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| **Summary of FCOI Noncompliance and FCOI Reporting** |
| **FCOI Report** **(within 60 days of identification)** | Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH. |
| **Retrospective Review** **(to determine bias)** | If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward. |
| **Update/Revise FCOI Report (following retrospective review)** | If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report. |
| **Mitigation Report (promptly after retrospective review)** | If bias is found, * Notify NIH promptly
* Submit mitigation report through FCOI Module
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| **Annual FCOI Report** | Submit annual FCOI report thereafter through FCOI Module |