
The Babel Group

Financial Conflict of Interest (FCOI) Policy for PHS/NIH-Funded Research

Effective date: September 4, 2025

Designated Official (DO): Rachel Khasky-Levy — rachel@thebabelgroup.com

Scope: This policy applies to all Investigators (as defined below) participating in research supported directly or indirectly by a Public Health Service (PHS) prime award (including NIH), including subawards issued to The Babel Group. It implements 42 CFR Part 50 Subpart F and 45 CFR Part 94 to promote objectivity in research by managing financial conflicts of interest.

1) Definitions (abbreviated)

- **Investigator:** Any person (regardless of title) responsible for the **design, conduct, or reporting** of PHS/NIH-funded research (may include collaborators/consultants).
 - **Institutional Responsibilities:** Professional duties on behalf of The Babel Group (e.g., research, teaching, administration, clinical service).
 - **Significant Financial Interest (SFI):** As defined in 42 CFR 50.603 (e.g., certain remuneration/equity thresholds, IP income, sponsored/reimbursed travel), subject to NIH thresholds and any stricter internal standards.
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2) Training Requirements (42 CFR 50.604(b))

The Babel Group will:

- Inform each Investigator of this policy, their SFI disclosure responsibilities (domestic **and foreign**), and applicable federal regulations/resources (NIH FCOI Training site).
- Require FCOI training:
 - **Before** engaging in any NIH-funded research,

- **At least every 4 years**, and
 - **Immediately** if: the policy is revised in a way that affects Investigator requirements; an Investigator is **new** to The Babel Group; or noncompliance is found.
- Accept the NIH online tutorial as meeting the training requirement; Investigators must retain completion certificates.
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3) Disclosure, Review & Monitoring

3.1 Who must disclose & when

Each Investigator must disclose all **foreign and domestic** SFIs (including those of **spouse and dependent children**) **related to their institutional responsibilities**:

- **No later than the time of application** for NIH-funded research,
- **At least annually** during the award, and
- **Within 30 days** of discovering/acquiring a new SFI.

Disclosures are submitted to the DO: **Rachel Khasky-Levy** (rachel@thebabelgroup.com).

3.2 Designated Official responsibilities

The DO will:

- **Solicit and review** SFI disclosures (including family SFIs) to determine **relatedness** to NIH-funded research and whether an **FCOI** exists.
- Use NIH-aligned criteria to determine relatedness: an SFI is related when it **could be affected** by the research or is in an entity **whose financial interest could be affected** by the research; an FCOI exists when the SFI **could directly and significantly affect** the **design, conduct, or reporting** of the research.
- If an FCOI exists, **develop and implement a written management plan** before funds are expended.

3.3 Examples of FCOI management conditions

May include: public disclosure (publications/presentations), disclosure to human subjects (when applicable), independent monitoring, protocol modifications, role changes or disqualification, reduction/elimination of the financial interest, or severance of conflicting relationships.

3.4 60-day reviews for new/late SFIs

If a **new Investigator** joins a project or an existing Investigator **discloses a new/late SFI**, the DO will, **within 60 days**, determine relatedness/FCOI and implement an (interim) management plan specifying actions taken/to be taken.

3.5 Ongoing monitoring

The Babel Group will **monitor Investigator compliance** with management plans **until project completion** (including applicable subrecipient Investigators).

4) Reporting to the NIH (via the PHS Grantee)

The Babel Group (as subrecipient) will provide the PHS Grantee (prime recipient) the required FCOI reports so the Grantee can submit to NIH **via the eRA Commons FCOI Module**:

- **Prior to expenditure of funds,**
- **Within 60 days** for an Investigator **newly participating,**
- **Within 60 days** for **new or newly identified** FCOIs for existing Investigators, and
- **At least annually** (status and any management plan changes) for the duration of the project.

No expenditures may be incurred **until** the PHS Grantee reports the FCOI to PHS/NIH and authorizes spending.

If a retrospective review updates prior information, the PHS Grantee/NIH will be updated accordingly.

5) Retrospective Review & Bias Mitigation (noncompliance)

When an SFI was not disclosed timely, not previously reviewed, or an FCOI was not identified/managed on time, The Babel Group will (within **120 days** of the noncompliance determination):

1. **Complete a retrospective review** of the Investigator's activities/research for bias;
 2. **Document** required key elements (project number/title; PD/PI; Investigator & entity with FCOI; reasons; methodology; findings; conclusions); and
 3. **Determine** whether the research was biased in its design, conduct, or reporting.
If bias is found, submit/enable the Grantee's **Mitigation Report** describing impact and actions taken to eliminate/mitigate the effects of bias; continue **annual FCOI reports** thereafter.
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6) Maintenance of Records

Maintain all FCOI-related records (disclosures, reviews, responses, actions, retrospective reviews) for **at least 3 years** from the date the **Final Federal Financial Report** is submitted, or longer as required by **45 CFR 75.361** in specific circumstances.

7) Enforcement & Remedies

The Babel Group establishes enforcement mechanisms and may impose sanctions or administrative actions (e.g., reprimands, restrictions on use of funds) to ensure compliance. Failure to comply may result in removal from the project and notification to the PHS Grantee; **no funds** may be spent until compliance and management plans are in place.

8) Public Accessibility

- This policy is posted at <https://www.thebabelgroup.com/fcoi-policy>.

- Consistent with 42 CFR 50.605(a)(5), information concerning **identified FCOIs held by senior/key personnel** (minimum required elements) will be made publicly accessible **prior to the expenditure of funds** either by posting or **within five (5) business days** of a written request. Posted information will be **updated at least annually** and **within 60 days** of newly identified FCOIs, and will remain available for **3 years** from the most recent update.
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9) Subrecipient Requirements (if The Babel Group issues subawards)

When The Babel Group is the awardee issuing a subaward (or if a subrecipient participates under our NIH-funded work), written agreements will:

- State whether the **subrecipient follows our FCOI policy or its own** compliant policy;
 - Obtain **certification** of the subrecipient's compliance; and
 - Require **timely reporting** of identified FCOIs by the subrecipient to allow our (awardee) reporting to NIH **within required timeframes**; or, alternatively, require The Babel Group to **solicit/review subrecipient Investigator disclosures** to identify, manage, and report FCOIs to NIH.
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10) Administrative Notes

- **Form & Process:** The DO will maintain and distribute an SFI Disclosure Form and instructions (internal document) and ensure timely collection/review.
- **Annual Attestations:** Investigators certify continued accuracy of disclosures annually and update within 30 days of new SFIs.
- **Human Subjects/Clinical Research:** When required, disclosure to participants and/or a data safety monitoring mechanism may be included in the management plan.
- **More Stringent Standards:** If The Babel Group adopts standards more stringent than federal minimums, we will follow our standards and ensure NIH reporting aligns with those standards and timelines.

Questions

Contact **Rachel Khasky-Levy** (Designated Official) at rachel@thebabelgroup.com.