



Storii, Inc. Financial Conflict of Interest (FCOI) Policy

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1. INTRODUCTION

The U.S. Department of Health and Human Services regulations at 42 CFR Part 50 Subpart F and 45 CFR Part 94 (Promoting Objectivity in Research) establish standards to ensure that the design, conduct, and reporting of research funded under National Institutes of Health (NIH) grants, cooperative agreements, and contracts are free from bias resulting from Investigator financial conflicts of interest (FCOIs). This Storii, Inc. policy implements the regulatory requirements and applies to all Investigators planning to participate in, or participating in, Public Health Service (PHS) funded research. The policy safeguards the integrity of NIH-funded research, the welfare of human and animal subjects, and the reputation of Storii, Inc. and its Investigators.

2. DEFINITIONS

- **Financial Conflict of Interest (FCOI):**

A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

- **Financial Interest:**

Anything of monetary value, whether or not the value is readily ascertainable.

- **Institutional Responsibilities:**

Professional duties an Investigator performs on behalf of Storii, Inc. (e.g., research, product development and testing, research publication and communication, consulting, operations management, administration, fund raising, or institutional committee memberships or panels).

- **Designated Official (DO):**

The Storii representative(s) assigned to solicit and review SFI disclosures and determine FCOIs.

- **Institution:**

Institution means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives,

PHS/NIH research funding.

- **Investigator:**

Project Director/Principal Investigator (PD/PI) and any person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research.

- **Research:**

Research implies a systematic investigation, study, or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or therapeutic drug).

- **Senior/Key Personnel:**

PD/PI and others identified as senior/key in the NIH application, progress report, or other submission.

- **Significant Financial Interest (SFI):**

1. **A domestic or foreign financial** interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities performed on behalf of Storii:
 - **With regard to any publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - **With regard to any non-publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or,
 - **With regard to intellectual property rights and interests (e.g., patents, copyrights)**, a significant financial interest exists upon receipt of income of greater than \$5,000 in the 12 months preceding the disclosure related to such rights and interests.
2. A Investigators must disclose the occurrence of **any reimbursed or sponsored travel that exceeds \$5,000** (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a

minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- a United States Institution of higher education,
- an academic teaching hospital,
- a medical center, or
- a research institute affiliated with a United States Institution of Higher Education

3. The term '**significant financial interest**' **does not include**, and therefore, investigators are not required to disclose, the following types of financial interests:

- **Salary, royalties, or other remuneration paid by Storii** to the Investigator if the Investigator is currently employed or otherwise appointed by Storii, including intellectual property rights assigned to Storii and agreements to share in royalties related to such rights.
- **Any ownership interest in Storii**, held by the Investigator since Storii is a commercial or for-profit organization. This exclusion only applies if the applicant or recipient (including a sub-recipient) is a for-profit or commercial institution.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education or,
- Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Foreign Financial Interests: Investigators must disclose all foreign financial interests (which include income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

3. SIGNIFICANT FINANCIAL INTEREST DISCLOSURE REQUIREMENTS

Investigators must disclose SFIs (including those of spouse and dependent children) to the DO using Storii's SFI Disclosure Form:

- At the time of NIH proposal submission.
- At least annually during the award period **(due annually on July 31st)**.
- Within 30 days of discovering or acquiring a new SFI (e.g., purchase, marriage, inheritance).

Reimbursed or sponsored travel that meets the SFI threshold must be disclosed within 30 days of travel.

4. REVIEW OF SFI DISCLOSURES BY STORII DESIGNATED OFFICIAL(S)

Storii has appointed its Chief Executive Officer (CEO) as the Designated Official (DO) responsible for reviewing Significant Financial Interest (SFI) disclosures. The DO will examine every SFI reported by an Investigator and compare each interest to the Public Health Service (PHS)/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of the research. Using the criteria in Section 5, the DO will determine whether (1) the SFI is related to the NIH-funded research; and (2) the related SFI constitutes a Financial Conflict of Interest (FCOI). If an FCOI is identified, the DO will develop and implement a written management plan before any NIH funds are expended.

a. Prior to the issuance of a new award

The DO will review the Investigator's SFI(s) before NIH issues a new award. If an FCOI is identified, Storii will submit an FCOI report to NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.

b. Annual SFI disclosure

Each year, Investigators must update the value or status of previously disclosed SFIs (e.g., changes in equity value). The DO will review these annual disclosures to determine whether revisions to an existing management plan are necessary. Any adjustments will be reported to NIH in the next scheduled Annual FCOI report, where applicable.

c. During the award period

Whenever, in the course of an ongoing NIH-funded research project, (i) an Investigator new to the project discloses an SFI, or (ii) a current Investigator reports a new or newly identified SFI, the DO will, within 60 days,

1. Review the SFI disclosure;
2. Determine whether the SFI is related to the NIH-funded research;
3. Decide if an FCOI exists; and
4. Implement, at least on an interim basis, a management plan specifying the actions that have been and will be taken to manage the FCOI.

The institution will submit the corresponding FCOI report to NIH via the eRA Commons FCOI Module **within 60 days of identifying the FCOI.**

5. GUIDELINES FOR DETERMINING ‘RELATEDNESS’ OF SFI TO NIH-FUNDED RESEARCH AND FCOI

The Designated Official will determine whether an Investigator’s SFI is related to the research under an NIH award and, if so, whether the SFI constitutes a Financial Conflict of Interest.

- **Relatedness Test.** An Investigator’s SFI is considered **related** to the NIH-funded research when the DO reasonably determines that the SFI:
 - could be affected by the NIH-funded research; **or**
 - is in an entity whose financial interest could be affected by the NIH-funded research.

The DO may involve the Investigator in making this determination.

- **Designated Official FCOI Determination.** A Financial Conflict of Interest exists when the DO reasonably determines that the SFI could **directly and significantly** affect the design, conduct, or reporting of the NIH-funded research (“significantly” means the financial interest would have a material effect on the research).

6. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS

If a Financial Conflict of Interest (FCOI) exists, the Designated Official will determine which management conditions and/or strategies will be implemented to manage the FCOI.

Examples of conditions that may be imposed include, but are not limited to:

1. **Public disclosure** of the FCOI (e.g., when presenting or publishing the research; to research personnel working on the study; to the Institution’s Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Data Safety and Monitoring Board (DSMB));
2. For research projects involving human subjects, **disclosure of the FCOI directly to participants** in the informed-consent document;
3. **Appointment of an independent monitor** capable of protecting the design, conduct, and reporting of the research from bias resulting from the FCOI;
4. **Modification of the research plan;**

5. **Change of personnel or personnel responsibilities**, or disqualification of personnel from participation in all or part of the research;
6. **Reduction or elimination** of the financial interest (e.g., sale or divestiture of an equity interest);
7. **Severance of relationships** that create financial conflicts.

When the DO determines that an FCOI exists, the DO will communicate its determination and the management plan, in writing, to the individual, the relevant Principal Investigator/Project Director, and the appropriate supervisor.

No NIH funds may be expended until the Investigator has complied with the disclosure requirements of this policy and has agreed, in writing, to abide by the management plan established by the DO. Storii's FCOI Designated Official will submit the FCOI report to NIH via the eRA Commons FCOI Module.

7. MONITORING INVESTIGATOR COMPLIANCE

Storii will monitor Investigators' compliance with each management plan **for the duration of the NIH award or until the FCOI no longer exists**. Monitoring of public-disclosure requirements will include reviewing publications and presentations to confirm that the Investigator has disclosed the FCOI in those communications.

To facilitate additional oversight, Investigators must disclose the FCOI **in writing** to all research personnel involved in the study and provide a copy of this communication to the Designated Official. The DO may also conduct periodic check-ins with the Investigator and study team and review informed-consent documents, as applicable, to ensure continued adherence to the management plan.

8. PUBLIC ACCESSIBILITY OF FCOI POLICY AND INFORMATION

a. **FCOI Policy:** Storii, Inc. has posted its Financial Conflict of Interest (FCOI) policy on its publicly accessible website, in accordance with NIH requirements outlined in Section 4.1.10 of the NIH Grants Policy Statement. The policy can be found at <https://storii.com/fcoi-policy>.

b. **Identified FCOIs Held by Senior/Key Personnel:** Prior to the expenditure of any funds under an NIH award, Storii, Inc. will ensure public access to information regarding identified FCOIs through a publicly accessible website or via a written response within five business days of a request. Such information will be provided for any Significant Financial Interest (SFI) that meets all of the following criteria:

1. The SFI was disclosed and is still held by Senior/Key personnel, defined as the Project Director/Principal Investigator and any other individuals identified by Storii, Inc. in the grant application, progress report, or other submissions to the NIH;
2. Storii, Inc. has determined that the SFI is related to NIH-funded research; and
3. Storii, Inc. has determined that the SFI constitutes a financial conflict of interest.

The information that will be made publicly accessible or provided in writing will include, at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the SFI is held;
4. The nature of the SFI; and
5. The approximate dollar value of the SFI, stated in the following ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000 and \$100,000 in \$20,000 increments; amounts above \$100,000 in \$50,000 increments; or a statement indicating that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If Storii, Inc. uses a publicly accessible website for this disclosure, the information will be updated at least annually and within 60 days of identifying a new FCOI. This includes FCOIs newly disclosed by existing Senior/Key personnel or those disclosed by individuals newly appointed to NIH-funded research projects. Publicly accessible information regarding an FCOI will remain available for at least three years from the date it was most recently updated.

9. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any funds under an award funded by NIH, Storii, Inc. will submit a Financial Conflict of Interest (FCOI) report in accordance with NIH regulations for any Significant Financial Interest (SFI) determined to constitute a conflict. Storii, Inc. will also ensure that the Investigator involved has agreed to and implemented an appropriate management plan to address the FCOI.

Storii, Inc. will designate an Institutional Official to serve as the FCOI Signing Official (SO) within the NIH eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports on behalf of Storii, Inc. Reports will be submitted only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award – no FCOI report).

The NIH FCOI Module User Guide is available at:
https://www.era.nih.gov/files/fcoi_user_guide.pdf.

Initial or Original FCOI Reports

- **Prior to the Expenditure of Funds:** When an FCOI is identified during the issuance of a new NIH award, Storii's FCOI SO will submit a "2011 FCOI" (Original) report prior to the expenditure of funds. This report will include all required information outlined in 42 CFR Part 50.605(b)(3), or as explained in NIH FAQ H.5: <https://grants.nih.gov/faqs#/financialconflict-of-interest.htm?anchor=52888>.
- **Within 60 Days of Identifying a New FCOI During Award Period:** If an FCOI is identified after the award begins—such as a newly disclosed SFI or a new

Investigator joining the project—Storii, Inc. will submit the FCOI report within 60 days of the identification.

Annual FCOI Reports

While the NIH award is active (including any no-cost extensions), Storii, Inc. will submit an annual FCOI report to update the NIH on the status of each previously reported FCOI. The report will indicate whether the FCOI:

- Is still being managed, or
- No longer exists, and
- Will describe any changes to the management plan, if applicable.

The annual report will be submitted at the same time as the Research Performance Progress Report (RPPR), multi-year progress report, or at the time of grant extension, per NIH FAQ H.2.

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888>

Annual FCOI reports are not required at the time of grant closeout.

Revision or Mitigation FCOI Reports

If a retrospective review identifies noncompliance or bias, Storii, Inc. will submit one of the following:

- **Revision Report:** If new information is discovered or changes must be made to a previously submitted FCOI report.
- **Mitigation Report:** If bias is found during a retrospective review.

Types of FCOI Reports

1. New FCOI Report (Initial Submission)

- **Content:**
 - Grant Number
 - Principal Investigator (PI)
 - Name of Entity with FCOI
 - Nature of the FCOI
 - Value of financial interest (in increments)
 - Description of how the financial interest relates to the research
 - Key elements of the Management Plan
- **Required When:**
 - Prior to the expenditure of funds under a new award
 - Within 60 days of any subsequently identified FCOI

2. Annual FCOI Report

- **Content:**
 - Status of each FCOI (e.g., still being managed or resolved)
 - Any changes to the Management Plan, if applicable
- **Required When:**
 - Annually, at the time of submitting a Research Performance Progress Report (RPPR), multi-year progress report, or grant extension

3. Revised FCOI Report

- **Content:**
 - Update to a previously submitted FCOI report
 - Description of actions to manage or amend the FCOI going forward
- **Required When:**
 - Following completion of a retrospective review, if noncompliance is identified

4. Mitigation Report

- **Content:**
 - Project Number and Title
 - Contact PI/PD
 - Name of Investigator with FCOI
 - Name of Entity with FCOI
 - Reason for the review
 - Detailed methodology
 - Findings and conclusion
- **Required When:**
 - When bias is found as a result of a retrospective review

10. TRAINING REQUIREMENTS

Each Investigator at Storii, Inc. will be informed of the company's Financial Conflict of Interest (FCOI) Policy and trained on their responsibilities regarding the disclosure of Significant Financial Interests (SFIs), both foreign and domestic, in accordance with 42 CFR Part 50 Subpart F.

FCOI training is required:

- **Prior to engaging in any PHS/NIH-funded research,**
- **At least once every four years, and**
- **Immediately** under any of the following circumstances:
 1. Storii revises its FCOI Policy or related procedures in a way that affects Investigator responsibilities;

2. An Investigator is new to Storii or newly participating in NIH-funded research (training must be completed prior to engaging in the project);
3. Storii determines that an Investigator is not in compliance with the FCOI Policy or with a management plan issued under the Policy (in such cases, training must be completed within 30 days in a manner specified by the Designated Official).

To fulfill these training requirements, Storii, Inc. mandates that all Investigators complete the NIH's Financial Conflict of Interest online tutorial, available at:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Investigators are required to print a certificate of completion at the end of the tutorial and retain it for their records and audit purposes.

Additionally, Storii encourages Investigators to review the NIH Virtual Seminar on FCOI, which provides helpful guidance on developing or refining institutional FCOI policies:

<https://www.youtube.com/watch?v=D292YZ6BX24>

11. FAILURE TO COMPLY WITH FINANCIAL CONFLICT OF INTEREST POLICY

In the event Storii, Inc. identifies a Significant Financial Interest (SFI) that was not disclosed, reviewed, or managed in a timely manner, the Designated Official will, within 60 days:

- Review the SFI;
- Determine whether it is related to NIH-funded research;
- Determine whether it constitutes a Financial Conflict of Interest (FCOI); and
- If so, implement, at minimum, an interim management plan specifying actions taken and to be taken to manage the FCOI.

Storii, Inc. will also submit an FCOI report to the NIH through the eRA Commons FCOI Module in accordance with regulatory requirements.

Additionally, in all instances of untimely identification or management of an FCOI—such as:

- Failure by the Investigator to disclose an SFI determined by Storii to be an FCOI;
- Failure by Storii to review or manage a known FCOI; or
- Failure by the Investigator to comply with an established management plan—

Storii, Inc. will, within **120 days** of determining noncompliance:

1. Conduct a retrospective review of the Investigator's activities and the NIH-funded research project to assess whether any portion of the research was biased in its design, conduct, or reporting;
2. Document the retrospective review in accordance with 42 CFR §50.605(a)(3)(ii)(B) or as outlined in NIH's FAQ I.2:

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888>

If the retrospective review reveals bias, Storii, Inc. will:

- Promptly notify the NIH; and
- Submit a **Mitigation Report** through the eRA Commons FCOI Module, as required by 42 CFR §50.605(a)(3)(iii) or NIH FAQ I.3:

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896>

The Mitigation Report will address:

- The impact of the bias on the research project; and
- The corrective actions taken or planned to eliminate or mitigate the bias.

Following these actions, Storii, Inc. will continue to submit annual FCOI reports to NIH in accordance with applicable regulations and award terms and conditions.

Depending on the nature and severity of the FCOI, Storii, Inc. may determine that additional interim measures are necessary to safeguard the integrity of the research while the retrospective review is being conducted.

12. CLINICAL RESEARCH REQUIREMENTS

If HHS determines that NIH-funded clinical research evaluating safety or effectiveness of a drug, device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged FCOI, Storii will require disclosure of the FCOI in all public presentations and request addenda to previously published presentations.

13. SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds provided to Storii, Inc. under an NIH award are passed through to another entity or individual who will conduct a substantive portion of the PHS/NIH-funded research project and will be held accountable for programmatic outcomes and regulatory compliance.

Subrecipients may include, but are not limited to, collaborators, consortium partners, contractors, subcontractors, consultants, and sub-awardees. As part of its responsibility for NIH award compliance, Storii, Inc. will take reasonable steps to ensure that all subrecipient Investigators are in compliance with the federal Financial Conflict of Interest (FCOI) regulation set forth at 42 CFR Part 50, Subpart F.

Storii, Inc. will establish written agreements with all subrecipients that clearly specify whether Storii's FCOI Policy or the subrecipient's own NIH-compliant FCOI policy will apply to the subrecipient Investigators. (See NIH Grants Policy Statement Section 15.2.1 on Written Agreements:

[https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_o
ther_requirements.htm#Written](https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm#Written))

- **If the subrecipient's FCOI policy applies**, the subrecipient must certify in the agreement that its policy complies with the federal FCOI regulation. The agreement must also include a defined timeframe in which the subrecipient will report all identified FCOIs to Storii, Inc., allowing sufficient time for Storii to meet its own reporting obligations to NIH (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of any FCOI). For this purpose, the agreement may specify that subrecipient FCOIs be reported to Storii within 50–55 days of identification.

Storii, Inc.'s Designated Official will submit all applicable subrecipient FCOI reports to NIH through the eRA Commons FCOI Module.

- **If the subrecipient cannot provide certification of FCOI compliance**, the written agreement will state that the subrecipient Investigators are subject to Storii, Inc.'s FCOI Policy. In such cases:
 - All Investigator disclosures of Significant Financial Interests (SFIs) must be submitted directly to Storii, Inc.
 - The agreement will include timelines that enable Storii to review these disclosures, determine relatedness, manage any identified FCOIs, and comply with NIH reporting deadlines.
 - If an FCOI is identified for a subrecipient Investigator, Storii will implement a management plan, monitor compliance, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

14. MAINTENANCE OF RECORDS

Storii, Inc. will maintain complete records of the following:

- All Investigator disclosures of Significant Financial Interests (SFIs), regardless of whether a disclosure resulted in a determination of a Financial Conflict of Interest (FCOI);
- All reviews and determinations made by Storii regarding such disclosures;
- All actions taken under Storii's FCOI Policy, including any retrospective reviews and associated mitigation efforts, if applicable.

These records will be retained for a minimum of three (3) years from the date of submission of the final expenditures report to the NIH. Where applicable, records may be retained for longer periods in accordance with other provisions specified in 45 CFR §75.361, which includes requirements related to litigation, audits, and other specific circumstances.

Storii, Inc. will ensure record retention compliance for each competitive segment as outlined in the regulation.

15. ENFORCEMENT ACTIONS: INVESTIGATOR NON-COMPLIANCE

Compliance with Storii, Inc.'s Financial Conflict of Interest (FCOI) Policy is a condition of employment and/or participation in PHS/NIH-funded research. Investigators who fail to comply with this policy—including failure to disclose Significant Financial Interests, failure to complete required training, or failure to adhere to a management plan—will be subject to appropriate disciplinary actions.

Disciplinary actions may include, but are not limited to:

- Formal letters of reprimand;
- Restriction or suspension of access to NIH or other research funds;
- Termination of employment or contractual relationships; and/or
- Disqualification from participation in current or future PHS/NIH-funded research projects.

Storii, Inc. reserves the right to notify the NIH of any serious or repeated noncompliance and to implement any additional corrective or administrative measures deemed necessary to ensure compliance with federal regulations and the integrity of its research activities.

16. USEFUL FCOI AND NIH RESOURCES

- NIH FCOI Website: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- FCOI Regulation (42 CFR Part 50 Subpart F): <https://www.ecfr.gov/current/title-42/part-50/subpart-F>
- NIH FCOI Tutorial: <https://grants.nih.gov/grants/policy/foi/tutorial2018/story.html>
- NIH FCOI FAQs: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>
- FCOI Compliance Email: fcoicompliance@mail.nih.gov

17. POINT OF CONTACT

Research Compliance Officer / Signing Official

Name: Cameron Graham

Email: cameron@storii.com

Phone: 650-924-9930

18. PUBLIC POSTING REQUIREMENT

This policy will be posted at: <https://storii.com/fcoi-policy>