

# Financial Conflicts of Interest (FCOI) Policy

## Indelible Learning, Inc.

### I. INTRODUCTION

#### A. Purpose

This policy implements U.S. federal requirements pertaining to “Objectivity in Research” promulgated by the Public Health System (“PHS”) of the U.S. Department of Health and Human Services (“HHS”), which includes the U.S. National Institutes of Health (“NIH”), the Biomedical Advanced Research and Development Authority (“BARDA”), the Center for Disease Control and Prevention, and the Agency for Healthcare Research and Quality (“FCOI Policy”). Financial Conflict of Interest (“FCOI”) requirements, related to PHS Organization-funded research, are published in U.S. regulations [42 CFR Part 50, Subpart F](#) and [45 CFR Part 94](#).

The intent of this FCOI Policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research performed under grants or contracts with PHS Organizations will be biased by any conflicting financial interest. To apply for funding with PHS Organizations, Indelible Learning will certify, in each application for funding, that the company:

- has in effect, an up to date, written and enforced administrative process to identify and manage FCOI;
- will promote and enforce Covered Individual compliance with the regulation;
- will manage FCOI and provide initial and ongoing FCOI reports;
- will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- will fully comply with the regulation’s requirements.

Indelible Learning’s FCOI process addresses:

- *training requirements*
- *disclosure, review, and monitoring requirements*
- *reporting requirements; maintenance of records*
- *enforcement mechanisms and remedies for noncompliance*
- *sub-recipient requirements*
- *public accessibility requirements*

#### B. Scope

An Indelible Learning employee or contractor who submits a grant or contract proposal or conducts research under a PHS Organization’s funding grants or contracts must adhere to the applicable requirements of the PHS Organization, including those involving the disclosure and regulation of outside activities and financial interests. Specific FCOI laws and regulations are applicable to all project directors and principal investigators, whether employees or contractors, who are responsible for the design, conduct and reporting of research work under grants and contracts with PHS Organizations.

Indelible Learning adheres to the requirements of federal regulations regarding reporting requirements. This policy governing financial conflicts of interest applies to all Covered Individuals of the institution. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies will constitute cause for disciplinary or other administrative action pursuant to institutional policy.

### II. DEFINITIONS

**A. Covered Individual (CI):** means any Indelible Learning employee or contractor who is responsible for the design, conduct or reporting of a PHS-Funded Research project or proposed for such project, including any project

director, principal investigator and any other key personnel designated as such in a PHS-Funded grant application or contract. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants, as appropriate.

**B. Covered Individual Responsibilities:** means a Covered Individual's professional responsibilities performed on behalf of an entity that proposes to undertake or undertakes PHS-Funded Research.

**C. Equity Interest:** means any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

**D. Financial Interest:** means anything of monetary value received or held by an Covered Individual or an Covered Individual's Immediate Family Member, whether or not the value is readily ascertainable, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works), equity interests (e.g., stocks, stock options, or other ownership interests), or intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

1. salary, royalties, or other remuneration from the institution,
2. income from the authorship of academic or scholarly works,
3. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state or local governmental, or foreign agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers, or
4. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Covered Individual does not directly control the investment decisions made in these vehicles.

Travel: For Covered Individuals, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Covered Individual and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Covered Individual as well as travel that is reimbursed, even if the exact monetary value is not readily available. The de minimis threshold for reporting is \$5,000. It excludes travel reimbursed or sponsored by U.S. federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

**E. Significant Financial Interest (SFI)** means a Financial Interest consisting of one or more of the following interests of a Covered Individual (and those of the Covered Individual's Immediate Family) that reasonably appear to be related to Covered Individual Responsibilities, but specifically excludes any Non-SFI, and:

1. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000, or
2. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000, or
3. if with a publicly or non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure, or
4. is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the institution, or
5. is reimbursed or sponsored travel exceeding \$5,000 related to the Covered Individual's Institutional Responsibilities.

As defined in 42 CFR 50.603 Definitions, a "Significant Financial Interest" does not include "...any ownership interest in the [applicant or awardee] Institution held by the Covered Individual, if the Institution is a commercial

or for-profit organization". Therefore, the Covered Individual's equity interest is excluded from the disclosure requirement when the for-profit company is the Institution that is applying for, or that receives, the PHS research funding in which the Covered Individual is participating.

**F. Non-Significant Financial Interests (Non-SFI):** include the following types of Financial Interests:

1. remuneration paid by an entity to which a Covered Individual owes Covered Individual Responsibilities, if the Covered Individual is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or
2. any ownership interest in an entity held by the Covered Individual or income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles; or
3. income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
4. income from service on advisory committees or review panels for a US federal, state or local government agency, an institution of higher education, as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

**G. Financial Conflict of Interest (FCOI):** means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of research, or the performance of duties and responsibilities on behalf of the Lundquist Institute. A financial COI can exist in a variety of situations, including the following examples:

1. Education: A financial interest that could directly and significantly affect a mentoring relationship or educational presentations. Examples of such presentations are lectures, web-based teaching, and review articles.
2. Purchasing: A financial interest that could directly and significantly affect a purchasing decision. Examples of such decisions are purchases of equipment, supplies, and services.
3. Research: A financial interest that could directly and significantly affect the design, conduct, or reporting of research. FCOI is present in a situation in which a primary interest or responsibility is affected, real or perceived, perhaps unduly, by a secondary interest or responsibility. This means that a subjective component of a primary interest (e.g. research) is affected, or potentially affected, by a financial secondary interest, either ongoing (e.g. consulting) or where there is the potential for increased valuation (of stock or an option). FCOI is present when the outcome of the research could affect future income or the value of an asset (including an option for equity).

**F. Immediate Family:** A Covered Individual's spouse or domestic partner and dependent children.

**G. Institutional Official:** means the individual within the institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Covered Individual's Immediate Family Member related to the Covered Individual's Institutional Responsibilities.

**H. Institutional Responsibilities:** means the Covered Individual's professional responsibilities associated with his or her institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

**I. Indelible Learning, Inc. (Indelible Learning):** A California corporation.

**J. PHS:** Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including, among others, the NIH. A listing of the PHS agencies and their offices may be located on the [U.S. Department of Health and Human Services Organizational Chart](#).

**K. PHS-Funded Research:** any Research funded by way of a grant from, or a contract with, a PHS Organization.

**L. PHS Organization:** (i) an agency that is part of the PHS or (ii) an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.

**M. PHS Regulations:** U.S. [42 CFR Part 50, Subpart F](#) and [45 CFR Part 94](#)

**N. Remuneration:** (i) salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the Covered Individual Responsibilities.

**O. Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

### III. TRAINING REQUIREMENTS

#### Informing each Covered Individual

Indelible Learning has established a process to inform each Covered Individual of:

- Indelible Learning's FCOI Policy
- the Covered Individual Responsibilities
- the PHS Regulations.

#### Training

Covered Individuals will complete FCOI training on the [NIH FCOI Training website](#) prior to engaging in PHS-Funded Research, at least every four years, and immediately, if Indelible Learning revises the FCOI Policy that affects requirements of Covered Individuals, a Covered Individual is new to Indelible Learning or a Covered Individual is not in compliance with the FCOI Policy or of a management plan.

### IV. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

#### **A. Disclosure:**

Each Covered Individual is required to disclose all foreign and domestic Significant Financial Interests (SFIs) and those of the CI's Immediate Family that reasonably appear to be related to the CI's Institutional Responsibilities. The CI is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the research. That determination is made by Indelible Learning's Institutional Official, as is further described below.

CI disclosures are required as follows:

1. No later than at the time of application for NIH-funded research
2. At least annually during the period of the award
3. Within thirty (30) days of discovering or acquiring a new SFI

#### **B. Review:**

1. Initial Review and Action. *Before the Indelible Learning disburses any funds for a research project, the Institutional Official will:*

- a. Review all Covered Individual's SFI disclosures and any other information deemed relevant (e.g., research proposal summary, IRB application, etc.). In connection with this review, the Institutional Official may require the CI to provide additional information as deemed necessary to clarify issues;
  - b. Determine, using federal standards and best judgment, an initial determination whether an CI's SFI is related to research;
  - c. Determine, if it is related, to invite the CI to propose a management plan for review by the Institutional Official and refer the issue to the Institutional Official for review and action, along with a recommended course of action, and any management plan that the Investigator may have developed.
2. Review by the Institutional Official. The Institutional Official will review the federal standards, the particular circumstances related to any individual research, along with any proposed management plan and determine whether the CI's SFI is related to research and, if it is, whether the SFI is an FCOI. Investigators may be required to provide additional information. *An FCOI exists when Indelible Learning, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.*
  3. Decision by the Institutional Official. If the Institutional Official determines that an FCOI exists, the Institutional Official shall recommend a management plan. The Institutional Official will provide copies of the final decision to the CI and the responsible Institutional Review Board (if human subjects research is involved). If human research is involved, the IRB must review and approve the management plan. It should be noted that the IRB has the final authority on the management plan and can implement additional strategies if they deem necessary. Upon receipt of the decision, the CI must either acknowledge his/her agreement to comply with the management plan by signature or submit an appeal. Funding will be held (1) during the appeals process, and/or (2) until the CI agrees to comply with the management plan.
  4. Covered Individual Appeals. The CI has five (5) days from receipt of the final decision to submit an appeal, in writing, to the Institutional Official. An extension can be requested, if necessary. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The CI may also propose an alternative management plan and any supplemental information that might be helpful in making a final determination. The Institutional Official will review the appeal and issue a decision. A second appeal should be submitted to the CEO. The decision issued by the CEO shall be final and not further appealable.
  5. Submission of the Research Application. Indelible Learning will certify in the application that it has implemented and maintains an effective policy that is in full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k) (1)-(5)

### **C. Remedies and Monitoring Requirements:**

1. Remedies: to manage a CI's Financial Conflict of Interest, Indelible Learning might impose one or more of the following conditions or restrictions:
  - a. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; and to the relevant Institutional Review Board).
  - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
  - d. Modification of the research plan;
  - e. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
  - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - g. Severance of relationships that create financial conflicts
2. Monitoring new Covered Individuals: when a CI who is new to participating in the research project or when an existing CI discloses a new SFI, the Institutional Official will review within sixty (60) days disclosures of



SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and, if so, 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.

3. **Monitoring new SFIs:** whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward.
4. The Institutional Official will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor CI compliance with management plans until completion of the project.

## **V. REPORTING REQUIREMENTS**

Indelible Learning will send, via the eRA Commons FCOI Module, initial, annual (i.e., ongoing) and revised FCOI reports for the Institution's CIs and those of its subrecipients, if applicable, including all required information defined in the regulation as well as the:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the Financial Conflict of Interest;
4. Name of the entity with which the Investigator has a Financial Conflict of Interest;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
8. A description of the key elements of the Institution's management plan, including:
  - a. Role and principal duties of the conflicted Investigator in the research project;
  - b. Conditions of the management plan
  - c. How the management plan is designed to safeguard objectivity in the research project;
  - d. Confirmation of the Investigator's agreement to the management plan;
  - e. How the management plan will be monitored to ensure Investigator compliance; and
  - f. Other information as needed.

FCOI Reports will be sent

1. Prior to the expenditure of funds
2. Within sixty (60) days of identification for a Covered Individual who is newly participating in the project
3. Within sixty (60) days for new, or newly identified, FCOIs for existing CIs
4. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
5. After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
6. Based on the results of a retrospective review, Indelible Learning will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation report will include the key elements of the Retrospective review plus information to explain

what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

- a. To ensure compliance with retrospective review and bias mitigation reporting requirements, the policy and/or procedures should include all of the key elements documented in the retrospective review as well as the elements of a mitigation report that must be submitted to NIH.

Indelible Learning will notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

Indelible Learning will notify NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.

## **VI. MAINTENANCE OF RECORDS**

Indelible Learning will maintain all FCOI-related records relating to all Covered Individual disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable:

1. For at least three (3) years from the date the final expenditures report (Final Federal Financial Report) is submitted.
2. Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

## **VII. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE**

1. **Enforcement Mechanism:** Indelible Learning will provide corrective action to ensure Covered Individual compliance. Enforcement mechanisms include, but are not limited to, letters of reprimand, or restriction on the use of funds.
2. **Conditions that would trigger a Retrospective Review:**
  - a. Failure by the CI to disclose an SFI that is determined by the Institution to constitute a financial conflict of interest;
  - b. Failure by the Institution to review or manage such a financial conflict of interest;
  - c. Failure by the CI to comply with the financial conflict of interest management plan.
3. **Completion Deadline:** Indelible Learning will complete a retrospective review within 120 days after determination of FCOI policy noncompliance.
4. Key Elements of a retrospective review report will include:
  - a. Project number;
  - b. Project title;
  - c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - d. Name of the Investigator with the FCOI;
  - e. Name of the entity with which the Investigator has a financial conflict of interest
  - f. Reason(s) for the retrospective review;
  - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
  - h. Findings of the review; and
  - i. Conclusions of the review.
5. **Clinical research:** in any case where the Department of Health and Human Services determines that an NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an CI with an FCOI that was not managed or reported by Indelible Learning as required by the regulation, the Indelible Learning shall require the CI involved to:

- a. Disclose the FCOI in each public presentation of the results of the research, and
  - b. Request an addendum to previously published presentations.
6. Mitigation Report: if bias is found, Indelible Learning will notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a “Revised FCOI Report.” The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Indelible Learning will submit FCOI reports annually as prescribed by the regulation.
7. When bias is not found following the completion of a Retrospective Review, Indelible Learning is not required to notify the NIH.

## **VIII. SUBRECIPIENT REQUIREMENTS**

If Indelible Learning is the awardee and conducts research through a subrecipient (e.g. subcontractors or consortium members), the Institutional Official will take reasonable steps to ensure that subrecipient Covered Individuals comply with this policy, as follows:

1. Determination of which institution’s policies apply: Indelible Learning’s written agreement with the subrecipient will establish whether this policy or the subrecipient’s FCOI policy will apply to the subrecipient’s CIs. The written agreement will state either that:
  - a. The subrecipient certifies that its FCOI policy complies with the applicable federal regulations, and that the subrecipient's Investigators will comply with the subrecipient’s policy or,
  - b. if the subrecipient cannot provide such certification, subrecipient Investigators are subject to this policy.
2. If the subrecipient’s policy applies: the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to Indelible Learning. The time period(s) will be sufficient to enable Indelible Learning to provide FCOI reports to the Sponsor prior to the expenditure of funds and within 60 days of finding any additional FCOI.
3. If Indelible Learning’s policy, as awardee, applies: the subrecipient Investigators will disclose all SFIs that are directly related to the subrecipient’s work for Indelible Learning. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing Indelible Learning enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI reports to the Sponsor prior to the expenditure of funds, within sixty (60) days of finding any additional FCOI and annually thereafter.

## **IX. ACCESSIBILITY OF DISCLOSURE DOCUMENTATION**

Indelible Learning has made the FCOI policy accessible to the public on Indelible Learning’s website.

Prior to the expenditure of funds, Indelible Learning will make information concerning identified FCOIs available within 5 business days to a written request by an individual or organization that provides contact information, including mailing address, fax number, and email. The information will be updated by CIs at least annually, be updated within 60 days of a newly identified FCOI, and all records should remain available for three years from the date of the last payment by PHS Organization.

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