The cover features a large, light blue grid pattern that covers most of the right and bottom portions of the page. On the left side, there is a solid orange triangle pointing downwards. Below the orange triangle, there is a smaller, darker blue triangle pointing upwards. The text is positioned in the white space between these shapes.

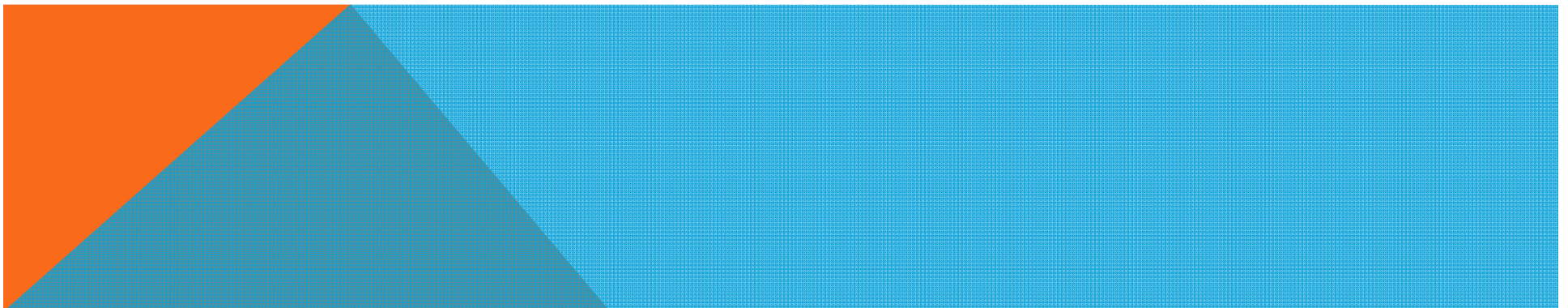
CONFLICT OF INTEREST 2012

AN IRB INFOSHORT
SEPTEMBER 2012

CHANGES IN FEDERAL REGULATION

Beginning August 24, 2012:

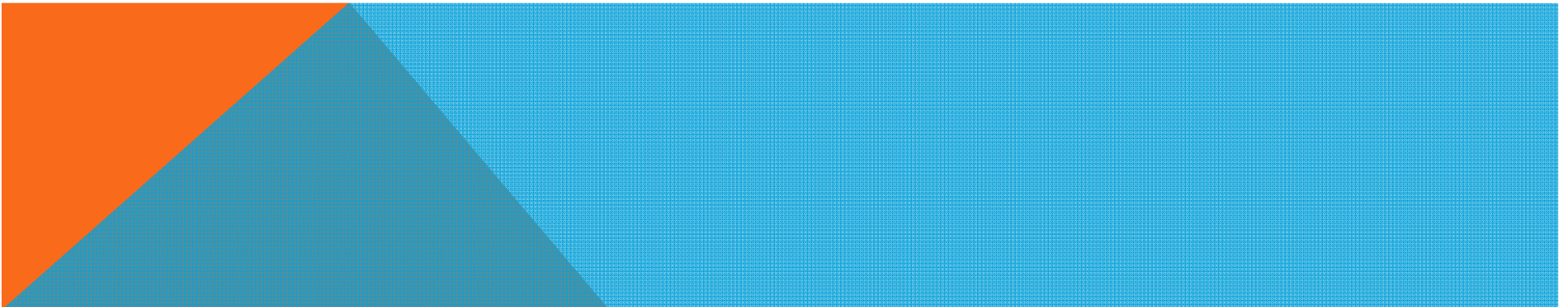
- * Training in COI is federally required
- * Threshold for a significant financial interest (SFI) has changed:
 - PHS threshold is \$5,000
 - NSF threshold is \$10,000



CHANGES IN FEDERAL REGULATION

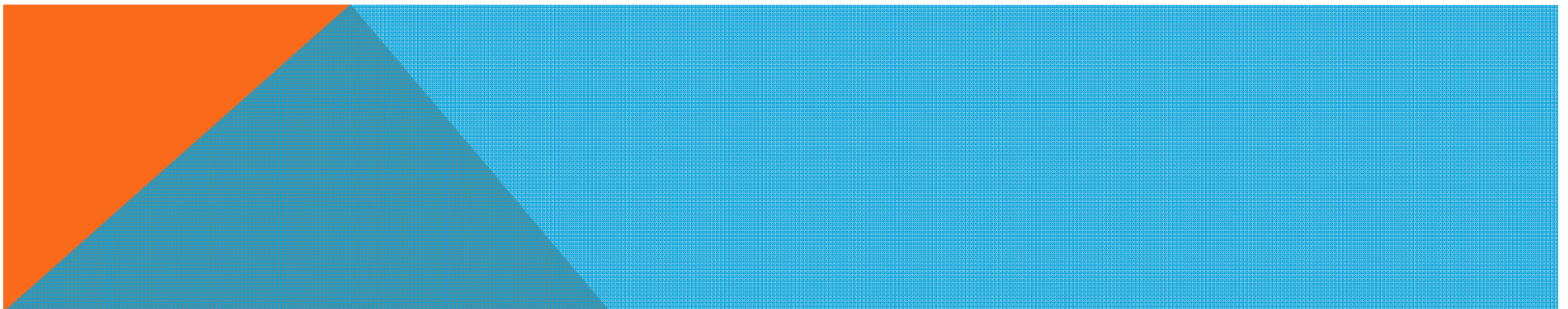
Elements of financial calculation have changed

- For PHS—last 12 months only
 - Includes paid travel, service to professional societies
- For NSF—last 12 months and next 12 months
 - Excludes paid travel, service to/income from professional societies



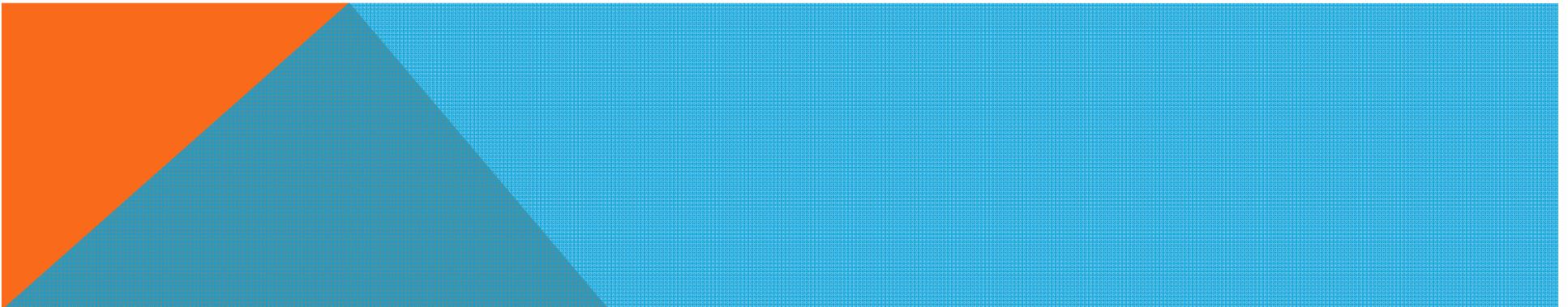
CHANGES IN YALE POLICY AND PROCEDURE

- * No change in annual disclosure requirement
- * COI training is embedded in disclosure process
- * Branched disclosure, based on funding
- * If no federal funding, the threshold for an SFI is \$10,000



IRB REVIEW AND CONSIDERATION

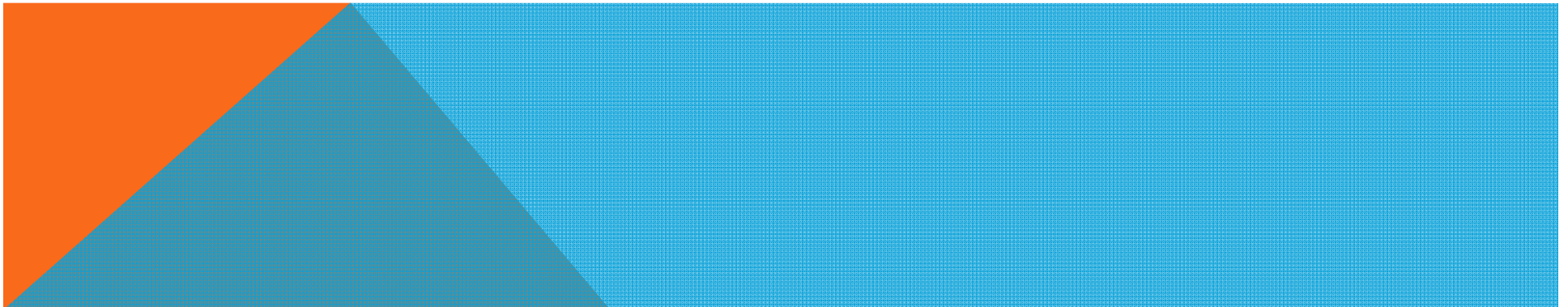
- * Investigator informs IRB of protocol-specific conflicts
- * IRB staff identify SFI (may be intellectual property)
- * IRB determines whether or not conflict requires management for protection of human subjects



THE KEY

The charge to the IRB remains the same:

- * the protection of subjects
- * the integrity of the study data



FOR FULL UNIVERSITY COI INFORMATION

See the COI website:

<http://coioffice.yale.edu/>

