

Financial Conflict of Interest Policy

Surgical Magic LLC

Document Number: SM-FCOI-001

Revision: 001

Effective Date: July 16, 2025

Issued: July 16, 2025

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Public Access: This policy is publicly posted at www.surgicalmagic.com/fcoipolicy and submitted to NIH via eRA Commons Institution Profile Module per federal requirements.

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1. Introduction

The Federal Department of Health and Human Services has developed regulations under 42 CFR Part 50 Subpart F and 45 CFR Part 94 on Promoting Objectivity in Research. These regulations describe the actions an individual and an organization must take to promote objectivity in Public Health Service (PHS) funded research. The regulations apply to all PHS agencies, including the National Institutes of Health (NIH), funded grants, cooperative agreements, and research contracts. The regulations are not applicable to Phase I Small Business Innovation Research or Small Business Technology Transfer applications and awards.

1.1 Regulation History

The financial conflict of interest regulations have evolved over time to address emerging challenges in research integrity and objectivity. The regulations were first developed in 1995 to establish initial requirements for managing financial conflicts of interest in federally funded research. In 2011, the regulations were revised and strengthened to enhance transparency, improve reporting requirements, and expand the scope of disclosure obligations. These 2011 revisions represented a significant enhancement of the regulatory framework, introducing more comprehensive disclosure requirements, enhanced public accessibility provisions, and stricter management and reporting obligations for institutions receiving PHS funding.

1.2 Policy Implementation

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for Surgical Magic LLC. The implementation of the regulation through the issuance of this policy ensures that the design, conduct, and reporting of PHS/NIH-Funded research will be protected from bias resulting from an investigator's financial conflict of interest (FCOI). In addition, the policy serves to protect the safety of animals and human research participants, the reputation of the recipient institution and the Investigator who participates in PHS/NIH-Funded research. These requirements work together to preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

2. Definitions

For the purpose of these policies and procedures, the following definitions apply and are essential to understanding the scope and application of this policy.

2.1 Financial Conflict of Interest (FCOI)

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. This determination is

made by the Designated Official based on their reasonable assessment of whether the financial interest would have a material impact on the research activities.

2.2 Financial Interest

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable. This broad definition encompasses various forms of financial relationships and interests that may create potential conflicts with research objectivity.

2.3 Institutional Responsibilities

Institutional responsibilities are the professional activities an investigator performs on behalf of Surgical Magic LLC. These responsibilities include but are not limited to research activities, clinical research activities, collaboration, developmental work, research publication efforts, consulting activities, administrative duties, and participation in institutional committee memberships. The scope of institutional responsibilities may vary depending on the investigator's role and position within the organization.

2.4 Designated Official (DO)

Designated Official (DO) refers to the individual who has been designated by Surgical Magic LLC as the official responsible for overseeing the financial conflicts of interest process. This includes the solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR §50.604(f), and management of the overall FCOI program within the organization.

2.5 Investigator

Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an award or proposed for funding. This may include, for example, collaborators or consultants who have significant responsibilities for the research project. Surgical Magic LLC will consider the individual's role and level of responsibility for the research, rather than the individual's title, when determining who meets the definition of "Investigator" and is therefore subject to the disclosure requirements of this policy.

2.6 Research

Research implies 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. The term encompasses basic and applied research activities such as those resulting in

published articles, books, or book chapters, as well as product development activities such as the development of diagnostic tests or therapeutic drugs.

2.7 PHS-Funded Research

PHS-Funded Research includes any research activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority. This encompasses all forms of federal funding from PHS agencies regardless of the specific funding mechanism employed.

2.8 PHS

PHS refers to the 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 the National Institutes of Health (NIH). This designation encompasses all agencies and components within the PHS system that may provide research funding.

2.9 NIH

NIH means the National Institutes of Health, which serves as the biomedical research agency of the PHS and is a primary source of federal funding for biomedical and health-related research activities.

2.10 Senior/Key Personnel

Senior/key personnel means the Project Director/Principal Investigator and any other person identified as Senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution. This term is defined specifically as it relates to the public accessibility requirements of identified FCOIs held by Senior/key personnel as described in Section 8 of this policy.

2.11 Significant Financial Interest (SFI)

Significant Financial Interest (SFI) represents a comprehensive category of financial relationships that must be disclosed when they meet specific thresholds and criteria. A significant financial interest consists of one or more financial interests of the Investigator, including 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 Surgical Magic LLC.

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, such as consulting fees, honoraria, and 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 such as stock, stock options, or other ownership interests.

With regard to intellectual property rights and interests, including patents and copyrights, a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests. This includes royalties, licensing fees, and other income derived from intellectual property owned or controlled by the investigator.

Travel Disclosure: Investigators must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000, specifically travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available, when such travel is 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 or organizer, the destination, and the duration of the travel.

2.11.1 Travel Exemptions

The disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

2.11.2 SFI Exclusions

The term "significant financial interest" does not include certain categories of financial relationships, and therefore investigators are not required to disclose these specific types of interests:

- Salary, royalties, or other remuneration paid by Surgical Magic LLC to the investigator when the Investigator is currently employed or otherwise appointed by Surgical Magic LLC are excluded from disclosure requirements, including intellectual property rights assigned to Surgical Magic LLC and agreements to share in royalties related to such rights.
- Any ownership interest in Surgical Magic LLC held by the Investigator is similarly excluded from the SFI definition since Surgical Magic LLC is a non-publicly traded entity and such interest is excluded from the SFI definition per regulation, provided that the applicant or recipient is a for-profit or commercial institution.

- Income from investment vehicles, such as mutual funds and retirement accounts, is excluded from disclosure requirements 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 qualifying government and academic entities is also excluded, specifically when such activities are sponsored by a federal, state, or local government agency located in the United States, 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.
- Income from service on advisory committees or review panels for these same qualifying entities is excluded from the definition of significant financial interest.

2.12 Foreign Financial Interests

Foreign Financial Interests represent a specific category of financial interests requiring enhanced disclosure under the FCOI regulations. Investigators must disclose all foreign financial interests, including 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, when such income meets the threshold for disclosure of income in excess of \$5,000.

These disclosure requirements are designed to ensure transparency regarding financial relationships with foreign entities that could potentially influence the objectivity of PHS-funded research. The enhanced scrutiny of foreign financial interests reflects concerns about foreign influence on U.S. federally funded research and the need to maintain research integrity. (See NIH FAQs E.18, E.21, E.36, and E.37)

3. Significant Financial Interest Disclosure Requirements

The disclosure requirements under this policy are structured to ensure comprehensive reporting of potentially conflicting financial interests at critical points during the research process.

3.1 Initial Disclosure Requirements

At the time of application for PHS/NIH funding, the Principal Investigator and all other individuals who meet the definition of "Investigator" must disclose their SFI's to the Designated Official at Surgical Magic LLC, Asheleigh Mowery, Chief Executive Officer, via email to asheleighmowery@surgicalmagic.com. Any new Investigator who, after applying to NIH for funding or during the course of the research project, plans to participate in the project must similarly disclose his or her SFI(s) to the Designated Official promptly and prior to participation in the project.

3.2 Annual Disclosure Requirements

Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, specifically on or before May 1st of each year, during the period of the award. Such annual disclosure must include any information that was not disclosed initially to Surgical Magic LLC pursuant to this Policy or in a subsequent disclosure of SFI. This includes any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee or indirectly through a sub-award that was transferred from another institution. The annual disclosure must also include updated information regarding any previously disclosed SFI, such as the updated value of a previously disclosed equity interest.

3.3 Ongoing Disclosure Requirements

Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty days of discovering or acquiring a new SFI. This requirement covers new financial interests acquired through various means such as purchase, marriage, or inheritance. In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence that meets the disclosure threshold.

4. Review of SFI Disclosures by Surgical Magic LLC Designated Official

Asheleigh Mowery, Chief Executive Officer, has been designated as the Designated Official at Surgical Magic LLC to conduct comprehensive reviews of SFI disclosures submitted by Investigators. The Designated Official will review any SFI that has been identified in a disclosure, comparing these interests to each PHS/NIH-Funded research application and award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research. This comparison process is essential to determine if the SFI is related to the PHS/NIH-Funded research and, if so, whether the SFI creates a Financial Conflict of Interest related to that research award.

Prior to the issuance of a new award, the Designated Official will review the Investigator's SFI(s) before the NIH issues a new award. If an FCOI is identified during this review process, the Institution will submit an FCOI report to the NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.

The annual disclosure process requires the Designated Official to review updated information provided by investigators. The Designated Official will review the Investigator's annual disclosure and will use the updated information to determine if any changes are needed to an existing management plan. Any changes to the existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.

During the award period, whenever an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official will, within 60 days, review the disclosure of SFI, determine whether the SFI is related to the 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. The institution will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

5. Guidelines for Determining "Relatedness" of SFI to PHS/NIH-Funded Research and a Financial Conflict of Interest

The Designated Official, Asheleigh Mowery, Chief Executive Officer, 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. The relatedness test establishes that an Investigator's SFI is "related" to the research when the Designated Official reasonably determines that the SFI could be affected by the PHS/NIH-Funded research or is in an entity whose financial interest could be affected by the PHS/NIH-Funded research. The Designated Official may involve the Investigator in determining whether an SFI is related to the research supported by the PHS/NIH-Funded award.

A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-Funded research. The term "significantly" means that the financial interest would have a material effect on the research, going beyond minimal or inconsequential impacts.

6. Management of Significant Financial Interests that Pose Financial Conflict of Interest

If a financial conflict of interest exists, the Designated Official, Asheleigh Mowery, Chief Executive Officer, will determine what management conditions and strategies will be implemented to manage the FCOI effectively. The management conditions and strategies that might be imposed include:

1. Public disclosure of financial conflicts of interest in presentations, publications, or to research personnel.
2. Informed consent disclosure for human subjects research, ensuring participants are informed about potential conflicts.
3. Appointment of an independent monitor to oversee research activities.
4. Modification of the research plan to address potential bias.
5. Change of personnel or personnel responsibilities, or disqualification from participation in the research.
6. Reduction or elimination of the financial interest through sale of equity interests.
7. Severance of relationships that create financial conflicts.

If the Designated Official determines that a conflict exists, she will communicate the determination and the means developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/project Director, and to the appropriate direct supervisor. No expenditures on an NIH award will be permitted until the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Designated Official necessary to manage the Financial Conflict of Interest. Asheleigh Mowery will submit the FCOI report to NIH via the eRA Commons FCOI Module.

7. Monitoring Investigator Compliance

Surgical Magic LLC will monitor investigators' compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring public disclosure requirements will include reviewing publications and presentations to confirm that the investigator disclosed the FCOI as required by the management plan. Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official, Asheleigh Mowery, Chief Executive Officer, via asheleighmowery@surgicalmagic.com.

8. Public Accessibility of FCOI Policy and Information Related to a FCOI

A copy of the FCOI policy is posted on Surgical Magic LLC's public website at www.surgicalmagic.com/fcoipolicy per the NIH requirements. For identified FCOIs held by Senior/key Personnel, Surgical Magic LLC will ensure public accessibility by written response to any request within five business days of a request for information concerning any SFI disclosed that meets specific criteria. The information will include:

- Investigator's name, title, and role with respect to the research project.
- Name of the entity in which the Significant Financial Interest is held and the nature of the Significant Financial Interest.
- Approximate dollar value of the Significant Financial Interest in ranges: \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999, \$20,000-\$100,000 by increments of \$20,000, above \$100,000 by increments of \$50,000, or a statement that the value cannot be readily determined.

The information will be updated at least annually and within sixty days of receipt or identification of a new SFI. Information concerning an individual's SFI will remain available for at least three years from the date that the information was most recently updated.

9. Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under an award funded by NIH, Surgical Magic LLC will provide to NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial

Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. Asheleigh Mowery, Chief Executive Officer, will serve as the FCOI Signing Official (SO) and submit reports via the eRA Commons FCOI Module.

9.1 Initial or Original FCOI Reports

Prior to the expenditure of funds, when an FCOI is identified upon the issuance of a new NIH award, the FCOI SO will submit an Original FCOI report. Within 60 days of identifying a new FCOI during the award period, an Original FCOI report will be submitted.

9.2 Annual FCOI Reports

The institution will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI, indicating whether the FCOI is still being managed or no longer exists, and any changes in the management plan. The Annual FCOI report will be submitted at the same time as the Research Performance Progress Report or at the time of grant extension.

9.3 Revision or Mitigation FCOI Reports

The institution will provide NIH with a Revision report if new information is discovered during the retrospective review process, or a Mitigation Report if bias is found during the retrospective review.

9.4 Summary of Required FCOI Reports

- **New FCOI Report (Initial submission):** Content includes Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, and Key Elements of Management Plan. Submit prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- **Annual FCOI Report:** Content includes Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable. Submit at the same time as when the institution is required to submit annual progress report, multi-year progress report, or at time of extension.
- **Revised FCOI Report:** Content includes updates to a previously submitted FCOI report to describe changes to the original report or to address new management actions. Submit following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
- **Mitigation Report:** Content includes Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings, and Conclusion. Submit when bias is found during retrospective review.

10. Training Requirements

Each Investigator will be informed about Surgical Magic LLC's Financial Conflict of Interest Policy and be trained on each Investigator's responsibility to disclose foreign and domestic SFI's per this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years, and immediately when:

- Surgical Magic LLC revises this Policy or procedures in a manner that affects the requirements of Investigators.
- An Investigator is new to Surgical Magic LLC research under an NIH award.
- Surgical Magic LLC finds that an Investigator is not in compliance with this Policy or a management plan.

Investigators must complete the National Institutes of Health's Financial Conflict of Interest tutorial and retain a certificate of completion for audit purposes. Additionally, investigators are required to review the NIH Virtual Seminar presentation on developing or refining institutional FCOI policies.

11. Failure to Comply with Surgical Magic LLC Financial Conflict of Interest Policy Applicable to NIH Funded Awards

11.1 Mandatory Retrospective Review Triggers

Surgical Magic LLC shall complete a retrospective review in the following three specific circumstances:

- 1. Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;**
- 2. Failure by the Institution to review or manage such a Financial Conflict of Interest; or**
- 3. Failure by the Investigator to comply with a Financial Conflict of Interest management plan.**

11.2 Retrospective Review Requirements

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including any of the three specific circumstances listed in Section 11.1 above, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

11.3 Initial Response to Noncompliance

Prior to conducting the retrospective review, the Designated Official, Asheleigh Mowery, Chief Executive Officer, will, within 60 days, review the SFI, determine whether the SFI is related to research, determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management

plan. Surgical Magic LLC will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI Module.

The retrospective review will be documented consistent with the regulation at 42 CFR §50.605(a)(3)(ii) (B) and will include:

- Project number
- Project title
- PD/PI or contact PD/PI
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has an FCOI
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review, including the approach taken, process, and what was reviewed
- Findings of the review
- Conclusions

If bias is found, Surgical Magic LLC shall notify NIH promptly and submit a mitigation report per 42 CFR §50.605(a)(3)(iii).

11.1 Interim Measures

Interim measures may be implemented immediately upon identification of noncompliance to protect the integrity of the research while the retrospective review is being conducted. These measures may include temporary modification of the research plan, appointment of independent oversight, or temporary restriction of the investigator's role in data collection or analysis.

12. Clinical Research Requirements

If the Department of Health and Human Services determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a Financial Conflict of Interest that was not managed or reported by Surgical Magic LLC, then the investigator involved must disclose the Financial Conflict of Interest in each public presentation of the results of the research and request an addendum to previously published presentations.

13. Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through Surgical Magic LLC to another individual or entity, and the subrecipient will be conducting a substantive portion

of a PHS-funded research project. Surgical Magic LLC will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Surgical Magic LLC's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient investigator(s).

If the subrecipient's FCOI policy applies, the subrecipient institution will certify compliance with 42 CFR Part 50 Subpart F and report identified FCOIs to Surgical Magic LLC within 50-55 days to allow Surgical Magic LLC to report to NIH within 60 days.

If the subrecipient cannot provide certification, the subrecipient Investigator is subject to Surgical Magic LLC's FCOI Policy, requiring disclosure of SFIs to asheleighmowery@surgicalmagic.com. Surgical Magic LLC will develop a management plan, monitor compliance, and submit FCOI reports to NIH for subrecipient Investigators.

14. Maintenance of Records

The Institution will keep all records of all investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure, whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest. Records will be maintained for at least three years from the date of submission of the final expenditures report or as specified in 45 CFR §75.361.

15. Enforcement Actions: Failure to Comply with This Policy

Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment or contract, and disqualification from further participation in any PHS/NIH-funded research.

16. Useful FCOI and NIH Resources

- FCOI Regulation: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- NIH FCOI Guidance: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>
- NIH Financial Conflict of Interest Tutorial: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>
- NIH Virtual Seminar on FCOI Policies: <https://videocast.nih.gov/watch=18853>
- FAQs: <https://grants.nih.gov/faqs/#financial-conflict-of-interest.htm?anchor=52888>
- Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- Welcome Wagon: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>
- eRA Commons FCOI Module: <https://era.nih.gov/>

- NIH Grant Policy Statement: <https://grants.nih.gov/policy/nihgps/>
- Research Performance Progress Reports: <https://grants.nih.gov/grants/rppr/>
- 42 CFR §50.605(a)(3)(ii)(B) Documentation Requirements: <https://www.ecfr.gov/current/title-42/section-50.605>
- 45 CFR §75.361 Records Retention: <https://www.ecfr.gov/current/title-45/section-75.361>

17. Point of Contact

Contact: Asheleigh Mowery, Chief Executive Officer

Email: asheleighmowery@surgicalmagic.com

18. Revision History

- **Revision 000:** Initial release with corrections for clarity, formatting, email address, and removal of confidentiality section. Effective Date: 07-04-2025
- **Revision 001:** Addressed NIH feedback – Added explicit retrospective review triggers per 42 CFR §50.605(a)(3), corrected FAQ references in Section 2.12, enhanced retrospective review documentation requirements. Effective Date: 07-16-2025