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CONFIDENTIAL: RESEARCH MISCONDUCT FINAL INQUIRY REPORT



SUNY
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CONFIDENTIAL

RESEARCH MISCONDUCT
FINAL INQUIRY REPORT

DECEMBER 12, 2019

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

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

Represented by:

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RESEARCH MISCONDUCT ALLEGATION SUBJECT: Allegation of Falsification/ Fabrication

RESEARCH MISCONDUCT INQUIRY COMMITTEE MEMBERS:

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

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

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

A. Summary 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)¹ 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

¹ Appended hereto as Appendix A

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R01 CA201536 and National Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK044525.

Allegations of reuse and relabeling of data contained within figures are alleged in a paper published in 2015 in *Molecular and Cellular Biology* on which Dr. Blain was the corresponding author² and a paper published in the *Journal of Pediatric Gastroenterology and Nutrition* on which Dr. Blain was the second author³.

Additionally, an anonymous complaint made to SUNY System directly by the complainant "Claire Francis" alleged falsification/ fabrication in an additional *Molecular Cell Biology* paper in 2008⁴.

B. Summary of Inquiry Process Utilized

The Inquiry Committee followed the SUNY Downstate Research Misconduct Policy and Procedure (available here: <http://research.downstate.edu/pdf/SUNY-DMC-Research-Misconduct-Policy-and-Procedure.pdf>).

Applicable documents were sequestered and an inventory⁵ has been maintained by the SUNY Downstate Office of Compliance and Audit Services.

C. List of Research Records Reviewed

1. DIO 6935 Letter
2. DIO Analysis⁶
3. R01 CA201536
4. 2015 *Molecular and Cellular Biology* paper- <https://mcb.asm.org/content/35/9/1506>
5. 2010 *Journal of Pediatric Gastroenterology and Nutrition* paper- <https://insights.ovid.com/crossref?an=00005176-201011000-00004>
6. 2008 *Molecular and Cellular Biology* paper- <https://mcb.asm.org/content/29/4/986.long>
7. 2007 *Molecular and Cellular Biology* paper- <https://mcb.asm.org/content/28/1/498.long>
8. 1997 *Journal of Biological Chemistry* paper- <http://www.jbc.org/content/272/41/25863.long>
9. Figures and claims in Provisional US Patent applications 62/113166 and 15/351904 and Utility US Patent application PCT/US2015/031128
10. Correspondence and recommendations from *ad hoc* investigative committee convened by Dr. Mark Stewart, Dean of Graduate School, to examine research misconduct allegations

² Patel P, Asbach B, Shteyn E, Gomez C, Coltoff A, Bhuyan S, Tyner AL, Wagner R, Blain SW. Brk/Proteintyrosine kinase 6 phosphorylates p27KIP1, regulating the activity of cyclin D-cyclin-dependent kinase 4. *Mol. Cell. Bio.* 2015;35(9):1506-22

³ 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;51(5):556-62

⁴ James M K, Ray A, Leznova D, Blain SW. Differential Modification of p27 Kip1 Controls its Cyclin D-cdk4 Inhibitory Activity. *Mol. Cell. Bio.* 2008

⁵ Appended hereto as Appendix B

⁶ Appended hereto as Appendix C

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made by Ms. Elina Shteyn, PhD student, against Dr. Priyank Patel, PhD student

11. Doctoral dissertation of Dr. Priyank Patel
12. Student records for Dr. Priyank Patel
13. Student records for Ms. Elina Shteyn
14. Raw data of experiments supporting figures and statements for the 2015 *Molecular and Cellular Biology* paper

D. Summary of Interviews

The Research Misconduct Inquiry Committee exchanged numerous emails, and met several times by telephone, video conferencing, and in person on the SUNY Downstate campus during the interval from September 16 to October 31, 2019.

Telephone interviews were conducted with Dr. William Chirico, Associate Professor, Cell Biology, and Dr. Lorin Weiner, Research Assistant Professor, Cell Biology, the two members of an original investigative committee formed in 2016 to look into claims of scientific misconduct made by one student member of the Blain laboratory against another⁷. This initial investigation was conducted by Dr. Mark Stewart as Dean of the Graduate School who handled it as a student academic misconduct issue and not a research misconduct issue. Therefore, he did not invoke SUNY Downstate's Research Misconduct policy and procedure. The Committee felt that this initial investigation by the Dean, Dr. Stewart, was incomplete because although the review uncovered evidence for data falsification in a published manuscript, he did not suggest a follow-up Research Misconduct Inquiry.

The Committee reviewed other evidence and email statements, including those provided by:

1. Dr. Janice Brissette, Associate Professor, Cell Biology; Priyank Patel thesis committee member
2. Dr. Carlos Pato, Dean of College of Medicine in 2016
3. Dr. David Schoenhaut, Director of Technology Commercialization
4. Dr. Miriam Feuerman, Associate Professor, Biochemistry; involved in 2016 student misconduct allegation review
5. Dr. Mark Stewart, Dean of Graduate School

On October 28th and 31st, the Committee also formally interviewed the following key parties with direct involvement or knowledge deemed to be necessary to assess the potential misconduct and its ramifications⁸.

1. Dr. Madiha Akhtar, Associate Dean of Student Affairs; involved in 2016 student misconduct allegation discussions

⁷ Appended hereto as Appendix D are the transcripts of these interviews.

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2. Dr. Christopher Roman, Associate Professor, Cell Biology; Priyank Patel thesis committee chairperson
3. Dr. Mark Stewart, Dean of Graduate School – with private Counsel (Mr. Sam Shapiro from Emery Celli Brinckerhoff & Abady LLP)
4. Dr. Stacy Blain, Associate Professor, Pediatrics and Cell Biology; Respondent – with private Counsel (Mr. Milton Williams, Ms. Caroline Sloane, Mr. Johnson Lin from Walden Macht & Haran LLP)
5. Dr. Priyank Patel, Voluntary Faculty at SUNY Downstate and Research Scientist at Concarlo Holdings LLC (Dr. Blain’s start- up company); graduate student working in the Blain lab in 2016 who was the subject of the student misconduct allegations and the first author of the 2015 MCB paper – with private Counsel (Ms. Nicole Gueron from Clarick Gueron Reisbaum)

Overall, the committee found each of the interviewees to be highly cooperative and willing to discuss matters related to the 2016 student allegations of misconduct as well as the NIH ORI allegations and the potential ramifications of each. Responses were deemed highly informative and useful for making a final determination.

E. Committee Determination

The Inquiry Committee believes that the allegation of research misconduct on the part of Dr. Stacy Blain warrants an investigation based upon the initial review of the available evidence. The essence of the alleged misconduct is the unexplained duplication of data contained in images appearing in multiple publications, grant applications, and patent applications, for which Dr. Stacy Blain was the responsible party. Additional concerns are raised by the failure to fully disclose the methods used to generate the data contained in other figures, which may have favorably biased the reviews of such work. There is no indication that Dr. Priyank Patel was responsible for the alleged misconduct, though he appears to have been complicit by not providing sufficiently detailed methods to support his data. It is not yet possible to determine whether other parties subordinate to Dr. Blain played any role in data misrepresentation.

F. Detailed Description of Supporting Evidence for Determination

- 1) Dr. Blain stated repeatedly that she bears full responsibility for the final data and their presentation in her publications, and that she reviews all data and figures generated in her lab.
- 2) Dr. Blain explained that the reason behind the appearance of duplicate bands appearing in several figures contained in the 2015 MCB paper was due to the stripping and re-probing of immunoblots with different antibodies (when chemiluminescent detection was used) or the dual channel detection of different antibodies (if fluorescent detection was used).
- 3) The above assertions were independently supported by Dr. Priyank Patel, who confirmed it was their common lab practice at the time, but also suggested that their failure to disclose the specific methods was due to limited space in the journals.

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- 4) Dr. Blain could not explain, and did not acknowledge, that several other bands and background areas contained in the gel images in publications from her lab appear to be duplicates as well. These particular instances could not be explained due to stripping and re-probing or dual fluorescent channel detection since they represented different conditions that were run in different lanes on the same gel. Furthermore, stripping and re-probing the blots would not explain identical background observed with different antibodies.
- 5) When presented with apparently identical images appearing in lanes from different conditions as described above, Dr. Blain refused to agree that they were in fact identical in appearance, or may have been a product of accidental copying and pasting of one image in two or more places in the composite figure, and suggested instead that the similarity might be due to ORI rendering practices with which she was unfamiliar.
- 6) Dr. Blain denied that she deliberately attempted to conceal the fact that many composite images in her publications were generated by selective copying and pasting of image contents, but acknowledged that rearranging and selectively presenting data from different gels or raw image acquisitions was a common practice in her lab until recently (when, according to Dr. Blain, journal policies have been modified; the Committee has not verified the validity of this claim).
- 7) Dr. Blain indicated precisely which students or trainees that she claimed had generated the original data used in the images in question, but also stated that one of these individuals (the first author on the paper, Dr. Kim- Doan Nguyen) was allowed to leave with all of her lab notebooks containing the raw data. Thus, the committee was unable to inspect any raw data for the 2010 *Journal of Pediatric Gastroenterology and Nutrition* paper.
- 8) Review of the raw data images for the 2015 *Molecular and Cellular Biology* paper indicated at least one instance where the films appeared to display different exposures of the same single immunoblot, but which were claimed to be two different immunoblots, and another instance where the raw data clearly did not appear to match the published data.

G. Other Actions Recommended by the Committee

1. An investigation committee should seek input and commentary from other coauthors on the 2015 *Molecular and Cellular Biology* paper who were claimed to have generated the data and images.
2. An investigation committee should seek input, commentary and raw research records from the first author, Dr. Nguyen, on the 2010 *Journal of Pediatric Gastroenterology and Nutrition* paper.
3. All raw electronic or film images contained in published papers from Dr. Blain's laboratory at SUNY Downstate should be examined in detail for evidence of duplication of image parts.
4. If a determination of deliberate concealment of image tampering is made, a disciplinary or remedial action should be recommended, which would be determined at a later date.

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5. If a determination of unexplained image duplication is made, this information should be communicated to the corresponding journals. It will be in the journal's discretion to decide whether the errors necessitate retraction of the article or publication of the appropriate corrections.
6. An investigation committee should consider recommendations regarding the formalization of student-on-student research misconduct accusation investigations to ensure that SUNY Downstate's Research Misconduct Policy and Procedure is invoked and followed in a timely manner.

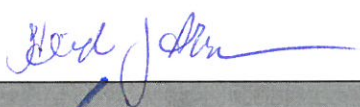
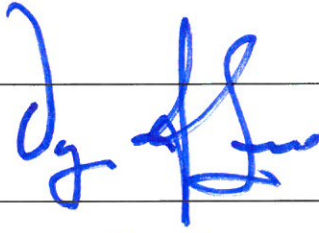
H. Committee Reply to Respondent Response Dated December 11, 2019⁹

The Committee carefully reviewed Dr. Blain's response to the Draft Inquiry Report and found that no new information was provided to justify modification of the Committee's determination and/or recommendations.

⁹ Appended hereto as Appendix E is the Respondent's 12/11/19 Response.

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Approved by Institutional Official (IO), Ms. Heidi Aronin:	<i>IO Signature</i>	<i>Date of IO Approval</i>
		12/16/19
Final Decision by Deciding Official/ SUNY Downstate Health Sciences University President, Dr. Wayne J. Riley:	<input checked="" type="checkbox"/> Accept Ad Hoc Committee Determination	
	<input type="checkbox"/> Reject Ad Hoc Committee Determination; Specify Alternate Decision:	
Signature of Deciding Official:		
Date of Final Decision:	12/16/19	