

# 1 Purpose

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F Responsibility or Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and 45 C.F.R. Part 94 Promoting Objectivity in Research Regulations, that Public Health Service (PHS) – sponsored Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator Financial Conflicts of Interest.

These regulations require Indivior ("Indivior" or the "Group") to maintain a written policy on Conflict of Interest disclosure as a condition for receiving PHS awards and ensure research be conducted in an unbiased manner. Therefore, Indivior is obligated to establish this policy consistent with these regulations to require disclosure, and identification and management of Financial Conflicts of Interest (FCOI) for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other nonfederal sponsors that adopt the PHS policy.

This policy is designed to ensure that research-related interests are reported and that potentially conflicting interests are evaluated and appropriately resolved or managed.

### 2 Scope

This Policy for disclosure and management of Financial Conflicts of Interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, FDA, etc.) and other non-federal sponsors that adopt the PHS policy for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

Consistent with PHS regulations, this policy will be made available via a publicly accessible website. All Indivior Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy and relevant reporting requirements may be accessed via the web. This includes

Indivior full or part time employees or contingent workers ("Workforce") or third parties working on behalf of Indivior.

# **3** Policy Detail

#### 3.1 Disclosure of Significant Financial Interests

- 3.1.1 Investigators seeking PHS research funding or receiving PHS research support are required to disclose Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests in accordance with Indivior's procedures. The requirement that an Investigator disclose a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential Financial Conflict of Interest. The existence of a Financial Conflict of Interest, based upon the relationship of the Investigator's Significant Financial Interests to the Investigator's Institutional Responsibilities, is determined by a Designated Official(s) or an Independent Substantive Review Committee (ISRC) with input from the Investigator. If a Financial Conflict of Interest is identified, the Designated Official(s) or the ISRC shall recommend additional steps to manage or eliminate the conflict, to the SVP of GMD or designee who is authorized to act on that recommendation. Investigators as defined by this policy, shall disclose all Significant Financial Interests related to their Indivior Responsibilities, no later than at the time of application for PHS funding. This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose to Indivior's Designated Official the Investigator's Significant Financial Interests (and those of the Investigator's spouse or registered domestic partner, and dependent children), related to the Investigator's Indivior **Responsibilities:** 
  - Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
  - At least annually throughout the period of the award. Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to Indivior. Under the terms of this Policy, Principal Investigators must identify all Investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting

the research to be funded by PHS) are required to disclose Significant Financial Interests.

- 3.1.2 Reimbursed or sponsored travel related to the Investigator's institutional responsibilities must be disclosed over the previous 12 months:
  - Information to be disclosed includes the purpose of the trip, the identity of the sponsor/organizer, destination and the duration of the trip, as well as any other information that may be required) for the twelve (12) month period following the filing of the Investigator's annual disclosure form; and
  - Within thirty (30) days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to previous paragraph or that significantly varied in the threshold reporting details from what was listed in the prospective report.
- 3.1.3 Collaborators are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed or, if their institution does not have a Conflict of Interest policy that complies with the DHHS regulations, they must comply with Indivior's policies and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards. Subawards issued by Indivior will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending Indivior notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.
- 3.1.4 Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by Indivior must be identified as Investigators by the Principal Investigator and must complete the Indivior disclosure forms. If, upon review, Indivior determines that these Financial Interests are significant and could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce or manage the identified FCOI.

#### 3.2 Review of Disclosures; Management Plan

3.2.1 With each PHS proposal, progress report, incremental funding or extension, Investigator's Significant Financial Interests disclosures will be reviewed either by an individual Designated Official or the ISRC to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

- 3.2.2 In the event that the Designated Official(s) conclude that an Investigator's Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research; or is in an entity whose Financial Interest could be affected by the research, the Disclosure and appropriate documentation shall be forwarded to the ISRC for consideration. When it is determined that there is a Financial Conflict of Interest, the ISRC (or designee) shall make a final recommendation to the SVP of GMD (or designee) about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.
- 3.2.3 The management plan must be implemented prior to Indivior's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:
  - The role and principal duties of the conflicted Investigator;
  - Conditions of the management plan;
  - How the plan will safeguard objectivity in the research activity;
  - Confirmation of the Investigator's agreement to the plan; and
  - How the plan will be monitored. The same review process takes place when an Investigator reports a new Significant Financial Interest.

#### 3.3 Reporting to PHS

- 3.3.1 Prior to Indivior's expenditure of any funds provided under a PHS award, Indivior must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, Indivior is not required to submit a report to the PHS funding agency.
- 3.3.2 During the period of the award, Indivior shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.
- 3.3.3 For any Financial Conflict of Interest that Indivior reports to a PHS awarding agency, Indivior shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the

Financial Conflict of Interest is still being managed or explain why it no longer exists. Indivior must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).

- 3.3.4 Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded research activity, the Designated Official(s) must implement a management plan and submit a report to the PHS funding agency.
- 3.3.5 In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Indivior as required by this policy and Federal regulation, Indivior shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### 3.4 Monitoring

3.4.1 The management plan put in place by Indivior shall specify the way in which the Investigator's compliance with the management will be monitored on an ongoing basis until completion of the PHS-funded research project.

#### 3.5 Retrospective Reviews and Mitigation Reports

- 3.5.1 When during the course of an ongoing PHS-funded research project, Indivior identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official(s) will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.
- 3.5.2 In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be a Financial Conflict of Interest, or Indivior did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, Indivior must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. Indivior will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial

Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

- 3.5.3 Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that Indivior will take to manage the identified Financial Conflict of Interest going forward.
- 3.5.4 If bias was found during the retrospective review, Indivior will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum: documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines Indivior's plans to eliminate or mitigate the effect of the bias.

#### 3.6 Record Retention

3.6.1 Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

#### 3.7 Training

3.7.1 Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training about this policy (Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards) and the PHS Conflict of Interest regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94) prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by Indivior in accordance with DHHS regulations. For PHS-funded Investigators who are new to Indivior, or who are joining an ongoing PHS Research Activity, training must be completed prior to engaging in PHS-funded research.

#### 3.8 Public Access to Information

- 3.8.1 The Designated Official(s) shall identify one email address and one office address as the recipient addresses for public requests for information under the PHS regulations and this policy and shall take the necessary action to provide reasonable notice of those addresses to the public, including prominently posting this information on the company web site.
- 3.8.2 The Designated Official(s), must respond within 5 business days to any request for information about Significant Financial Interests held by Key Personnel when Indivior has determined that the disclosed Significant Financial Interests are related to the PHS-

funded research and constitute Financial Conflicts of Interest. Indivior will designate on the website an address to which public requests for information should be sent. The 5day response time shall be measured from the date that the request for information is received at the designated address until the date a response is sent to the requestor.

3.8.3 Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under this policy are public records open to public inspection, under federal and state law.

Function	Responsibilities	
Investigators	<ul> <li>Must disclose to Indivior all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for PHS funding.</li> </ul>	
	• Throughout the period of the PHS research award, must disclose to Indivior their SFIs, and those of their spouse or registered domestic partner and dependent children:	
	<ul> <li>Within 30 days of discovering or acquiring any new SFI; and</li> </ul>	
	• At least annually throughout the period of the award.	
	• Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to Indivior.	
	• Principal Investigators must fully identify all Investigators on the award who are required to disclose SFIs under the terms of this Policy.	
	• Investigators must complete NIH-compliant training about PHS financial Conflicts of Interest regulation and Indivior's FCOI policy prior to engaging in research related to any PHS- funded project and at least every 4 years thereafter, while receiving PHS research funding and at other times as may be required by Indivior under this Policy.	
	<ul> <li>In cases where Indivior has identified a Financial Conflict of Interest held by the Investigator and has implemented a management plan to eliminate, reduce or manage the</li> </ul>	

### **Compliance / Responsibilities**

	<ul> <li>conflict, the Investigator must adhere to the terms of the management plan.</li> <li>Where DHHS determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Indivior as required by this policy and federal regulation, Indivior shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.</li> </ul>
Collaborators	<ul> <li>Must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a Conflict of Interest policy that is compliant with the DHHS regulations, they must comply with this policy and procedures for disclosure and review of SFIs related to PHS-sponsored awards.</li> <li>Must comply with all requirements of their institution's (or this) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter,</li> </ul>
Institutions that receive subawards issued by Indivior for PHS- funded research	<ul> <li>PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding</li> <li>In cases where the agreement between Indivior and the subrecipient specifies that the subrecipient's conflict of interest policy shall apply: <ul> <li>Must certify that the subrecipient's conflict of interest policy complies with the requirements of the DHHS regulations</li> <li>Must review financial disclosures made by Investigators at the subrecipient institution and, if any Financial Conflicts of Interest are identified, send Indivior notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.</li> </ul> </li> <li>In cases where the agreement between Indivior and the subrecipient specifies that Indivior's conflict of interest policy</li> </ul>

	shall apply, must submit to Indivior, within the time specified in its subrecipient agreement with Indivior, all disclosures by subrecipient Investigators of Significant Financial Interests, for Indivior's review.
Designated Official(s)	• Must solicit and review Investigators' SFI disclosures for each PHS proposal, progress report, incremental funding or extension, to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.
	• If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research activity, the reviewing Designated Official shall forward the disclosure and appropriate documentation to the ISRC for consideration.
	• Upon the ISRC's determination of a Financial Conflict of Interest (see below), must develop a Management Plan specifying actions required to manage the Financial Conflict of Interest, how the plan will safeguard objectivity in the research activity, confirms the investigator's agreement to the plan, and specifies the way in which the Investigator's compliance with the management plan shall be monitored.
	• Must respond within 5 business days to any request for information submitted in accordance with this policy about SFIs held by Key Personnel when Indivior has determined that the disclosed SFIs are related to the PHS-funded research and constitute Financial Conflicts of Interest.
	• Prior to Indivior's expenditure of any funds provided under a PHS award (and within 60 days of any subsequently identified financial conflict of interest), must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest (including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will follow Indivior's financial conflict of interest policy.
	• During the period of the award shall, within 60 days of receipt of disclosure new or newly discovered SFI, must review the disclosure, determine whether it constitutes a Financial Conflict of Interest, and if so, report the Financial Conflict of Interest to the PHS-funding agency. If a Financial Conflict of Interest ceases to exist during the course of the

		award, updated information about the status of that Financial Conflict of Interest should be reported to the PHS funding agency.
	•	Must provide an annual Financial Conflict of Interest report to the PHS awarding agency addressing the status of the conflict and any changes to the management plan, for the duration of the project period (including extensions with or without funds).
	•	Must submit a report to the PHS-funding agency within 60 days of determining that a Financial Conflict of Interest exists for new Investigator who joins an ongoing PHS-funded research activity.
	•	If Indivior is a subrecipient of a PHS award from another institution, must report to that institution any FCOIs that Indivior identifies for Indivior investigators
Independent Substantive Review Committee (ISRC)	•	Must determine whether, based on documentation received, there is a financial conflict of interest, and makes a final recommendation to the SVP of GMD (or designee) about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest.
Legal (Contracts)	•	If the PHS award is to be conducted through a subaward, must incorporate as part of a written agreement with subrecipients terms that establish whether the Indivior PHS COI policy or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators
Director (or designee)	•	Must determine, based on final recommendation of the ISRC, the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest.

# 4 Definitions

Term	Definition
Collaborator(s)	Non-Indivior workforce, consultants or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from Indivior
Designated Official(s)	An official or officials designated by the SVP of GMD, or designee, to solicit and review Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.
Financial Conflict of Interest (FCOI)	A Significant Financial Interest that is related to the PHS- funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-Funded research activity.
Independent Substantive Review Committee (ISRC)	The ISRC is a committee which may be appointed (in lieu of or in addition to a designated individual) by the Disclosure of Financial Interests & Management of COI, PHS Research Awards Chair (or designee) consisting of staff from Global Medicines Development, Legal, and Integrity & Compliance to review Investigators' Significant Financial Interests related to PHS funded research, and to serve as the Designated Official(s) who determines whether any of the Significant Financial Interests constitutes a Financial Conflict of Interest
Financial Interest	Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
Institutional Responsibilities	Teaching/education, research, outreach, clinical service, and services on behalf of Indivior which are in the course and scope of the Investigator's Indivior appointment/employment.
Key Personnel	A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.
PHS	Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including, among others, the NIH. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.

Term	Definition
PHS-Funded Research	Any Research funded by way of a grant from, or a contract with, a PHS Organization. (e.g., NIH, CDC, FDA)
Principal Investigator	An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.
Research	Any activity for which research funding is available from a PHS- awarding agency, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, training grants, program projects or research resources awards, conference grants, and Phase II Small Business Innovative Research (SBIUR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this Policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.

Significant financial	
Significant financial interest (SFI)	Significant Financial Interest means a Financial Interest consisting of one or more of the following interests of the investigator or the investigator's spouse or registered domestic partner and dependent children for the following categories:
	<ul> <li>A. With regard to any <i>publicly traded entity</i> (domestic or foreign), a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceptions below) 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. Included are salary (other than salary described in the exceptions below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value;</li> <li>B. With regard to any <i>non-publicly-traded entity</i> (domestic or foreign), including a non-U.S. institution of higher education or a non-U.S. government agency, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceeds \$5,000, or when the Investigator (or the Investigator's spouse, registered domestic partner, or dependent children) holds any equity interest;</li> <li>C. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding the twelve months preceding the twelve months any equity interest;</li> </ul>
	<ul> <li>D. Travel related to the Investigator's Indivior</li> <li>Responsibilities must also be disclosed when the travel is reimbursed or sponsored by an individual or</li> </ul>
	entity other than a U.S. federal, state or local government agency, a U.S. institution of higher
	education, or a research institute, academic medical center, or hospital affiliated with a U.S. Institution of higher education. Consistent with federal

Term	Definition
	regulations, Indivior has the discretion to require disclosure of all such reimbursed or sponsored travel related to a PHS-funded Investigators' Indivior responsibilities, regardless of amount, or require disclosure of such reimbursed or sponsored travel only if the aggregated total of such reimbursed or sponsored travel exceeds \$5,000 per entity during the twelve months preceding disclosure.
	Exceptions: The term "Significant Financial Interest" does not include the following types of Financial Interest:
	<ul> <li>Salary, royalties, or other payments made by Indivior to an Investigator who is currently employed or otherwise appointed by Indivior;</li> <li>Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels; sponsored by a government agency of the United States (including federal, state, or local government), a U.S. institution of higher education, or a research institute,</li> </ul>
	<ul> <li>academic medical center or hospital affiliated with a U.S. institution of higher education; or</li> <li>Income from investment vehicles, such as mutual funds and retirement funds, in which the investigator does not directly control investment decisions.</li> </ul>

# **5** Impacted Functions

**Global - All Functions** No

Functions

GMD - Global Medicines Development

# 6 Sanctions / Compliance Measurement and Policy Enforcement

6.1.1 Non-compliance with this policy and its related procedures and work instructions can subject Workforce, interns, consultants, and other third parties contracted for hire to

disciplinary actions up to and including termination of employment or contract. Further, improper activities that violate one or more laws and regulations could result in criminal and civil penalties for Workforce and the group.

Deviations and exceptions to compliance must be documented and authorized in accordance with global or local procedures.

- 6.1.2 Failure of any individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for discipline.
- 6.1.3 Agreements with Collaborators who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and Indivior policy.

### 7 Appendices

N/A

### 8 Revision History

Version	Author	Summary of Changes
1.0	D. Hutcheson	New policy