

## Federal Guidelines and Suggested Language for IRB & ICF

### Why is special language needed?

#### ***Protocol and ICF Requirements***

FDA regulations are published as part of chapter 21 of the CFR, and FDA's human subject protection regulations are in parts 50, 56, 312 and 812. All research must comply, including State of Florida funded research.

***Per the FDA, the protocol and the Informed Consent Forms must both reflect:***

- ***Payment amounts, and***
- ***Payment terms and appropriate disclosure of required personal information, if applicable.***

If one of these is missing, please submit a revision to the documents for approval to the HSRO office.

#### FDA language:

"The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence (21 CFR 50.20)."

"All information concerning payment, including the amount and schedule of payment(s) should be set forth in the informed consent document."

#### State of Florida language:

Section 3.3.1 of State of Florida Grant Manual – FINAL

"Policy on Research Involving Human Subjects

Grantee must comply with applicable federal and state laws and regulations, including 45 CFR 46, 45 CFR 160 and 164, and 21 CFR 50, 56, 312, 812, and other applicable regulations."

#### ***HIPAA Form B***

HIPAA information is at:

<https://hsro.uresearch.miami.edu/researchers/policies-procedures-and-regulations/hipaa/index.html>

Any study that is required to comply with HIPAA must have a HIPAA form B on file. A HIPAA form B is required for medical studies, i.e. where there is medical information that belongs to the UM medical system, such as a diagnosis, test or exam result.

### ClinCard Requirements

To be registered on and paid from the ClinCard website, a participant's Name, Address and Date of Birth are required on the website. Optional for communication are mobile phone number and email address.

The company behind ClinCard, GoldenEye Parent, LLC, aka Greenphire, requires the 3 fields (Name, Address & DOB) for customer service reasons: if a participant calls to inquire about card balance or get a card replacement, they are used for the proper identification of the participant. More than one person can share the same name or patient ID (from one study to another), but the other components will make them unique.

### W-9 Requirement

The IRS, therefore the controller's office, requires a Form W-9 to be collected from ***each*** research participant, regardless of the amount paid. This is detailed in the UM Petty Cash Policy, which also applies to ClinCard.

**Personal information and SSN is required by the IRS and UM. SSN will not be entered on the ClinCard website.**

## Suggested Language

The HSRO office has consent form templates available at:

<https://hsro.uresearch.miami.edu/submit-to-the-irb/forms-and-templates/templates/index.html>

Suggested language can be customized to the study's needs. For example, you can add the words "GoldenEye Parent, LLC, aka Greenphire" to describe the company and "ClinCard" for the name of the debit card.

- IRB local protocol / local addendum:

Participants will be issued a ClinCard, a reloadable MasterCard branded debit card that can be used for studies at the University of Miami. Funds will be loaded on the card according to the payment schedule. The study staff will provide information about how the card works. The company administering the card, requires name, address and date of birth entered online for payment; mobile phone number and/or email address are optional for study related communications. This information will only be used for payment and communication purposes and will not be given to another company or linked to any of the study data.

- ICF:

In addition to the payment schedule, please add information about payment method:

Payment for participating in this study will be made using ClinCard. ClinCard is a MasterCard branded debit card that can be loaded with funds by the study team. We will [give/mail] you the card. You will also get information about how to use this card and whom to call if you have any questions. Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth and will be overseen by the University of Miami study team. They will use this information only as part of the payment system for customer service reasons only. Your information will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study team for a replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Per IRS requirements, you will need to fill out a W-9 or W-8BEN where your information is entered in full. This form will remain in a secure location at the study site. Your SSN/TIN will not be entered on the ClinCard website.

If you receive \$600 or more during a calendar year from the University of Miami for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

**For multiple payment options, use something similar to the above, but with multiple options listed:**

- IRB local protocol / local addendum:

Participants will be paid by either cash or debit card. If by debit card, they will be issued a ClinCard, a reloadable MasterCard branded debit card that can be used for studies at the University of Miami. The study staff will provide information about how the card works. The card will be loaded according to the payment schedule. The company administering the card requires name, address and date of birth entered online for payment; mobile phone number and/or email address are optional and only for study related communications. This information will only be used for payment and communication purposes and will not be given to another company or linked to any of the study data.

- ICF:

In addition to the payment schedule, please add information about payment method:

Payment for participating in this study will be made either by cash or by debit card. If debit card, it will be a ClinCard. ClinCard is a MasterCard branded debit card that can be loaded with funds by the study team. We will [give/mail] you the card. You will also get information about how to use this card and whom to call if you have any questions.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth and will be overseen by the University of Miami study team. They will use this information only as part of the payment system for customer service reasons only. Your information will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study team for a replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Per IRS requirements, you will need to fill out a W-9 or W-8BEN where your information is entered in full. This form will remain in a secure location at the study site. Your SSN/TIN will not be entered on the ClinCard website.

If you receive \$600 or more during a calendar year from the University of Miami for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

**For participants under 18 years of age:**

***ClinCard cannot be issued to anyone under 18 because of banking rules. Receiving a ClinCard implies a legal agreement between the cardholder and MasterCard. Anyone under 18 isn't allowed to enter into a legal agreement. The card must be issued to a parent or guardian.***

- Assent Form (if the IRB approves the use a separate assent form for minors):  
In addition to the payment schedule, please add information about payment method:  
You will be paid through a card, like a debit card called ClinCard. The study team will add money to the card as you move along through the procedures. We will [give/mail] your parent/legal guardian.
- Consent Form for parent/legal guardian of minors:  
In addition to the payment schedule, please add information about payment method:  
Payment for your child who is participating in this study will be made using ClinCard. ClinCard is a MasterCard branded debit card that can be loaded with funds by the study team. We will [give/mail] you the card for your child. You will also get information about how to use this card and whom to call if you have any questions. Money will be added to the card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth and will be overseen by the University of Miami study team. They will use this information only as part of the payment system for customer service reasons only. Your information will not be given or sold to any other company. Greenphire will not receive any information about your child's health status or the study in which they are participating.

If the card is lost or stolen, please call the study team for a replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Per IRS requirements, you will need to fill out a W-9 or W-8BEN where your information is entered in full. This form will remain in a secure location at the study site. Your SSN/TIN will not be entered on the ClinCard website.

If you receive \$600 or more during a calendar year from the University of Miami for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.