

UP Oncolytics, Inc.

Financial Conflict of Interest (FCOI) Policy

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1. Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). The 2011 revised regulations are 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research," and 45 CFR Part 94, "Responsible Prospective Contractors," which set requirements for promoting objectivity in Public Health Service (PHS)-funded research for grants, cooperative agreements, and research contracts, respectively. The regulations and this policy do not apply to SBIR or STTR Phase I applications or awards.

This policy is intended to implement the regulatory requirements for PHS/NIH grants and cooperative agreements per the regulation at 42 CFR Part 50 Subpart F and NIH's guidance. UP Oncolytics, Inc. ("UP Onc," the "Company," or the "Institution") adopts this policy for all Investigators (as defined below) engaged in PHS/NIH-funded research. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NIH-supported research.

2. Applicability

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. This policy applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in, or who participate in, PHS/NIH-funded research.

3. Definitions

For the purpose of these policies and procedures, the following definitions apply:

Financial Conflict of Interest (FCOI): A significant financial interest that the Institution's designated official(s) determines is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

Institutional Responsibilities: The professional responsibilities of an Investigator on behalf of UP Oncolytics, Inc., which may include activities such as research, research consultation and collaboration, product development, product testing and validation, development of datasets, models, or systems, publication and communication of research results, fundraising, business development, and other professional services performed on behalf of UP Oncolytics, Inc. These responsibilities also extend to institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Designated Official (DO): The individual appointed by UP Oncolytics, Inc. to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI. For purposes of this policy, the Designated Official is Richard A. Rovin, MD, Chief Executive Officer of UP Oncolytics, Inc. (richard.rovin@uponc.com; 906-360-9275).

Institution: Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for, or receives, PHS/NIH research funding.

Investigator: The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants. The Institution determines who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, considering the individual's role rather than title and the degree of independence in carrying out the work.

Manage: Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

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. The term encompasses basic and applied research and product development (e.g., a diagnostic test or drug), and includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

PHS-Funded Research: Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

PHS: 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).

NIH: The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by the Institution in a grant application, progress report, or other submission to PHS/NIH. For this policy, the term applies specifically to the public accessibility requirement in Section 9, which mandates disclosure only of financial conflicts of interest held by these senior/key personnel.

Significant Financial Interest (SFI):

1) A domestic or foreign (non-United States) 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 the Institution:

- i. Publicly traded entity: An SFI 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. 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.
- ii. Non-publicly traded entity: An SFI 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

- iii. Intellectual property (IP) rights and interests (e.g., patents, copyrights): An SFI exists upon receipt of income greater than \$5,000 in the twelve months preceding the disclosure that is related to such rights and interests. Includes royalties from such rights, and agreements to share in royalties related to licensed IP rights.

2) Investigators must disclose any reimbursed or sponsored travel related to their Institutional Responsibilities in excess of \$5,000. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip. 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.

3) The term "significant financial interest" does NOT include, and therefore Investigators are not required to disclose, the following:

- Salary, royalties, or other remuneration paid by UP Oncolytics, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by UP Oncolytics, Inc., including intellectual property rights assigned to UP Oncolytics, Inc. and any agreements to share royalties related to those rights;
- Any equity interest in UP Oncolytics, Inc., since UP Oncolytics, Inc. is a commercial or for-profit organization;
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education;
- Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Exclusions Related to Foreign Financial Interests: Investigators must disclose all foreign financial interests (which includes 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).

4. Significant Financial Interest (SFI) Disclosure Requirements

Investigators will disclose their SFIs that are related to their Institutional Responsibilities as defined in this policy. The disclosure is not limited to an Investigator's research responsibilities or their funded research, as this would be too narrow in scope and not consistent with the 2011 regulation. Investigator SFI disclosures

will be retained by the Institution as part of the record-maintenance requirements. Investigators are required to disclose SFIs at the following times:

- A. At the time of application:** The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO. Any new Investigator who joins the project after the NIH application has been submitted or during the course of the research must also disclose their SFI(s) to the DO promptly and before participating in the project, using the SFI Disclosure Form.
- B. Annual disclosure during the award:** Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually as prescribed by UP Oncolytics, Inc. (on or before **September 30th**) during the award period. The annual disclosure must include (1) any new information not previously disclosed to the DO under this policy, including SFIs associated with NIH-funded projects transferred from another institution; and (2) updated details for any previously disclosed SFI, such as changes in the value of an equity interest.
- C. Ad-hoc basis during the award:** Each Investigator participating in PHS/NIH-funded research must submit an updated SFI disclosure within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

5. Review of SFI Disclosures

The Designated Official (DO) is responsible for reviewing all SFI disclosures and making determinations of FCOI. Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

In any instance where the disclosure under review is that of the Designated Official, or where the Designated Official otherwise has a Financial Interest or other circumstance that prevents an impartial review of a particular disclosure, the review, relatedness determination, and FCOI determination will instead be performed by an Alternate Reviewer. The Alternate Reviewer for UP Oncolytics, Inc. is its Board of Directors. The Alternate Reviewer has, for that disclosure, the same authority and responsibilities as the Designated Official under this policy, including developing and implementing any management plan and monitoring the affected Investigator's compliance with it. The Designated Official will not participate in the review of, or the determination regarding, his or her own Financial Interests, and any such recusal will be documented.

The SFI disclosures will be reviewed as described below:

- A. Prior to the issuance of a new award or before any expenditure of awarded funds (e.g., during Just-in-Time):** The DO will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.
- B. Annual SFI disclosure:** The DO will review updates provided in the annual disclosure (e.g., revised value of an equity interest) to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.
- C. Ad hoc basis during award period:** If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DO will, within 60 days: (1) review the disclosure; (2) determine whether the SFI is related to the PHS/NIH-funded research; (3) determine

whether an FCOI exists; and, if so, (4) implement, on at least an interim basis, a management plan. An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

6. Relatedness of SFIs to PHS/NIH-Funded Research and FCOI

The DO is responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute an FCOI.

Relatedness Test: The DO determines whether an Investigator's SFI is related to research under an NIH award. An SFI is considered "related" when the DO reasonably determines that:

- the SFI could be affected by the PHS/NIH-funded research (meaning the investigator could benefit from the PHS/NIH funded research), or
- the SFI is in an entity whose financial interests could be affected by the PHS/NIH-funded research (meaning the entity could benefit from the PHS/NIH funded research).

Investigator involvement: The DO may consult with the Investigator when assessing whether an SFI is related to the research.

FCOI determination: An FCOI exists when the DO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research ("significantly" meaning that the financial interest would have a material effect on the research).

7. Management of SFIs that Pose an FCOI

When an FCOI is identified, the DO will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include, but are not limited to:

- Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board);
- For human subjects research, disclosure of the FCOI to participants in the informed consent document;
- Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research;
- Modification of the research plan;
- Change of personnel roles or removal from portions of the research;
- Reduction or elimination of the financial interest (e.g., divesting equity);
- Severance of relationships that create financial conflicts.

The DO will communicate the determination and the management plan in writing to the Investigator and will require the Investigator to certify compliance with the management plan. No expenditures on an NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. The DO will submit an FCOI report to NIH via the eRA Commons FCOI Module.

8. Monitoring Investigator Compliance

UP Oncolytics, Inc. will monitor Investigator compliance with the management plan for the duration of the NIH award. When the Institution's FCOI policy applies to subrecipient Investigators, the Institution will monitor subrecipient Investigator compliance with the management plan.

As part of this monitoring process, the DO may request and review documentation demonstrating compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters, and written communications to study personnel. Investigators must provide copies of such materials, including relevant emails or other written disclosures, to the DO for recordkeeping. These records will be maintained to document compliance with the management plan and to support institutional review and audit activities.

9. Public Accessibility of the FCOI Policy and FCOIs Held by Senior/Key Personnel

FCOI Policy: Because UP Oncolytics, Inc. receives NIH funding to further its research, UP Oncolytics, Inc. is required to make this Financial Conflict of Interest (FCOI) policy publicly available. A copy of this FCOI policy is available on the UP Oncolytics, Inc. public website at www.uponc.com, located in the footer, as required by Section 4.1.10 (Financial Conflict of Interest) of the NIH Grants Policy Statement.

Identified FCOIs held by Senior/Key Personnel: Before any funds are spent under an NIH award, UP Oncolytics, Inc. will ensure public accessibility by providing a written response within five business days to requests for information about any SFI that meets all three of the following criteria:

- The SFI was disclosed and is still held by Senior/Key Personnel (the PD/PI and any other individual identified by UP Oncolytics, Inc. as senior/key personnel in the application, progress report, or other NIH submission);
- UP Oncolytics, Inc. has determined that the SFI is related to the NIH-funded research; and
- UP Oncolytics, Inc. has determined that the SFI constitutes an FCOI.

When applicable, UP Oncolytics, Inc. will make available at least the following information:

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

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates at least annually and within 60 days of the Institution's identification of a new FCOI. If UP Oncolytics, Inc. uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded research that was not previously disclosed, or a new SFI disclosed by Senior/Key Personnel joining the project and determined by the DO to be related and an FCOI. Information subject to public accessibility will remain available for at least three years from the most recent update.

10. Reporting Identified Financial Conflicts of Interest

Prior to spending any funds under an NIH-funded award, UP Oncolytics, Inc. will submit an identified FCOI report to NIH, in accordance with the FCOI regulations, for any Investigator's SFI determined to be an FCOI,

and will ensure that the Investigator has agreed to and begun implementing the associated management plan.

UP Oncolytics, Inc. will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO for UP Oncolytics, Inc. Richard A. Rovin, MD, Chief Executive Officer. The FCOI SO is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified. The NIH eRA Commons FCOI Module User Guide is available at https://www.era.nih.gov/files/fcoi_user_guide.pdf.

The Institution will submit the following types of reports:

- A. Initial (Original) FCOI Reports:** Must include all information required under 42 CFR 50.605(b)(3). An Original report is submitted (i) prior to the expenditure of funds, if an FCOI is identified when a new NIH award is issued; and (ii) within 60 days of identifying a new FCOI during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project).
- B. Annual FCOI Reports:** For the duration of an award, including any extensions with or without funds, the Institution will submit an annual FCOI report indicating whether each previously reported FCOI is still being managed or no longer exists, and describing any changes to the management plan. The annual report is submitted at the same time as the RPPR or multi-year progress report, and at the time of any grant extension. Annual FCOI reports are not required at grant closeout.
- C. Revision or Mitigation FCOI Reports:** After completing a retrospective review, the Institution will submit a Revision report if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

Initial FCOI reports include: grant number; PD/PI; name of the entity with the FCOI; nature of the FCOI; value of the financial interest (in required increments); a description of how the financial interest relates to the research; and the key elements of the management plan.

11. Training Requirements for Investigators

Each Investigator will be informed of the UP Oncolytics, Inc. FCOI policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly when any of the following occur:

- UP Oncolytics, Inc. revises this policy or related procedures in a way that affects Investigator requirements;
- an Investigator is new to UP Oncolytics, Inc. research under an NIH award (training must be completed before participating in the research); or
- UP Oncolytics, Inc. determines that an Investigator has not complied with this policy or with a management plan issued under it (training must be completed within 30 days as directed by the DO).

To satisfy the training requirement, UP Oncolytics, Inc. requires Investigators to complete either:

- the [NIH FCOI training module](#), printing and retaining the Completion Certificate for audit purposes and sharing it with the DO; or
- the [NIH Virtual Seminar presentation](#) on FCOI compliance, sending the DO the date of completion by email for audit purposes.

12. Noncompliance With FCOI Policy and Corrective Actions

If UP Oncolytics, Inc. identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DO will, within 60 days: review the SFI; determine whether it is related to NIH-funded research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan. UP Oncolytics, Inc. will also submit an FCOI report to NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner — including failure by the Investigator to disclose an SFI later determined to constitute an FCOI, failure by the Institution to review or manage an FCOI, or failure by the Investigator to comply with an established management plan — UP Oncolytics, Inc. will, within 120 days of identifying the noncompliance:

1. Complete a retrospective review of the Investigator's activities and the NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting; and
2. Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B). Based on the results, if appropriate, the Institution will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, UP Oncolytics, Inc. will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) via the eRA Commons FCOI Module. The report will include the impact of the bias on the research project and the plan of action or corrective steps taken to eliminate or mitigate the effect of the bias. UP Oncolytics, Inc. will thereafter submit FCOI reports annually to NIH as required. If bias is not found, no further action will be taken unless new information is discovered that must be reported to NIH.

13. Clinical Research Requirements

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, UP Oncolytics, Inc. will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations.

14. Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through UP Oncolytics, Inc. to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to UP Oncolytics, Inc. for programmatic outcomes and compliance. Subrecipients (e.g., collaborators or consortium members) are subject to UP Oncolytics, Inc.'s terms and conditions. UP Oncolytics, Inc. will take reasonable steps to ensure that all subrecipient Investigators comply with 42 CFR Part 50 Subpart F, and will include in each written agreement terms specifying whether the UP Oncolytics, Inc. FCOI policy or the subrecipient's own policy will apply to subrecipient Investigators (see NIH Grants Policy Statement Section 15.2.1, Written Agreement).

- **If the subrecipient's FCOI policy applies:** the subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to UP Oncolytics, Inc. in time to meet NIH deadlines (before funds are spent and within 60 days of the subrecipient identifying an FCOI) — typically within 50–55 days of identification. The UP Oncolytics, Inc. FCOI SO will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

- **If the subrecipient cannot certify compliance:** the agreement will specify that the UP Oncolytics, Inc. FCOI policy applies. Subrecipient Investigators must disclose to UP Oncolytics, Inc. their SFIs directly related to the subrecipient's work for UP Oncolytics, Inc. When an FCOI is identified, UP Oncolytics, Inc. will implement a management plan, monitor the subrecipient Investigator's compliance, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

15. Maintenance of Records

UP Oncolytics, Inc. will maintain records of all Investigator financial-interest disclosures, the Institution's review and response to those disclosures (whether or not they resulted in a determination of an FCOI), and any actions taken under this policy or through retrospective review. These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 2 CFR 200.334 for different situations. UP Oncolytics, Inc. will retain these records for each competitive segment as required by regulation. Copies of management plans will be retained as part of the record-maintenance requirements and are not submitted to NIH.

16. Enforcement Actions for Investigator Noncompliance and Remedies

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Failure to comply — including failure to disclose Significant Financial Interests, failure to comply with a management plan, or failure to complete required training — may result in appropriate corrective or disciplinary actions. Such actions may include, but are not limited to, formal notification or disciplinary measures, restrictions on participation in research activities or use of research funds, suspension or termination of employment or contractual relationship, and/or disqualification from participation in Government Award-funded research.

In addition, the PHS/NIH Awarding Component and/or HHS may inquire at any time — before, during, or after an award — into any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure. UP Oncolytics, Inc. will submit, or permit on-site review of, all records pertinent to compliance with the regulation and this policy. The PHS/NIH Awarding Component may determine that imposition of specific award conditions under 2 CFR 200.208, or suspension of funding or other enforcement action under 2 CFR 200.339, is necessary until the matter is resolved.

17. Useful FCOI and NIH Resources

- NIH email for FCOI-related inquiries: fcoicompliance@mail.nih.gov
- FCOI Regulation, 42 CFR Part 50 Subpart F: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- Financial Conflict of Interest: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>

18. Point of Contact

If you have a question related to the UP Oncolytics, Inc. FCOI policy, or would like to disclose a financial interest, contact:

Richard A. Rovin, MD

Chief Executive Officer, UP Oncolytics, Inc.

1904 E Lafayette Pl

Milwaukee, WI 53202

richard.rovin@uponc.com · 906-360-9275

Approved by: Richard A. Rovin, MD — Chief Executive Officer, UP Oncolytics, Inc.

Signature: _____ Date: _____