Financial Interest Disclosure System
FIDS

Ciara Nic Mhathúna
ORIS
Financial Interest Disclosure System

New system for disclosing SFI that integrates with SAGE
Replaces existing paper SFI disclosure process for eGC1s
Necessary to support new PHS FCOI rules and revised GIM 10
Revised GIM 10

- New thresholds for SFI
- Definition of Investigator
- Additional disclosure and reporting requirements, including travel disclosures and annual disclosures
- FCOI training for PHS investigators
- Public FCOI report for PHS
SAGE eGC1 CHANGES
Investigator Responsibilities

- PI will be responsible for identifying all Personnel who are also Investigators.
- PI responsible for reporting Investigator identity within ten days.
- Investigators will be personally responsible for their own SFI and Travel Disclosures.

“Investigator” means any University personnel regardless of title or position, including a University Research Employee, responsible for the design, conduct, or reporting of University Research.
Investigator Responsibilities

• PI will be responsible for identifying all Personnel who are also Investigators.

• PI responsible for reporting Investigator identity within ten days.

• Investigators will be personally responsible for their own SFI and Travel Disclosures.
Identifying Investigators

• New Yes/No indicator for Investigator on the PI & Personnel page of the eGC1.
• System sets it to “Yes” for individuals with the role PI, Multiple PI or Co-Investigator. Preparer cannot change it.
• Defaults to “Yes” for all other roles, but the preparer can change it as needed.
Investigator

A new column for Investigator will be added to the Personnel list. Investigator will be set to Yes for all existing eGC1s and new eGC1s where the role type is PI, Multiple PI or Co-Investigator. For new eGC1s, Investigator will default to Yes for Key Personnel, Mentors, Fellows and Other, but the user can change it to No as necessary.
Investigator Responsibilities

• PI will be responsible for identifying all Personnel who are also Investigators.

• **PI responsible for reporting Investigator identity within ten days.**

• Investigators will be personally responsible for their own SFI and Travel Disclosures.
Reporting Investigator Identity

- No change to current process while eGC1 is routing; eGC1 can be withdrawn and investigator can be added.
- Once eGC1 has been approved by OSP, the PI & Personnel page will be opened up and **changes to personnel will be required post-approval**.
- History section to track changes to personnel
Post-approval eGC1 changes

- Investigators should be added to the eGC1 as they start working on the project.
- If an Investigator is already on the Budget for that eGC1, they can also add themselves through FIDS.
- PI responsible for alerting OSP of any personnel changes that require approval by the sponsor.
Post-Approval Personnel Changes

<table>
<thead>
<tr>
<th>Name</th>
<th>Role Type</th>
<th>Entered by</th>
<th>Date</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benjamin Cornell</td>
<td>Key Personnel</td>
<td>Ciara Nicomhathuna</td>
<td>8/7/2012 2:16:21 PM</td>
<td>Added to eGC1</td>
</tr>
<tr>
<td>Jason Myers</td>
<td>Co-Investigator</td>
<td>Ciara Nicomhathuna</td>
<td>8/7/2012 2:16:32 PM</td>
<td>Role changed from Key Personnel to Co-Investigator; Investigator status changed from False to True</td>
</tr>
<tr>
<td>Richard Fenger</td>
<td>Key Personnel</td>
<td>Ciara Nicomhathuna</td>
<td>8/7/2012 2:17:01 PM</td>
<td>Added to eGC1</td>
</tr>
<tr>
<td>Richard Fenger</td>
<td>Key Personnel</td>
<td>Ciara Nicomhathuna</td>
<td>8/7/2012 2:23:02 PM</td>
<td>Investigator status changed from True to False</td>
</tr>
</tbody>
</table>

PI & Personnel History displays all personnel changes that occur after an eGC1 has been approved by OSP

PI & Personnel post-approval history
Investigator Responsibilities

- PI will be responsible for identifying all Personnel who are also Investigators.
- PI responsible for reporting Investigator identity within ten days.
- **Investigators will be personally responsible for their own SFI and Travel Disclosures.**
Disclosing SFI

- Yes/No indicator for SFI will be removed from PI & Personnel page.
- SFI status will come from the Investigator’s disclosure on FIDS.
- Investigators must make a new disclosure for every eGC1.
- Investigator must disclose whether or not they have SFI.
SFI
SFI will no longer be a Y/N question, and the answer will instead be derived from the Investigator's disclosure for that eGC1.

There are four possible statuses for SFI:

- **Yes.** The investigator has completed a disclosure and indicated that they have SFI (PHS) or that they have SFI that is related to this research (non-PHS).
- **No.** The investigator has completed a disclosure and indicated that they do not have SFI (PHS) or that they do not have SFI that is related to this research (non-PHS).
- **Unknown.** The investigator has not yet completed their disclosure; their SFI status is unknown until they complete the disclosure.
- **Not applicable.** The person listed is not an investigator.
Linking Disclosures to eGC1s

• eGC1 Preparers should notify the Investigators using the new “Send Disclosure Notification” feature on the PI & Personnel page.

• Disclosures that are made without using this tool will not be linked to that eGC1.

• Disclosures cannot be escalated; the investigator must complete their own disclosure.
The Disclosure Notification feature appears on the PI & Personnel page. It is used to notify investigators that they have to complete a disclosure (thus linking the disclosure with the eGC1). It is available both before and after the eGC1 is approved by OSP.

Disclosure Notifications should be sent:
- As soon as possible when eGC1 is composing, but no later than time of completion.
- At JIT for eGC1s that were approved prior to 8/16.
- Whenever a new investigator is added.
Completing an eGC1

• To complete and route an eGC1, all investigators must have received notification that they are required to disclose.
• To mark the eGC1 as “Ready to Submit”, all investigators must have completed their disclosure.
Tracking GIM 10 Compliance

- Compliance Details section on eGC1 PI & Personnel page
- Will display disclosure status and training status for each investigator.
- Anything that is listed in **bold** text is something that requires an action.
Compliance Details.
The Compliance Details column on the Personnel list will display the PHS FCOI training status and the disclosure status for all people listed. Only PHS investigators are required to take the training. All personnel who are listed as investigators are required to disclose for each eGC1, regardless of whether the sponsor is PHS or non-PHS.
On the Compliance Details column, anything that requires action will be displayed in bold font. This may include actions required by the eGC1 preparer (i.e. send disclosure notification) or actions that are required by the investigator (i.e. take training, or complete their disclosure).

Training requirements will be listed first. There are three possible statuses for training
• **PHS training required.** The eGC1 is for a PHS sponsor, and the investigator has not yet completed the PHS training, or the PHS training has expired.
• **PHS training complete.** Expires on M/D/YY. The investigator has taken the PHS training and the expiry date of their training is listed. PHS training is valid for 4 years.
• **PHS training not required.** The person listed is not an investigator, or the eGC1 does not have a PHS sponsor.

The disclosure status is also listed. In the next system iteration, we will be augmenting the disclosure status to show what the review status of that disclosure is.
For this iteration, there are four possible statuses for the disclosure:

- **Disclosure Required.** The person listed is an investigator, and has been notified of their obligation to disclose.

- **No Disclosure Required.** Person is not an investigator, and therefore is not required to disclose.

- **Disclosure Notification not Sent.** Person is an investigator and is required to disclose, but they have not yet been notified of their disclosure requirements. If the eGC1 preparer (or anyone with read/write access to the eGC1) clicks on the "Send Disclosure Notifications" button on the PI & Personnel page, the investigator will be notified.

- **Disclosure Submitted.** Person is an investigator and has completed a disclosure for this eGC1.
Screenshot of the new PI and Personnel page.
FIDS
Screenshot of the FIDS profile page. It is composed of the following sections:

- **Investigator Details**, which includes contact details plus a list of current sponsored projects
- **SFI**
- **Disclosures**. This may include disclosures that were previously made, or Pending Disclosures.
Current eGC1s include the eGC1s that have the following conditions
• Composing, Withdrawn, Returned, Routing and In OSP where today’s date is less than proposed start date plus one month.
• Awarded, where the end date is in the future, or within the previous 12 months.
• Approved where the start date is in the future, or is 6 months in the past.
• All eGC1s where the personnel record for the user has been updated in the previous 12 months.

eGC1s with the following statuses will not be displayed in the list of current eGC1s:
• eGC1s that are Composing, Withdrawn, Returned, Routing, In OSP, Awarded or Approved where the start/end dates are outside the time limits set above, except where the personnel record has been updated for that user.
• Denied eGC1s
• Permanently withdrawn eGC1s
• Discarded eGC1s
When a disclosure notification is sent from an eGC1, a “Pending Disclosure” is created. These disclosures are indicated with a “Complete Disclosure” button.
Indicating that you have no SFI

Disclose Significant Financial Interests

Significant Financial Interests (SFI) [key: foo, sfi, ted] Use the add link to create any additional significant financial interests you have to disclose at this time. You are required to update your SFI on an annual basis and to submit a disclosure of all new Financial Interests within 30 days of acquisition.

I do not have any SFI to disclose  
I have SFI to disclose  

Next
Once the investigator reaches this page, the eGC1 is updated to indicate that they do not have any SFI
If the investigator has SFI, then clicking on Next will bring them to the SFI Entry page.
If the investigator wishes to add more SFI for other entities, they can do so by clicking on the Add SFI link.
List of current eGC1s is displayed so that the investigator can indicate if any of their other research activities are related to the SFI.
Updated SFI and Disclosure Lists on Profile Page

**Significant Financial Interests**

[Significant Financial Interests](#)  
This displays any existing SFI. If you need to create new SFI, or edit existing SFI, click on the link below.

<table>
<thead>
<tr>
<th>Name of Entity</th>
<th>Interest Holder</th>
<th>Nature of Interest</th>
<th>Entity Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simpsonsomics</td>
<td>Self</td>
<td>Equity interest</td>
<td>For Profit: Privately Held</td>
<td>$3,000</td>
</tr>
</tbody>
</table>

Add / Edit SFI

**Disclosures**

[Link Your SFI With Your Research Activities](#)  
Your disclosures link your research activities with your declared financial interests. Some examples of connections could include, but are not limited to, situations where the entity is also a sponsor, or is a supplier, or is a competitor of a sponsor of your research activities.

Previous disclosures will be listed here. A "Complete Disclosure" button indicates that you need to finalize this disclosure.

<table>
<thead>
<tr>
<th>Disclosure ID</th>
<th>Date Disclosed</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>D144</td>
<td>8/2/2012 5:19:44 PM</td>
<td>Disclosure Complete</td>
</tr>
<tr>
<td>D148</td>
<td>8/7/2012 9:17:09 PM</td>
<td>Disclosure Complete</td>
</tr>
<tr>
<td>D161</td>
<td>8/9/2012 3:38:39 PM</td>
<td>Disclosure Complete</td>
</tr>
</tbody>
</table>
SUMMARY
Future Enhancements

• Additional disclosure statuses:
  – Review Required
  – No Review Required
  – Waiting on JIT
  – Review Complete

• Attachments

• Enhanced Routing
Timeline

• SAGE Changes available 8/17
• FIDS available 8/17
  – FIDS Support Site
  – Online Course
  – Disclosures should be made at new thresholds
• Training environment for FIDS available 8/20
Before August 16th

- Ensure any eGC1s that have imminent deadlines have been completed and are with OSP.
- eGC1s that are withdrawn after August 16th will have the new rules applied; disclosures will be required from all investigators.
Reminder!

- Personnel changes that occur after the eGC1 has been awarded should now be entered on the PI & Personnel page.
- PI & Personnel page also updated to send requests for disclosures and track status.
- Investigators will have to make a disclosure for every eGC1.
  - Request the disclosure as soon as possible; it cannot be escalated if the investigator is away.