

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 for ***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 website.

Suggested Language

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 reloadable 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:
After you enter the study, the study team will give you a debit card that you will use while you are in this study. The study team will show you how to use the card, and you will be responsible for the card for the duration of the study. As you progress through the study, they will load funds on the card according to the payment schedule. The company providing the card requires the team to enter your name, address, and birth date on a website. If you want to receive messages about the study, the study team can also include your cellphone number and/or your email address. The company will use this information only for payment, customer service inquiries and messaging purposes. The company will not give your information to another company or link it to any of your study data.

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

- IRB local protocol / local addendum:
Participants will be reimbursed XXX for YYY.
Participants will be paid by either cash or debit card. If by debit card, they will be issued a reloadable 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:
You will be reimbursed XXX for YYY.
After you enter the study, the study team will pay you either by cash or debit card. If a debit card is used, the study team will show you how to use the card, and you will be responsible for the card, which is reloadable, for the duration of the study. As you progress through the study, the team will load funds according to the payment schedule. The company that issues the card requires your name, address, and date of birth on a website. If you want to receive messages about the study, the study team can also include your cellphone number and/or your email address. The company that issues the card will use this information only for payment, customer service inquiries and messaging purposes. Your information will not be given to another company or be linked to any of your study data.