Financial Disclosure Forms

Guidance and Tips

IMPAACT
International Maternal Pediatric
Adolescent AIDS Clinical Trials Network

Background

- The requirement to collect financial disclosure information for studies conducted under an IND is not new
- DAIDS issued new guidance on collection of this information effective 1 July 2014
- Study monitors began to assess compliance with this guidance beginning Q1 2015

Background

- Financial Disclosure documentation is different than the Conflict of Interest documentation that is collected through HANC

Note

DAIDS Financial Disclosure Guidance uses the terms:

- Investigator – referring to the IoR
- Sub-investigator – referring to all study staff listed in the Form FDA 1572 who are not the IoR

Requirements

At the time a clinical research site (CRS) completes a Form FDA 1572 for a study conducted under an IND/IDE, **all study staff members listed on the Form FDA 1572,** must complete the DAIDS approved network financial disclosure form or the drug company-specific financial disclosure form/statement.

Requirements

At any time when a **new study staff member is added to the Form FDA 1572**, the new staff member must complete the network financial disclosure form or the drug company-specific financial disclosure form/statement

Requirements

At any time **when the financial interests of a study staff member** listed on the FDA Form 1572 changes, the staff member must complete an updated network financial disclosure form or an updated drug company-specific financial disclosure form/statement

Requirements

The network financial disclosure form or a drug company-specific financial disclosure form/statement must be **completed prior to the initiation** of **and again** at the **completion of the clinical trial** at a CRS

Who completes the form?

Any study staff listed on the

Form FDA 1572

on behalf of himself/herself **plus** spouse and dependent children

When to complete the form?

Multiple timepoints prior to, during, and after the study:

- When completing the Form FDA 1572 for the first time for a study
  - A financial disclosure form should be completed for each investigator listed on the Form FDA 1572 **prior to study activation**
- If the Form FDA 1572 changes or is updated during the study
  - An investigator's name changes (the Form FDA 1572 should also be updated), **staffing changes**
- After completion of the study at the site
  - IMPAACT Operations Center can provide guidance to sites on this timing during **study closeout** activities

Example: IMPAACT P1110

Please complete all of the information below, including providing your signature where indicated.
1. Protocol Number: IMPAACT P1110
2. Protocol Title: A Phase I Trial to Evaluate the Safety and Pharmacokinetics of Raltegraivir in HIV-1 Exposed Neonates at High Risk of Acquiring HIV-1 Infection
3. Site Name/Number: <INSERT SITE NAME/NUMBER>
4. Participating Pharmaceutical/Biotechnology Company(s): Merck & Co., Inc.
5. Principal Investigator/Subinvestigator name as listed on 1572 : <INSERT INVESTIGATOR NAME> ☐ **Principal Investigator** ☐ **Subinvestigator**
6. Investigator Contact Information: <INSERT INSTITUTION NAME, TELEPHONE NUMBER, FAX NUMBER, E-MAIL ADDRESS>

Example: IMPAACT P1110

7. Indicate by marking YES or NO if any of the financial interests or arrangements of concern to FDA (as described below) apply to you, your spouse, or dependent children.	
Any financial arrangement entered into between you and any participating pharmaceutical/ biotechnology company whereby the value of the compensation to you for conducting the study could be influenced by the outcome of the study? This includes compensation that could be greater for a favorable clinical result, compensation in the form of an equity interest in any participating pharmaceutical/biotechnology company or compensation tied to sales of the product tested in the above study such as a royalty interest. If yes, please describe: _____	YES ☐ NO ☐
Any significant payments of other sorts from any participating pharmaceutical/biotechnology company? This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than $25,000 (i.e. a grant to fund ongoing research compensation in the form of equipment, or retainers for ongoing consultation of honoraria). If yes, please describe: _____	YES ☐ NO ☐
Any proprietary interest in the product tested in the study such as a patent, trademark, copyright, or licensing agreement..? If yes, please describe: _____	YES ☐ NO ☐
Any significant equity interest in any participating pharmaceutical/biotechnology company? This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding $50,000. If yes, please describe: _____	YES ☐ NO ☐
In accordance with 21 CFR § 54.1 to 54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year after the last patient has completed the study as specified in the protocol, I will notify DAIDS promptly.	
8. Signature	**9. Date:**

How to complete the FD form

For most IMPAACT studies, a study-specific template form will be provided, and available on the study IMPAACT website.

- Items 1, 2, and 4 will already be completed by the CTS for the study-specific template form.
- Items 3, and 5-9 must be completed by the study staff member
  - Item 8 is the signature block, and item 9 is the date for the signature

Common Mistakes

- Contact information (item 6) does not match the investigator/ sub-investigator listed on the form (in item 5)
  - Most likely due to copy and paste errors when copying the CRS address across multiple forms

Common Challenges

- Implementation of guidance initiated after study start (for older IMPAACT studies)

- Name changes (e.g. married or divorced) during the study

Tips

- Confirmation of completed FD forms for all staff listed on the Form FDA 1572 will be an activation requirement for IMPAACT studies
- For staffing changes during a study, sites may want to include completion of the study-specific FD form as part of staff training requirements
- When staff leave or transition off a study, FD forms should be reviewed and updated (if needed) to ensure compliance
- Similar to site's internal annual review of SOPs and other essential documents, an annual review of these forms will help ensure that they are kept up to date and in compliance

Resources

- DAIDS RSC website:

http://rsc.tech-res.com/clinical-research-sites/daids-financial-disclosure-forms

- IMPAACT Operations Center CTS for your study.

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Questions?

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