## Annual Disclosure Period Planning

#### Timing

- 1. Determine the date to start the disclosure period
  - a. Typically, the start date should be on or around the same date as the prior year.
  - b. Communicate the desired start date to the HUIT team at least 4 weeks before the date to ensure that you and the HUIT team have sufficient time to review the discloser population.
  - c. The HUIT team will set the start date in the OAIR system.
- 2. Determine the date to end the disclosure period
  - a. It is helpful to have a deadline for report completion when communicating with the discloser population.
  - b. The system does not enforce the deadline but it will send reminders to disclosers who have not completed their certifications 7, 21 and 30 days after the start of the disclosure period.
  - c. It may also be helpful to plan for an escalation path in cases where disclosers do not complete their reports by the deadline.

### Communications

#### School-specific communications

Your school should plan to send an email to all disclosers in the week prior to the start of the annual period to remind them of the annual disclosure requirement, inform them that they should expect to see an email from the system with specific instructions on completing the report, and provide them with any school-specific guidance on policies and processes. For examples, see the <u>OAIR Workgroup</u> <u>Resources</u> folder on SharePoint.

#### System communications

On the start date, the system will send emails to all the people affiliated with your school who have been automatically identified as needing to disclose and to the people who have been manually flagged as needing to disclose as of the start date.

HUIT will also manually initiate the system emails to any disclosers who are not primarily affiliated with your school but who are included in your annual disclosure process.

The system notification is not school-specific and primarily includes basic instructions on accessing and completing the report. Schools can add a few lines of locally relevant text to appear in the body of the notice. Schools can share this information with HUIT when defining the annual start date.

The subject line of the system notification is: Action Required - Annual Outside Activity and Interest Report.

The notice contents are:

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### Discloser Population Review

Who will receive the Annual Certifications is one of the most important parts of the rollout process. The annual rollout preparatory period is a good opportunity for your school to ensure that its disclosing population is accurate and take any necessary actions to update this person data.

*Review the job codes to determine which jobs include disclosure requirements* 

- 1. Review the job codes currently set to include disclosure requirements through the Harvard Report: School Discloser Job Codes (in reports).
- Communicate any changes to the list of relevant job codes to the HUIT team so that they can update the system.
- 3. Determine if any new jobs not currently included on the report should be added.
  - a. The Harvard Report: School Affiliates (<u>in reports</u>) includes job codes for all active affiliates. This report can be used to identify any new job codes that might need to be added. Export the report to Excel and remove all duplicate job codes to identify all the unique job codes for review.
  - b. You may also want to communicate with your school HR to find out if new jobs have been added since the last annual disclosure period.

#### Review the list of individual disclosers identified as needing to disclose

- Review the current list of disclosers through Harvard Report: School Disclosers (in reports). Anyone identified in the system as needing to disclose based off their job and/or status as an investigator on projects with disclosure requirements and anyone manually flagged as needing to disclose will be included in the report. NOTE: If you have identified changes to be made to the job codes currently set to include disclosure requirements, any resulting changes to the discloser list will take approximately one day to take effect.
- 2. Identify anyone currently included who should be excluded.
  - If there are people who need to be excluded from the requirements, you can complete the Update COI information activity to manually exclude them or, if you determine that they have been included because of job code/FTE status that should be excluded,

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communicate with HUIT to update the included job code. If there is a high volume of expected changes, contact HUIT for additional options.

- When taking this action, ensure you are not viewing the record as a guest reviewer. Only members of the school of primary appointment should take this action on the person. To confirm you are representing the school of primary appointment, view the school named on the person profile.
- 3. Identify anyone not currently included who should be.
  - For people who are missing from the discloser population, you can complete the Update COI information activity to manually include them or, if you determine that they have not been included because of job code/FTE status that should be included, communicate with HUIT to update the included job code. If there is a high volume of expected changes, contact HUIT for additional options. You can review disclosers who have been manually excluded in the past using the Harvard Report: Manually Excluded Affiliates (in reports).
  - When taking this action, ensure you are not viewing the record as a guest reviewer. Only members of the school of primary appointment should take this action on the person. To confirm you are representing the school of primary appointment, view the school named on the person profile.
- 4. Identify anyone who does not have an email address in the system people without an email address in the system will not receive system notification. If possible, work with HR to determine what the correct email address is and update the central directory ahead of the annual start date. Alternatively, you may choose to email these disclosers directly with instructions for logging into the system and completing their certification.
- 5. Identify any disclosers who are not primarily affiliated with your school but who should be included in your school's annual disclosure process You will see disclosers for whom your school has been provided guest access in the discloser report. However, these disclosers will not be included in the annual process for your school automatically. If any of these disclosers should be included, provide a list to the HUIT team in advance of the annual period start date. A list of current manually included disclosers is available in the <u>Resources folder on SharePoint</u>.
- 6. Working with HUIT, identify any disclosers flagged by HUIT as needing to disclose because of participation on active GMAS projects at the time of the OAIR launch and update their disclosure status if they are no longer on active projects. If a person has been flagged as a discloser automatically in OAIR, compare end dates for pre-OAIR projects with post-OAIR projects to determine if manual disclosure flag can be removed. If a person is no longer an investigator on any active projects, the manual disclosure flag can be removed. NOTE: The GMAS team will provide a report to identify these disclosers.

### Plan for any people who are required to disclose annually who do not have a HUID

Review the list of non-HUID investigators on active projects with disclosure requirements that is
provided by HUIT. Your school will need to communicate directly with these disclosers and ask
them to complete the disclosure form outside of OAIR. See <u>OAIR Guidance – Investigators</u>
without a HarvardKey for more information on how these investigators can meet the disclosure
requirements.

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#### Review and update those with guest access

- Review the list of individuals with guest access set up (where your school has assigned guests) using the Harvard Report: My School Disclosers with Guest Access Configured Affiliates (in reports). Also reference: <u>OAIR Guidance – Guest Management</u>.
- 2. Your school may determine that guest access is no longer warranted (and can remove access) or may need to communicate directly with guest reviewers for some disclosers to determine appropriate timing and purview for that discloser's annual certification.

### Additional Final Preparation

- 1. Withdraw any annual certifications from prior year that are still in Draft status.
- 2. Complete reviews of all submitted certifications, if possible. Any disclosures still under review will not be editable by disclosers.
- 3. [Wyss only] Add Wyss guest access for all disclosers who should be visible to the Wyss reviewers. HUIT can bulk update guest information for these disclosers.

## During the Annual Disclosure Period

On the start date, annual certifications will be created automatically for all school affiliates needing to disclose as of that date. Once the annual certifications are created, each discloser will receive an email from the system as described above. The HUIT team will monitor and report back on the system process.

The HUIT team will manually create annual certifications for any disclosers not affiliated with your school and will send the notifications to those disclosers. Any special school message included when defining the annual start date with HUIT will not be included in the notification to these individuals. The school message only shows for those primarily affiliated with your school.

Disclosers will receive reminders 7, 21 and 30 days after the start of the certification period if they have not completed their reports.

Any certifications not submitted will remain in Draft status until manually withdrawn by the reviewers.

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# **Reference Checklist**

TIMING	TAS	-	USE THIS REPORT	NOTES
ONE MONTH PRIOR TO PERIOD START		Communicate start date and any school-specific notice text (including possible due date) to HUIT team		School-specific text cannot be special format (i.e. no bold text) and notice text should be brief.
		Confirm included job codes	Harvard Report: School Discloser Job Codes ( <u>in reports)</u>	
		Add any new job codes	Harvard Report: School Affiliates ( <u>in</u> <u>reports</u> )	This may require contact with your HR representative or FAR team, to identify any new or changed job codes that should be included.
THREE WEEKS PRIOR TO PERIOD START		Review included disclosers	Harvard Report: School Disclosers ( <u>in</u> <u>reports)</u>	
		Review guest reviewers for included disclosers	Harvard Report: My School Disclosers with Guest Access Configured Affiliates ( <u>in reports</u> )	
		Confirm any exclusions (listed but should not be and are primarily affiliated with your school)		<ul> <li>Visit each person workspace by clicking on their name to:</li> <li>1. Click the Update COI Information activity on the left. (also see reference)</li> <li>2. Mark the appropriate yes/no option for the admin override option.</li> </ul>
		Confirm any additions (not already listed and primarily affiliated with your school)		See above steps for managing exclusions.
		Notify HUIT of any non-affiliates to be included in annual population		
TWO WEEKS PRIOR TO PERIOD START		Withdraw any annual certifications in Draft from prior year	Harvard Report: Annual Certifications in Draft ( <u>in reports</u> )	
ONE WEEK PRIOR TO PERIOD START		Email disclosing community to inform them of the coming system notice	Harvard Report: School Disclosers ( <u>in</u> <u>reports)</u>	
		Complete review of any certifications in the Administrative Review status (where possible)		
START DAY OF PERIOD		Monitor the creation of submissions and distribution of notices	Harvard Report: Annual Certifications In Draft ( <u>in reports)</u>	
		Email non-OAIR certification to non- HUID disclosers	GMAS Report (to be provided by HUIT)	See <u>OAIR Guidance –</u> Investigators without a HarvardKey