

## Wolff, Axel (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, July 21, 2017 7:55 AM  
**To:** (b) (6)  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Hello (b) (6)

This is currently a case that is open and under investigation by OLAW. Upon completion you should be informed by the institution as to the outcome since it concerns (b) (6). Because this is open I cannot provide any additional information.

Axel Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
OLAW

**From:** (b) (6)  
**Sent:** Thursday, July 20, 2017 5:54 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
<olawdco@od.nih.gov>  
**Subject:** RE: Assurance D16-00028 University of South Carolina

(b) (6)

**From:** (b) (6)  
**Sent:** Thursday, July 20, 2017 5:42 PM  
**To:** 'OLAW Division of Compliance Oversight (NIH/OD)'  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Dr Wolff,  
(b) (6)

Thank you,  
(b) (6)

**From:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]  
**Sent:** Tuesday, May 16, 2017 10:27 AM  
**To:** (b) (6)  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Thank you.

**From:** (b) (6)  
**Sent:** Tuesday, May 16, 2017 10:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Dr Wolff,

(b) (6)

Thank you.

**From:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

**Sent:** Tuesday, May 16, 2017 7:30 AM

**To:** (b) (6)

**Subject:** RE: Assurance D16-00028 University of South Carolina

Thank you for contacting OLAW about this issue,

(b) (6)

(b) (6)

(b) (6) Let me know what you would like OLAW to do with the information you submitted before I begin an official case.

Axel Wolff, M.S., D.V.M.

Director, Division of Compliance Oversight

OLAW

**From:** (b) (6)

**Sent:** Monday, May 15, 2017 4:46 PM

**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

**Cc:** (b) (6)

**Subject:** Assurance D16-00028 University of South Carolina

Please find attached concerns regarding a protocol suspension at the University of South Carolina.

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

A3049-1L

**From:** COGGINS, TOMMY <TCOGGINS@mailbox.sc.edu>  
**Sent:** Wednesday, May 17, 2017 12:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** BARLOW, SHAYNE; walsh@uscmed.sc.edu; (b) (6)  
**Subject:** RE: Report of Non-Compliance - A3049 (D16-00028)

That is correct. We will provide a follow-up report pending the outcome of the suspension.

Thomas Coggins  
Director  
Office of Sponsored Awards Management & Research Compliance  
University of South Carolina  
(b) (6)  
[tcoggins@mailbox.sc.edu](mailto:tcoggins@mailbox.sc.edu)

**From:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]  
**Sent:** Wednesday, May 17, 2017 12:47 PM  
**To:** COGGINS, TOMMY <TCOGGINS@mailbox.sc.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** BARLOW, SHAYNE <BARLOWS@mailbox.sc.edu>; walsh@uscmed.sc.edu; (b) (6)  
(b) (6)  
**Subject:** RE: Report of Non-Compliance - A3049 (D16-00028)

Mr. Coggins,

Thank you for this report. We assume that this is intended as a preliminary report and that a final report will be forthcoming after completion of the corrective actions and reinstatement of the protocol.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

**From:** COGGINS, TOMMY [mailto:TCOGGINS@mailbox.sc.edu]  
**Sent:** Wednesday, May 17, 2017 9:08 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** BARLOW, SHAYNE <BARLOWS@mailbox.sc.edu>; walsh@uscmed.sc.edu; (b) (6)  
(b) (6)  
**Subject:** Report of Non-Compliance - A3049 (D16-00028)

May 17, 2017

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Dear Dr. Wolff:

The University of South Carolina, in accordance with Assurance D16-00028 and PHS Policy IV.F.3., provides this report regarding a recent case of non-compliance and subsequent suspension of an Animal Use Protocol (AUP). The non-compliance occurred on a PHS-funded, NIH grant number R01 DA013137. After a series of sick animal reports, the IACUC, at its August meeting, began considering what are appropriate humane endpoints for HIV transgenic rats. During an interim review of protocols using these animals, an error (misstatement) was discovered in one of the protocols. While this particular protocol did not involve research that was relevant to the humane endpoints, the IACUC requested that the PI correct and/or clarify the statement in question.

Subsequent to the interim review and original request for clarification, the IACUC sent multiple notifications requesting that an amendment be submitted to correct the information in the protocol. Such an amendment requires only that the investigator provide revised wording/explanation for one statement in the protocol. To date, the PI has not provided a satisfactory response.

At its meeting on May 11, 2017, the IACUC voted to suspend the AUP based on the PI's repeated and willful failure to comply with directives from IACUC to correct/clarify the protocol. During the period of suspension, any expenses associated with animals obtained under this protocol will be paid from non-federal institutional funds.

The University of South Carolina is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions concerning this report, please do not hesitate to contact me.

Sincerely,

Thomas Coggins  
Institutional Official  
Director, Office Research Compliance  
University of South Carolina

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**Sent:** Tuesday, May 16, 2017 10:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Dr Wolff,

(b) (6)  
Thank you.

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**From:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]  
**Sent:** Tuesday, May 16, 2017 7:30 AM  
**To:** (b) (6)  
**Subject:** RE: Assurance D16-00028 University of South Carolina

Thank you for contacting OLAW about this issue, (b) (6)  
(b) (6)  
(b) (6) Let me know what you would like OLAW to do with  
the information you submitted before I begin an official case.

Axel Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
OLAW

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**From:** (b) (6)  
**Sent:** Monday, May 15, 2017 4:46 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Assurance D16-00028 University of South Carolina

Please find attached concerns regarding a protocol suspension at the University of South Carolina.

(b) (6)

## Wolff, Axel (NIH/OD) [E]

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**Sent:** Tuesday, May 16, 2017 7:30 AM  
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**Subject:** RE: Assurance D16-00028 University of South Carolina

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the information you submitted before I begin an official case.

Axel Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
OLAW

**From:** (b) (6)  
**Sent:** Monday, May 15, 2017 4:46 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Assurance D16-00028 University of South Carolina

Please find attached concerns regarding a protocol suspension at the University of South Carolina.

(b) (6)

A3049

March 15, 2017

Axel Wolff, DVM

Director, Division of Compliance Oversight

Office of Laboratory Animal Welfare

Dear Dr Wolff,

(b) (6)



(b) (6)



## BOOZE, ROSEMARIE M

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**From:** (b) (6)  
**Sent:** Thursday, April 27, 2017 11:16 AM  
**To:** COGGINS, TOMMY; (b) (6) Kenneth Walsh  
**Cc:** (b) (6)  
**Subject:** RE: IACUC amendment request Topaz 100885

Tommy and Ken,

(b) (6)

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**From:** COGGINS, TOMMY  
**Sent:** Thursday, April 27, 2017 10:59 AM  
**To:** (b) (6) Kenneth Walsh  
**Cc:** (b) (6)  
**Subject:** RE: IACUC amendment request Topaz 100885

(b) (6)

(b) (6)

Thomas Coggins  
Director  
Office of Sponsored Awards Management & Research Compliance  
University of South Carolina  
(b) (6)  
[tcoggins@mailbox.sc.edu](mailto:tcoggins@mailbox.sc.edu)

**From:** (b) (6)  
**Sent:** Wednesday, April 26, 2017 11:04 AM  
**To:** COGGINS, TOMMY <[TCOGGINS@mailbox.sc.edu](mailto:TCOGGINS@mailbox.sc.edu)>; (b) (6) Kenneth Walsh <[Kenneth.Walsh@uscmed.sc.edu](mailto:Kenneth.Walsh@uscmed.sc.edu)>  
**Cc:** (b) (6)  
**Subject:** FW: IACUC amendment request Topaz 100885

Tommy and Ken,

(b) (6)

(b) (6)

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**From:** (b) (6)  
**Sent:** Friday, April 14, 2017 3:08 PM  
**To:** (b) (6)  
**Cc:** (b) (6) COGGINS, TOMMY; WALSH, KEN; BARLOW, SHAYNE  
**Subject:** IACUC amendment request Topaz 100885

(b) (6)

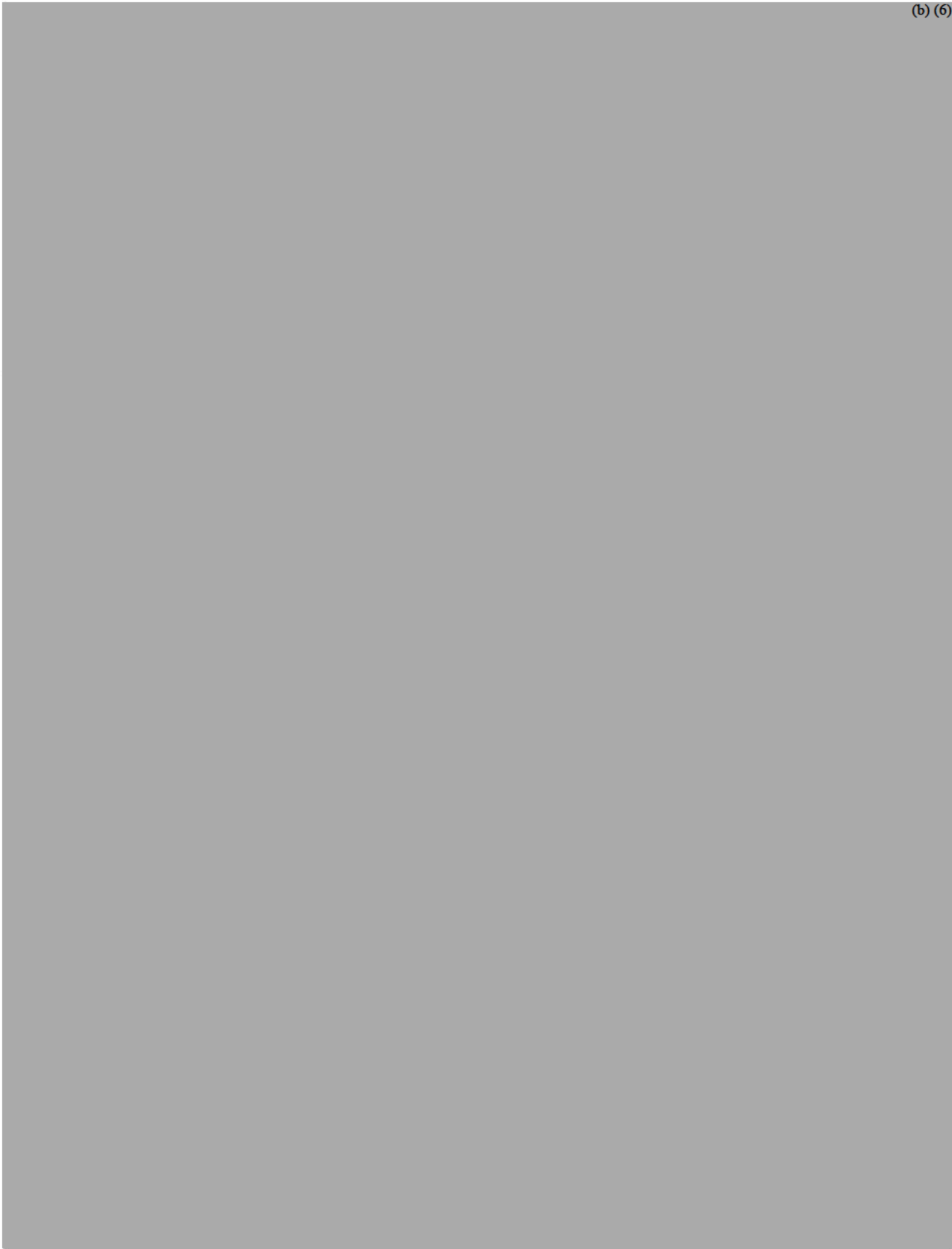
Please see the attached amendment request.

(b) (6)

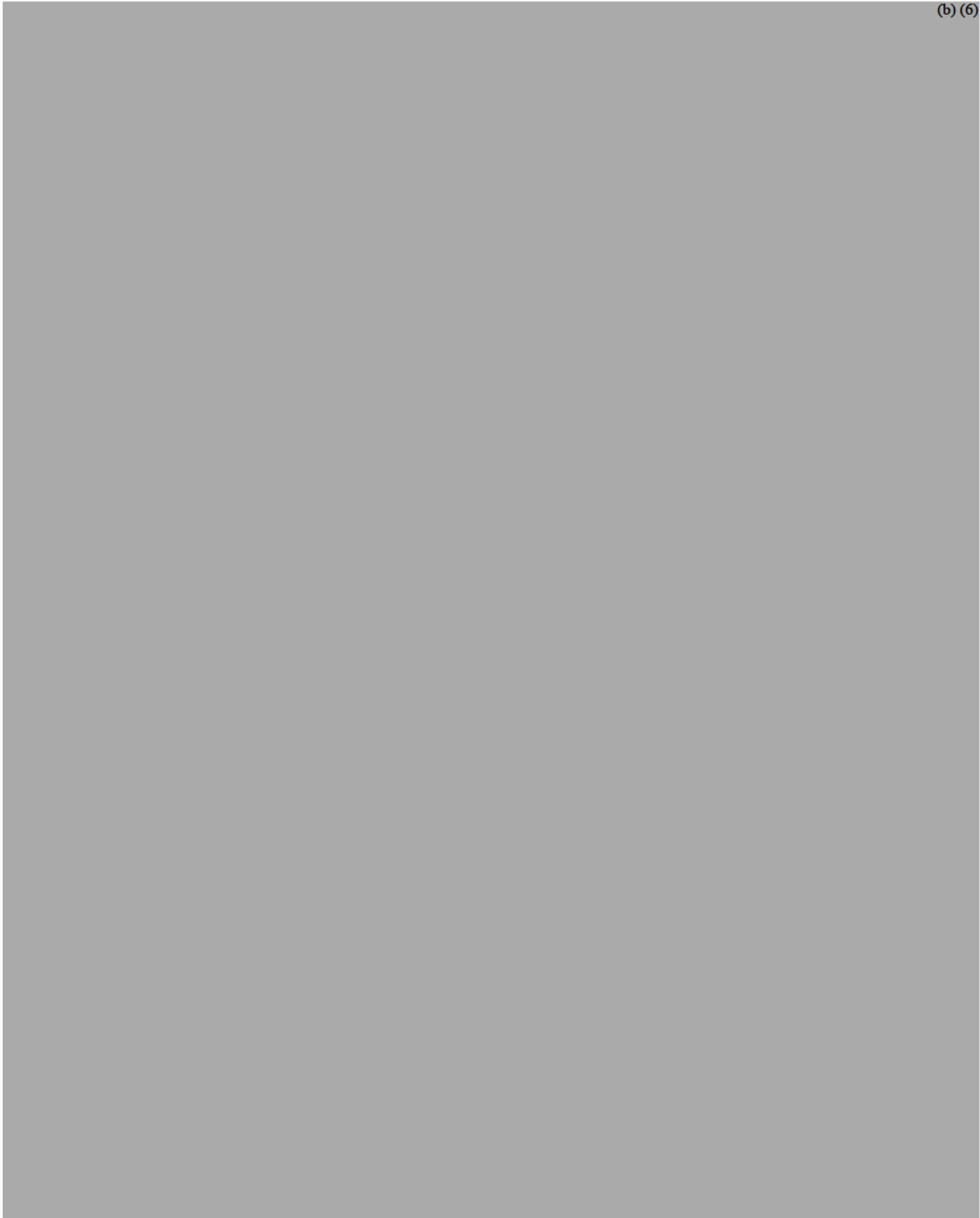
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