



# MCW Office of Research Standard Operating Procedure

## **SUBJECT PAYMENTS FOR RESEARCH PARTICIPATION**

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Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW Faculty and Staff involved in human research

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### **PURPOSE**

The purpose of this SOP is to facilitate the management of payments to study subjects participating in human subject research (HSR). Payments for participation in research studies should not be considered a benefit; rather it is compensation for a subject's time, effort and for study-related expenses. This SOP details available payment options, procedures for disbursement, requirements for social security number collection, and IRS tax reporting.

### **SCOPE**

This SOP applies to all Medical College of Wisconsin (MCW) faculty and staff involved in HSR, who provide payments to study subjects for either: a) expenses incurred as a result of participation (i.e. travel related costs); or b) payments to compensate participants for their time and effort in a research study at MCW, Froedtert Health (FH) and Children's Wisconsin (CW). This policy applies specifically to cash, checks, debit cards and/or gift cards used as compensation to a study subject.

### **DEFINITIONS**

**Subject:** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

**Payment:** term used when discussing money given to a subject to offset time and inconvenience and/or to provide incentive to participate in a research study.

**Reimbursement:** term used when subjects will be paid back for any out of pocket expenses related to their study participation (i.e. travel related costs)

#### **MCW Accounts Payable:**

MCW Accounts Payable is available to offer additional guidance or answer questions related to the use of a Purchase Order or a Check Request.

**Study Payments®:** Sponsored by the Office of Research and key clinical research stakeholders, the MCW Study Payment System allows study coordinators to authorize subject payments and/or reimbursements directly to an MCW-branded VISA bank debit card via a secure web-based application, providing fast and easy payment to research study subjects. The system is free to use and studies already entered in OnCore can easily feed study information and participant details into the Study Payment System.

**De Minimis payments:** Individual gift card or cash payments to research study participants for amounts of \$60.00 or less are considered by MCW to be *de minimis* in nature, or so minor as to merit disregard, and do not require a social security number to be collected from participants.

**Rare Disease**

According to the National Institutes of Health (NIH), a rare disease, also known as an “orphan” disease, is generally any disease or condition that affects less than 200,000 people in the United States.

**PAYMENT / REIMBURSEMENT OPTIONS**

There are four acceptable methods for paying and/or reimbursing study subjects for their participation in HSR. The Principal Investigator (PI) may select the method most appropriate for each human research study, as it is understood that some payment types may be necessary and/or preferred for certain research subject populations. Regardless of the method of payment chosen, the PI or designee must maintain supporting documentation of payment to the study participant or parent/LAR. In addition, the actual payment method must align with the IRB-approved informed consent forms. Study stipends are payable to study subjects using the following methods, listed in order of convenience and institutional preference.

Approved Payment Types	Considerations	SSN Collection Requirements	Procedure
<p><u>Study Payments® Card</u></p>	<ul style="list-style-type: none"> <li>• Fast and efficient; stipends are loaded at the time of subject’s study visit and funds can be used anywhere VISA is accepted</li> <li>• May be used at an ATM to withdraw cash (fee applies) or subjects can request cash back (no fee) with a small purchase.</li> <li>• Card must be used every 90 days, otherwise inactivity fee of \$3/month is applied to the balance of the card.</li> <li>• Cards are reloadable and can be used for multiple studies.</li> <li>• Funds typically available within one business day.</li> <li>• Reduced staff time/effort required than processing paper checks</li> <li>• Ability to upload receipts and send reimbursement requests for department review.</li> <li>• If lost, a new card can be issued.</li> </ul>	<p>Use of the Payments Card does <u>not</u> require subject’s SSN to be collected until their annual cumulative study payments reach <b>\$200.00</b> in a calendar year. The Payments system will alert study team members when a subject reaches the \$200.00 threshold for research payments paid via debit card.</p>	<p>See <a href="#">Payments Info</a> for training and account setup.</p> <ul style="list-style-type: none"> <li>• Payment approvers will need to review/approve daily to ensure real-time payment.</li> <li>• Study teams should review the payments handout in advance of distributing the cards to subjects</li> <li>• Study teams utilizing OnCore CTMS will benefit from the integration between OnCore &amp; Payments system, eliminating duplicate entry of subject information.</li> </ul>

<p style="text-align: center;"><b>Check Payment</b></p>	<ul style="list-style-type: none"> <li>• Check processing time may take up to 30 days</li> </ul>	<p>A subject's SSN is required for <b>all</b> check payments, regardless of amount</p>	<ul style="list-style-type: none"> <li>• Check Requests for individual subjects must be submitted using iProcurement by the department's authorized user.</li> <li>• The research subject's legal name, home address, and social security number are required to be collected for check payments. This information must be stored securely (i.e. in locked drawer if paper format, or an encrypted file if in electronic format; the key for which is kept by a limited number of people who have a need to know) at the research study site and submitted via secure means (i.e. encrypted file) to MCW Accounts Payable.</li> </ul>
<p style="text-align: center;"><b>Gift Card</b></p>	<ul style="list-style-type: none"> <li>• Gift cards for retail locations may not be preferred and/or convenient for subjects to use</li> <li>• Any loss or theft of gift cards must be reported to MCW Public Safety. Departments are responsible for replacing any gift cards that are not covered by institutional insurance.</li> <li>• PI/department are responsible that all gift cards are stored securely.</li> <li>• A distribution log must be kept documenting the funds disbursed to study subjects.</li> </ul>	<p>A subject's SSN is required for any gift card payments <b>greater than \$60.00</b>. Individual gift card payments to research study participants for amounts of \$60.00 or less are considered by MCW to be de minimis in nature and do not require a social security number to be collected from participants.</p>	<ul style="list-style-type: none"> <li>• Gift cards may be purchased from vendors who accept a Purchase Order (preferred), or by an authorized department Procurement card holder.</li> <li>• The research subject's legal name, signature, date and amount received are required to be collected. This information must be stored securely</li> </ul>

			<p>(i.e.g. in locked drawer if paper format, or an encrypted file if in electronic format; the key for which is kept by a limited number of people who have a need to know) at the research study site and submitted via secure means (e.g. encrypted file) to MCW Accounts Payable.</p> <ul style="list-style-type: none"> <li>Once a payment or reimbursement recipient has been entered into iProcurement this only needs to be updated if there is a new address.</li> </ul>
<b>Cash Payment</b>	<ul style="list-style-type: none"> <li>Requests for Cash Payments are approved on a per case basis.</li> <li>Cash cannot be replaced if lost/stolen.</li> <li>PI/department are responsible that cash is stored securely.</li> <li>A distribution log must be kept documenting the funds disbursed to study subjects.</li> <li>Studies involving cash payments may be subject to routine audit my MCW Research Compliance.</li> </ul>	<p>A subject's SSN is required for any cash payments greater than <b>\$60.00</b>. Individual cash payments to research study participants for amounts of \$60.00 or less are considered by MCW to be de minimis in nature and do not require a social security number to be collected from participants.</p>	<ul style="list-style-type: none"> <li>PI must complete the <a href="#">Research Subject Stipend Cash Request</a> to the Office of Research <u>prior</u> to IRB submission</li> <li>Office of Research will notify MCW Finance of cash approval</li> <li>Public Safety will deliver the requested cash for study payments to the study PI.</li> </ul>

**IRS Regulatory Requirements and collection of Subject Social Security Numbers (SSN)**

The Internal Revenue Service (IRS) requires that individuals are responsible for reporting all payments that are cumulative of \$600.00 or more during a calendar year to the IRS through their personal yearly tax return. To maintain compliance with IRS reporting requirements and monitor individuals' research payments, MCW Finance requires that a subject's SSN be collected for each payment type as outlined in the table above. MCW Finance will be responsible for sending the 1099-MISC form to any study subject who receives \$600.00 or more

per calendar year and a copy to the IRS. Reimbursements for travel, etc. are non-taxable and are not included in the \$600 threshold for IRS reporting.

**Informed Consent:**

If applicable, study subjects should be informed that they may receive payment for their participation and/or reimbursement for out-of-pocket expenses in the IRB-approved informed consent form. The consent form should also detail the payment type used, payment amounts and schedule (i.e. per visit). Please note that payment to research participants is not a benefit and should not be listed in the benefits section of the protocol or informed consent documentation.

**Pediatric Subjects:**

Pediatric study subjects (under age 18 years) are warranted payment for their involvement in HSR studies. At the discretion of the sponsor, multi-center PI, site PI or study team, if the subject can generally understand the concept of payment based on participation effort, it is appropriate that the payment be issued to the child. For younger children and/or for travel expenses to be reimbursed, payments may be issued to the subject's parent/guardian. Requirements for collection of SSN, as noted above, also apply to parents/guardians who receive payments on behalf of the child.

**Subjects with Rare-diseases:**

A Federal law known as the "Ensuring Access to Clinical Trials Act of 2015" allows patients with rare diseases to receive up to \$2,000 in payment per year, without having the \$2,000.00 payment count as income that could jeopardize eligibility for Supplemental Security Income (SSI) and Medicaid. Reimbursement for a subject's out-of-pocket expenses incurred while participating in the trial are not included in the \$2,000 calendar year maximum. Subjects enrolled on a trial for rare diseases will still need to provide their SSN to MCW as outlined in the table above and will receive a 1099-MISC form if they exceed the \$600.00 IRS threshold. It is the subject's responsibility to verify income exclusion for clinical trial compensation per Social Security Administration (SSA) [guidelines](#) (specifically that the clinical trial involves research and testing of treatments AND targets a rare disease or condition). MCW study teams may assist by providing subjects with a copy of the IRB-approved consent form or a letter from the study PI.

**CONTACT**

If you have any questions regarding this SOP or options for subject payment, please contact the MCW Office of Research at [research@mcw.edu](mailto:research@mcw.edu). Questions regarding check requests or purchase orders for gift cards can be sent to MCW [Accounts Payable](#).

**REFERENCES**

- [MCW Policy BF.PA.010: Business Purchases, Payments and Reimbursements](#)
- [Study Payments System Forms](#)
- [Ensuring Access to Clinical Trials Act of 2015"](#)
- [MCW Research Subject Stipend Cash Request](#)
- [SSA: SI 00830.735 Payments for Clinical Trial Participation](#)

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