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CONFIDENTIAL: RESEARCH MISCONDUCT FINAL INVESTIGATION REPORT



**DOWNSTATE**  
HEALTH SCIENCES UNIVERSITY

**CONFIDENTIAL**

**RESEARCH MISCONDUCT  
FINAL INVESTIGATION REPORT**

**DECEMBER 2, 2021**

**RESPONDENT: STACY W. BLAIN, PhD  
ASSOCIATE PROFESSOR, DEPARTMENTS OF  
PEDIATRICS & CELL BIOLOGY**

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**RESEARCH MISCONDUCT FINAL INVESTIGATION REPORT**

**RESEARCH MISCONDUCT ALLEGATION RESPONDENT:** Stacy W. Blain, PhD, Associate Professor, Departments of Pediatrics and Cell Biology ([stacy.blain@downstate.edu](mailto:stacy.blain@downstate.edu))

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**RESEARCH MISCONDUCT ALLEGATION SUBJECT:** Allegation of Falsification/ Fabrication

**RESEARCH MISCONDUCT INVESTIGATION COMMITTEE MEMBERS<sup>1</sup>:**

Vitaly Citovsky, PhD, SUNY Distinguished Professor, Biochemistry and Cell Biology, SUNY Stony Brook

Richard M. Gronostajski, PhD, Professor, Biochemistry, SUNY Buffalo

Patricia M. Kane, PhD, Professor and Chair, SUNY Distinguished Teaching Professor, Biochemistry and Molecular Biology, SUNY Upstate

Frank Middleton, PhD, Professor, Neuroscience & Physiology, Biochemistry & Molecular Biology, Pediatrics, Psychiatry & Behavioral Sciences, SUNY Upstate

Laurie K. Read, PhD, Professor of Microbiology & Immunology and Biochemistry, SUNY Buffalo

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<sup>1</sup> Appended hereto as Exhibit A are the Committee members' CV's.



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**A. History of Allegations**

On July 17, 2019, SUNY Downstate received a letter from the Department of Health and Human Services (HHS) Office of Research Integrity (ORI) Division of Investigative Oversight (DIO) in regard to allegations of possible research misconduct against Stacy Blain, PhD, Associate Professor of the Departments of Pediatrics and Cell Biology. DIO stated that the questioned research was supported by US Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA201536 and National Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK044525.

The allegations concern possible falsification and/or fabrication of data in two (2) published papers that were coauthored by Dr. Blain<sup>2</sup>. Specifically, lanes of protein bands in Western blots were allegedly reused and relabeled in Figures 2C, 2H and 2I in MCB 2015 and in Figure 1C in JPGN 2010. Additionally, an anonymous complaint made to the SUNY System directly by the complainant "Claire Francis" pointed to a Pub Peer website<sup>3</sup> in which further allegations of falsification/ fabrication were identified. Accordingly, the notification to Dr. Blain included all work performed:

1. Under NCI NIH Grant R01 CA201536
2. Under National Diabetes and Digestive and Kidney Diseases (NIKDDK) NIH Grant R01 DK044525
3. For paper MCB 2015
4. For paper JPGN 2010
5. For paper "Differential Modification of p27 KIP1 Controls Its Cyclin D-cdk4 Inhibitory Activity" Molecular Cell Biology 2008<sup>4</sup>

For purposes of sequestration, SUNY Downstate required Dr. Blain to identify the exact location of lab and offices where research and/or collaboration took place; PI, post- doc, grad student computers and media devices (including all computers used for PI's work, lab computers, external hard drives, laptops, thumb drives, etc.); Computers used in conjunction with Adobe Photoshop and Western blots; Digital images and

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<sup>2</sup> Patel P, Asbach B, Shteyn E, Gomez C, Coltoff A, Bhuyan S, Tyner AL, Wagner R, Blain SW. Brk/ Protein tyrosine kinase 6 phosphorylates p27KIP1, regulating the activity of cyclin D-cyclin-dependent kinase 4. *Mol Cell Biol*. 2015 May;35(9):1506-22 (hereafter referred to as "MCB 2015").

Nguyen KD, Blain SW, Gress F, Treem WR. Inflammatory mediators of esophagitis alter p27 Kip1 expression in esophageal epithelial cells. *J Pediatr Gastroenterol Nutr*. 2010 Nov;51(5):556-62 (hereafter referred to as "JPGN 2010").

<sup>3</sup> [www.pubpeer.com/search?q=stacy+blain](http://www.pubpeer.com/search?q=stacy+blain)

<sup>4</sup> On May 1, 2020, SUNY Downstate specifically requested the identification of raw data for Figures 1B, 1F, 1G, 3A, 3B, 4B, 4D, 5F, 6B. Respondent declined to identify raw data through a communication dated May 15, 2020. The Committee reiterated the request on June 29, 2020 and again Dr. Blain demurred.



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scans of original films; Gels, autoradiographs for each image; Lab notebooks; Cloud storage accounts such as DropBox and any other information or data applicable to her research and research collaborations.

After sequestering relevant materials, SUNY Downstate initiated an Inquiry on September 16, 2019 and concluded that Inquiry on December 12, 2019 with the acceptance by the Deciding Official on December 16, 2019 of the Committee's determination that an investigation was warranted<sup>5</sup>.

### B. Charge to the Investigation Committee & Process Utilized

On January 15, 2020, the Institutional Official informed Dr. Blain that the Investigation Committee would be comprised with the same membership as the Inquiry Committee. On January 22, 2020, SUNY Downstate received a communication from Dr. Blain's attorney requesting re-consideration of the committee membership, specifically that it should not be entirely composed of the same members on the Inquiry Committee. SUNY Downstate consulted with ORI who advised that additional members could be added to the Investigation Committee<sup>6</sup>. Thereafter, additional members were recruited, updated membership was sent to Dr. Blain on February 13, 2020 and the Investigation Committee was provided with its charge on February 26, 2020.

The purpose of the Investigation was to conduct a thorough examination of all relevant facts and evidence to determine, based upon a preponderance of evidence, whether research misconduct occurred and if so, the nature and seriousness of the research misconduct. Specifically, the Investigation Committee was charged with evaluating potential research misconduct related to the following:

- NCI NIH Grant R01 CA201536
- National Diabetes and Digestive and Kidney Diseases (NIKDDK) NIH Grant R01 DK044525
- Paper MCB 2015
- Paper JPGN 2010
- Paper "Differential Modification of p27 KIP1 Controls Its Cyclin D-cdk4 Inhibitory Activity" Molecular Cell Biology 2008

The Investigation Committee was also provided with the authority to identify, in the course of its duties, other possible research misconduct, which would justify broadening the scope of the proceeding beyond the initial allegations. Consistent with its charge, and based on its review of the Pub Peer website and additional publications from Dr. Blain's lab that served as basis for Dr. Blain's requests for US Public Health Service (PHS) funds, the Committee requested raw data for the following additional research records that were not included in the initial allegations:

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<sup>5</sup> Contrary to the claims made by Dr. Dahlberg in the Rebuttal Attachment- Dr. Dahlberg memo where it is stated (page 4): "the seven months needed for the inquiry phase is well in excess of the 60 days specified in 42CFR Part 93", the Inquiry was completed in three months and all requests for extensions of time were approved by ORI.

<sup>6</sup> Contrary to the claims made by Dr. Dahlberg in the Rebuttal Attachment- Dr. Dahlberg memo (page 4, footnote 5), ORI did not recommend "the use of new committee members along with perhaps one individual from the inquiry committee to provide background and continuity".

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1. R21 CA252585 NIH 01-Jul-2020 Submission, Targeting Cell Cycle Plasticity in Pancreatic Ductal Adenocarcinoma- Specifically, Figure 3A<sup>7</sup>.
2. Patel P, Tshiperson V, Gottesman SRS, Somma J, Blain SW. Dual Inhibition of CDK4 and CDK2 via Targeting p27 Tyrosine Phosphorylation Induces a Potent and Durable Response in Breast Cancer Cells. *Mol. Cancer Research* 2018 (hereafter referred to as "MCR 2018")- Specifically, Figures 5B and 5F<sup>8</sup>
3. R21 AG049190- 2014 NIH Submission, un- funded- Specifically, Figure 3B<sup>9</sup>
4. Ray A, James MK, Larochelle S, Fisher RP, Blain SW. p27Kip1 Inhibits Cyclin D-cyclin-dependent Kinase 4 by Two Independent Modes. *Mol. Cell. Biol.* 2009 (hereafter referred to as "MCB 2009")- Specifically, Figures 2A, 2B and 3A<sup>10</sup>

The definition of research misconduct utilized by the Committee is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication – making up data or results and recording or reporting them.
- Falsification – 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 – the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

The Investigation Committee followed SUNY Downstate’s Research Misconduct Policy (available at: <https://research.downstate.edu/pdf/sponsored-programs/SUNY-DMC-Research-Misconduct-Policy-and-Procedure.pdf>), a copy of which was provided to Dr. Blain.

Under the terms of the Downstate policy, the Investigation Committee was charged with:

- Interview the Respondent, the co- authors on the questioned publications and any other person reasonably identified as having relevant information.
- Identify and obtain the original source data for the questioned images to ascertain the correct labeling of the data and the individual(s) involved in the alleged falsifications and/ or fabrications.
- Examine all research records and evidence relevant to reaching a decision on the merits of the allegations.
- Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible image duplications or

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<sup>7</sup> Notice was provided on March 30, 2020 with response due April 13, 2020. On April 14, 2020, a reminder was sent. A response was provided by Respondent on April 15, 2020. Request was discussed again on May 1, 2020 with a response on May 15, 2020.

<sup>8</sup> Notice was provided on March 26, 2020 (without identification of a particular figure) and again on March 30, 2020 with response due April 13, 2020. On April 14, 2020, a reminder was sent. A response was provided by Respondent on April 15, 2020. Request was discussed again on May 1, 2020 with identification of specific figures with a response on May 15, 2020. Request made again on June 29, 2020.

<sup>9</sup> Notice was provided on March 30, 2020 with response due April 13, 2020. On April 14, 2020, a reminder was sent. A response was provided by Respondent on April 15, 2020. Request was discussed again on May 1, 2020 with a response on May 15, 2020. Request made again on June 29, 2020.

<sup>10</sup> Notice was provided May 1, 2020. Respondent provided a response on May 15, 2020. Request made again on June 29, 2020.



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other research misconduct, and continue the Investigation to completion. The Committee should focus on the scope of the misconduct, including other papers published by Dr. Blain, manuscripts submitted but not accepted for publication, progress reports, posters, presentations, grant applications (funded or not) and other research records within a six year period, unless the Respondent continues or renews an incident of research misconduct that occurred before the six year limitation through citation, republication or other use for the potential benefit of the Respondent.

- Determine if PHS funds were used for the research conducted in Dr. Priyank Patel's doctoral dissertation and US Patent applications 62/113166, 15/351904, and PCT /US2015/031128 and if there are possible falsifications/ fabrications.
- Identify if there is more than one researcher responsible for the alleged falsification/ fabrication and abide by the notification processes for a Respondent.
- Come to a finding for each allegation, determining whether research misconduct occurred and to what extent, taking into account that a finding of research misconduct requires:
  - A preponderance of evidence;
  - A significant departure from accepted practices in the relevant scientific community; and
  - That the research misconduct must have been committed intentionally, knowingly or recklessly. Each finding should address who did what, where and how it was done.

The Committee utilized the following definitions in its deliberations, based upon the National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings, November 19, 2018<sup>11</sup>:

Intentionally: "Purposefully acts to propose, perform, review research, or report research results that included falsified, fabricated or plagiarized materials."

Knowingly: "Uses falsified, fabricated, or plagiarized material to propose, perform, review research, or report research results knowing that the material has been falsified, fabricated or plagiarize."

Recklessly: "Uses falsified, fabricated or plagiarized material to propose, perform, review research, or report research results without exercising the proper care or caution, and disregarding or showing indifference to the risk that the materials were falsified, fabricated or plagiarized."

- Prepare a draft Investigation Committee Report, review any comments/ rebuttals received by the Respondent relative to that report, and prepare a Final Investigation Committee Report.

The Committee submitted its draft Investigation Report to Respondent on July 22, 2020 with comments due on August 21, 2020. After requesting and receiving an extension to the deadline, Respondent submitted extensive comments on September 4, 2020<sup>12</sup>. The Committee carefully reviewed the comments and attachments (including a letter from Dr. Dahlberg, previous ORI Director) and determined that additional work was necessary to properly assess and respond to the comments. Therefore, the Committee modified its original July 22, 2020 draft report and provided Respondent with a revised draft report dated August 27, 2021. The Respondent has since reviewed and responded to the revised draft report in a rebuttal dated October 29, 2021<sup>13</sup>. Herewith, the Committee provides a detailed response to each of the Respondent's major concerns raised in the rebuttal document.

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<sup>11</sup> [https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical\\_conduct/policy-nih\\_irp\\_research\\_misconduct\\_proceedings.pdf](https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/policy-nih_irp_research_misconduct_proceedings.pdf)

<sup>12</sup> Appended hereto as Exhibit B is the Respondent's rebuttal and associated attachments dated 09/04/20.

<sup>13</sup> Appended hereto as Exhibit C is the Respondent's rebuttal and associated attachments dated 10/29/21.



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**C. List of Research Records Reviewed & Sources of Support****Publications:**

1. MCR 2018  
Support: CCLM Research Fund (CCLM Holdings Inc. is registered at 11 Willow Place, Brooklyn, NY – which is Dr. Blain’s home address. Jason Mraz, Dr. Blain’s spouse, is the Registered Agent of this company) and NIH R01CA201536
2. MCB 2015  
Support: American Cancer Society and the Car-Con Research Fund to S.W.B. and NIH grant DK44525 to A.L.T.
3. JPGN 2010  
Support: American Cancer Society
4. MCB 2009  
Support: American Cancer Society to S.W.B. and NIH grant GM056985 to R.P.F.  
Referenced in MCR 2018
5. MCB 2008  
Support: Leukemia Research Foundation, the Wendy Will Case Cancer Fund, and the American Cancer Society to S.W.B.
6. Blain SW, Montalvo E, Massague J. Differential interaction of the cyclin-dependent kinase (Cdk) inhibitor p27Kip1 with cyclin A-Cdk2 and cyclin D2-Cdk4. *J Biol. Chem.* 1997

**Other Research Related Records:**

1. NIH R01 CA201536
2. All grant submissions by Dr. Blain within the last six (6) years<sup>14</sup>
3. DIO Analysis
4. Figures and claims in provisional US Patent applications 15/351904 and divisional application 16/447,696, 62/113166, 61/994987 and Utility US Patent application PCT/US2015/031128
5. Computer files and email records
6. Twenty- five (25) laboratory notebooks/ binders

The Committee spent a substantial amount of time seeking to correlate data from both the sequestered electronic files and paper documents to support the figures in question. There were twenty-five (25) binders (twenty- one binders related to work completed in 2003-2008 & 2012-2015 with another four binders related to 2009 work) containing raw data and/or lab notes that were not clearly labeled in a way that allowed the Committee to retrace the laboratory’s steps. Similarly, the Committee found it difficult, and sometimes impossible, to link data in the electronic files to specific experiments and/or figures. The electronic files were generally lacking specific folder designations; instead, during the sequestration process, Dr. Blain stated that she

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<sup>14</sup> Appended hereto as Exhibit D is the Committee’s review of the federal and non-federal Blain submissions within the last six (6) years.

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identified particular files based upon the last date she opened the file. This lack of organization made it difficult for the Committee to identify relevant raw data<sup>15</sup>.

The Committee also notes that under SUNY Downstate's Research Misconduct policy and procedure, Dr. Blain has an obligation both to "cooperate with DMC officials in the review of allegations and the conduct of inquiries and investigations" and "to provide evidence relevant to research misconduct allegations". Accordingly, the Committee requested on multiple occasions that Dr. Blain identify what she contended were the raw data for the questionable figures, specifically for the 2008 MCB paper. Dr. Blain was in the best position to point the Committee to these data and has an obligation, as the Principal Investigator, to maintain adequate records of the research. However, throughout the proceedings, Dr. Blain declined multiple requests to review the notebooks and identify the data that she asserts supports the figures in the manuscript and was, therefore, in violation of SUNY Downstate's policy.

#### D. List of Allegations

The Committee performed a detailed analysis of the figures in the research records noted above. The Committee identified the following problematic figures that were presented to Dr. Blain and discussed in detail during her interview<sup>16</sup>.

##### 1. MCB 2015 Paper

###### **Allegation A: MCB 2015, Figure 2C**

Specific Allegation: Duplication of lanes in the 15 min Src time point in rows 1 and 3. The same image was used for both lanes which purport to be different lanes (Exhibit F, slides 3-6).

###### **Allegation B: MCB 2015, Figure 2H**

Specific Allegation: Duplication and reuse of lanes 1-4 as lanes 5-8 of p27 row using the same data to represent different conditions (Exhibit F, slides 6-9).

###### **Allegation C: MCB 2015, Figure 2I**

Specific Allegation: Duplication and reuse of lane 1 as lanes 7 (horizontally inverted) and lane 10 and reuse of lane 4 as lane 8 and lane 5 and lane 9 in cyclin D Western blot row (Exhibit F, slides 10-13).

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<sup>15</sup> Appended hereto as Exhibit E is a summary of the Committee members' efforts in identifying the raw data for the figures. We further note that ORI guidance states that laboratory notebooks are supposed to be organized with sections and headings: "Someone from outside your lab should be able to read what was done without your verbal interpretation." See [https://ori.hhs.gov/education/products/wsu/data\\_lab.html](https://ori.hhs.gov/education/products/wsu/data_lab.html). As noted above, the laboratory notebooks and files in question appear to constitute a significant departure from these standards insofar as they did not allow the Committee to locate pertinent data and other content relevant to this proceeding.

<sup>16</sup> Appended hereto as Exhibit F is the Committee's analysis of questionable figures presented to and discussed with Dr. Blain at her interview.



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**Allegation D: MCB 2015, Figure 6E**

Specific Allegation: Splicing of individual lines into the image with the intent to deceive and present data as being from a single gel (Exhibit F, slides 14-16).

**2. R21 AG049190- 2014 NIH Submission**

**Allegation E: R21 AG049190, Figure 3B**

Specific Allegation: Duplication of data shown in the "Hcy + G1 inhibitor" panel in the panel labeled "0 h". The center and right panels of Figure 3B were published as Figure 5F in W. Ye and S.W. Blain (2010) Brain 133:2295-2312. (The paper figure indicated that the G1 inhibitor was Gleevec, which is appropriate, but there is no 0 h time point.) (See Exhibit F, slides 19- 20).

**3. JPGN 2010**

**Allegation F: JPGN 2010, Figure 1C**

Specific Allegation: Duplication and reuse of data from a lane labeled "DMSO" into multiple adjacent lanes of an immunoblot what are labeled "NO TX", "100 uM" and possibly "300 uM" (Exhibit C, slides 22-26). Notably, this resulted in a change in the published interpretation of the results, substantiating a claim that p27 protein levels were not different between conditions, which is very different from the interpretation that would likely have been supported by the original data provided to the committee by the first author of the paper, which appears to represent the experiment in question (Exhibit F, slide 26, right panel).

**4. MCB 2009**

**Allegation G: MCB 2009, Figure 2A**

Specific Allegation: Manipulation of images in the middle panel ( "cdk6" row/"-cdk7 A" column ) and the right hand panel ( "cdk2\*" row/ "-cdk7 G0" column) through splicing of lanes from different images. (Exhibit F, slides 28, 29).

**Allegation H: MCB 2009, Figure 3A**

Specific Allegation: Duplication of a lane in Fig. 3A bottom panel: first lane (zero or low concentration cyclin D/cdk4) and last lane (normal rabbit serum; NRS). (Exhibit F, slide 30).



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**5. MCB 2008**

**Allegation I: MCB 2008, Figure 1F**

Specific Allegation: Duplication and reuse of background in row 4 condition labeled “cyclin D1 bound cdk4” in lanes 18 – 23 (Exhibit F, slide 33). Based on this, it is not possible to know if data were obscured or background noise was removed from the original image.

**Allegation J: MCB 2008, Figure 3A**

Specific Allegation: Duplication and reuse of row 1 lanes labeled .2, .4 and .8 as lanes labeled 1,2 and 4nM to represent different conditions (see slides 33-27 of Exhibit F). Also, splicing of individual bands onto a clean background in order to make it appear that they were run simultaneously (Exhibit F, slides 40-41).

**Allegation K: MCB 2008, Figure 4B**

Specific Allegation: Manipulation of bands in panel 2, lanes 40, 80, 160, 320, and in panel 4, lanes 160, 320 (Exhibit F, slides 42-44, 48).

**Allegation L: MCB 2008, Figure 6B**

Specific Allegation: Reuse of a band and its manipulation to obscure this reuse in bottom panel (Abl\*YY88,89FF), lanes .4, .8 (Exhibit F, slides 45-47, 48).

**E. Summary of the Interviews**

The Committee spent significant time locating and endeavoring to interview personnel who formerly worked in the Blain lab, as well as the co-authors on her papers. In some cases, the Committee was unable to locate former members of the Blain lab and in others, the former employees declined to participate in this process, or did so only in an informal manner.

**A. 2015 MCB Co- Authors:**

1. Patel, Priyank, scientist at Boehringer Ingelheim- Interviewed during Inquiry process, re- interviewed January 28, 2021
2. Asbach, Benedikt, University of Regensburg, Germany- Interviewed on November 19, 2020
3. Shteyn, Elena- Unable to interview.
4. Gomez, Cindy, Medical Director of Med Comms- Interviewed on November 16, 2020.
5. Coltoff, Alexander- Spoke on the phone on 2/02/21 and stated that he worked under Priyank Patel and had no involvement in the figures.

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6. Bhuyan, Sadia- Unable to locate.
7. Tyner, Angela L, University of Chicago- Did not respond to contact.
8. Wagner, Rolf, University of Regensburg, Germany- Did not respond to contact; however, Dr. Benedikt reports to Dr. Wagner and stated that Dr. Wagner was not involved in figure preparation.

B. 2010 JPGN Co- Authors:

1. Nguyen, Katrina D, University of Illinois- Interviewed on March 18, 2020.
2. Gress, Frank, private gastroenterology practice- Informed the Committee that he reviewed the figure and can confirm that he had no involvement in the production, interpretation or preparation of this figure.
3. Treem, William R, Janssen Research and Development- Informed the Committee that he was the Chief of Pediatric Gastroenterology at SUNY Downstate until June 2010. His role was to find mentors for 2nd and 3rd year fellows to do research. He reviewed the paper from a clinical perspective but was not involved in data acquisition, analysis or figure preparation.

C. 2009 MCB Co- Authors:

1. Ray, Arpita, Adjunct Professor- Did not respond to contact.
2. James, Melissa K- The Committee located this author but she refused to be interviewed due to her "unpleasant experiences" during her time in the Blain lab.
3. Laroche, Stephane, Senior Editor for Nature Communications- No involvement in the production of the data for publication; simply provided the Blain lab with purified proteins that were used in some of the assays.
4. Fisher, Robert P, Professor at Mount Sinai- Did not respond to contact.

D. 2008 MCB Co- Authors:

1. James, Melissa K- See above comments.
2. Ray, Arpita- See above comments.
3. Leznova, Dina- Unable to locate.

With respect to lab personnel, several of the individuals who were traceable did not respond to the contact attempts, except for the individuals listed below. Note that the Committee did not reach out to the current Blain lab members as they were not involved in the papers in question and the Committee was cognizant and sensitive to the need of maintaining confidentiality and allowing the Blain lab to continue to run efficiently.



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Dr. Sarah Nataraj, who worked in the Blain lab from 2005 to 2010 and is currently at Memorial Sloan Kettering, stated that she left SUNY Downstate almost a decade ago and did not witness any impropriety during her six years working in the lab of Dr. Blain. She declined to be interviewed by the Committee formally.

The Committee formally interviewed by video conferencing the following key parties with direct involvement or knowledge necessary to determine the potential scientific misconduct and its ramifications<sup>17</sup>.

Dr. Nguyen, a Pediatric GI Fellow who trained in the Blain lab from July 2007 to June 2009, was interviewed on March 18, 2020. She is the first author of the 2010 JPGN paper and was not accompanied by private counsel. The Committee found Dr. Katrina Nguyen to be cooperative and willing to discuss matters related to the allegations of misconduct in regard to construction of figures and, in particular, Fig. 1C of the 2010 JPGN paper. Overall, Dr. Nguyen's responses were deemed honest, without obfuscation; she was, however, unable to supply original data that matched exactly for the published Fig. 1C or explain the apparent identity of several bands. In a follow-up email, also from March 18, 2020<sup>18</sup>, Dr. Nguyen confirmed that she has no possession of original data that matches exactly for Fig. 1C.

Dr. Blain was interviewed on July 7, 2020. She was accompanied by private Counsel (Mr. Paul S. Thaler from Cohen Seglias Pallas Greenhall & Furman PC). While in her initial interview during the inquiry phase, Dr. Blain took full and unqualified responsibility for all of the figures in papers in which she was the corresponding author, in this second interview she repeatedly stated that "others" had prepared the figures and that she only examined them to determine whether they reflected and/or adequately represented the raw data. She insisted that all figures adequately represented the raw data, irrespective of whether individual lanes might have been copied and pasted to represent different conditions. This type of response was provided for almost every allegation.

Dr. Cindy Gomez, a co- author on the 2015 MCB paper, was interviewed on November 16, 2020. Dr. Gomez stated that she had no idea who made the figures for the paper and that the paper was submitted years after she left the Blain lab. She also indicated that there were times during which she felt there was insufficient instruction given to students and post-docs, but that this was perhaps because "...that's her style..." (Invest. Tr. 6:16). Dr. Gomez discussed Figure 2H of the 2015 MCB paper but had no explanation for how different exposures of the same Western blot could have been used to generate the figure and assigned to different samples. She agreed

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<sup>17</sup> Appended hereto as Exhibit G are the transcripts of these interviews. Please note that both Dr. Blain and Dr. Gomez did not submit executed versions of their transcripts pursuant to the Committee's request.

<sup>18</sup> Appended hereto as Exhibit H is the Nguyen email.



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that she had run the experiment but that the writing on the Western blot films "...don't look like my numbers..." (Invest. Tr. 14:5-6) and that Dr. Blain might have repeated the experiment "...after I left..." (Invest. Tr. 12:16). She denied any culpability in any research misconduct. It should be noted that subsequent to the interview, Dr. Gomez stated that "upon reflection, I feel that, given how long ago this was, and the fact that the paper was published years after I left, I don't wish to have this interview on record". However, since the information she provided was utilized by the Committee in this research misconduct proceeding, the Committee believes it is required to include Dr. Gomez's un-executed transcript in this report.

Dr. Benedikt Asbach from the University of Regensburg, Germany was a co-author on the 2015 MCB paper. On November 19, 2020, a videoconference was conducted with Dr. Benedikt Asbach in regard to his knowledge about data acquisition and figure construction for the MCB 2015 manuscript. Overall, Dr. Asbach's responses were considered honest and forthcoming; yet, he was unable to supply original data for the figures in question. Specifically, Dr. Asbach explained that he works in Germany, and that his interaction with Dr. Blain was limited to collaboration on a single figure, Fig. 1; incidentally, this figure was not questioned by the Committee's investigation. As for other figures, Dr. Asbach stated that he had "trouble to say who did exactly which experiment and which part of the figure, because this was coordinated by Stacy and done in New York" (Invest. Tr. 3:16-17). As for general interactions with Dr. Blain, Dr. Asbach stated that he has never met her personally and has never visited her lab; instead, the interactions occurred by email and once by phone and they have been "always between Stacy and [him] and she got the figures ... from her lab workers that's the way how we work" (Invest. Tr. 5:5-7). Dr. Asbach did not know "whether the PhD students put together the figures and the style in which they end up in the paper, or whether this was done by Stacy" (Invest. Tr. 5:7-9). Dr. Asbach then shared with the Committee an original autoradiogram contributed by Dr. Blain; according to Dr. Asbach, these data are "of course, not a figure from the paper" (Invest. Tr. 5:22-23), but similar to it. Dr. Asbach then discussed how these original data were modified, i.e., some lanes removed and the other, non-adjacent lanes attached to each other, for publication, albeit he did not know who made these modifications. Dr. Asbach concluded the interview by emphasizing that he is "an outsider to the field, ... a virologist and not really an expert on cell cycle regulation" (Invest. Tr. 11:11-12) which was the topic of the MCB 2015 paper.

Dr. Priyank Patel, first author of the 2015 MCB paper, was interviewed on January 28, 2021. Dr. Patel had been previously interviewed by the Inquiry Committee. At that time, he was employed at Dr. Blain's company, Concarlo. A short time after the Inquiry Committee interview, Dr. Patel left Concarlo and accepted a position as a scientist at Boehringer Ingelheim. Via his attorney, Ms. Nicole Gueron, he agreed to be interviewed by the Committee a second time if the questions were limited in scope. Dr. Patel explained that the 2015 MCB paper had been predominantly worked on by many individuals prior to his joining the Blain lab. It had been submitted for publication, but was rejected; therefore, he was involved in additional work on the paper and prepared the panels for the work he performed. He explained the general lab practices; the person who was responsible for the paper would coordinate with Dr. Blain and both of them together would make the figures. In his experience, these would be post-docs and not lab techs. The lab utilized TIFF files that were communicated via Dr. Blain's own Dropbox

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account from 2016 and on and prior to that via flash- drives. For the 2015 MCB paper, he did not know how the figures were made. “So, basically, all the figures were made by Dr. Gomez, Dr. Blain, or whoever worked on it.” (Invest. Tr. 6:8-9) “So the process of putting together figures was predominantly done by her and other colleagues.” (Invest. Tr. 6:14-15) “That everybody would have, you know, done the experiment, but they are right to say they probably did not prepare the figures.” (Invest. Tr. 9:3-4) Dr. Patel also informed the Committee that Dr. Blain taught him Photoshop, that she sometimes did experiments herself and that she made the final editorial decisions.

#### F. Scope of Alleged Misconduct

The Committee has concluded by a preponderance of the evidence that Dr. Blain committed research misconduct through fabrication and/or falsification, as well as reckless evaluation of the raw data generated in her laboratory and preparation of resulting figures for her publications and grant submissions.

The Committee identified data manipulations that occurred over a period of at least eight (8) years and included publications and grant submissions with different coauthors, with Dr. Blain being the only common author on all manuscripts and the senior author on all but one of the papers, thereby establishing a pattern to Dr. Blain’s conduct.

The primary defense raised by Dr. Blain was that others prepared the final figures and that she only looked to see that they were consistent with the raw data and did not see that certain bands were copied and/or duplicated and used to represent different conditions. She, therefore, utilizes the ‘honest error’ defense though her failure to identify the requested raw data undermines her ability to meet her burden in that regard. Moreover, many of these image manipulations would be readily apparent to any cell biologist.

Precedent has found that recklessness can be shown when a person “uses materials without exercising proper care or caution and disregards or shows indifference to the risk that the materials were false, fabricated or plagiarized thereby causing harm to the integrity of the research process or waste of public funds”. Thus, failing to scrutinize fabricated or false images before including them in publications or grant applications can constitute recklessness. Simply asserting an ‘honest error’ defense without providing any support for such a position does not meet the governing preponderance of the evidence standard.<sup>19</sup>

Dr. Blain has asserted that the altered or fabricated information was created by other individuals in her lab. However, even if these assertions are true, they do not relieve Dr. Blain of the responsibility to take due care to assess whether information that she published or included in a grant application was neither fabricated nor falsified. She can be found to have engaged in research misconduct by virtue of publishing information without caring whether or not it was accurate.

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<sup>19</sup> See *Off. of Rsch. Integrity v. Christian Kreipke*, DAB No. CR5109 (2018)



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Lastly, the Committee has found that the question of who fabricated or falsified the images is not always dispositive to an allegation of research misconduct because 42 CFR § 93.103 contemplates the *reporting* of research results, even if the individual reporting the research results did not *create* the data.

Finally, the Committee would specifically note that if the raw data had been available, the Committee would likely have been able to make a more definitive conclusion of knowing and intentional misconduct.

### G. Committee Determination

#### Allegation A: MCB 2015, Figure 2C

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- It is apparent that duplication of an image and its use to represent a different condition was performed (Exhibit F, slides 3-5) as was initially identified by the ORI analysis as a possibility. This meets the definition of falsification.
- b. Intentional, knowing or reckless conduct- While Dr. Blain initially took responsibility and stated she “performed the experiment and probably generated the figure” herself during the Inquiry (See Inquiry Transcript 29:6-7), she revised her position during the Investigation and denied responsibility, indicating that the differences could only be seen with forensic analysis and that whoever prepared the figure was responsible, without naming any particular person. The Committee went through each co-author to determine who could have potentially created the figures other than Dr. Blain. Dr. Asbach is a biochemist not a cellular biologist and his involvement was only with Figure 1. Dr. Coltoff was a medical student who did not prepare any figures. Sadia Bhuyan was a technician and the technicians would do the experiments and hand over the raw data to Blain without making figures (Patel Invest. Tr. 7:19-21). While the Committee was unable to contact Dr. Tyner from the University of Chicago, none of the authors indicated that she had any involvement in this aspect of the paper. Dr. Wagner was Dr. Asbach’s supervisor and was included as a co- author under that purview.

According to Patel, “the general convention was that post docs prepared the figure in coordination with Dr. Blain and if it was a paper for a graduate student’s thesis, then they prepared the figures in coordination with Dr. Blain.” (Invest. Tr. 9:10-13)

The post-docs in the Blain lab who were co- authors on the paper are Patel, Shteyn and Gomez.

Patel denies making the figures in question. (Invest. Tr. 5:22, 6:8-9, 6:14-15, 9:3-4, 12:7-9, 21:6-7) This statement is supported by information separately verified by the Committee. In the Graduate School’s file, Patel’s thesis statement which includes the 2015 paper states: “I performed all the experiments shown in Fig 3A, B, Fig 4A-E, Fig 5-8 (Patel et al., 2015). The

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other experiments were performed by my collaborators listed as authors. S.W. Blain co-wrote the manuscript.”<sup>20</sup>

The Committee was unable to interview Shteyn; however, the Committee concluded that Shteyn did not produce the figures in question in part because she had already formally reported falsification of data in the Blain lab to the Graduate School in 2016 and had multiple communications with the university after this date related to these allegations.

Gomez stated that “she didn’t create any of the figures for this paper” and that she was contacted after she left the lab to review the paper with the figures already generated (Invest. Tr. 2:13-14, 16-17).

In Patel’s interview, he stated: “So, basically, all the figures were made by Dr. Gomez, Dr. Blain or whoever worked on it...So, in that paper, I made the panels and then Dr. Blain just put them in because the paper was already ready. So, the process of putting together figures was predominantly done by her and other colleagues. I was less involved in that. (Invest. Tr. 6: 8-15) That everybody would have, you know, done the experiment but they are right to say that probably they did not prepare the figures. (Invest. Tr. 9:3-4)

I know she knows Photoshop because that is the same platform we use to make figures for any paper. So, she has actually taught me some of the things from Photoshop software. And then, whenever I would give her say a TIFF file or something of those panels that I have prepared, then she would take those panels and then she would have incorporated, say, in 2015 Publication, for example, in Photoshop. So, clearly, she knew how to do Photoshop, I guess.” (Invest. Tr. 9:21-25, 10:1)

Based upon the exclusion of each of the co- authors from preparing the figure as evidenced by the information they provided, the only remaining author who could have prepared the figure is Dr. Blain. Dr. Blain could not provide the Committee with evidence that she didn’t prepare this figure and initially stated that she “probably generated the figure”.

However, because the Committee cannot locate specific evidence identifying Dr. Blain as the creator of the figure, it determines that Dr. Blain acted recklessly in the preparation of this figure.

- c. Significant departure from the research community- Under no circumstances should gel lanes be duplicated and be used to represent conditions that they did not measure.

**Response to Respondent’s rebuttal comments:**

The committee does not accept the Respondent’s rebuttal that “...the mere fact that Dr. Blain cannot now recall the particular individual who prepared this figure does not make her responsible for the error...”.

The Respondent ultimately bears responsibility for submitting honest research results. Her assertion that others contributed to the figure does not trump her responsibility as the senior author to take due care to ensure the accuracy of the data being reported. Here, Dr. Blain

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<sup>20</sup> Appended hereto as Exhibit I is the relevant sections from Patel’s graduate school file.



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demonstrated reckless conduct whether she personally prepared the figure or published it without taking adequate care to assess its accuracy.

NIH grant DK44525 to A.L.T. was cited in this paper but does not have a specific link to Allegation A. The paper was, however, cited in applications for PHS support<sup>21</sup>.

**Respondent's 10/29/21 Rebuttal:**

Given that the raw data looked like the figure, any accidental duplication of a lane had no impact on the reported results. While we recognize that there can still be falsification without an impact on the results, we respectfully submit that the lack of impact on results provides strong evidence weighing against a finding that Dr. Blain possessed the requisite intent for research misconduct. Indeed, the fact that the raw data is reflected in the figure — even with the error — inherently demonstrates that there would be no reason for Dr. Blain or her coauthors to provide anything other than the correct raw data in the figure.

In other words, the Investigation Committee bases its finding of intent on Dr. Blain's role as the PI, with ultimate responsibility for the accuracy of reported results. Where, as here, the figure depicted the results consistently with the raw data, there is insufficient evidence to find that Dr. Blain acted recklessly in this capacity.

Where even the erroneous image adequately reflects the underlying raw data, there is no risk of harm, and there is certainly no conscious disregard for or indifference to any such risk.

In sum, regardless of who was involved in generating this figure, there was nothing in the figure's appearance that suggested to Dr. Blain that the figure required additional scrutiny. The figure looked to Dr. Blain like the raw data she had previously seen (and which she provided to SUNY Downstate during this process), thereby adequately depicting the actual results. Under these circumstances, it was reasonable for Dr. Blain to miss the error in this figure, and there is insufficient evidence to support the Investigation Committee's finding that Dr. Blain recklessly engaged in falsification.

**Committee's Final Response:**

The Committee sees this as one example of an extensive practice of using lanes to represent something that they are not. The lanes in the figures should be the raw results and not resemble them. It is inexcusable to reuse any lanes, including "blank" lanes, in a figure. In other words, it is irrelevant whether the raw data do or do not "look like" the falsified and published data; the sole presence of manipulated images in a published manuscript represents a breach of scientific integrity and is misconduct. Thus, the Committee concludes that Dr. Blain recklessly engaged in falsification.

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<sup>21</sup> Refer to Exhibit D for identification of the specific applications that cite each questionable paper referenced in the list of allegations.

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The Committee believes that motivation for the falsification may have been due to the unconvincing or dirty results of the experimental systems so that the entire experiment either needed to be repeated or the results could simply have been falsified; this is especially tempting if the system in question is a control.

**Allegation B: MCB 2015, Figure 2H**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

a. Falsification, fabrication or plagiarism- In this allegation, originally identified by ORI, it is apparent that four (4) lanes were duplicated and used to represent four (4) other lanes representing different conditions (Exhibit F, slides 6-9). From the raw data, it appears that two (2) different exposures of the same chemiluminescent blot were used to represent two (2) different conditions. Dr. Blain stated that no other data were available and therefore, it is impossible to confirm that the figure accurately represents the missing data. This represents falsification.

b. Intentional, knowing or reckless conduct- There is evidence that Dr. Blain ran the experiment as the writing in the notebook where the problematic raw data was found is Dr. Blain's handwriting<sup>22</sup>. In accordance with the analysis of the other co-authors' involvement in figure preparation discussed in Allegation A above, the only remaining author who could have prepared the figure is Dr. Blain.

Blain's honest error defense included: "And it is possible there was a mistake made. However, this is the data that I have to work with. It is unclear to me if they were the same exposure, why they would be on two different films, right, they would have been the same, a top and a bottom on the same film." (Invest. Tr. 10-11:24-8)

It is the Committee's opinion that any reasonably trained modern cell biologist or biochemist<sup>23</sup>, upon looking at the raw data, would conclude that the two (2) blots were of the same gel at two (2) different exposures and that there is no plausible honest error claim as Dr. Blain could not possibly not have noticed the similarity. The error would have been detected through validation and would have been obvious to Dr. Blain prior to publishing it, meaning she either falsified the figure or was indifferent to its accuracy, supporting reckless conduct.

c. Significant departure from the research community- It is against all research norms to duplicate lanes and have them represent data that are false. The same lanes cannot represent different conditions, and this was done clearly to deceive.

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<sup>22</sup> Though Dr. Gomez stated she worked on the experiment, she also stated that Dr. Blain repeated her experiments. (Invest. Tr. 9:3-5, 10:17-21)

<sup>23</sup> The Committee did not find Dr. Asbach's testimony (Invest. Tr. 5:16-17) that "If you simply look at the printed-out paper, you don't realize such minute details" persuasive as Dr. Asbach has limited experience with Western blots.



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**Response to Respondent's rebuttal comments:**

The Committee stands by its statement that any cell biologist would easily recognize that the four lanes were simply a different exposure of the other four lanes, i.e., they were a duplication that purported to represent different conditions. Dr. Blain did not meet her burden to establish honest error.

NIH grant DK44525 to A.L.T. was cited in this paper but does not have a specific link to Allegation B. The paper was, however, cited in applications for PHS support.

**Respondent's 10/29/21 Rebuttal:**

The fact that numerous scientists — including other cell biologists at SUNY Downstate and one of Dr. Blain's coauthors from another institution (Dr. Asbach) — reviewed the data in question without identifying any issues demonstrates that the Investigation Committee's conclusion is unsupported by the evidence. The data in the lanes at issue looks remarkably similar to the raw data used in generating the figure — because it is, in fact, the same data. We note that while "[t]here is evidence that Dr. Blain ran the experiment," Dr. Blain never developed gels to produce the scans. Ms. Sadia Bhutan is the lab technician who would have produced the scans and given them to Dr. Blain. As labeled, the scans state they are from two different conditions. The relevant lab notebook makes clear that there was data generated for lanes 5-9, so when Dr. Blain was presented with an image that purported to show data for lanes 1-4 and 5-9, she had no reason to doubt that it contained all of the original data.

The Investigation Committee provides no evidence to support its finding of research misconduct as to Allegation B other than its conclusion that the error "would have been obvious to Dr. Blain" simply due to its "opinion that any reasonably trained modern cell biologist or biochemist" would have recognized the error. See Revised Report at p. 17. The Investigation Committee's opinion is not evidence. It is the Investigation Committee's burden to show that there is a preponderance of evidence to support its conclusion. Citing no actual evidence and merely providing conjecture does not satisfy its burden. Instead, the evidence demonstrates that multiple cell biologists and other scientists reviewed the figure and did not make the conclusion the Investigation Committee opines should be obvious. Therefore, a preponderance of the evidence demonstrates there should be no finding of research misconduct as to Allegation B.

**Committee's Final Response:**

It was clear to the Committee members who examined the images that one set of lanes was simply a longer exposure of the other set of lanes and thus cannot represent the two experimental conditions listed in the figure. The demonstration of absolute overlap of all of the bands and even the registration marks on the two autoradiograms shows this conclusively. This is not conjecture, it is fact. Reviewers of papers unfortunately do not always look at figures as carefully as they should because they are not looking for fabrication or falsification, they are looking to see whether the figures support the conclusions drawn by the author. The fact that

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reviewers, and others, missed this duplication and misrepresentation does not alter the conclusions of the Committee. Additionally, the Committee agrees that the lab probably did run the experiment as described in the lab notebook; however, strong motivation for the falsification would result from the reactions in four of the eight lanes not working or showing 'undesirable' results; i.e., the gel of the lanes that did work (lanes 1-4) were re-exposed for a different amount of time and used for the lanes that did not work (lanes 5-8), thereby falsifying the figure.

**Allegation C: MCB 2015, Figure 2I**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- In this allegation, originally analyzed by ORI, it is apparent that multiple instances of copying and pasting of single lanes was performed to represent different conditions (Exhibit F, slides 10-13). The fact that not only was the same copied image used to represent three (3) different conditions, but in one case the image was horizontally inverted, which strongly suggests a deliberate effort to deceive and hide one's tracks. While Dr. Blain stated that these are control lanes and that they were all similar in the original raw data, these manipulations indicate deliberate falsification due to the reuse of the same images to represent different conditions.
- b. Intentional, knowing or reckless conduct- While Dr. Blain initially took responsibility during the Inquiry and stated "this was done by me and Sadia and probably Cindy Gomez was involved in this as well" (Inq. Tr. 29:13-14), she revised her position during the Investigation and stated that someone else produced the figure and that she only reviewed it to see if it adequately reflected the original data, not noticing the band similarities. In accordance with the analysis of the other co-authors' involvement in figure preparation discussed in Allegation A above, the Committee has determined that the only remaining author who could have prepared the figure is Dr. Blain who demonstrated reckless conduct in submitting the figure for publication.
- c. Significant departure from the research community- It is the Respondent's duty to ensure that all figures are accurate and do not include falsified lanes. The duplication of lanes is falsification and departs from all research norms.

**Response to Respondent's rebuttal comments:**

The Committee does not accept the rebuttal "...that these are control lanes...". The same image cannot be used to represent different conditions just because it is a control lane. This negates the very idea of a control lane in which the control is used to verify that all conditions in the various treatments were uniform. This is unacceptable behavior and constitutes intentional and knowing disregard for research norms.

NIH grant DK44525 to A.L.T. was cited in this paper but does not have a specific link to Allegation C. The paper was, however, cited in applications for PHS support.



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**Respondent's 10/29/21 Rebuttal:**

Indeed, the Investigation Committee's finding of research misconduct as to Allegation C is undermined by its own analysis of this allegation. Specifically, the Investigation Committee noted that "not only was the same copied image used to represent three (3) different conditions, but in one case the image was horizontally inverted, which strongly suggests *a deliberate effort to deceive and hide one's tracks.*" See Revised Report at p. 18. The finding of research misconduct against Dr. Blain is based on her "duty to ensure that all figures are accurate and do not include falsified lanes"; in other words, her responsibility as PI. See *id.* The fact that Dr. Blain did not notice an error that was apparently deliberately concealed weighs against a finding that Dr. Blain was reckless. As Dr. Blain previously explained, these control lanes should have all been the same and she did not notice any issue. Furthermore, as Dr. Patel explained during his interview, the panels would have been made by a student, and then Dr. Blain would have put the panels into the image with the box around it for the figure. Dr. Blain does not recall who specifically made this particular panel. However, because the control data in the panel adequately reflected the original data, Dr. Blain did not notice any error and did not think that additional scrutiny was required.

The 2015 MCB Paper alone contains the data from more than 115 individual experiments performed by five different members of Dr. Blain's lab, which were all performed at least two or three times from 2010-2015. It is unreasonable to expect that a PI such as Dr. Blain should analyze each experiment's data in such detail as to recognize all instances of potentially duplicated data. Dr. Blain had no reason to question the figure when she reviewed it, as it adequately reflected the appropriate control data. Under these circumstances, a preponderance of the evidence weighs against a research misconduct finding as to Allegation C.

**Committee's Final Response:**

Once again, the Respondent is making the argument equivalent to "if the figure looks similar to the raw data, then it doesn't matter whether the lanes are actually from the experimental conditions shown." This is unacceptable and represents recklessness. The Committee stands by its conclusion that this is another example of research misconduct on the part of the Respondent. The PI has the responsibility to ensure that the figures represent actual experiments, and not just a compilation of bands that "look good" and demonstrate what the author wishes to show. The Committee does not find the argument by the Respondent that "Dr. Blain did not notice an error that was apparently deliberately concealed" persuasive. There is no evidence that the Respondent did not notice the falsification; in fact, the Committee's analysis is that the Respondent acted recklessly.

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**Allegation D: MCB 2015, Figure 6E**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- In this allegation, first identified by ORI, it is clear that individual bands from gels were cut and pasted onto a clear background in order to deliberately suggest that the material was run on the same gel at the same time (Exhibit F, slides 14-16). Dr. Blain indicated that it was common practice in her laboratory to do such cutting and pasting of bands onto clear backgrounds. The Committee finds by a preponderance of the evidence that here such cutting and pasting appears to have been designed to deceive the reader into thinking that all of the data were generated simultaneously on the same gel and that backgrounds were uniform when that had not been so. This represents falsification.
- b. Intentional, knowing or reckless conduct- The Respondent stated that it was common practice of her lab to cut and paste lanes onto clear backgrounds. Thus, the activity was intentional and knowing.
- c. Significant departure from the research community- At the time of publication, several articles had already been published stating that any cutting and pasting of lanes should be noted by clear cut marks to indicate the spliced lanes. Cutting individual bands and pasting them onto a clear background has never been acceptable and is a clear departure from research norms.

**Response to Respondent's rebuttal comments:**

The committee does not accept the rebuttal that these actions were "an unintentional oversight...". It is one thing to cut and paste bands, it is another to cut and trim the bands so closely and then to paste them onto a clean background to give the false impression that the bands were as clean as shown. Such "beautification" goes beyond research norms. Additionally, the deliberate failure to show any of the splices goes far beyond research norms.

NIH grant DK44525 to A.L.T. was cited in this paper but does not have a specific link to Allegation D. The paper was, however, cited in applications for PHS support.

**Respondent's 10/29/21 Rebuttal:**

The Investigation Committee previously described this allegation as "relatively `minor'" (See Initial Report at p. 10). The Investigation Committee now finds that Dr. Blain intentionally and knowingly engaged in research misconduct as to this allegation. See Revised Report at p. 19.

As Dr. Blain acknowledged, her lab added the data to a preexisting box to control for the strokes box size. One box was made for panel A, then that box was copied and panel B was added, and then the box was copied and panel C was added. This results in each box appearing as the same size. Dr.



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Blain and her lab only ever cuts and pastes *from the same gel*. This is in contrast to the Revised Report's finding that "such cutting and pasting appears to have been designed to deceive the reader into thinking that all of the data were generated simultaneously on the same gel[.]" See Revised Report at p. 19. These data *were* generated on the same gels. The original gels demonstrate that this is the original, correct raw data. The bands were simply cut and pasted onto the stroked boxes that were generated already in the figure. There is therefore no falsification and no intent to deceive. The Investigation Committee is in possession of this data, clearly labeled in the "Patel 2015 data" folder. Furthermore, despite claiming that "[s]uch 'beautification' goes beyond research norms," the Investigation Committee has taken no steps to confirm or refute Dr. Blain's explanation that this was an accepted practice at the time. This is not beautification; rather, it is a way to create figures with boxes, which is typical in figures in any journal. Even if this was a departure from research norms, however, the fact remains that the bands in the figure *are* the bands from the original raw data. Thus, because the original raw data is accurately reflected, a preponderance of the evidence weighs against a research misconduct finding as to Allegation D.

Additionally, the Investigation Committee has, on several occasions, made as its finding a determination that the Respondent acted with more than one level of intent ("intentionally, knowingly and recklessly"). Such a finding is a serious deviation from acceptable analyses of research misconduct matters. The regulations all require a finding of a level of intent requiring a conclusion as to which level has occurred. To lump them all together with the word "and" instead of selecting one is no finding at all. It merely references all of the possible outcomes. Of course, the level of intent finding becomes important when a committee is concluding that there was research misconduct. A sanction for an intentional act of research misconduct, for example, would nearly always be, appropriately, more severe than a reckless act. By essentially "punting" on its obligation to reach a conclusion, the Investigation Committee is tacitly admitting it cannot determine which level of intent is found. Accordingly, by definition, there can be no finding of research misconduct since there is a missing element.

**Committee's Final Response:**

The central theme of the Respondent is that the bands in the image were from the same gel. This is irrelevant to the allegation because the Committee's conclusions were not guided by consideration of the number of gels from which the data were collected; rather, it is the digitally cutting out of the specific bands; i.e., just cutting the bands, even without the rest of the lane, is a violation of scientific integrity. In other words, selective manipulation of bands constitutes data falsification regardless of the source of the bands. Thus, the Committee is puzzled and distressed by the notion which the Respondent applies virtually to all of her responses to the Committee's conclusions that manipulation of data is irrelevant as long as the experiment was performed and as long as it does not contradict the conclusions of the manuscript.

Additionally, in regard to Respondent's comment: "... despite claiming that "[s]uch 'beautification' goes beyond research norms," the Investigation Committee has taken no steps to confirm or refute Dr. Blain's explanation that this was an accepted practice at the time", the Committee has reviewed and discussed at great length the allowable and prohibited image processing as defined by



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numerous, diverse, and respected professional journals today and 10-20 years ago. At no time were image manipulations, such as those uncovered by the Committee, tolerated in the scientific community. Furthermore, numerous papers have been published discussing acceptable and unacceptable image processing<sup>24</sup>.

**Allegation E: R21 AG049190, Figure 3B**

Committee Determination: Research misconduct occurred in the form of fabrication by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- In this figure, a microscopic image from one condition is duplicated and labeled as coming from a different condition. The experiment involves fixed and permeabilized cells, and there is no possibility that these two images could be identical. This represents fabrication.
- b. Intentional, knowing or reckless conduct- Dr. Blain acknowledges that the 0 hr image is a duplication that was not in the original publication, which was published four years before this grant submission. She attributes the fluorescence in both images to “background” and indicates that is why she did not notice the duplication. Although both images are described by Dr. Blain as “background”, there is in fact staining present, and duplication of an image from the publication to provide a 0 time point control is fabrication. Of note, Dr. Blain is the sole PI on this grant, and the co-author of the original publication, Dr. Ye, is not included. When it was pointed out that she submitted this grant several years after the paper was published, Dr. Blain suggested that Dr. Ye could have made the figure with the duplicated panel in the past but advanced no evidence supporting her contention that Dr. Ye prepared the figure and/or that she did not recognize the duplication. As a result, the preponderance of evidence supports fabrication by Dr. Blain. Moreover, even if Dr. Ye had prepared the source figure, for the reasons described below, Dr. Blain should have recognized the duplicated image. Therefore, her inclusion of this figure in her grant application means she either fabricated it or was indifferent to its accuracy. As the sole PI on the grant, Dr. Blain bears responsibility for submitting accurate research data. Here, the Committee found that she acted recklessly by including fabricated data to represent an image that did not exist.
- c. Significant departure from the research community- A well-trained cell biologist would recognize that the duplicated image is not “blank” and thus the argument that Dr. Blain perceived both images as “background” and thus did not notice the duplication is not valid.

**Response to Respondent’s rebuttal comments:**

In the rebuttal (Versfelt, page 2 and Dahlberg memo, page 2 footnote 3), it is noted that this grant application was not funded. That is not relevant to a determination of falsification since research

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<sup>24</sup> For example, see [Sci Eng Ethics. 2010 Dec; 16\(4\): 639–667.](#)



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misconduct is defined by NIH as "fabrication, falsification, or plagiarism in proposing, performing or reviewing research" (NIH Grants Policy Statement, Title 42, CFR93).

Allegation E affects NIH submission # G11583127, R21 AG049170, an application submitted for PHS funding.

**Respondent's 10/29/21 Rebuttal:**

According to the Revised Report, "[a]lthough both images are described by Dr. Blain as 'background,' there is in fact staining present, and duplication of an image from the publication to provide a 0 time point control is fabrication." See Revised Report at p. 20. Dr. Blain respectfully submits that there is no staining, and that the instrument has to be "blanked" with the controls. If the instrument is not "blanked," there will always be outlines of the cells visible, which is what the Investigation Committee is seeing here when the exposure is increased too high. When preparing this application, Dr. Blain was looking for a blank image at the correct, blanked exposure. Dr. Blain could not look at the unblanked images, as that would have rendered the entire experiment meaningless. When Dr. Blain selected this image, she believed it was blank because she did not manipulate the exposure and find the cell outlines. Furthermore, Dr. Blain is not trained on the confocal scope that was used to make this image; only Dr. Blain's trainees are trained on the confocal scope. This image was given to Dr. Blain in a pile of images that Dr. Ye left for her when he left Dr. Blain's lab. Dr. Blain reasonably believed that this was an appropriate image to use, because she had no reason to manipulate the exposure and discover that it was not "blank." Contrary to the Investigation Committee's belief that "[a] well-trained cell biologist would recognize that the duplicated image is not 'blank[,]'" Dr. Blain notes that one cannot simply expose one image without the others to obtain immunofluorescence data. Even more importantly, Dr. Blain has explained why she believed the image was blank, and the Investigation Committee has pointed to no evidence beyond its own opinion that any cell biologist would have recognized it was not.

We note that despite the fact that Dr. Blain previously explained Dr. Ye's involvement in generating the image and suggested that the Investigation Committee should interview Dr. Ye, there remains no indication that the Investigation Committee made any attempt to speak with Dr. Ye. Dr. Blain has explained how this mistake happened, and the Investigation Committee has identified no evidence of intent other than its statement that "[a]s the sole PI on the grant, Dr. Blain bears responsibility for submitting accurate research data." This conclusory statement alone does not overcome Dr. Blain's explanation that this was a mistake. For these reasons, a preponderance of the evidence weighs against a finding of research misconduct as to Allegation E.

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**Committee's Final Response:**

The image manipulation described here does not require training on a confocal microscope, as asserted by the Respondent, but is instead a result of post-acquisition image processing of brightness and contrast, followed by duplication of an image which is then presented by the Respondent as a different condition. If the original and duplicated image were truly "blanked" by reducing the exposure at the time the image was taken, then the cells would not have been visible. However, the cells are visible in the published image even without contrast adjustment, and an identical image is presented in the grant as "time 0" in the R21 grant application. This suggests that Dr. Ye had properly acquired and adjusted the image at the time of publication and recognized that it was not "blank". However, the Respondent appears to have duplicated this image for the grant application to represent an image that was not available. This is reckless fabrication of data.

**Allegation F: JPGN 2010, Figure 1C**

Committee Determination: The Committee has found by a preponderance of the evidence that there was falsification but lacks sufficient evidence as to the elements of research misconduct to assign culpability to Dr. Blain.

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- In at least two lanes labeled "NO TX" and "100uM", and likely a third lane labeled "300uM", the data from the "DMSO" lane appear to have been duplicated to indicate p27 protein when none were readily apparent in the image obtained from the original experiment (Exhibit F, slides 22-26). This clearly affected the interpretation of the data, as stated in the published paper, which read "To directly examine p27 expression, lysates from the CDC-treated cells were assayed by immunoblot analysis using p27 antibodies (Fig. 1C), which showed that p27 levels in whole cell lysate were unchanged in the presence of CDC." This represents falsification.
- b. Intentional, knowing or reckless conduct- The Committee contacted all the co-authors on this paper. Dr. Nguyen, the first author, was interviewed by the Committee, was cooperative and supplied data; however, she was unable to supply original data that matched exactly the published Fig. 1C or explain the apparent identity of several bands. Drs. Gress and Treem had no involvement in the figure preparation. Dr. Blain states that Dr. Nguyen was responsible for this figure. The denial of any knowledge of how the p27 protein band appears in multiple lanes by both Dr. Blain and Dr. Nguyen does not lessen the fact that the data generated in her lab was manipulated in a way that produced data in a publication that was strikingly different from the original data. However, based on the available information obtained through this investigation, it is not possible to attribute the modifications of the figure specifically to Dr. Blain or Dr. Nguyen.
- c. Significant departure from the research community- The modifications that were committed with the figure clearly deviate from any acceptable scientific standard and would substantiate a finding of data falsification.



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**Response to Respondent's rebuttal comments:**

Dr. Blain contends that she did not perform the experiment or generate the figure and was not the first or communicating author, and cannot therefore be held accountable despite the fact that the work was performed in her lab. It is unclear based on the data falsification that was apparent what Dr. Blain stood to gain by the alternative explanation, other than potentially having an easier time of the manuscript being deemed acceptable for publication. The committee found the respondent's rebuttal arguments plausible, and does not therefore consider this allegation to be adequately substantiated to merit an allegation of research misconduct specifically against Dr. Blain at this time.

**Allegation G: MCB 2009, Figure 2A**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Although this paper is greater than 6 years old, its inclusion in this report is called for because it is referenced in MCR 2018.

**Support for Determination with preponderance of evidence:**

- a. Falsification, fabrication or plagiarism- In two panels of Figure 2A (middle and right panels), lanes were clearly spliced in from a different image. This image manipulation occurred in the middle panel, in the "cdk6" row/"-cdk7 A" column and in the right hand panel in the "cdk2\*" row/ "-cdk7 G0" column. (Exhibit F, slides 28, 29) This represents falsification.
- b. Intentional, knowing or reckless conduct- It is clear to the naked eye that the lane in question was not run contiguously with the flanking lanes. The band is wider than the flanking bands, the background pattern changes abruptly, and the white splice marks are clearly visible. In reviewing approximately 400 images provided by Dr. Blain, which were said to pertain to these experiments, the committee did not observe any images with labels corresponding to the conditions shown in this figure, or any images that could have served as a basis for creating this figure. Dr. Blain did not provide any information regarding who made the figure but indicated that she agreed that this lane had been spliced from a different location and was unable to point to the raw data for the image. Because the image manipulations required precise digital excision of a portion of one image and its precise digital pasting into another image and is clear to the naked eye, the preponderance of evidence indicates that this research misconduct was committed recklessly by Dr. Blain.
- c. Significant departure from the research community- Dr. Blain stated that the 2009 MCB Paper was submitted over the course of several years. During the submission process, the journal asked the coauthors to reduce the size of the figures by only showing the required lanes and adding the W (for Western blot) on the panels to distinguish them from the kinase assay (marked with an \*). Thus, Dr. Blain states, that the journal was not only aware of, but approved of and requested this form of splicing throughout the publication. However, in the January 2009 volume of the journal in which these images were published,

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*Molecular and Cellular Biology (MCB)*, in the For Authors (Illustrations) section it states: "Unacceptable adjustments to images include, but are not limited to, the removal or deletion, concealment, duplication (copying and pasting), addition, selective enhancement, or repositioning of elements within the image." This statement was included in the For Authors section of *MCB* as far back as at least 2000. Thus, the *addition* of exogenous images from a different figure clearly violates the standards in the field as well as the guidelines of the journal.

**Response to Respondent's rebuttal comments:**

Dr. Blain's contention that the intentionally spliced figure was generated at the request of the journal is not credible. This type of data manipulation would have been in direct contradiction to the journal's policies, as stated in c above.

NIH grant GM056985 to R.P.F. was cited in this paper but does not have a specific link to Allegation G. The paper was, however, cited in applications for PHS support.

**Respondent's 10/29/21 Rebuttal:**

However, there is no proof that these were spliced from different images. To the contrary, the lanes were spliced from the same image, as was common practice in the field at the time. Dr. Blain's lab ran all of these experiments in a dose response fashion, meaning they would have run many concentrations and then cut out the bands to use in the experiment. In fact, the journals instructed Dr. Blain and her coauthors to consolidate the bands, which is what they did. See Attachment 2, 2006 *MCB* Reviewer Comments at p. 1 (recommending that Figures 1-3 be removed or combined "since this is data already known . . . All these results are essentially controls and do not contribute to the central message"), p. 4 (recommending that the "figures/panels . . . be presented in a user friendly way . . . to distinguish between kinase assays . . ., western blots, immunoprecipitations, etc."). Dr. Blain acknowledges that the splice lines were not added; however, this was also consistent with the accepted practices at the time.

As discussed above, the raw data for the 2009 *MCB* Paper (and the 2008 *MCB* Paper) would be in the lab notebooks of Dr. James and Dr. Ray, and any absence of or inability to identify that data cannot itself be used as evidence of research misconduct given the age of the data in question. For these reasons, a preponderance of the evidence weighs against a finding of research misconduct as to Allegation G.

**Committee's Final Response:**

Regarding Attachment 2, these responses are referring to a different manuscript (*MCB* 2006) than the one in question and are thus, largely irrelevant. Even in the Attachment 2 example, the reviewers ask Dr. Blain to combine three figures or move them to supplemental, not to move specific lanes or combine results from different portions of a given image. Regarding the figure in question (*MCB* 2009, Fig. 2A), the fact that the spliced lane is wider and has a different



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background than the surrounding lanes (as described above) argues that it is from a different image. Moreover, regardless of whether the spliced image was from a different image or a different part of the same image, the splicing of this image clearly violates the policy of the journal at the time (and as far back as 2000) which explicitly stated that this practice was not allowed. This includes “repositioning of elements within the image” which is the terminology utilized when the image comes from the same gel, as the Respondent contends. Therefore, this was not at all ‘common practice’ and represents a significant departure of the research community.

**Allegation H: MCB 2009, Figure 3A**

Committee Determination: Research misconduct occurred in the form of fabrication by Dr. Stacy Blain

Although this paper is greater than 6 years old, it’s inclusion in this report is called for because it is referenced in MCR 2018.

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- In the bottom panel of Fig. 3A, the first and last lanes are identical. These lanes purportedly represent very different conditions: first lane, anti-p27 immunoprecipitation of a reaction containing zero (or low concentration) cyclin D/cdk4; last lane, immunoprecipitation with normal rabbit serum. (Exhibit F, slide 30) This represents fabrication.
- a. Intentional, knowing or reckless conduct- The actual data from the experiment illustrated were not reported and remain unknown. However, although the duplicated lane is “blank”, its duplication seriously obfuscates the data. For example, one of the negative controls represented by the duplicated image may not have appeared negative in the actual experiment. Or, the assay may not have been performed at all under one of these conditions, necessitating fabrication of the lane from elsewhere. Dr. Blain did not provide any information regarding who made this figure. She did indicate that because similar control conditions were shown in other figures in this same manuscript, that she had no motive to fabricate these data. The committee did not find this assertion credible, as controls must be performed simultaneously with an experiment to be meaningful. Fabrication of these data indicates that such controls, which would likely be needed for publication, were not performed in this case. Based on the multiple steps of precise digital manipulation required for image fabrication, the preponderance of evidence indicates that this research misconduct did not represent an honest error of simple image duplication. In reviewing approximately 400 images provided by Dr. Blain, which were said to pertain to these experiments, the committee did not observe any images with labels corresponding to the conditions shown in this figure, or any images that could have served as a basis for creating this figure. Although the Committee requested, Dr. Blain was unwilling to point to any specific raw data in the materials she provided to the Committee to support the image.

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Therefore, the Committee has determined that this research misconduct was committed recklessly by Dr. Blain.

- b. Significant departure from the research community- This fabrication of an image by digitally excising a portion of that image representing one condition and duplicating it to represent a very different condition is a significant departure from practices accepted across the entire scientific community of experimental biologists.

NIH grant GM056985 to R.P.F. was cited in this paper but does not have a specific link to Allegation G. The paper was, however, cited in applications for PHS support.

**Respondent's 10/29/21 Rebuttal:**

However, the Revised Report provides no evidence that Dr. Blain conducted the experiment or generated the figure. Indeed, as the Revised Report acknowledges, "the duplicated lane is 'blank[.]'" See *id.* The very fact that the lane in question was blank is precisely the reason that Dr. Blain did not notice that it was duplicated: it was blank.

Dr. Blain does not know who made this figure because of the age of the paper and how long ago the experiments underlying the paper were conducted; however, as we stated in our September 4, 2020 Comments to the Initial Report, Dr. Blain believes that Dr. Ray (as first author) would have performed the experiment and generated the figure — particularly because the 2009 MCB Paper was Dr. Ray's thesis document. The Revised Report contains no evidence that would contradict Dr. Ray's responsibility for the figure.

Dr. Blain did not perform the experiment or generate the figure, nor was Dr. Blain the only member of SUNY Downstate's faculty who reviewed the data supporting the 2009 MCB Paper. Given that the 2009 MCB Paper was Dr. Ray's thesis document, four other faculty members from Dr. Ray's thesis committee reviewed Dr. Ray's data over a five-year span, along with Dr. James, Dr. Stephane Larochelle, and Dr. Robert P. Fisher (all of whom are cell biologists) and several other independent readers who reviewed the data.<sup>2</sup> Nobody noticed any errors with respect to this figure or any of the others involved in the allegations surrounding the 2009 MCB Paper. This provides clear evidence weighing against any intent by Dr. Blain sufficient to support a research misconduct finding. The duplicated lane was blank and there was no reason for Dr. Blain to engage in additional scrutiny of the figure. In fact, the Investigation Committee's finding of reckless conduct appears to be based in large part upon Dr. Blain's "unwilling[ness] to point to any specific raw data in the materials she provided to the Committee to support the image." See Revised Report at p. 23. As discussed previously, Dr. Blain cooperated fully with SUNY Downstate by providing all of the raw data in her lab relating to the allegations. Any absence of data cannot on its own serve as evidence of research misconduct in this matter, given the age of the data in question. It would take Dr. Blain hundreds of hours (if not more) to review the lab notebooks containing the relevant data; a task that Dr. Blain should not be required to undertake simply because the Investigation Committee cannot locate the correct image. There is no evidence that Dr. Blain acted recklessly, and Dr. Blain has provided a reasonable explanation as to why she did not notice that a blank lane was duplicated in a figure that she did not prepare based on an



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experiment that she did not conduct. For these reasons, there should be no finding of research Misconduct as to Allegation H.

**Committee's Final Response:**

This represents another example of Dr. Blain's contention that because a manipulated image looked similar to raw data she had previously seen, she did not realize it had been manipulated. Yet, if an experiment was repeated two to three times as required by standard scientific practice to demonstrate reproducibility, and the raw data looked like the manipulated image, why was it not possible to use those original raw data for the final images? The use of the same "blank" image to depict two entirely different control conditions argues very strongly that no raw data corresponding to this final image exist. Indeed, the Committee reviewed approximately four hundred images that it was told should contain such raw data, and none was found. In this specific instance, reuse of the same "blank" lane very strongly argues that one of the control conditions either was not performed or that the raw images did not support the conclusion that Dr. Blain wanted to make from the figure. Such fabrication of data goes against all agreed upon scientific norms.

**MCB 2008: Basis for Dr. Blain's use of this manuscript outside the ORI limitations period**

The MCB 2008 paper was published outside the ORI six-year limitations period; however, its findings were cited subsequently in support of the following NIH grant applications: R01CA201536 (start date 09/2017), R01CA201536 (unfunded, requested start date 07/2019), R01CA249667 (start date 04/2020), R01CA24536-04A1 (start date 07/2020). Thus, this manuscript is within the scope of investigation by this Committee.

**Allegation I: MCB 2008, Figure 1F**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication, or plagiarism- The duplication and reuse of background from one region of the row 4 condition labeled "cyclin D1 bound cdk4" across multiple lanes (18 – 23, Exhibit F, slide 33) is very evident. The Committee was not provided with the original data specific to this experiment that would support the appearance of the data in its published form, although it was requested on multiple occasions. Thus, the Committee cannot determine if the data manipulation was meant to obscure other data or simply modify and improve the background to give an impression of better data quality (i.e., beautification). In either case, the committee views this as falsification.
- b. Intentional, knowing, or reckless conduct- The Committee determined by a preponderance of the evidence that Dr. Blain was aware of image manipulation in the figures and approved their publication due to the following facts.

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- i. In her interview on 10.28.2019, Dr. Blain stated “So basically the way that it works in my lab is, someone does experiments, they come in and we look at the experiments in the raw form. And then we decide, oh, let's put this together as a figure, and there's a figure made. Then we look at the figure and we'll go back and make sure everything is okay.” (Inq. Tr. 25: 23-25, 26: 1) This statement has two main implications for the normal process of vetting of manuscript figures in the Blain lab: (1) Dr. Blain examines all raw data that would be included in the figures, (2) Dr. Blain compares the completed figures to the raw data from which the figure was derived.
- ii. The image manipulations are readily identifiable by any experienced molecular biologist and cannot remain unnoticed during close inspection of the data in the figure. Her review of the figure would have disclosed the problem; therefore, Dr. Blain either falsified the data or was indifferent to its truth and, therefore, she has not met her burden of establishing an honest error defense.
- ii. It is physically impossible for the images for which the Committee made a determination of research misconduct to exist and, therefore, be present in the raw data. Therefore, the Committee determined that this falsification represents intentional, knowing and reckless misconduct.
- c. Significant departure from the research community- Contrary to the respondent's claim that the image manipulation which occurred was “common practice”, there have been specific instructions to authors detailing what is acceptable or unacceptable for gel images of this sort for more than 15 years. Numerous journals had policies in effect dating back to 2007 or earlier that adjusting the brightness, contrast, or color balance of an image could only be done if such changes were applied to the whole image and as long as there was no misrepresentation of any information in the image. More recently, journals have taken a much more stringent stance, often stating that touch-up tools, such as cloning and healing tools in Photoshop, or any feature that deliberately obscures manipulations, should not be used. The respondent's actions at the time of publication, and defense of those in the present, therefore represent a clear and significant departure from the research community.

**Response to Respondent's rebuttal comments:**

Dr. Blain's response to this allegation is two-fold. The Respondent first claims that the Investigation Committee “did not conduct a review of the lab notebooks to examine that data.” (see Sept 4, 2020 rebuttal letter, p 16, para 2, line 12). However, the Investigation Committee actually spent hundreds of hours reviewing thousands of digital pages of lab notebooks and data, and was unable to find an image that represented what was published as claimed data. This is because the falsified data does not exist in the raw unadulterated form. In the second part of the rebuttal, the Respondent claims that it was “common practice” to create an outside box and then move data images into it by pasting on top of the background, without regard to the traces of “old data” visible in the forensic analysis. This is not accurate, because it represents at least falsification of background in a technique where the ratio of signal to background is the basis for quantifying the result and comparing to other data. Moreover, if this practice is engaged in as the respondent describes, it is impossible to know if actual non-specific or secondary bands might



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have been pasted over. Taking the respondent's word as evidence that "because the reported data was not impacted by the background traces...there should be no finding of research misconduct" is inconsistent with this practice of image alteration.

This paper was cited in Blain applications for PHS support and, therefore, Allegation I relates to requests for PHS funds.

**Respondent's 10/29/21 Rebuttal:**

The Investigation Committee claims that it "was not provided with the original data specific to this experiment that would support the appearance of the data in its published form, although it was requested on multiple occasions." See Revised Report at p. 24. This remains a misstatement of fact. As Dr. Blain has repeatedly stated, she identified for the Investigation Committee the lab notebooks that contain the original data, which she provided to SUNY Downstate in full cooperation with the sequestration process. Given the age of the data in question and the voluminous amount of data in the relevant lab notebooks, the Investigation Committee's inability to identify the specific raw data cannot itself be used as evidence of research misconduct.

The experiment underlying this figure would have been run on at least three separate gels, as there are only nine lanes per gel.<sup>21</sup> This is why the raw data "does not exist in the raw unadulterated form." See Revised Report at p. 25. However, the three separate gels containing the raw data all exist, as the experiment was in fact performed and the figure accurately represents the experimental results. Thus, the data has not been falsified. Because the data is from three separate gels, the lanes would then have been spliced together for the figure, as was common and an accepted practice in the research community at the time. The spliced data would have been pasted into a standard-sized box to ensure conformity of box size. Thus, as the Investigation Committee states, Dr. Blain was aware of the manipulation to the extent the Investigation Committee is referring to the splicing of lanes and pasting them into a duplicated box to ensure conformity. However, this does not indicate an awareness of falsification, nor any intent sufficient to support a finding of research misconduct. Furthermore, the Investigation Committee makes the assertion that "if this practice is engaged in as the respondent describes, it is impossible to know if actual non-specific or secondary bands might have been pasted over." See *id.* This is incorrect. The new image would have been pasted on top of the old and would have blocked out the old image entirely, except for the traces only visible through use of forensic analysis techniques that were not available in 2008. This was simply the way figures were routinely assembled at the time, consistent with then-accepted practices that have evolved over time. Splice marks did not become more common until 2015. None of the reviewers of the 2008 MCB Paper (or any of Dr. Blain's other papers from around that time) ever requested splice marks. As soon as one journal requested splice marks in 2015, Dr. Blain began including them in all of her papers.<sup>22</sup> For these reasons, a preponderance of the evidence weighs against a finding of research misconduct as to Allegation I.

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**Committee's Final Response:**

The Respondent has misinterpreted the Committee's point about not being able to find raw data that support the published image and the highly questionable background pattern present in the published image. To reiterate, the Committee could not locate any gel image that had the same background pattern as what was published. The background in the gel lanes 18-19 and gel lanes 21-22 are identical on a point by point basis, which is not possible to exist in reality, so one or both were clearly altered. This background cloning is obvious with minimal enhancement of the image (i.e., simple enlarging and contrast-enhancing reveals it), contrary to the Respondent's assertion otherwise. The impression from the published image is that there was no signal in those lanes but there was signal in other lanes (lanes 24-25). However, this distinction is what cannot be supported given the presence of falsified background, since the true background in one or both sets of lanes 18-19 and/or 21-22 has been obscured or cloned. This significantly affects the representation and interpretation of the specific presence or absence of cyclin D1 bound cdk4 in the different samples.

**Allegation J: MCB 2008, Figure 3A**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- The Committee examined the original allegation by "Claire Francis" and then performed its own forensic analysis (Exhibit F, slides 35-41). The Committee determined that lanes in row 1 marked .2, .4 and .8 were duplicated and used to represent the lanes marked 1, 2 and 4 respectively (or vice versa). Thus, it is impossible to tell whether the inhibitor was ineffective against the High5 lysate as stated. This represents falsification. The three other alleged duplications on this figure were found to be suspicious but there was insufficient evidence in the absence of the raw data to conclude that they were falsified.
- b. Intentional, knowing, or reckless conduct- The Committee determined that Dr. Blain was aware of image manipulation in the figures and approved their publication due to the following facts.
  - i. In her interview on 10.28.2019, Dr. Blain stated "So basically the way that it works in my lab is, someone does experiments, they come in and we look at the experiments in the raw form. And then we decide, oh, let's put this together as a figure, and there's a figure made. Then we look at the figure and we'll go back and make sure everything is okay." (Inq. Tr. 25: 23-25, 26: 1) This statement has two main implications for the normal process of vetting of manuscript figures in the Blain lab: (1) Dr. Blain examines all raw data that would be included in the figures, (2) Dr. Blain compares the completed figures to the raw data from which the figure was derived.
  - ii. It is physically impossible for the images for which the Committee made a determination of research misconduct to exist and, therefore, be present in the raw data. This



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impossibility would be readily identifiable by any experienced molecular biologist looking at the image.

Therefore, the Committee determined that this falsification represents intentional, knowing and reckless misconduct.

- c. Significant departure from the research community- No researcher is allowed to use the same lanes to represent two different conditions. At least one of the two conditions must have been misrepresented. This is a gross departure from regular research practices.

**Response to Respondent's rebuttal comments:**

The Respondent's rebuttal admits to clear falsification but somehow suggests that Dr. Blain was not to blame for this falsification because she believes she could not have identified the falsification during her review. The Committee does not find this defense credible because the image manipulations are readily identifiable, as stated above, and whether or not they were false when included in her publication was not even considered by the Respondent.

This paper was cited in Blain applications for PHS support and, therefore, Allegation J relates to requests for PHS funds.

**Respondent's 10/29/21 Rebuttal:**

We and Dr. Blain respectfully disagree with this assertion. A molecular biologist deals with DNA, whereas the data in question relates to proteins analyzed by Western blot, a technique with limits. Dr. Blain would have looked at the image and said that the controls look good, and would have reasonably believed that the final panels accurately reflected the underlying data, as they reflected the results that Dr. Blain had been shown. Dr. Blain would not have compared each panel directly to the raw images, because she would not have had any reason to do so. Had the figure differed from the results that Dr. Blain had previously been shown, *then* she would have questioned the figure. Furthermore, the fact that other experienced cell biologists, including thesis committee members, more than nine reviewers, and Dr. Gottesman (during regular lab meetings) did not recognize any image manipulations contradicts the Investigation Committee's unsupported opinion that "the image manipulations are readily identifiable." See Revised Report at p. 26. Furthermore, we note that the Revised Report provides no additional explanation for the conclusion that these particular lanes in this figure were the result of falsification, whereas "there was insufficient evidence in the absence of the raw data to conclude" that the other three alleged duplications in the figure were falsified. See *id.* at p. 25. There is no evidence that Dr. Blain is responsible for any errors in this figure, no evidence that "any experienced molecular biologist" would have readily identified an error, nor any evidence to support the Investigation Committee's conclusion that Dr. Blain acted intentionally, knowingly, and recklessly. For the reasons explained above, the Investigation Committee's inability to conclude which level of intent was proven means

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that no research misconduct may be found. Therefore, a preponderance of the evidence weighs against a finding of research misconduct as Allegation J.

**Committee's Final Response:**

The Committee did identify raw data underlying this figure. The conclusion of data falsification can result from two different situations. First is when the comparison of the published data to the raw data reveals differences. Second is when the analysis of the published image itself, regardless of any experiments, shows digital manipulation (e.g., cloning, duplication, excision and pasting, etc.). The latter scenario is relevant to this allegation. Image manipulation uncovered in this allegation is clear and should be apparent to a professional expert. Thus, failure to observe this manipulation is reckless.

As for the Respondent's assertion that "a molecular biologist deals with DNA, whereas the data in question relates to proteins analyzed by Western blot, a technique with limits" is both incorrect and nonsensical. Molecular biology is commonly defined as "the study of life at the level of atoms and molecules" and is not limited to DNA molecules. In fact, western blot analysis is a molecular biology technique (and as such represents a part of most molecular biology methodology publications, such as the "Current Protocols in Molecular Biology" collection). Furthermore, definition of western blotting as "a technique with limits", while correct, is applicable to all methodologies of all experimental sciences, making this argument irrelevant.

**Allegation K: MCB 2008, Figure 4B**

Committee Determination: Research misconduct occurred in the form of falsification by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- Initially, Figure 4B was questioned by the complainant "Claire Francis". Detailed analysis by the Committee made the following two determinations.
  - i. In panel 3 labeled "cdk4-bound p27", bands in lanes Ahisp27 0, 40, 80, 160, and 320 nM were duplicated and inverted vertically (top-to-bottom), generating enhanced bands with complete bilateral symmetry about the horizontal central axis (Exhibit F, slides 44, 48).
  - ii. In panel 4 labeled "cdk4-bound p27", bands in lanes G0hisp27 160 and 320 nM were duplicated and inverted vertically (top-to-bottom), generating enhanced bands with complete bilateral symmetry about the horizontal central axis (Exhibit F, slides 44, 48). This represents falsification.
- b. Intentional, knowing, or reckless conduct- Technically, the falsification of complete bands was performed by duplication and inversion of the half-bands, followed by pasting of the duplicated images in a fashion that obscures this image falsification and results in an image of apparently intact bands. Based on these multiple technical steps required for



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image falsification, this research misconduct did not represent an honest error of simple image duplication. The Committee determined that Dr. Blain was aware of image manipulation in the figures and approved their publication due to the following facts.

- i. In her interview on 10.28.2019, Dr. Blain stated “So basically the way that it works in my lab is, someone does experiments, they come in and we look at the experiments in the raw form. And then we decide, oh, let's put this together as a figure, and there's a figure made. Then we look at the figure and we'll go back and make sure everything is okay” (Inq. Tr. 25: 23-25, 26: 1). This statement has two main implications for the normal process of vetting of manuscript figures in the Blain lab: (1) Dr. Blain examines all raw data that would be included in the figures, (2) Dr. Blain compares the completed figures to the raw data from which the figure was derived.
- ii. It is physically impossible for the images for which the Committee made a determination of research misconduct to exist and, therefore, be present in the raw data. This impossibility would be readily identifiable by any experienced molecular biologist looking at the image. Therefore, the Committee determined that this falsification represents intentional, knowing and reckless misconduct.
- c. Significant departure from the research community- Duplication of data and publication of the modified data represents a significant departure from accepted practices in the molecular/cell biology and biochemistry scientific community.

**Response to Respondent's rebuttal comments:**

The Respondent acknowledged that the image in this specific allegation appears to have been manipulated but raised two defensive points: (i) the manipulated image does not change the results, and (ii) the manipulated image does not demonstrate who is responsible for the image manipulation. The Committee was not persuaded by either contention. Falsification of data/images, and the reporting of such, is an act of scientific misconduct per se regardless whether or not the altered data also impact the conclusion of the experiment. The second point is irrelevant as the fact that others may have contributed to the creation of the figure does not excuse Respondent from her responsibility to take due care to submit accurate data; the error should have been detected by the Respondent, which means she either fabricated the data or was indifferent to its accuracy; and the Respondent reported the research results even if she did not create them.

This paper was cited in Blain applications for PHS support and, therefore, Allegation K relates to requests for PHS funds.

**Respondent's 10/29/21 Rebuttal:**

A. The missing data in question relates to the 2008 MCB Paper...; in other words, the relevant figures were published more than a decade before the allegations in this matter arose. Data more than three years old is routinely discarded, let alone data as old as the data at issue here (more than a decade old by the time the allegations arose)... We also note that, as the Investigation

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Committee recognizes, there was no federal funding supporting Dr. Blain's lab's research for the 2008 MCB Paper.

B. For the committee to make a reckless finding, they would need evidence that Dr. Blain knew the images incorrectly represented the experiments and chose to use those data anyway.

C. The Investigation Committee's conclusion that Dr. Blain "was aware of image manipulation in the figures" appears to be based entirely on (1) a statement that Dr. Blain made during her inquiry interview in which she described her process of reviewing the raw data following an experiment and then reviewing the final figure once it has been prepared, and (2) the Investigation Committee's opinion that "any experienced molecular biologist looking at the image" would have recognized the error. The former misinterprets the "implications" of Dr. Blain's statement. Dr. Blain has consistently explained that, in her lab, she reviews the raw data following an experiment to see the results and asks that the experiment be repeated at least n=3 independent biological replicates to ensure integrity of the results. Once a member of her lab then generates a figure utilizing those experimental results, Dr. Blain reviews the figure to ensure that the figure adequately depicts the results. She does not, however, perform any forensic analysis. ... Blain was therefore not indifferent to the accuracy of the figure; the figure looked like it should based on the actual raw data.

D. [W]hat Dr. Blain consistently explained, was that various lab members made the figures and that she then reviewed the figures to ensure they looked like the data.

E. Indeed, despite finding that the relevant data was falsified, in finding Dr. Blain responsible for research misconduct the Investigation Committee states that "the error should have been detected by [Dr. Blain], which means she either fabricated the data or was indifferent to its accuracy; and [Dr. Blain] reported the research results even if she did not create them." See Revised Report at p. 27 (emphasis added). Dr. Blain did not fabricate any data, nor did her lab members. The experiments were performed and the figure looked as Dr. Blain would expect from her review of the raw data. The fact that the errors do not impact the results provides clear evidence that Dr. Blain had no motive to falsify data through the error in the figure. Dr. Blain had no reason to question the figure. As Dr. Hohmann explained in her memorandum (as discussed above), a reckless finding "would need evidence that Dr. Blain knew the images incorrectly represented the experiments and chose to use those data anyway. The committee had no such evidence." See Attachment 1, Dr. Hohmann Memo at p. 5. For these reasons, a preponderance of the evidence weighs against a finding of research misconduct as to Allegation K.

**Committee's Final Response:**

A. The Respondent is correct only if the >3-year-old data have not been used in subsequent NIH submissions within the ORI six-year limitations period. This is not the case for the MCB 2008 paper. Specifically, this manuscript's findings were cited in support of the following four NIH grant applications: R01CA201536 (start date 09/2017), R01CA201536 (unfunded, requested start date 07/2019), R01CA249667 (start date 04/2020), and R01CA24536-04A1 (start date 07/2020). All



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four applications—and, consequently, the MCB 2008 paper which represents partial basis for these applications—fall within the scope of investigation by this Committee.

B. This statement is correct. The Committee has determined that Dr. Blain had a duty and ability to detect the manipulated images and chose to use them anyway.

C. Dr. Blain's response repeatedly indicates "that she then reviewed the figures to ensure they looked like the data", "the figure looked like it should [be] based on the actual raw data". And this indeed represents the control expected of any PI over the results of his/her lab personnel's work. The operative word of these statements is "the data" notwithstanding the implied argument of the Respondent that as long as a Figure reflects the expected results and confirms the results of other experiments, the PI bears no responsibility. Based on our explanation and description of our findings in Allegations K and L, (1) the raw data that "look like" the corresponding Figure cannot exist physically and, therefore, the Respondent could not have compared them to the Figure; (2) the relevant images in the Figure appear manipulated to a naked eye of any qualified molecular biologist/biochemist and do not require "forensic analysis" for detection; the failure of the Respondent to make/disclose such detection goes to the heart of scientific integrity, representing clear professional misconduct.

D. The Respondent's statement that "various lab members made the figures and that she then reviewed the figures to ensure they looked like the data" (see footnote 4 in the Rebuttal) is correct, and it negates the potential role of lab personnel in producing the images in question. In fact, much of our conclusions, e. g., regarding both Allegations K and L, are based on this determination. Specifically, we concluded that "(1) Dr. Blain examines all raw data that would be included in the figures, (2) Dr. Blain compares the completed figures to the raw data from which the figure was derived." Based on our own analyses of the images described in Allegations K and L, we concluded that it "is physically impossible for [these] images to exist and, therefore, be present in the raw data". This impossibility would be easily detectable by any experienced molecular biologist, such as Dr. Blain, simply by looking at the image; that Dr. Blain did not make or disclose such detection represents a clear case of intentional, knowing, and reckless misconduct. It also renders moot the Respondent's arguments that the research misconduct determination cannot be made due to the "inability to locate the raw data" simply because such data that support the authenticity of the manipulated images cannot exist.

E. We are puzzled by these arguments of the Respondent. It is irrelevant whether falsified data do or do not impact the work; the sole presence of manipulated images in a published manuscript represents a breach of scientific integrity and is misconduct. Furthermore, the idea of "motive" clearly is not limited to an intent to impact the results; rather, simple attempts to reduce the workload/number of experiments, reduce time to submission, or just make the presented data more convincing impact motive as well.

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**Allegation I: MCB 2008, Figure 6B**

Committee Determination: Research misconduct occurred in the form of fabrication by Dr. Stacy Blain

Support for Determination with preponderance of evidence:

- a. Falsification, fabrication or plagiarism- Initially, Figure 6B was questioned by the complainant "Claire Francis". Detailed analysis by the Committee made the following determination.

In bottom panel labeled "Abl\*YY88,89FF", bands in lanes p27 :4 and .8 nM are identical. One of them was duplicated and inverted about the vertical axis (left-to-right). Each of the bands was pasted over different background to represent two different experimental conditions (Exhibit F, slides 47, 48). This represents fabrication.

- b. Intentional, knowing, or reckless conduct- Technically, this fabrication was performed by digital excision of the original band, its inversion about the vertical axis (i.e., left-to-right flip) and pasting both bands (i.e., the original and the duplicated and inverted) over different backgrounds in a fashion that obscures this image fabrication and results in an image of two apparently different bands that represent two different experimental conditions. Obviously, the true data from the experiment represented by the fabricated band were not reported and remain unknown. Based on the multiple technical steps required for image fabrication, this research misconduct did not represent an honest error of simple image duplication. The Committee determined that Dr. Blain was aware of image manipulation in the figures and approved their publication due to the following facts.

i. In her interview on 10.28.2019, Dr. Blain stated "So basically the way that it works in my lab is, someone does experiments, they come in and we look at the experiments in the raw form. And then we decide, oh, let's put this together as a figure, and there's a figure made. Then we look at the figure and we'll go back and make sure everything is okay" (Inq. Tr. 25: 23-25, 26: 1). This statement has two main implications for the normal process of vetting of manuscript figures in the Blain lab: (1) Dr. Blain examines all raw data that would be included in the figures, (2) Dr. Blain compares the completed figures to the raw data from which the figure was derived.

ii. It is physically impossible for the images for which the Committee made a determination of research misconduct to exist and, therefore, be present in the raw data. This impossibility would be readily identifiable by any experienced molecular biologist looking at the image.

Therefore, the Committee determined that this falsification represents intentional, knowing and reckless misconduct.

- c. Significant departure from the research community- Duplication of data and publication of the modified data represents a significant departure from accepted practices in the molecular/cell biology and biochemistry scientific community.

**Response to Respondent's rebuttal comments:**

The Respondent raised three defensive points to this specific allegation: (i) "the purportedly fabricated data will look just like the raw data", (ii) that the Committee's finding is invalid because



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the Committee “was not provided with the original data for this paper”, and (iii) the “purportedly fabricated” image does not demonstrate who is responsible for the image manipulation. The Committee was not persuaded by Dr. Blain’s contentions. The first point is unclear and confusing; the entire reason for the Committee’s focus on this figure was that the images physically cannot derive from any actual experiments and that this impossibility would be readily identifiable by any experienced molecular biologist looking at the image. In regards to the second point, as described in detail in Section C above, the Committee has invested tremendous efforts and time in trying to obtain the raw data yet failed to do so because (a) the data were not found in any of the very large number of often chaotic lab books provided by Dr. Blain and (b) Dr. Blain declined numerous requests to aid the Committee in this search. That is consistent with the Committee’s conclusion that the figure images physically cannot be produced by actual experiments. Yet, it is the final published image that is provided to the scientific community at large, and it is this image that had been fabricated based on the Committee’s analysis. The third point is irrelevant as the fact that others may have contributed to the creation of the figure does not excuse Respondent from her responsibility to take due care to submit accurate data; the error should have been detected by the Respondent, which means she either fabricated the data or was indifferent to its accuracy; and the Respondent reported the research results even if she did not create them.

This paper was cited in Blain applications for PHS support and, therefore, Allegation L relates to requests for PHS funds.

**Respondent’s 10/29/21 Rebuttal:**

A. The Investigation Committee again concludes that Dr. Blain “intentionally, knowingly, and recklessly” engaged in research misconduct, this time in the form of fabrication. See *id.* at p. 28. As with other allegations relating to the 2008 MCB Paper, the Investigation Committee relies entirely on Dr. Blain’s statement about reviewing raw data and then reviewing figures, and the Investigation Committee’s opinion that “any experienced molecular biologist looking at the image” would have recognized an error. The Investigation Committee’s opinions entirely ignore the fact that numerous other experienced molecular and cell biologists reviewed the data in question and did not notice the errors and the conclusions regarding Dr. Blain’s statement misinterpret what Dr. Blain said.

B. She never claimed to “compare the completed figures to the raw data from which the figure was derived.” See *id.* at p. 28. To the contrary, Dr. Blain has consistently explained that her later review of the figure does not include any direct comparison to the raw data. Further, the Investigation Committee once again fails to make an actual conclusion as to a specific level of intent, as required by the regulations. For these reasons and those described above in response to the other allegations regarding the 2008 MCB Paper, a preponderance of the evidence weighs against a finding of research misconduct as to Allegation L.

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### **Committee's Final Response:**

A. This aspect was considered; one must always bear in mind fundamental differences between reviewers of scientific papers and the author of the paper itself, their knowledge of the specific experimental data and mental and physical investment in the success of the manuscript. The Committee is obligated to use and rely upon our its own professional judgement and skills.

B. Dr. Blain consistently emphasized her ultimate responsibility for her manuscripts and her insistence on vetting all Figures relative to the corresponding data.

### **H. Implication for Patents**

The Committee reviewed the patent applications and patents applicable to Blain's work and determined that questionable figures (MCB 2015 Figures 2C, 2H, 2I and 6E) were incorporated into patent application 15/351904 (issued July 7, 2020 as US Patent No. 10,702,570) and divisional application No. 16/447,696 pending (no new material with respect to the issued application)<sup>25</sup>.

The Committee determined that patent applications **61/994087**, **62/113166**, and **PCT/US2015/031128** were all filed in 2014-2015, prior to any NIH award to Dr. Blain. Therefore, it appears that no PHS funds were used for the research included in these three patent applications.

In regard to the newly issued US Patent No.10,702,570, this application was filed on Nov 15, 2016 after Dr. Blain was awarded the NIH grant. It has new experimental data not included in the other three applications. The new data are represented by Figures 13, 14 & 15. They illustrate, respectively, that:

- NP-ALT (ALT in drug delivery formulation) arrests growth when added to cultures of 3 breast cancer cell lines
- in a mouse tumor model, ALT together with Pfizer drug palbociclib (Ibrance®) causes tumor regression
- in a breast cancer cell line engineered to express ALT internally, addition of palbociclib causes tumor cell senescence.

The Committee determined that none of the questionable images are incorporated into these figures. Therefore, there is no indication that PHS funds were utilized.

### **I. Recommended Institutional Actions**

It is the Committee's opinion that there is evidence of repeated, sustained reckless research misconduct on the part of Dr. Blain. Therefore, the Committee recommends that SUNY

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<sup>25</sup> Appended hereto as Exhibit J are the applicable patent documents.



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Downstate consider serious action based upon these findings. Additionally, the Committee recommends the following:

1) Scientific journals which have published all of Dr. Blain's papers found to contain falsified or fabricated data should be contacted and informed about the results of this Investigation. The Committee recommends that these papers be retracted or at a minimum that significant corrections be published listing the altered figures, depending on the standards of the journal.

2) SUNY Downstate Administration should confer with the Research Foundation to discuss SUNY Downstate's license agreement with Concarlo and determine whether any actions should be taken.

**Committee's General Response to Respondent 10/29/21 Rebuttal**

The Committee would like to address several incorrect statements included in the 10/29/21 rebuttal.

1. The Committee restates that Respondent was provided with all appropriate, prior notifications as detailed in the footnotes of Page 5 of the report.
2. The Committee restates that Respondent was repeatedly uncooperative and continuously declined to identify raw data requested by the Committee. In fact, the Committee believes that the absence of raw data- that can technically exist- may have been due to the maintenance of experimental data in other repositories that Respondent failed to identify and turn over during the sequestration process. The Committee has located emails from the Respondent that indicate use of personal Yahoo accounts for transmission of Blain lab data dating back to 2012, Dropbox folders dating back to 2014, and a Blain lab SciNote account dating back to 2017 (created by the lab upon the request of the Respondent)<sup>26</sup>. The Committee specifically inquired as to these repositories in a letter dated 02/24/21; however, the Respondent denied use of these repositories in a response dated 03/09/21<sup>27</sup>; stated that the lab Dropbox account was first established after the 2018 MCR paper was published; and denied knowledge of SciNote (*"is generally unaware of what a SciNote account is....and if anyone in her lab is doing so, it is without her knowledge or approval"*).

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<sup>26</sup> Appended hereto as Exhibit K are the aforementioned emails.

<sup>27</sup> Appended hereto as Exhibit L are the 02/24/21 and 03/09/21 communications.

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3. The Committee emphasizes that the disorganized lab notebooks and electronic files belonged not only to the lab personnel, but also to the Respondent herself. The statement, “...*there has been no disorganization identified with respect to records maintained by Dr. Blain*” is inaccurate.
  
4. The Committee strongly disagrees with the Respondent’s assertion that the Committee was convinced of her guilt before initiating the investigation, as reflected in the following comments from the Respondent: “...*we find it striking that the Investigation Committee gives such deference to Dr. Nguyen despite her inability to locate the relevant raw data... This further demonstrates that the Investigation Committee’s members (particularly those who continued on from the Inquiry Committee) had predetermined the outcome of this matter before even interviewing Dr. Blain during the investigation*”. In fact, the Committee is comprised of expert senior scientists who hold the rank of Professor or Distinguished Professor, and have considerable experience in the design, performance, and analysis of experiments involving an extensive range of biochemical, molecular, and cell biology techniques. Furthermore, all of the Committee members have served in editorial roles, as well as empaneled federal grant reviewers, and manuscript reviewers, and maintained highly active research labs with undergraduate and graduate trainees. The panel was thus very well qualified and accepted their charge of reviewing the data and conducting interviews without any preconceived notions in regard to the Respondent. The Committee at all times conducted itself with integrity and professionalism while maintaining the utmost confidentiality. The Committee provided every opportunity for the Respondent to properly identify or provide requested raw data and explain the problematic images; however, the Respondent consistently failed to do so. In contrast, Dr. Nguyen’s conduct and responses aided the Committee in formulating its opinions regarding the credibility of Dr. Nguyen’s testimony.
  
5. The Respondent questions why the Committee did not interview Dr. Susan Gottesman who “*has been part of Dr. Blain’s lab since 2003 and has seen all of the data generated by the lab since then*”. In fact, the Committee believes the claim that Dr. Gottesman is a part of the Blain lab is a misrepresentation. Dr. Gottesman is a Professor in the Department of Pathology with extensive clinical duties as the Director of the Clinical Hematology Lab and Hematopathology Service at SUNY Downstate Health Sciences University. She had not appeared in a single publication with the Respondent until 2018, well after the time during which most of the data fabrication and falsification would have occurred. Moreover, Dr. Gottesman had never been identified by the Respondent or any other person the Committee interviewed as someone who would have knowledge and insight about the workings of the Blain lab, despite several opportunities to do so.

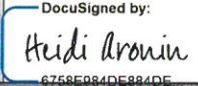
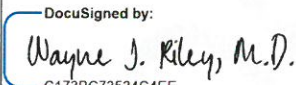


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6. A consistent theme utilized by the Respondent to rebut the allegations is that some of this work occurred years ago under a different set of norms and available technology; and the Committee's analysis utilizes the practices of today as its basis. However, this is inaccurate. The technologies, as utilized in the work of these papers, have been relatively straightforward, unsophisticated, without involvement of more modern high- throughput/ proteomic analyses and have hardly changed in the last decade. The specific cases of image manipulation determined by the Committee identified duplications of cell images and protein gel bands of portions thereof. These alterations are post- acquisition and independent of the methods of acquisition of the raw data. Furthermore, the Respondent's assertion that the image manipulation could only be discovered through the use of forensic analysis techniques that were not available at the time is incorrect. The Committee's determinations were based upon alterations that should be apparent to an experienced experimental biologist without the use of specific forensic analysis tools and were based upon the relevant journal guidelines and scientific community norms at the time the papers were published.

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<b>Approved by Institutional Official (IO), Ms. Heidi Aronin:</b>	<i>IO Signature</i>	<i>Date of IO Approval</i>
	DocuSigned by:  Heidi Aronin <small>6758E984DE884DE...</small>	12/14/21   3:06 PM EST
<b>Final Decision by Deciding Official/ SUNY Downstate Health Sciences University President, Dr. Wayne J. Riley:</b>	<input checked="" type="checkbox"/> Accept Ad Hoc Committee Determination	
	___ Reject Ad Hoc Committee Determination; Specify Alternate Decision:	
<b>Signature of Deciding Official:</b>	DocuSigned by:  Wayne J. Riley, M.D. <small>C173BC73534C4EE...</small>	
<b>Date of Final Decision:</b>	12/14/21   12:11 PM PST	