reimbursement	

☑ Save   Cancel

The Guidelines entry should define the document that will govern the reimbursement policy for the Protocol. Absent any study provided guidelines, the university's travel and entertainment policy will govern the reimbursement.

The remaining fields will be completed consistent with those guidelines.

When all the Protocol data has been defined by entries, the user will select "Save".

Step 5 Assigning Users to Protocols:

The final step to establishing a Protocol is to define which users will have access to the Protocol (add, assign and pay participants).

Assigning Users to a Protocol

Protocol Users   + Add

Last Name ↑	First Name ↑	Site	Status	
MacGregor	Dan	George Washington University - Non Production	Active	✖ Deactivate

The user will select "+Add".

Add Users   ✖

Protocol *	GW0987test
User *	
Site *	Tara Davis ... on
Active? *	Al Talley
	Brenda Tate

✔ Add ▾   Cancel

As the user begins to type the additional user's name, the system will return all available users that match the data entered (TA is the example). By selecting a user and selecting "Add" the user will be added to the Protocol.

Adding a Participant (Project Plan 8.6)

The objective is to enroll Participants in the system and then assign the Participants to the appropriate study or studies. Accordingly, the first step in adding a Participant is the search the system for the Participant (non-OnCore studies only).

Step 1

From the Menu select Payments, then Participant Check-in. The following screen appears:
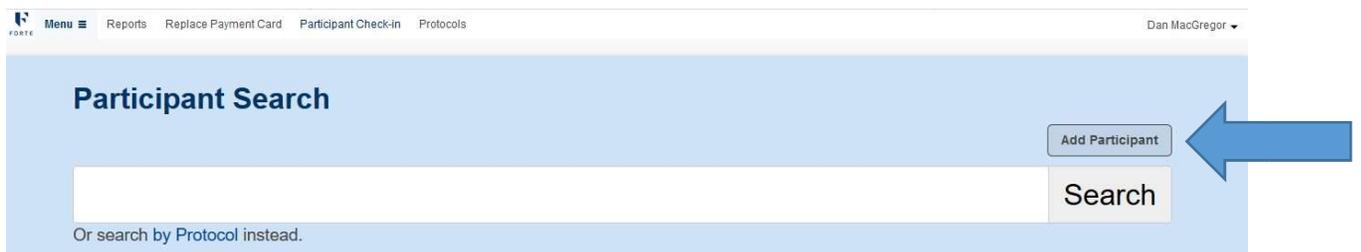
The user will type in a portion of the participant's name. The system will return the enrolled participants that match the information entered.

For studies in OnCore that have been integrated with Payments: Participants will come over from OnCore automatically. Do not create a new participant directly in Payments or associate them to a study directly in Payments.

For non-OnCore studies: If the system does not return any participants to match the information entered, the user will select "Add Participant."

The information required by this screen is self-explanatory.

For studies linked to OnCore, most of these fields will have been automatically filled out. Since patient demographics come over from Epic, if any of this information needs to be changed, please make sure this happens in Epic so that the changes can flow to OnCore and then to Payments. The one exception is email address. The participant's email address will need to be added directly into OnCore for it to show up in Payments.

Accordingly, the notable items are:

If the participant is a minor, the guardian must be enrolled in the system first. Then when enrolling the minor participant select the box "Has Guardian." The Guardian's account must be linked to the minor's account. The payments will be made to the Guardian per the payment method described below.

The university has decided to limit the Personal Identifiable Information collected during the enrollment process. Accordingly, the "No Address" box can be selected to hide the address related fields. This functionality will default the address on record to the university's address

The system and its payment partner require additional information for customer service purposes. Accordingly, the "Date of Birth" and "Gender" fields are required.

The Participant Identifier field should be populated with the participant's Date of Birth (second field the capture this data). The reason is when we have multiple participants with the same name, the fields

available to the user to verify the participant do not include the Date of Birth, but do include the Participant Identifier field. Accordingly, we need a data point that the participant can verify.

Participant Identifier		
Social Security Number		Override SSN
Payment type	Checking Account Payment Card	×

Add Participant

The university has decided to limit the Personal Identifiable Information collected during the enrollment process. Accordingly, the "Social Security Number" will not be collected at the time of enrollment. We may collect the social security number if the participant is a risk to exceed the IRS 1099 reporting threshold (See the 1099 Report below)

The Participant Payments system offers 2 payment methods:

1) "Checking Account," an electronic payment via ACH deposit into the participant's bank account. To provide this payment method the participant must provide an email address which is used as the participant's log in credential to the system's banking partner's portal. On the portal the participant can enter their banking information.

2) "Payment Card," a reloadable credit card assigned to the participant. When this option is selected the user will provide a reloadable card to the participant after entering the ICN number from the card envelope into the system. The ICN number links the user to the reloadable card. The image below is an actual card envelope with the ICN number visible through the window.

FORTE
123 Townsend Street
6th Floor
San Francisco, CA 94107

34756866

VALUED CARDHOLDER
51002297-08190363 ← ICN Number
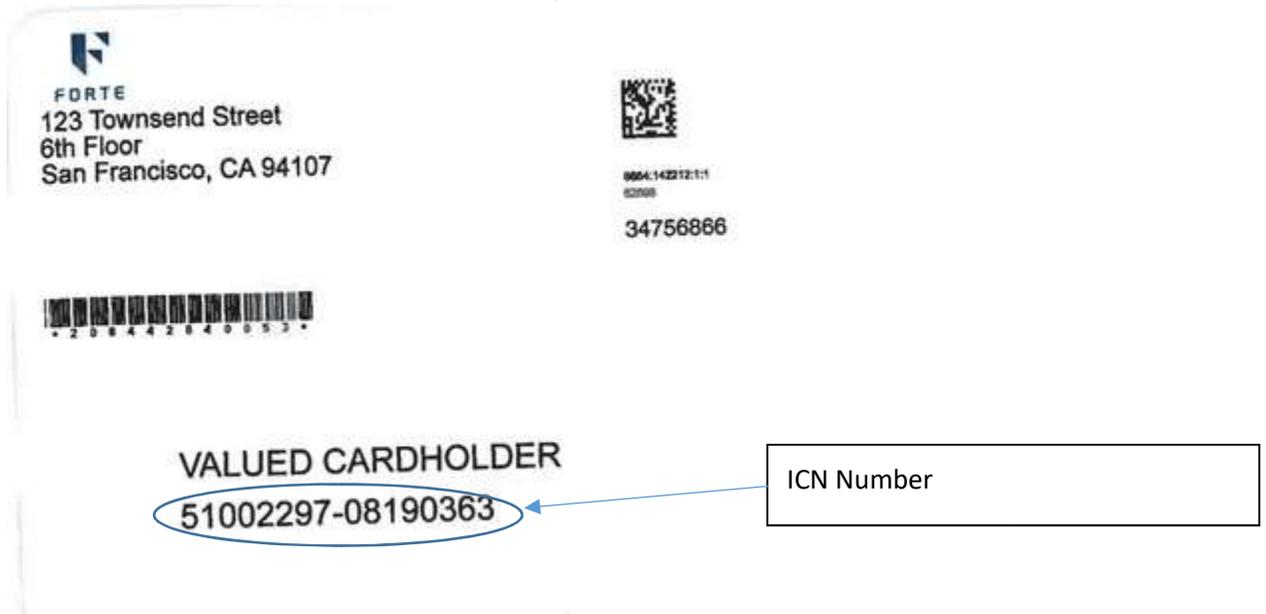
Select "Add Participant"

Forte Participant Payments will begin to establish the participant in the system as well as its banking partner's solution. This process should only take a few minutes.

Step 2

The next step is to assign the participant to the user's Protocol. (If a study is linked to OnCore, this step has already happened.)
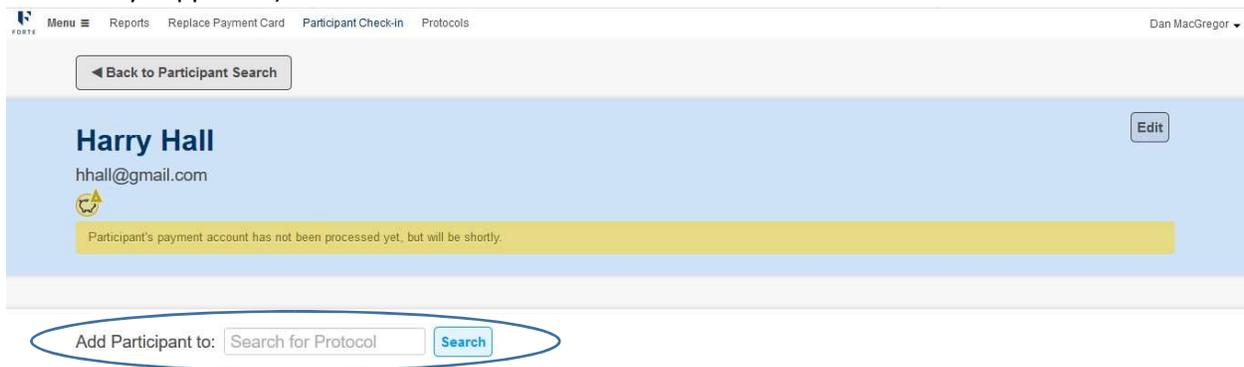
The yellow bar on the screen shot above indicates that Payments and its banking partner are still establishing the participant's record for this participant.   This process takes less than 10 minutes.

The user will enter the Protocol Number of the Protocol to which the participant will be assigned and then select that Protocol from the dropdown options. The system will only list those Protocols to which the user has been provided access.

Paying a Participant (Project Plan 8.7 and 8.8)

When checking in a participant already enrolled in the system, the user will search Payments for the participant by name. When the appropriate participant is selected or added and assigned to the Protocol, the system will display the participant and the Protocol.

From this screen the user can select the currently assigned Protocol or assign the participant to another Protocol. Note – the user will only see the Protocol assigned this participant if the user also has access to that Protocol. In addition, studies linked to OnCore get their participant lists from OnCore itself, so there is no need to assign a participant to another OnCore-linked protocol within Payments. That association happens in OnCore and will flow over to Payments automatically.

To pay the participant for a Protocol Visit, select the Protocol. The next available payment scheduled for this participant will display. If the task required is complete, select "Pay".

The user should confirm that the correct Visit is displayed. If the participant missed a Visit and is appearing for his next
Visit (Visit 2 in this example), the user can mark Visit 1 as missed. Payments will advance to the next Visit.

If for some reason the participant completed the task but the Stipend will not be paid, the "N/A" option should be selected. This will also advance Payments to the next visit.

Note – Regarding payment at or above the tax reporting threshold:

When the accumulated payments to a participant across all Protocols in the system exceed the university established threshold, the system will alert the user during the payment process.

A larger image of the alert appears below:

The user should provide the participant with a W-9 form (or W-8 if the participant identifies themselves as a non-resident alien). These forms can be found at IRS w-9 Form (or IRS w-8 Form). The participant should complete the form, which the user will then send in to the Finance Division (attn.: Accounts Payable). The departments or schools should not retain W-9 or W-8 forms due to the Personally Identifiable Information contained on the form.

The user can select "Continue With Errors" to complete the payment to the participant.

Reimbursements

If the Protocol had been marked to pay out of pocket reimbursements, a reimbursement option would appear below the "PAY" button. By selecting this Reimbursement option, you can then enter the amounts to be reimbursed. The Add Attachment button at the top right of the page can be used to attach images of receipts to the Reimbursement.

All reimbursements require an approval by a Financial Reviewer before they are paid.

Finance Division paying Forte, Recording Participant Payments on the Award (Project Plan 8.9)

The university is required to pay Advarra (Forte) weekly for Participant Payments and the fees associated with the transactions. The Finance Division will be assessed all fees associated with the transactions.

The Finance Division will run the Forte Itemized Receipt Report for the appropriate dates.

The report is generated in an EXCEL format.

The report output provides the detailed payments for each Protocol on individual tabs and a summary tab listing summary information for each Protocol. The output provides the Financial Reference (Banner) and Internal Reference (PTA) for each Protocol. It also breaks down the amounts paid to the participant(s) from the fees associated with the transaction.

Forte Research, Inc.
Itemized Receipts Report for George Washington University - Non Production
Report Run Date: 01 Oct 2019
From Date: 01 Sep 2019
To Date: 30 Sep 2019

Protocol	Financial Reference #	Internal Reference #	Business Unit	Card Fees	Transaction Fees	Protocol Fees	Participant Payments	Total Amount
GW12tn555	617006	12345 -1234 -11		$ -	$ 2.00	$ -	$ 200.00	$ 202.00
617006.12345-56789-CMLSC12345DM.MacGregor	617006	12345-56789-CMLSC12345DM	SMHS	$ -	$ 8.00	$ -	$ 70.00	$ 78.00
GW0987 - test	617004	Proj Task Award		$ -	$ 10.00	$ -	$ 80.00	$ 90.00
617004.PTA.MacGregor	617004	PTA	SMHS	$ -	$ 14.00	$ -	$ 600.00	$ 614.00
		Total		$ -	$ 34.00	$ -	$ 950.00	$ 984.00
		Total Test from other sheets			$ 34.00		$ 950.00	

... | 617006.12345-56789-CMLSC123... | GW0987 - test | GW12tn555 | Total | ⊕

The Finance Division will treat this summary report as an invoice to record the expenditures and remit payment to Advarra (Forte) as follows:

1. When the Finance Division executes the report, it will send a copy of the total page only to Treasury Management to validate the amount of the automatic withdrawal.
2. The Finance Division will enter the payment transaction into CONCUR Invoice with Forte as the payee and charge the appropriate departments or awards for the Stipends and Participant Reimbursements paid. The fees associated with the transactions or the cards which also appear on the report will be entered as a second transaction in CONCUR Invoice and will be matched to the Purchase Order established for such fees.
3. The transaction will include a payment method 'Wire-Manual' to facilitate the manual posting of the invoice as we do for wires disbursed through Treasury Management.
4. A pdf copy of the total page would be attached as the invoice in CONCUR Invoice.
5. When the payment appears on the bank website, FINANCE DIVISION will then manually post the payment in EAS/Oracle.
6. Should there be a discrepancy between the total amount withdrawn and the report from the Forte system then the appropriate parties will be advised of the variance.
7. The Excel output will be stored on the appropriate Finance Division Box Folder by calendar year.

FINANCE DIVISION 1099 Review (Project Plan 8.10)

The university is responsible for reporting any supplier, payee that receives $600.00 for services in any calendar year on an IRS form 1099. Participant payments, excluding reimbursements, are considered reportable transactions if the threshold is exceeded. The Finance Division performs a review of its suppliers quarterly to ensure the payments are reportable and that the university has valid tax identification numbers for each supplier before or when they exceed the threshold amount. The system will provide the Finance Division with its 1099 Report to assist with this process.

1099 Report for George Washington University - Non Production
Report Run Date: 02 Oct 2019
From Date: 01 Jan 2019
To Date: 31 Dec 2019

Participant First Name	Participant Middle Name	Participant Last Name	Social Security Number	Address	City	State	Zip	Stipend Payments	
David		Diemert						$ 10.00	
Annabelle		Dunn			Ashburn		20147	$ 80.00	
Caleb		Dunn						$ 50.00	
Harry		Hall						$ 460.00	Invalid SSN
Barbara		MacGregor		45155 Research Place	Ashburn	Virginia	20147	$ 930.00	Invalid SSN

The report provides a list of participants and their personal information or missing information and the total amount of participant payments (excluding reimbursements) made to the individual across all Protocols. The Finance Division will sort and review the activity for participants approaching $450.00 and will alert the study administrators at the completion of their review.

In addition, when the accumulated payments to a participant across all Protocols in the system exceed the university established threshold of $450.00, the system will alert the user during the payment process.

Name ↑	Description	Report Group	Type
1099 Report	Information needed to generate 1099 forms.		Standard
All Transactions Report	List of all paid transactions made within a specific date range.		Standard
Card Inventory Report	Tracking report for all cards at your organization, and their assignment status.		Standard
Incomplete Participant Registrations	Participants that don't yet have a Hyperwallet account set up.		Standard
Itemized Receipts Report	List of participant payments and fees within a specified date rage.		Standard
Payment Audit Report	List of all payments and their status changes through time.		Standard
Payments Contact Audit Report	List of all contacts who have roles in Payments, those roles, and relevant fields.		Standard
Payments Contact Audit Report by Protocol	List of contacts by selected protocol, including contacts who have roles in Payments, those roles, and relevant fields.		Standard
Sponsor Invoicing Report	List of payments and fees with Card fees listed by protocol for sponsor invoicing.		Standard

9 Total Records

The study administrator will collect the W-9 from the participant before the next payment is processed for the participant. The W-9 will be submitted to the Finance Division. The departments or schools should not retain W-9 forms due to the Personally Identifiable Information contained on the form.

When a research team is advised of a participant who has reached the $450.00 warning threshold, the research administrator has the following responsibilities:

1. Collect the completed W-9 from the Participant and forward the form to the Finance Division (Attn. Accounts Payable) or
2. Advise the Finance Division that there are no further stipend payments to be made this calendar year or
3. The participant is no longer involved in the study or
4. Advise the Finance Division that the Protocol has ended.

Operating Procedures when using Forte and Interacting with Participants

1. When adding a new participant, the GW user will provide the study consent form to the participants and will enroll the participant when the participant agrees and signs the study consent form.

2. While enrolling a new participant the following information must be collected from the participant and entered into the Forte Participant Payments system (or synced from OnCore):

    a. Name
    b. Date of Birth
    c. Gender
    d. It is also recommended but not required to enter an email address for the participant, see item 3 below. (If the study is synced with OnCore, please enter this email address directly in the subject's record in OnCore.)

3. The participants will be asked to choose a method by which to receive compensation:

    a. Reloadable debit card – funds are available on the card the same day. The card is re-usable for future payments from this study or any other GW study the participant enrolls in. By providing the participants email address as recommended above, the participant will be able to access their card balance and activity via a secure portal.
    b. An electronic funds transfer directly to a bank account defined by the participant. Funds are available within 3 business days. An email address is required for this option. The participant will receive an email from Forte's banking partner providing the participant with access to a secure portal to enter their banking information. The GW user should not collect the bank information under any circumstance.
    c. Paper check mailed to the participant address. Funds are available within 3 business days plus delivery time. An email address is required for this option. The participant will receive an email from Forte's banking partner providing the participant with access to a secure portal to enter their mailing address and to finalize the selection the paper check option. The GW user is not required to enter the address into the Payments system at this time.

4. The GW user will provide the participants with the appropriate handout providing information / instructions about their selected payment option:

    a. Reloadable Debit Card
    b. Electronic Funds Transfer or Paper Check.

5. The GW user will securely store any paper records containing participant information and consider such documents part of the study record.

6. When a participant's payments equal 450.00, the GW user will receive a notice from the system and will respond as outlined in the procedures manual above. This may include communication to the participant to obtain a tax form (W-9, or W-8). If tax forms would pose previously unforeseen risk to participants, research team members will reach out to the GW IRB for consultation. Communication and collaboration may need

to occur across study teams if the participant is enrolled in more than one study. Communication with the participant about eligibility for future funding may need to occur.