Research Policies

Scientific Misconduct (SC-200)

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Section I: Introduction, Scope, and Definitions

Policy

As an organization dedicated to biomedical research in the public interest, the Howard Hughes Medical Institute (the "Institute") expects that its scientists will conduct research and engage in related academic activities according to the highest scientific and ethical standards. The Institute's commitment to these standards embraces the belief that integrity, responsibility, and accountability are part of the fabric of science. Scientific research is, ultimately, a cooperative endeavor based on the central principle of truth (see also Science Policy SC-100 – Guidelines for Scientific Research).

The purpose of this policy is to establish procedures to address specific allegations or apparent instances of scientific misconduct. A scientist must be assumed to be innocent of scientific misconduct until a contrary conclusion is reached using the procedures set forth in this policy. A finding of scientific misconduct under this policy requires that (a) there be a significant departure from accepted practices of the relevant research community; (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence (i.e., a conclusion that the allegation is more probably true than not).

The Institute will respond to each allegation or apparent instance of scientific misconduct that it is responsible for addressing under this policy in a thorough, competent, objective, and fair manner, including by taking precautions to ensure that individuals responsible for carrying out proceedings under this policy do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses.

The Responsible Vice President (as defined below) has primary responsibility for implementing this policy but may consult with his or her senior staff. If, with respect to a particular allegation or apparent instance of scientific misconduct, the Responsible Vice President is unable to take on primary responsibility or has a conflict of interest, the President of the Institute will designate an alternate who is able to take on primary responsibility and does not have a conflict of interest. In this event, references in this policy to the Responsible Vice President will mean the designated alternate.

The procedures set forth in this policy are intended to be complementary to any procedures of host institutions, home institutions of visitors, professional societies, or journals that may also apply in a specific case. For allegations of scientific misconduct relating to activities that are alleged to have occurred at or in relation to another institution, the Responsible Vice President may in his or her discretion defer to the other institution to take primary responsibility for resolving the allegations if the other institution will take on such responsibility. Although in this event, proceedings (including notifications and securing of evidence) will be handled by the other institution, the provisions of Section 2: Confidentiality, Cooperation, Retaliation, and Obstruction) continue to apply to all Institute personnel; the Responsible Vice President should keep the President informed as described in Section 8: Miscellaneous Provisions; and the Institute may impose sanctions based on the outcome of the other institution's proceedings. The Responsible Vice President may at any time, in his or her discretion, reverse a decision to defer to another institution, and commence separate proceedings under this policy.

Scope of Policy

This policy applies to all Institute employees, regardless of rank or status. An Institute employee who also has or had an appointment at or formal affiliation with another institution (including enrollment as a student at another institution) may also be subject to the policies of that institution with respect to allegations of scientific misconduct, and any proceedings under this policy may in such instances be coordinated with that institution at the discretion of the Responsible Vice President. Coordination with another institution may include allowing the other institution to take primary responsibility for resolving the allegations as described above, in which case there may not be separate proceedings under this policy.

If an allegation of scientific misconduct is made against an Institute employee based on activities that occurred prior to his or her employment by the Institute, this policy may be applied at the discretion of the Responsible Vice President.

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If an allegation of scientific misconduct is made against a person who is no longer employed by the Institute based on activities that occurred during his or her employment by the Institute, this policy may be applied at the discretion of the Responsible Vice President.

If an allegation of scientific misconduct is made against a researcher who is visiting the Janelia Research Campus, and relates to work done at Janelia, this policy may be applied at the discretion of the Vice President and Director, Janelia, and proceedings may be coordinated with the other institution(s) with which the researcher is affiliated.

Definitions

Scientific Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, and also includes any other serious deviations or significant departures from accepted and professional research practices, such as the abuse or mistreatment of human or animal research subjects. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Scientific misconduct does not include honest error or differences of opinion.

<u>Inquiry</u> means preliminary information gathering and preliminary fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

<u>Investigation</u> means the formal development of a factual record and the examination of that record leading to (a) a decision not to make a finding of scientific misconduct, or (b) a recommendation for a finding of scientific misconduct which may include a recommendation for other appropriate actions.

<u>Proceeding</u> means any actions taken under this policy relating to alleged or apparent scientific misconduct.

Complainant means a person who in good faith makes an allegation of scientific misconduct.

Respondent means the person against whom an allegation of scientific misconduct is directed or who is the subject of a scientific misconduct proceeding.

Responsible Vice President means (1) for host based sites, the Vice President and Chief Scientific Officer, and (2) for Janelia, the Vice President and Director. If an allegation of scientific misconduct is made that involves both one or more Institute employees at a host-based site and one or more Institute employees at Janelia, it is generally expected that the Responsible Vice President will be the Vice President with responsibility for the site at which the Respondent is located; however the Vice President and Chief Scientific Officer and the Vice President and Director, Janelia may agree otherwise.

<u>Host-Based Sites</u> means Institute sites at host institutions.

Janelia means the Janelia Research Campus.

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Section 2: Confidentiality, Cooperation, Retaliation, and Obstruction

Confidentiality

Any inquiry into or investigation of alleged scientific misconduct has the potential to jeopardize the reputation of both the respondent and the complainant. For this reason, while these procedures are being followed, great care should be taken to limit voluntary disclosure of information about an allegation of misconduct. To the extent possible, such information should be disclosed only to those within and outside the Institute who have a need to know the information, consistent with a thorough, competent, objective, and fair scientific misconduct proceeding.

Notwithstanding the foregoing, the Responsible Vice President may, at his or her discretion and at any time, report in writing the progress and/or the results of any proceeding to the complainant and any other appropriate persons. Other appropriate persons may include, but are not limited to, (1) co-authors, co-investigators, or collaborators; (2) editors of journals in which work was published or to which work was submitted; (3) professional societies; (4) state professional licensing boards; and (5) other institutions with which the respondent is or has been affiliated. Any written report provided pursuant to this paragraph will also be sent to the respondent.

Cooperation

All Institute personnel and all researchers visiting Janelia, and all those who were employed or visiting at Janelia during the time in which the relevant incidents took place, are expected to cooperate fully with proceedings under this policy. If another institution is taking the lead on an inquiry or investigation into alleged misconduct involving an Institute laboratory, Institute personnel are expected to cooperate with those proceedings to the best of their ability as well. Cooperation includes, but is not limited to, providing information, research records, or other evidence.

Retaliation Prohibited

Any retaliation against a complainant who has made an allegation in good faith, or against a person who in good faith provides information about suspected or alleged misconduct, is a violation of this policy and will not be tolerated. The Institute will take reasonable and practical steps to protect the positions and reputations of complainants who have acted in good faith and protect them from retaliation by respondents and others within the institute.

Obstruction of Proceedings

Obstruction of any proceedings under this policy, or of proceedings of another institution that is taking the lead on an inquiry or investigation into alleged scientific misconduct involving an Institute laboratory, is a violation of this policy and may itself constitute scientific misconduct. Obstruction includes, but is not necessarily limited to, intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting, or giving false testimony; and attempting to intimidate witnesses, potential witnesses, or potential leads to witnesses or evidence.

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Section 3: Reports of Misconduct, Notice to Respondent, and Preservation of Records

Reporting Possible Misconduct

A person who believes that an act of scientific misconduct has occurred or is occurring may wish to discuss his or her concerns with the individual whose work is in question or with the supervisor of the individual whose work is in question. If the person does not wish to do so, or has done so and believes that an act of scientific misconduct has occurred and has not been addressed appropriately by the individual whose work is in question, or believes that scientific misconduct is continuing to occur, he or she is expected to put the allegation of scientific misconduct in writing and direct it to the attention of the Responsible Vice President.

At host-based sites, Investigators who become aware of possible scientific misconduct by an Institute employee must promptly inform the Vice President and Chief Scientific Officer, preferably in writing, in order to ensure that these procedures are followed.

At Janelia, Group Leaders or Fellows who become aware of possible scientific misconduct at the site, whether by an Institute employee or a visitor, must promptly inform the Vice President and Director, preferably in writing, in order to ensure that these procedures are followed.

Insubstantial, Unfounded, or False Reports of Alleged Misconduct

If the Responsible Vice President, upon reasonable inquiry, determines that a report of alleged misconduct is insubstantial or trivial, or has no reasonable foundation, no further action need be taken under this policy, although absent unusual circumstances the parties involved should be notified of the outcome.

It is a violation of this policy for a person knowingly, recklessly, or in bad faith to bring a false accusation of scientific misconduct against another person. The bringing of a false allegation, if done knowingly, recklessly, or in bad faith, is a violation of Institute policies and may result in disciplinary action, up to and including termination of employment or visitor status.

Notification of the Respondent

If the allegation is not determined to be insubstantial, trivial, or lacking a reasonable foundation, the Responsible Vice President must promptly notify the respondent of the allegation, in writing. The notice should include sufficient information about the allegation to allow the respondent to prepare to respond. The respondent must also be provided with a copy of this policy.

The respondent may submit one or more written responses to the allegation to the appropriate individual(s) prior to or during any proceeding under this policy. Any such written responses will become part of the record of the proceeding.

Respondent's Participation in Procedures

The respondent is expected and required to participate in the procedures under this policy. During any interview of the respondent pursuant to any proceeding under this policy, the respondent may be accompanied by an advisor who is either a faculty member of the host institution, an employee of the Institute, a scientist, or a lawyer. The respondent may consult with the advisor but the advisor may not direct questions or answers, offer argument, or participate directly in the proceedings unless asked to do so by the Responsible Vice President in his/her sole discretion.

Preserving Records

The Responsible Vice President must, before or when notifying the respondent, (a) promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to

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conduct the scientific misconduct proceeding, (b) inventory the records and evidence, and (c) sequester the records and evidence in a secure manner. Those responsible for handling inquiries and investigations must also undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a scientific misconduct proceeding.

Where the research records or evidence encompass scientific instruments, including computers, shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies have evidentiary value that is substantially equivalent to the evidentiary value of the instruments.

Where appropriate, the Responsible Vice President should give the respondent copies of, or reasonable, supervised access to, the research records in his or her custody.

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Section 4: Notice to and Proceedings at Other Institutions

Notification to Host Institution (Host-Based Sites)

For allegations related to activities that are alleged to have occurred at host-based sites or that relate to activities at host-based sites, the Vice President and Chief Scientific Officer must notify the appropriate host institution of any allegation that is judged not to be insubstantial, trivial, or lacking a reasonable foundation, and of the results of any inquiry or investigation undertaken.

If an allegation involves host institution personnel or the use of federal research funding, the Vice President and Chief Scientific Officer will consult with the appropriate host institution as to whether primary responsibility for resolving the allegation should rest with the Institute or the host institution, or whether joint efforts should be used to resolve the allegation.

If the allegation does not involve activities alleged to have occurred at or in relation to host-based sites, host institution personnel, or the use of federal research funding, and does not significantly implicate the interests of the host institution, the Vice President and Chief Scientific Officer may, at his or her discretion, keep the host institution informed of the progress of proceedings under this policy.

Notification to Home Institution (Janelia)

For allegations related to Janelia that involve a researcher who is visiting the Janelia Research Campus and who has an appointment at or formal affiliation with another institution (including enrollment as a student at such institution), the Vice President and Director must notify the researcher's home institution of any allegation that is judged not to be insubstantial, trivial, or lacking a reasonable foundation, and of the results of any inquiry or investigation undertaken.

The Vice President and Director will consult with the home institution as to whether primary responsibility for resolving the allegation should rest with the Institute or the home institution, or whether joint efforts should be used to resolve the allegations.

Deferral If Other Institution Is Handling The Matter

For allegations related to activities that are alleged to have occurred at or in relation to host-based sites, the Vice President and Chief Scientific Officer may in his or her discretion defer commencement or continuation of any proceeding under this policy if the host institution has begun or will begin proceedings concerning the allegations.

For allegations related to Janelia, the Vice President and Director may in his or her discretion defer commencement or continuation of any proceeding under this policy if the home institution of a researcher alleged to have committed scientific misconduct has begun or will begin proceedings concerning the allegations.

Institute proceedings may be deferred whether the host or home institution handles the allegation internally or uses the services of an outside consortium or person, provided that the consortium or person has been reasonably determined by the host or home institution to be qualified by practice and experience to conduct scientific misconduct proceedings.

Sharing of Information

Where the interests of both the Institute and the host or home institution are significantly implicated, it is expected that the institution assuming primary responsibility for resolving the allegation will keep the other institution informed as to the proceedings. This includes providing copies of written reports, evidence, and other relevant documentation as requested by the other institution.

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Section 5: Inquiries

Initiation

An inquiry must be initiated promptly upon the receipt by the Responsible Vice President of an allegation that the Responsible Vice President, upon reasonable inquiry, determines to be substantial and nontrivial and to have a reasonable foundation, or upon the receipt by the Responsible Vice President of substantial evidence of misconduct. The Responsible Vice President will designate two or more individuals, chosen from among the Institute's scientific personnel or other qualified scientists, to conduct the inquiry. These individuals should, to the extent reasonably feasible, have the expertise to conduct a thorough and authoritative evaluation of the relevant evidence and no real or apparent conflicts of interest bearing on the matter. At the discretion of the Responsible Vice President, these individuals may be assisted by one or more professional advisors, including members of the Institute's legal staff. The Responsible Vice President will not participate in the conduct of the inquiry.

Proceedings

Those conducting the inquiry should review all evidence that has already been sequestered, and should request, secure, and review all additional information or documentation they believe is directly relevant to the allegation. If possible, they should interview all complainants and respondents. They may interview others who may have knowledge that is directly relevant to the allegation.

Those conducting the inquiry should inform the Responsible Vice President immediately if they discover an immediate health hazard, an immediate need to protect human or animal research subjects, an immediate need to protect Institute or host institution funds or equipment, an immediate need to protect the complainant or the respondent, a likelihood that the allegation will be reported or disclosed publicly, or evidence of a possible criminal violation. The Responsible Vice President may take such actions as he or she determines are necessary to address any of these circumstances.

Written Report

A written report must be prepared by those conducting the inquiry that (a) describes the process used to conduct the inquiry, (b) states what evidence was reviewed, (c) summarizes relevant interviews, and (d) includes the conclusion of the inquiry. The conclusion of the inquiry shall be either (1) that there are no reasonable grounds for believing that scientific misconduct occurred and no further investigation is warranted, or (2) that there are reasonable grounds for believing that scientific misconduct occurred and further investigation is warranted.

If the conclusion of the inquiry is that no further investigation is warranted, the report of the inquiry must include sufficiently detailed documentation to permit a later assessment of the reasons for reaching that conclusion.

The report must be submitted to the Responsible Vice President, together with any statement submitted by the respondent, for a decision as to whether further investigation is warranted. The Responsible Vice President must review the report and other evidence sufficiently promptly that an investigation, if warranted, may be undertaken within 30 days of the completion of the inquiry.

The Responsible Vice President will send a copy of the report to each of the respondent and the complainant.

Period for Completion

The inquiry must be completed within 60 calendar days after the individuals who are to conduct the inquiry have been designated, unless circumstances clearly warrant a longer period. If an inquiry takes longer than 60 days, the record of the inquiry must include documentation of the reasons for exceeding the 60-day period.

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Decision to Dismiss

If, after reviewing the written report and other evidence, the Responsible Vice President concludes that there are no reasonable grounds for believing that scientific misconduct occurred and no further investigation is warranted, the Responsible Vice President may dismiss the matter.

If the matter is dismissed, the Responsible Vice President will determine what actions, if any, the Institute reasonably should take to help restore and protect the reputation of the respondent, and will see that those actions are taken. The Responsible Vice President will also determine what actions, if any, the Institute reasonably should take against any complainant employed by the Institute who is found to have knowingly or recklessly brought a false accusation of scientific misconduct, and will see that those actions are taken.

If the matter is dismissed but the Responsible Vice President believes that the conduct of any Institute employee has not met the standards described in the Institute's Guidelines for Scientific Research, the Responsible Vice President will determine what actions should be taken by the Institute and will see that those actions are taken.

If Misconduct is Admitted

If the written report concludes that an investigation is warranted, but the respondent admits to the scientific misconduct that has been alleged, the Responsible Vice President may decide that an investigation is unnecessary and may determine appropriate sanctions. Possible sanctions include, among others: removal from a project; a letter of reprimand; retraction or correction of publications; special monitoring of future work; probation; suspension from employment; and/or termination of employment.

The Responsible Vice President may proceed with the imposition of any sanction except for suspension or termination of employment, which is subject to the prior approval of the President.

Decision that an Investigation is Warranted

If, after reviewing the written report and other evidence, the Responsible Vice President concludes that there are reasonable grounds for believing that scientific misconduct occurred and further investigation is warranted, the Responsible Vice President will designate a panel of at least three individuals to conduct an investigation of the matter. The individuals designated will normally not be Institute employees, but may be past or present members of the Institute's Medical Advisory Board or Scientific Review Board or persons otherwise affiliated with the Institute.

The individuals who comprise the panel that will conduct an investigation should, to the extent feasible, have the expertise to conduct a thorough and authoritative evaluation of the relevant evidence and no real or apparent conflicts of interest bearing on the matter. At the discretion of the Responsible Vice President, these individuals may be assisted by one or more professional advisors, including members of the Institute's legal staff. The Responsible Vice President will not participate in the conduct of the investigation.

Notification to Respondent and Complainant

The Responsible Vice President will promptly provide written notice of the results of the inquiry to the respondent and to the complainant.

If there is to be an investigation, the respondent will also be informed of the membership of the panel that will conduct the investigation. Any written objection promptly made by the respondent to the Responsible Vice President that a panel member has a conflict of interest will be considered by the Responsible Vice President, but the Responsible Vice President's evaluation of and decision concerning any such objection will be final.

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Section 6: Investigations

Initiation

If it is decided that an investigation is warranted, the investigation should normally begin within 30 days of the completion of the inquiry.

The Responsible Vice President will make available to the panel such professional staff support, access to professional advisors, and other resources as the Responsible Vice President deems reasonably necessary.

Proceedings

The investigation should include examination of all relevant documentation, including but not necessarily limited to relevant research data and proposals, publications, paper and electronic correspondence, and memoranda of telephone calls.

If possible, interviews should be conducted of all complainants and respondents, as well as others who might have information regarding key aspects of the allegations. Complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

The panel should also provide the respondent with the opportunity to submit evidence and suggest witnesses. The respondent is expected and required to provide evidence as requested by the panel. The panel is expected to pursue diligently all significant issues, and to carry its investigation through to completion. The panel is not bound by the conclusions of the prior inquiry.

The panel should inform the Responsible Vice President immediately if it discovers an immediate health hazard, an immediate need to protect human or animal research subjects, an immediate need to protect Institute or host institution funds or equipment, an immediate need to protect the complainant or the respondent, a likelihood that the allegation will be reported or disclosed publicly, or evidence of a possible criminal violation. The Responsible Vice President may take such actions as he or she determines are necessary to address any of these circumstances.

Written Report

A written report must be prepared by those conducting the investigation. The report must describe:

- the procedures used in the conduct of the investigation;
- how and from whom information relevant to the investigation was obtained;
- a summary of the substance of the documentary and other evidence on which the panel relied to reach its finding;
- the panel's finding, which shall be based on the weight of the evidence and shall be either (1) a finding that no scientific misconduct was committed or (2) a finding of scientific misconduct including specifications of the precise nature of that conduct; and
- a recommendation for appropriate action. Appropriate action may include, for example, sanctions against the respondent, or steps that should be taken to restore the respondent's reputation if the finding is that no scientific misconduct was committed.

The respondent must have an opportunity to review the report and to indicate in writing any clarifications or corrections he or she believes would be appropriate. The complainant may, at the panel's discretion, be provided with an opportunity to comment on those portions of the report that address his or her role in the matter.

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The report must be submitted to the Responsible Vice President, together with any statement submitted by the respondent, for a decision as to whether any sanctions are warranted, and if so, what those sanctions should be.

Time Period

The investigation should ordinarily be completed, and the report submitted to the Responsible Vice President, within 120 calendar days after the panel that is to conduct the investigation has been fully constituted. If an investigation takes longer than 120 days, the record of the investigation should include documentation of the reasons for exceeding the 120-day period.

Decision to Dismiss

If the finding is that no scientific misconduct was committed, and after reviewing the written report and other evidence the Responsible Vice President concurs, the Responsible Vice President will dismiss the matter.

If the matter is dismissed, the Responsible Vice President will determine what actions, if any, the Institute reasonably should take to help restore and protect the reputation of the respondent, and will see that those actions are taken. The Responsible Vice President will also determine what actions, if any, the Institute reasonably should take against any complainant employed by the Institute who is found to have knowingly or recklessly brought a false accusation of scientific misconduct, and will see that those actions are taken.

If the matter is dismissed but the Responsible Vice President believes that the conduct of any Institute employee has not met the standards described in the Institute's <u>Guidelines for Scientific Research</u>, the Responsible Vice President will determine what actions should be taken by the Institute and will see that those actions are taken.

Request to Supplement Report

The Responsible Vice President may, after reviewing the written report and other evidence, ask the panel to supplement its report.

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Decision Regarding Sanctions

If the finding is that scientific misconduct occurred, and after reviewing the written report and other evidence the Responsible Vice President concurs, the Responsible Vice President will determine appropriate sanctions. Possible sanctions include, among others: removal from a project; a letter of reprimand; retraction or correction of publications; special monitoring of future work; probation; suspension from employment; and/or termination of employment.

The Responsible Vice President may proceed with the imposition of any sanction except for suspension or termination of employment, which is subject to the prior approval of the President.

Notification to Respondent and Complainant

The Responsible Vice President will promptly provide the respondent and complainant with written notice of the results of the investigation and any sanctions to be imposed on the respondent.

Review by the President

Any respondent who has been sanctioned under this policy is entitled to have the matter reviewed by the President of the Institute upon written request submitted within twenty days of the date the written notice of the sanctions was sent to the respondent. The written request may include any matter related to the investigation and/or sanctions that the respondent desires the President to consider.

The President shall notify the respondent and complainant in writing of the results of the review, with a copy of the notification to the Responsible Vice President, the host or home institution if relevant, and, at the discretion of the President, to other appropriate persons.

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Section 8: Miscellaneous Provisions

Interim Reports to President

The Responsible Vice President shall regularly report the progress, status, and results of any proceeding under this policy to the President.

Recordkeeping

All records generated or obtained as a result of any proceedings under this policy will be maintained by the Responsible Vice President's office for at least seven years after the termination of the last proceeding taken under this policy.

Computation of Time Periods

In computing any period of time prescribed or allowed by this policy, the day of the event from which the designated period of time begins to run shall not be included. The last day of the period shall be included, unless it is a Saturday, Sunday, or Institute holiday, in which event the period runs until the end of the next business day which is not a Saturday, Sunday, or Institute holiday.

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