

Appendix F:

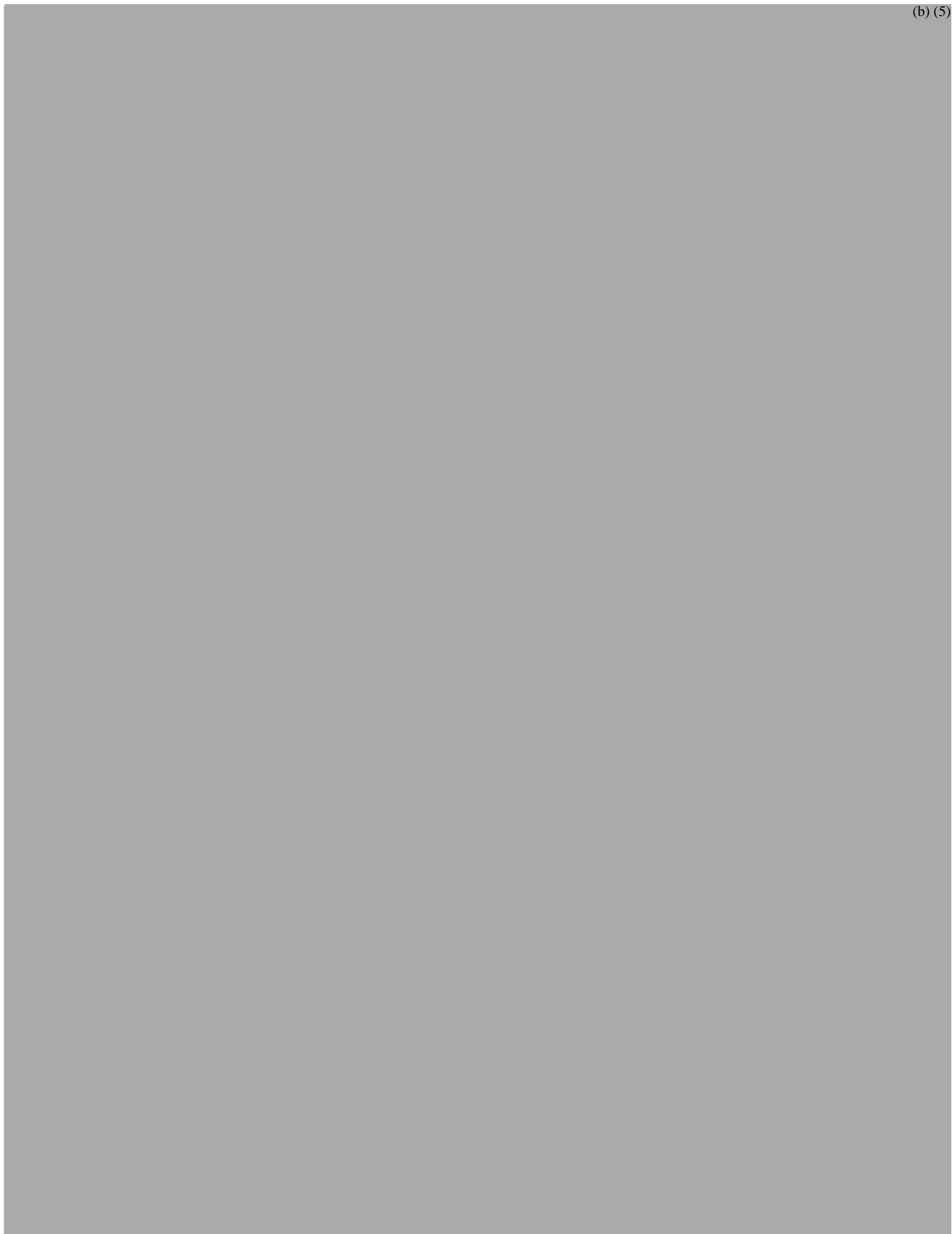
Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

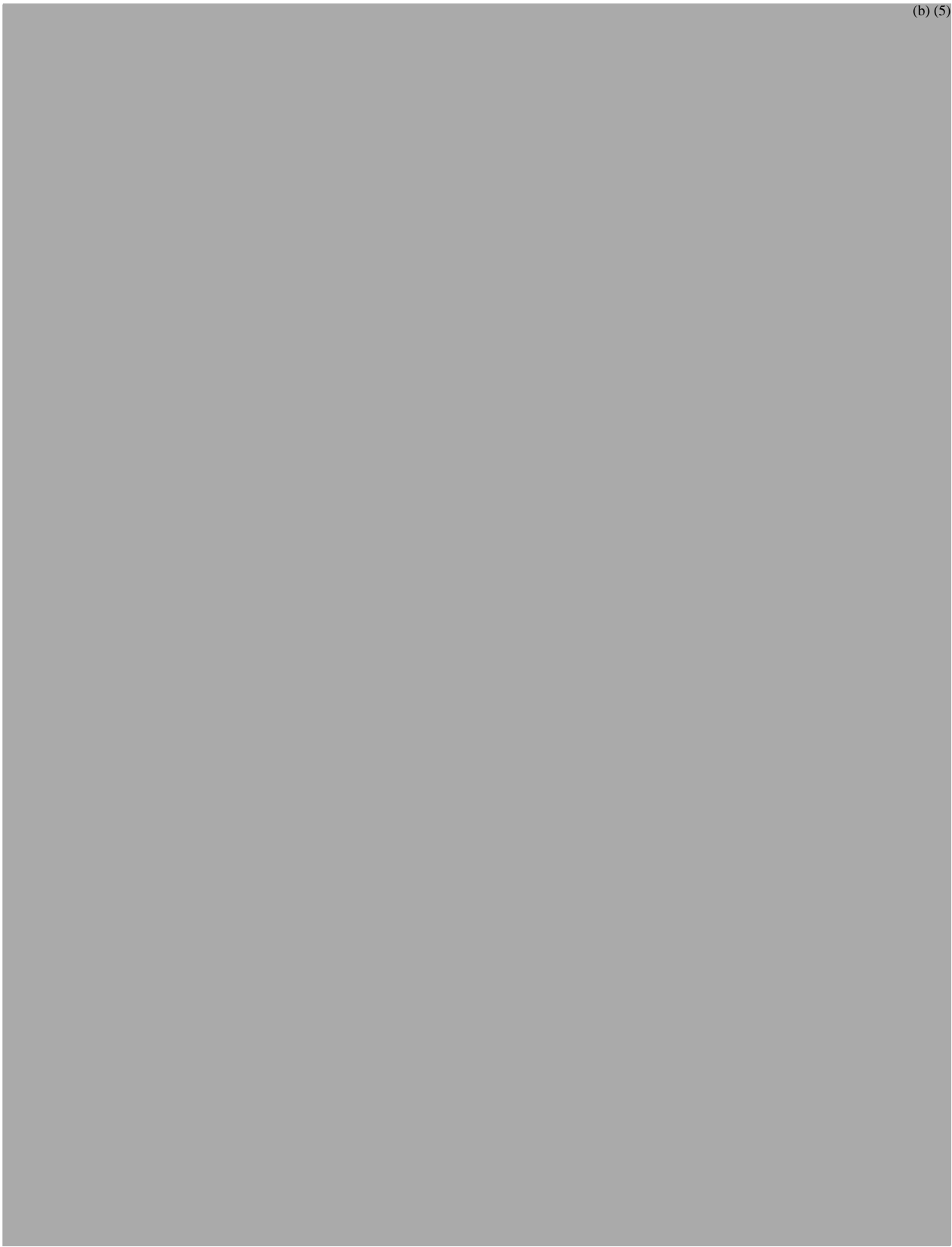
(b) (5)

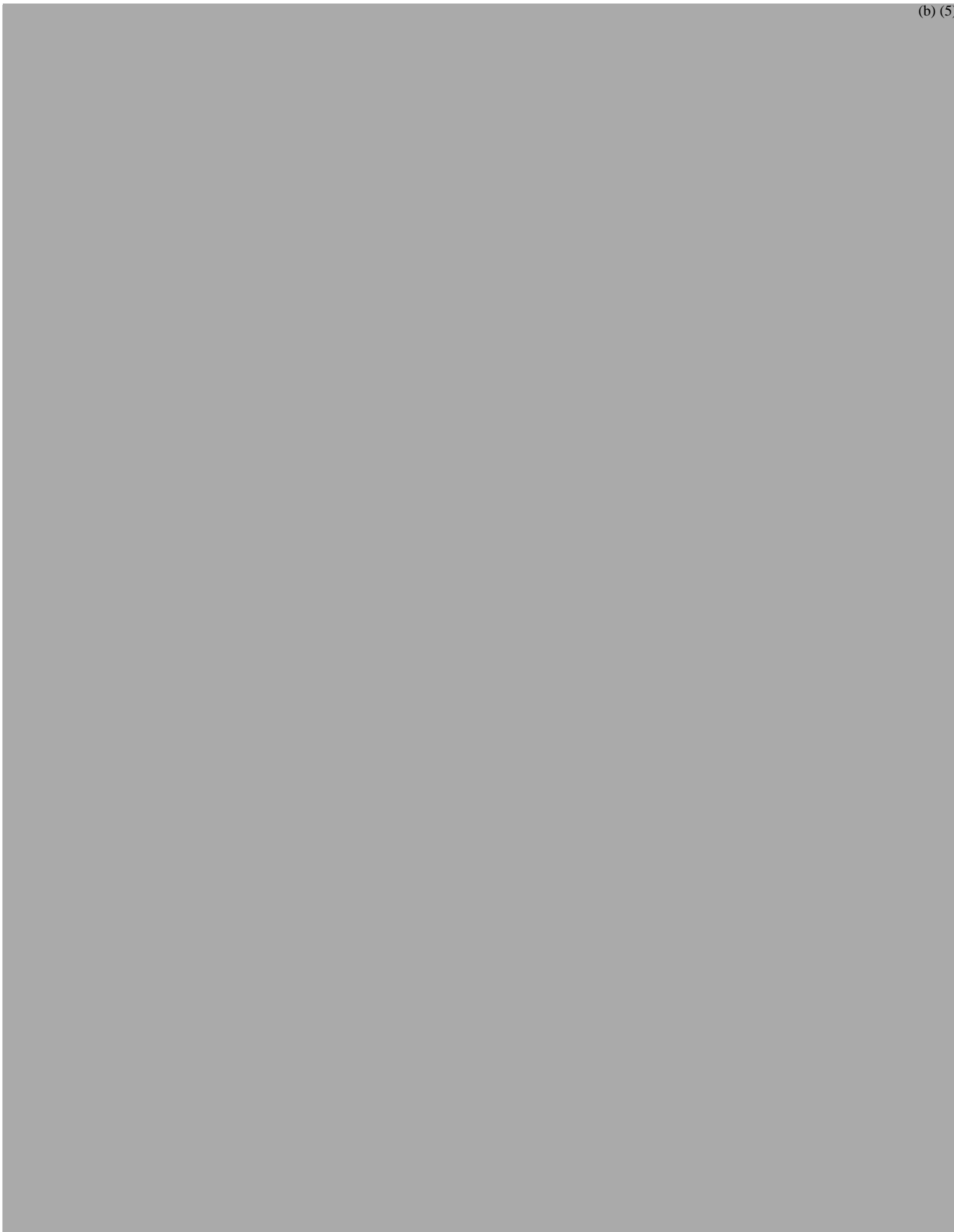
Appendix G:

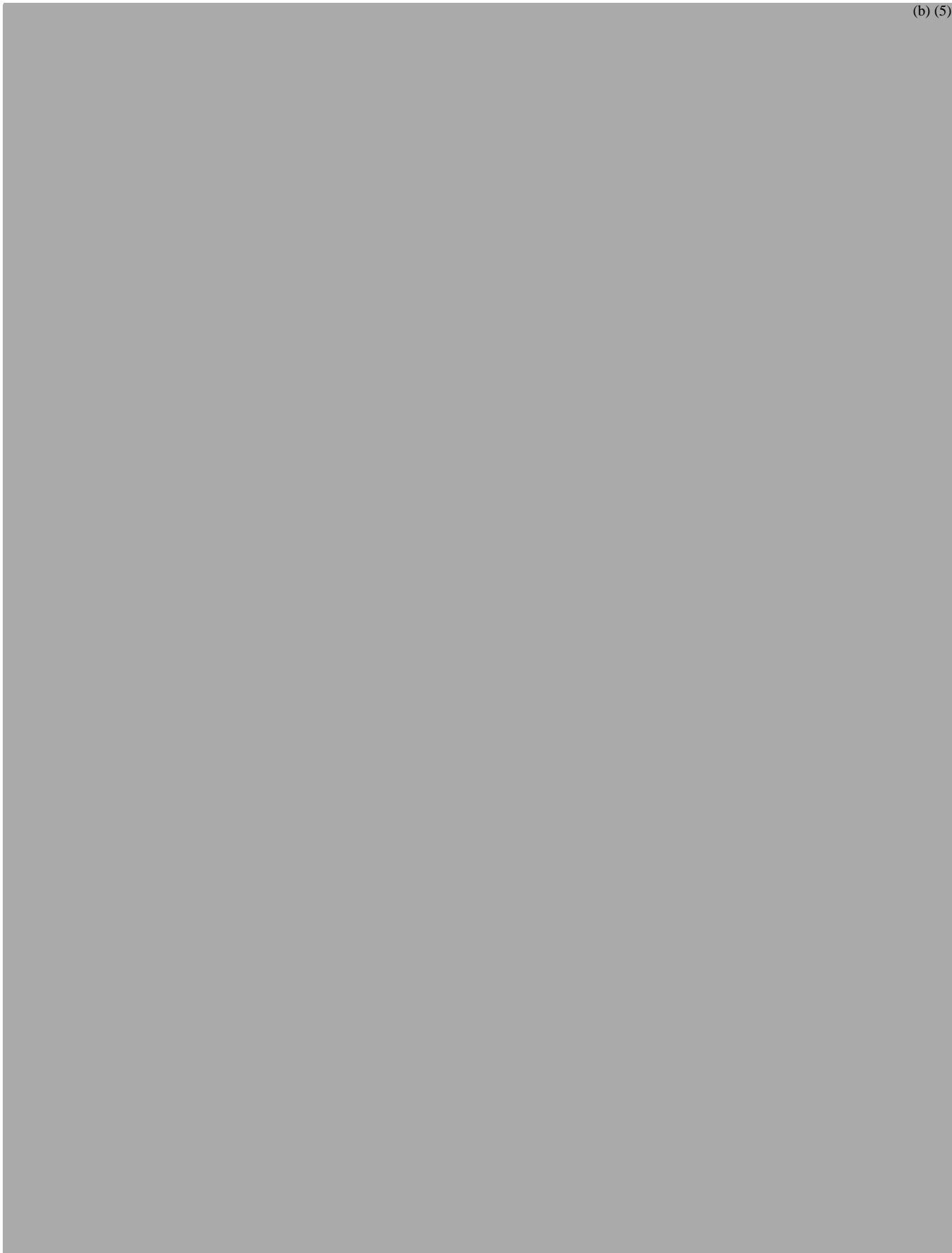
Catalog of Disease Registries, Databases, and Biomedical Information Systems

(b) (5)

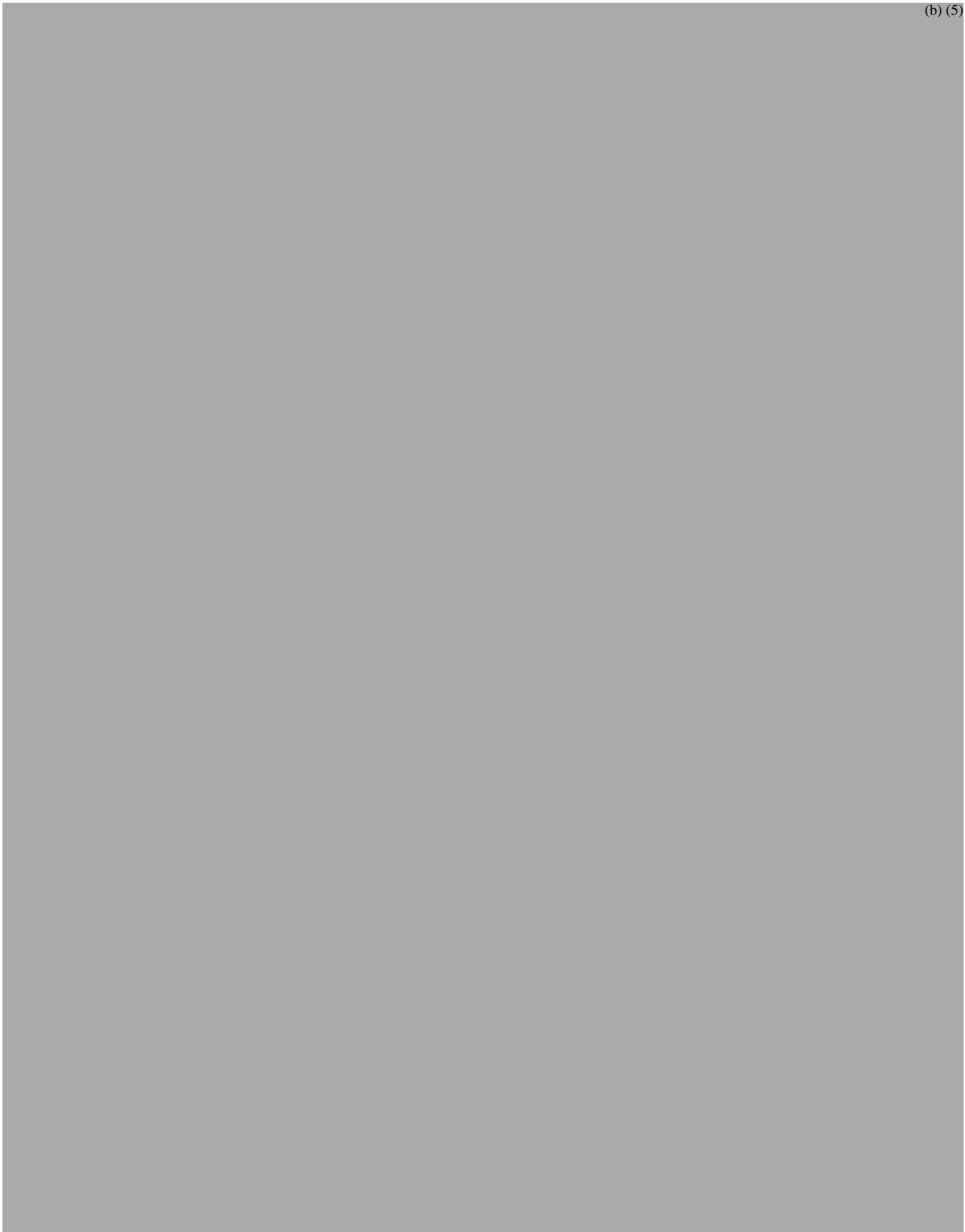




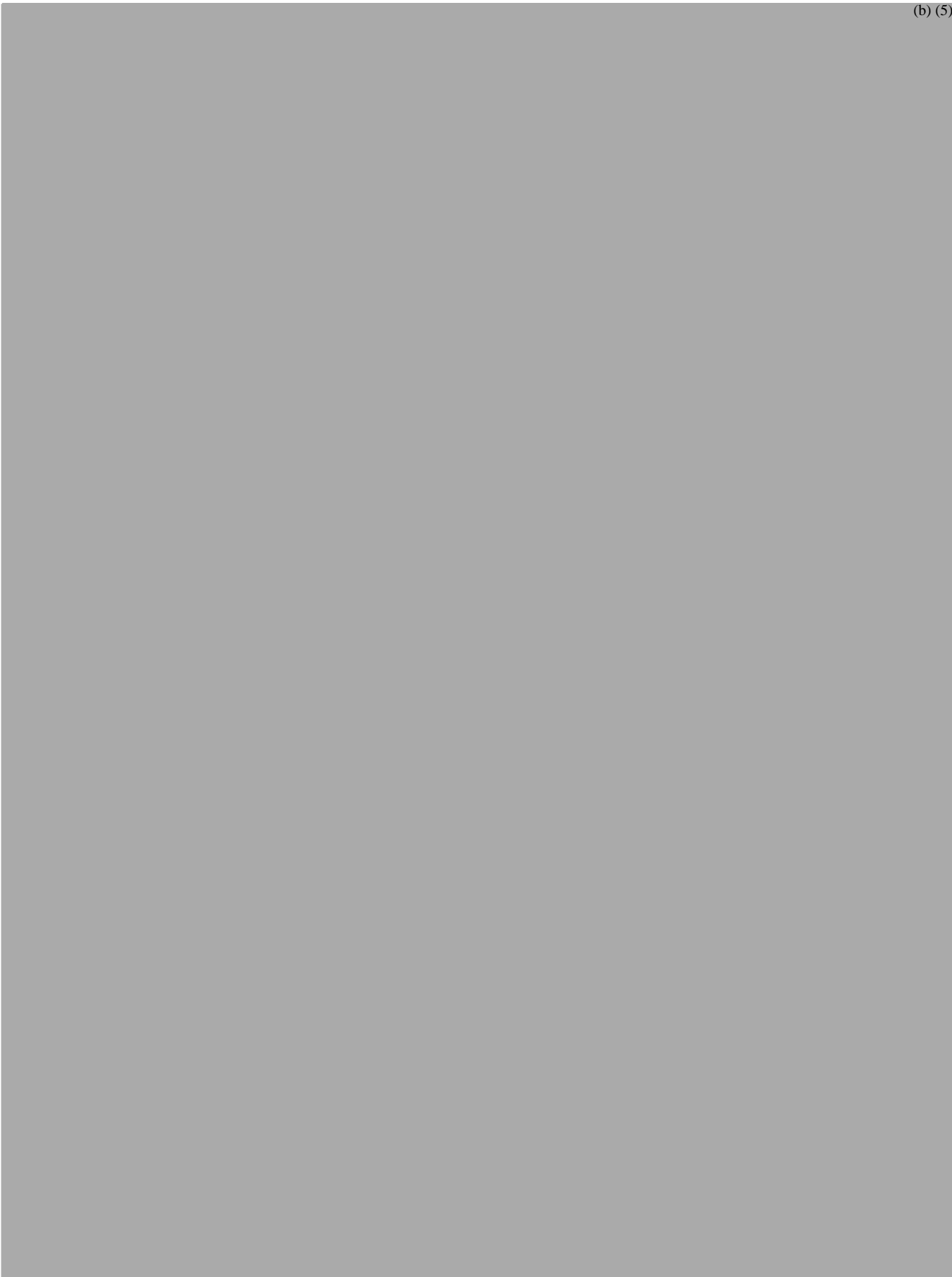




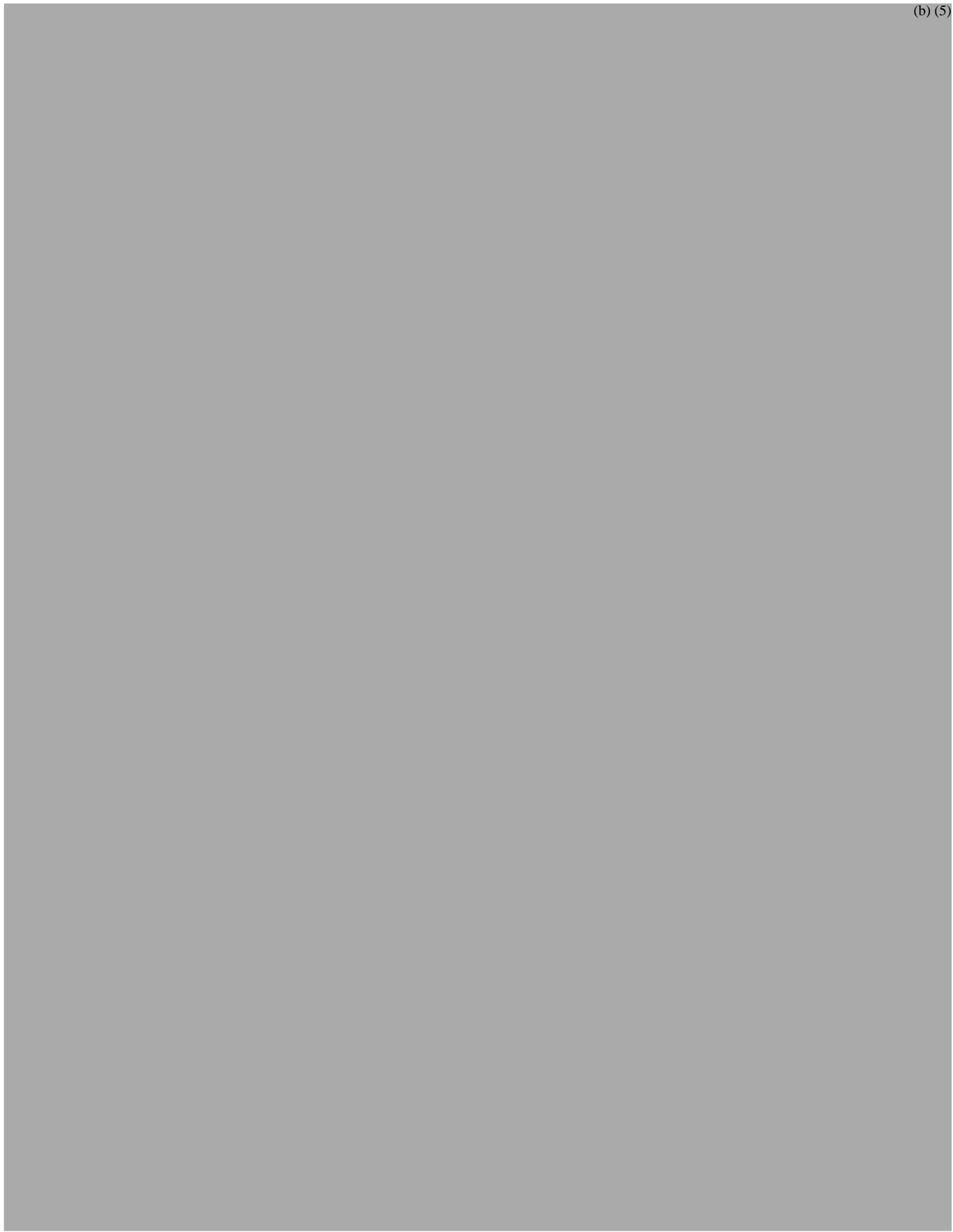


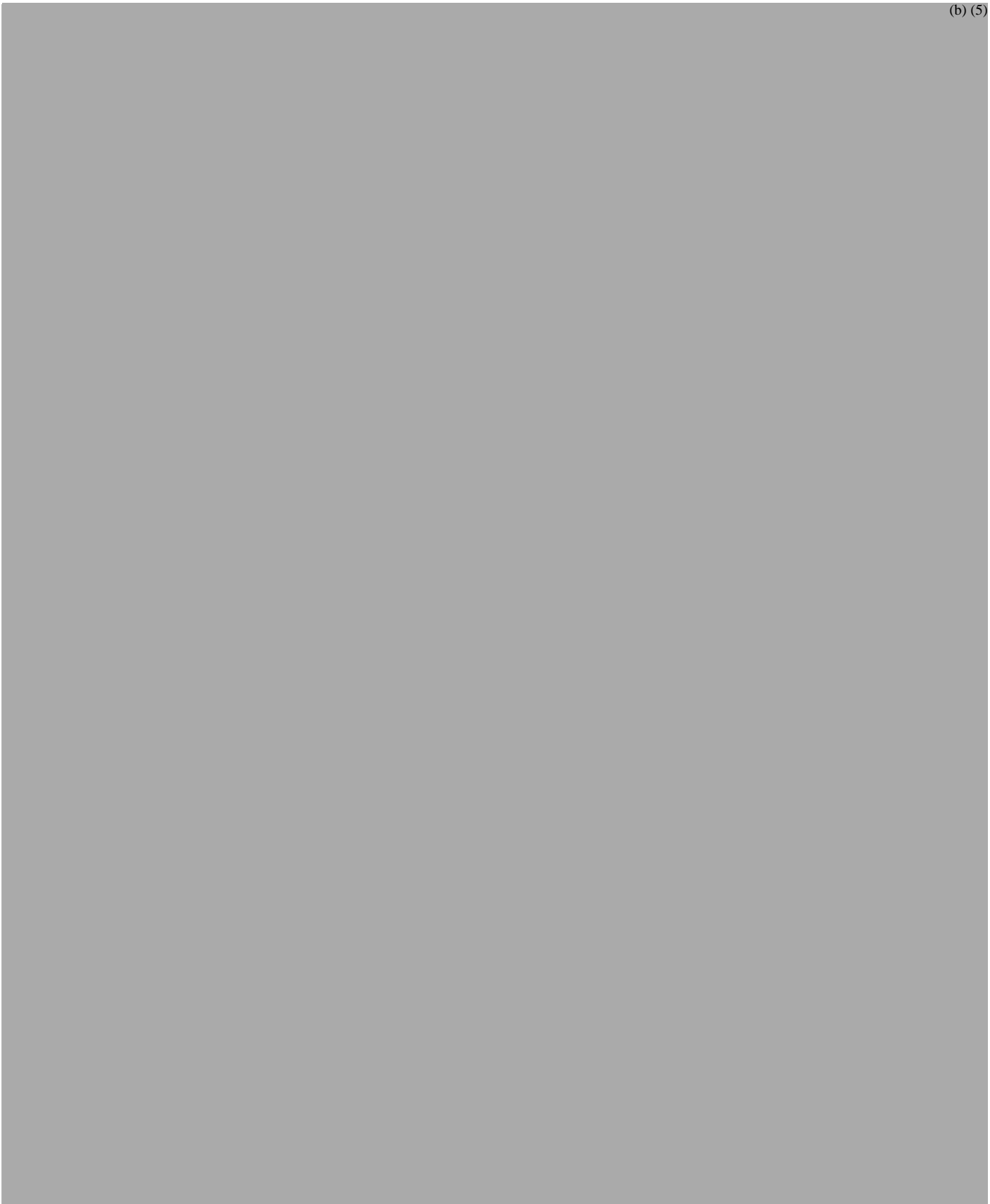








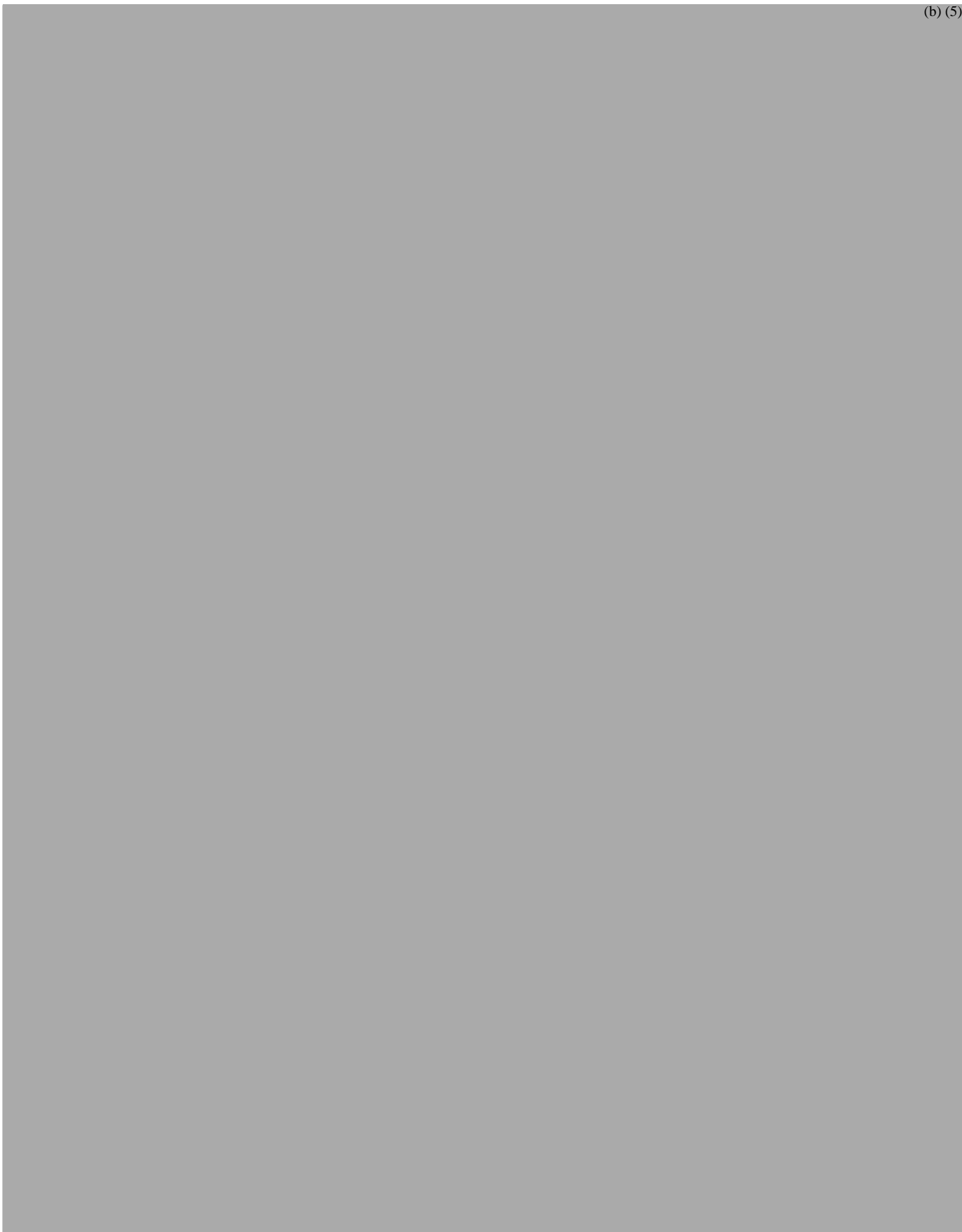


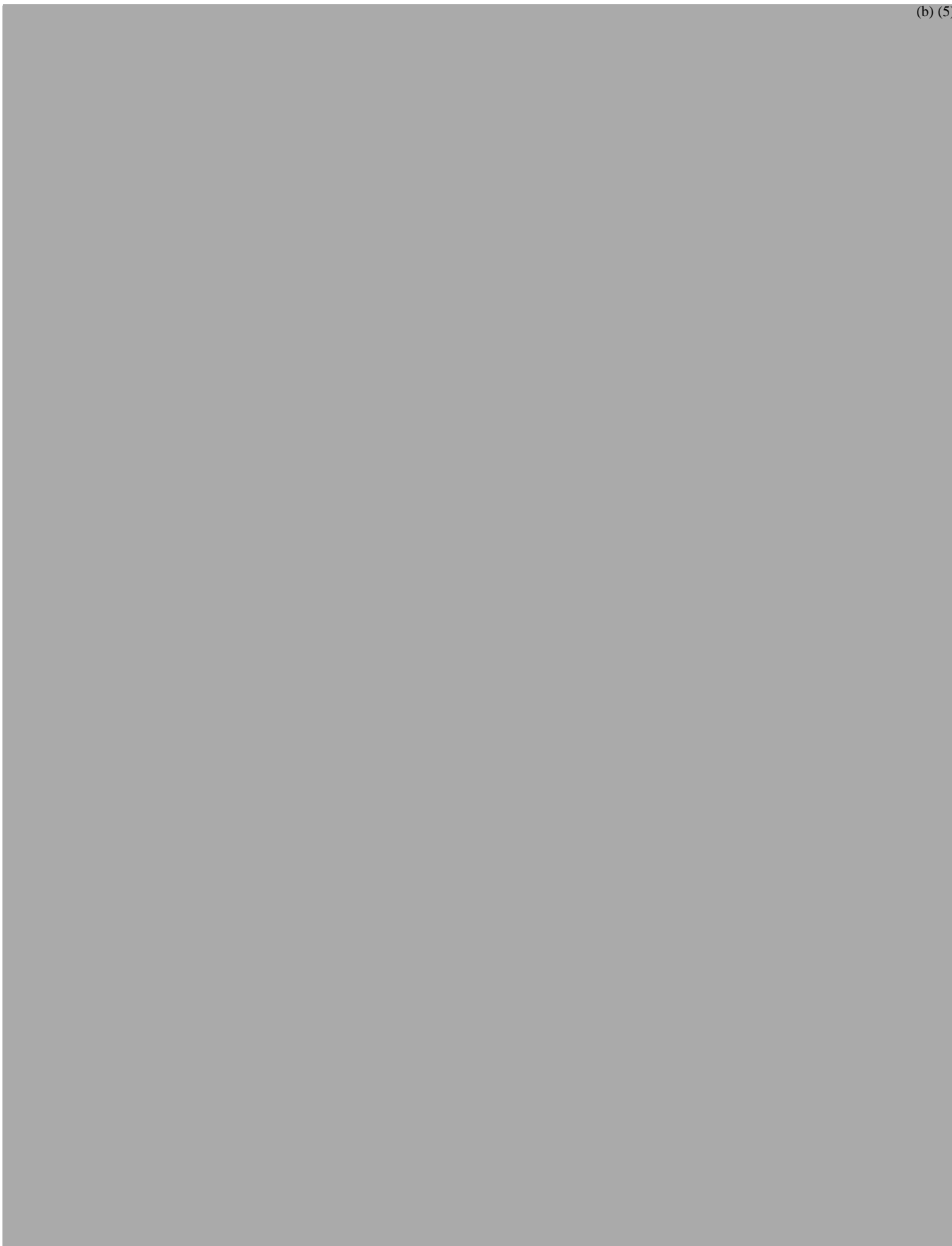




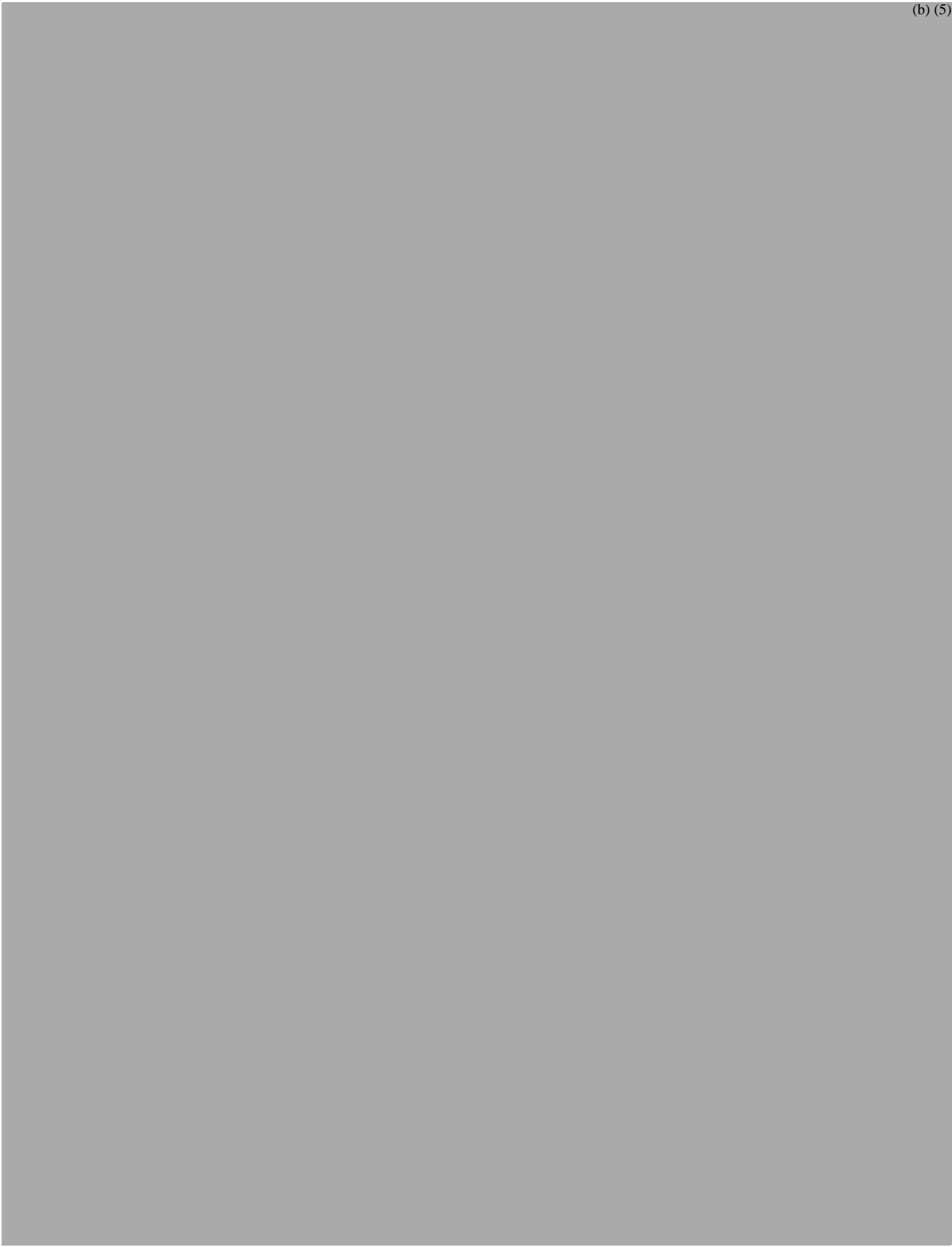




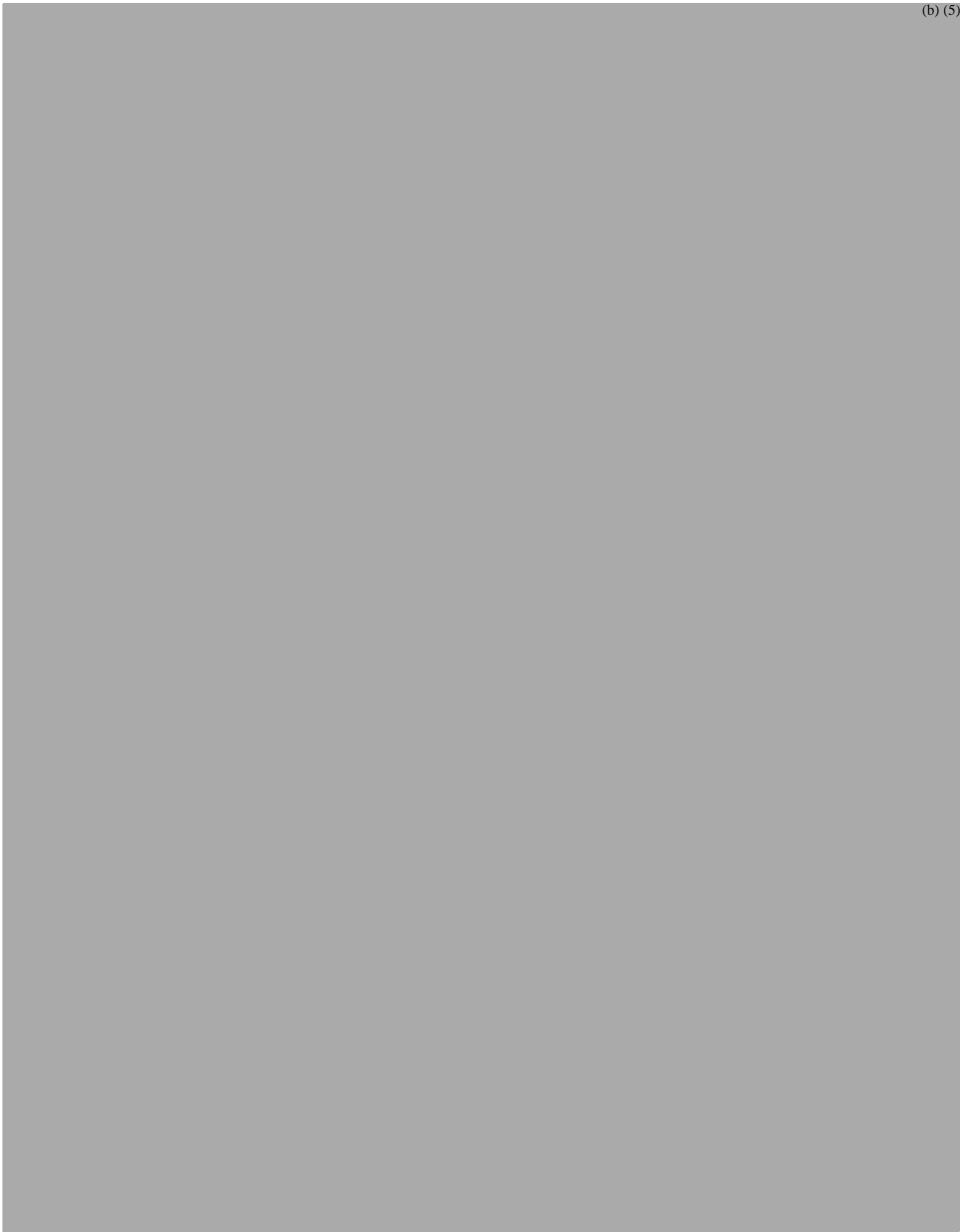


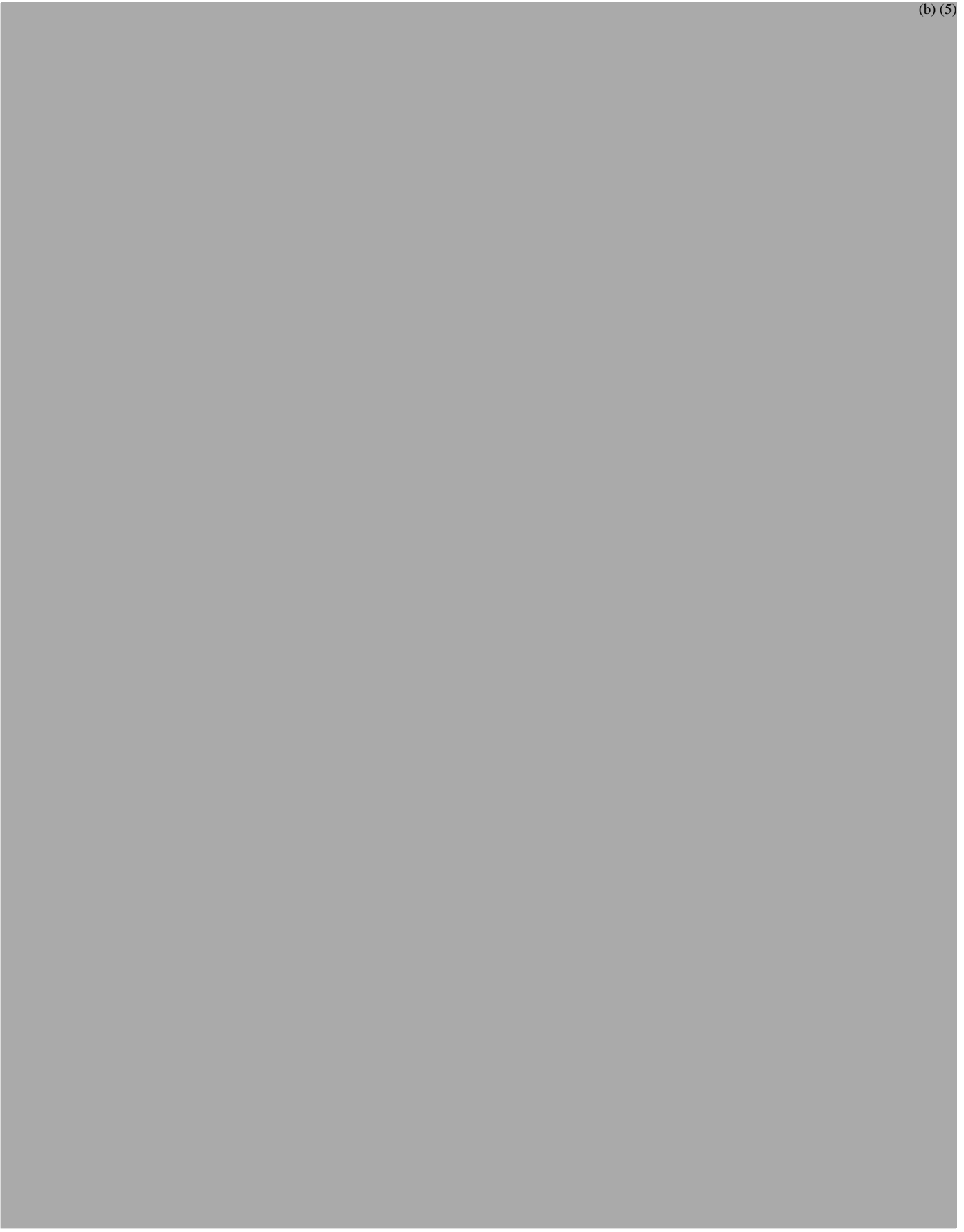








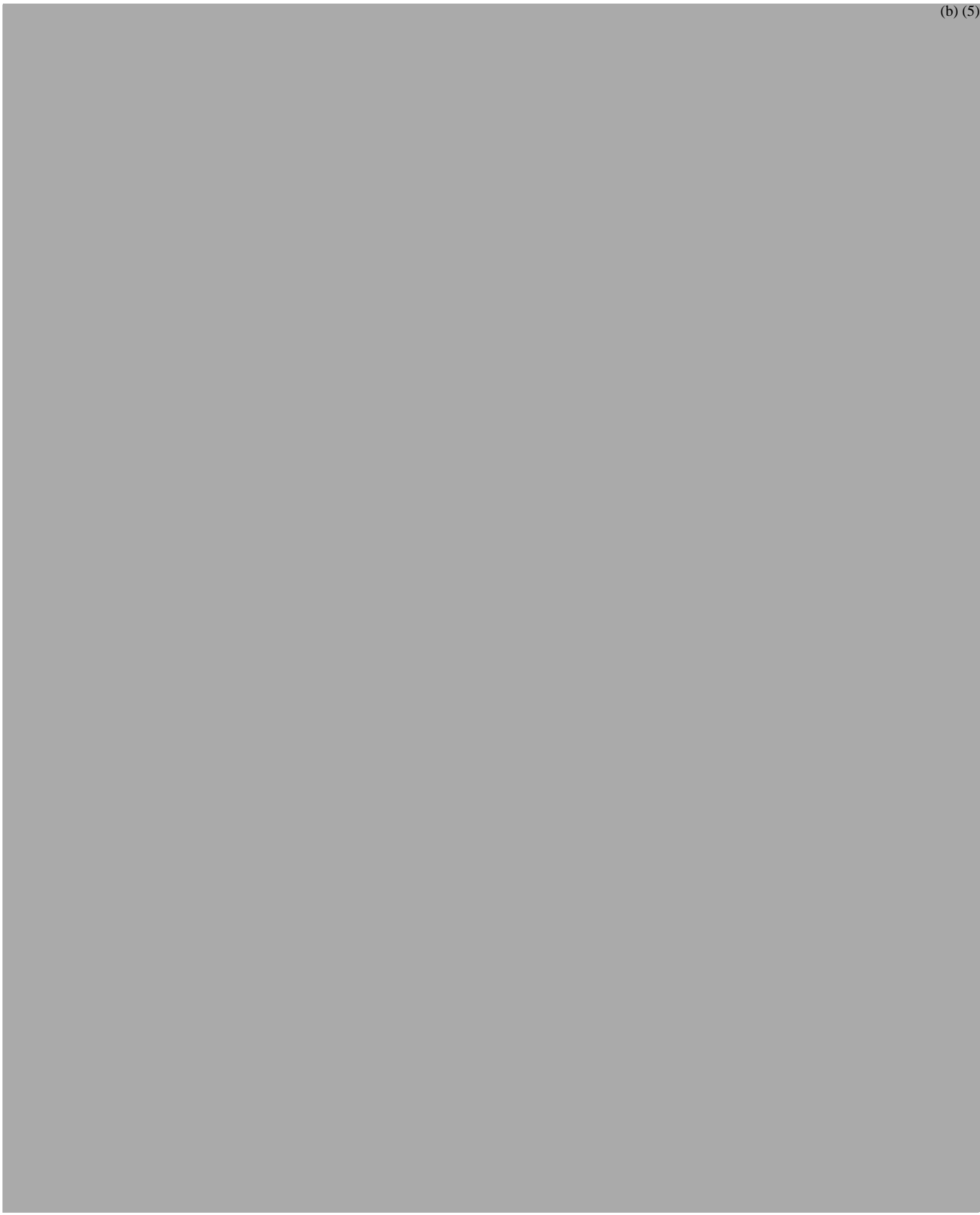


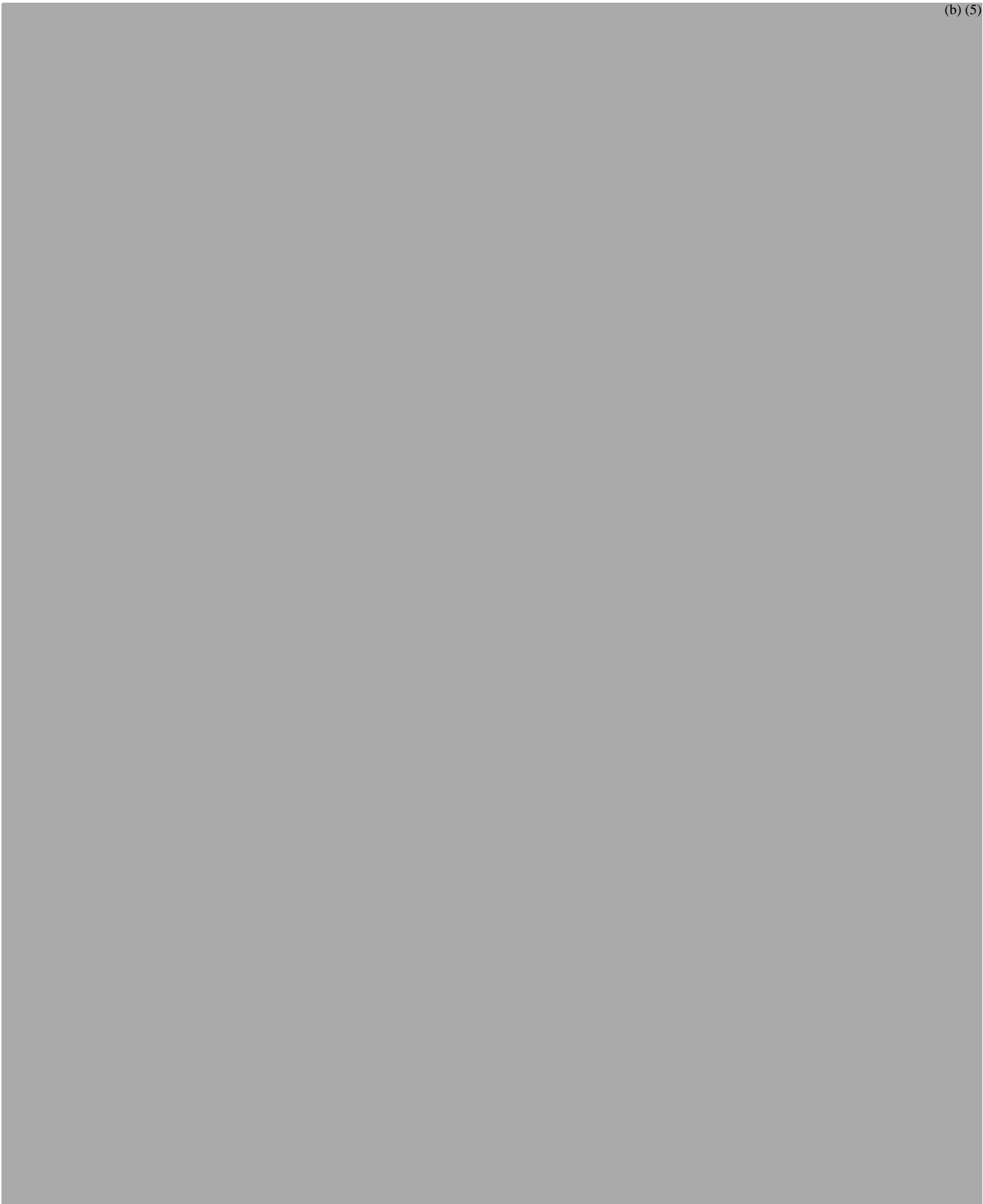


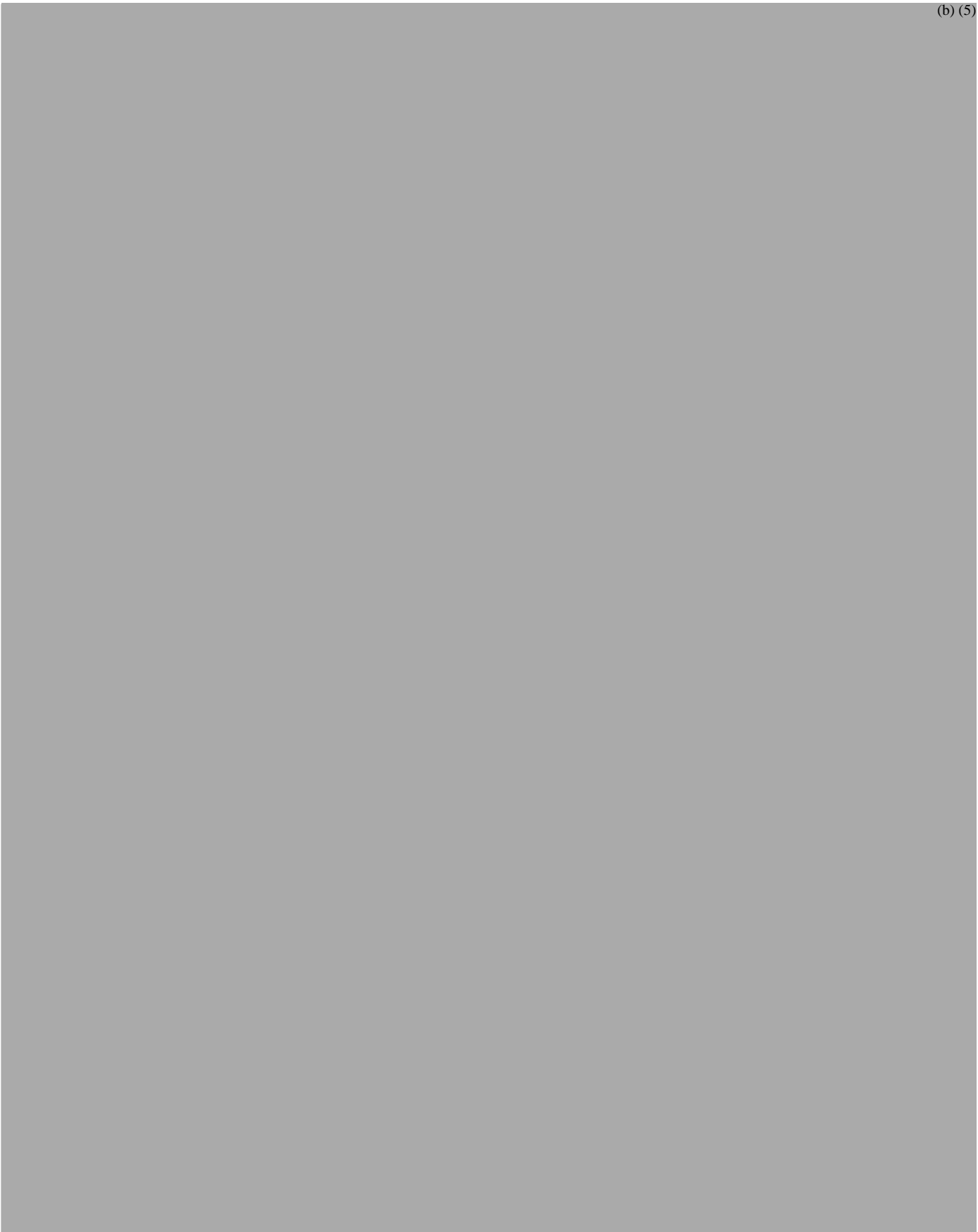
















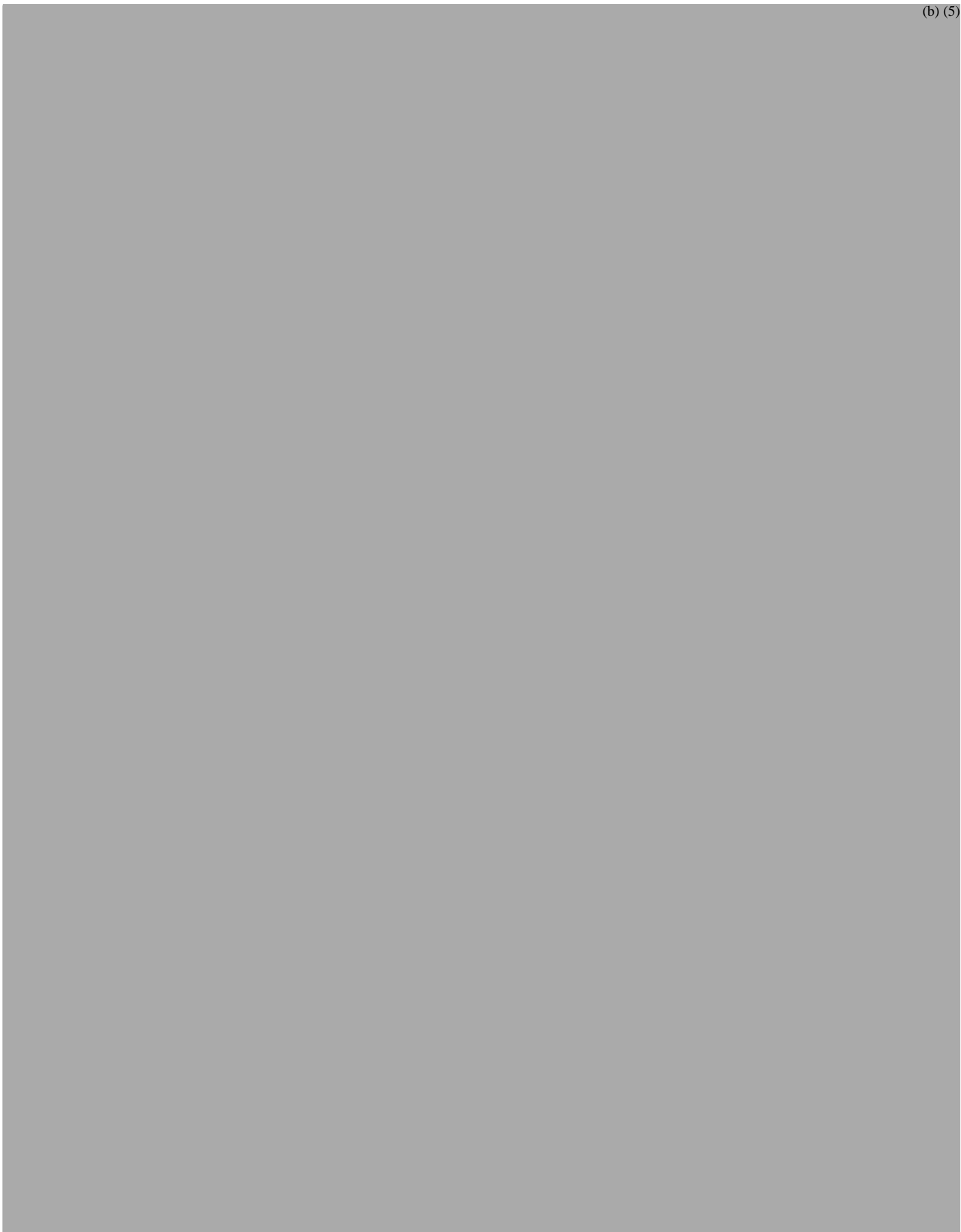


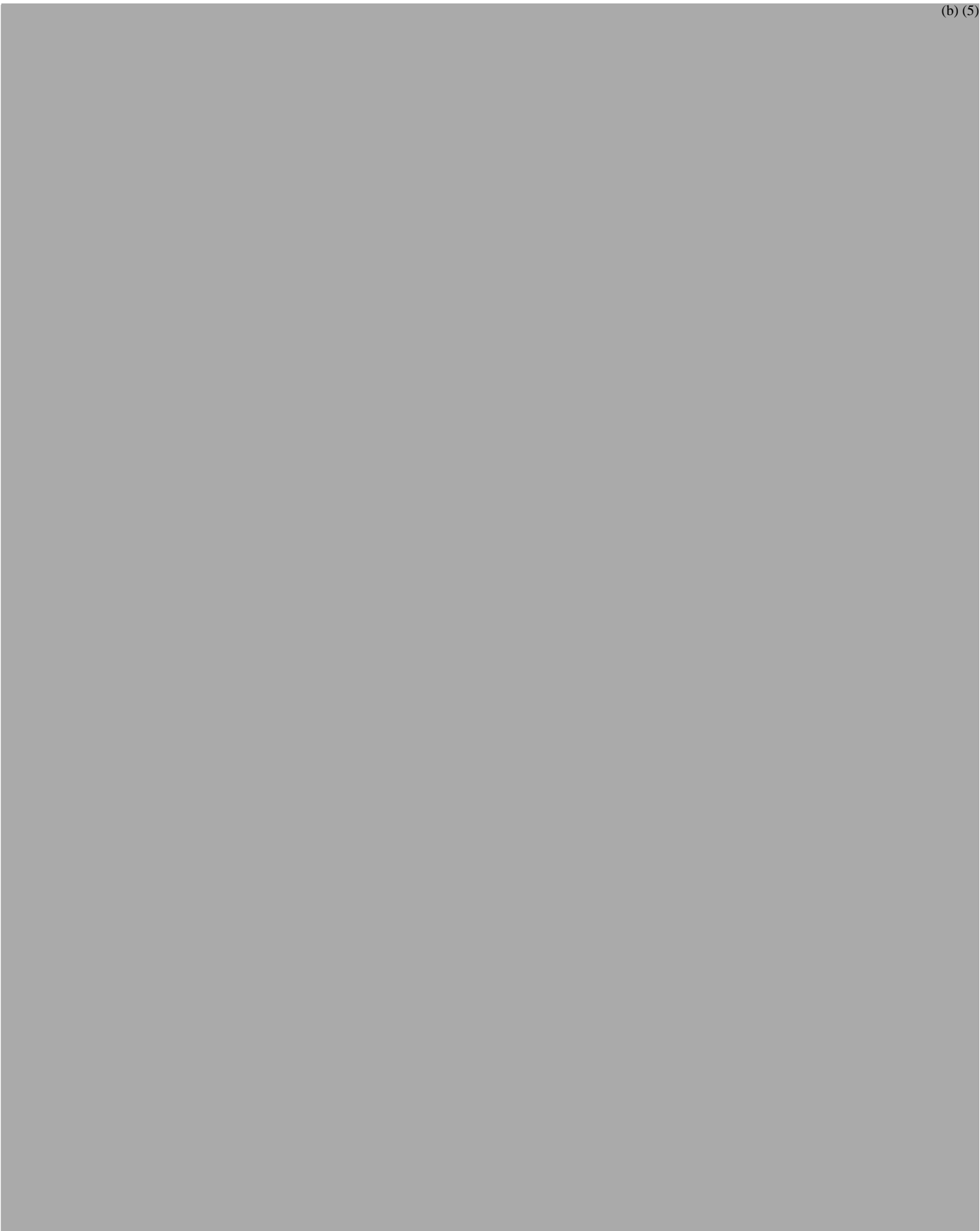


Appendix H:

Actions Undertaken to Carry Out Scientific Frameworks on Recalcitrant Cancer

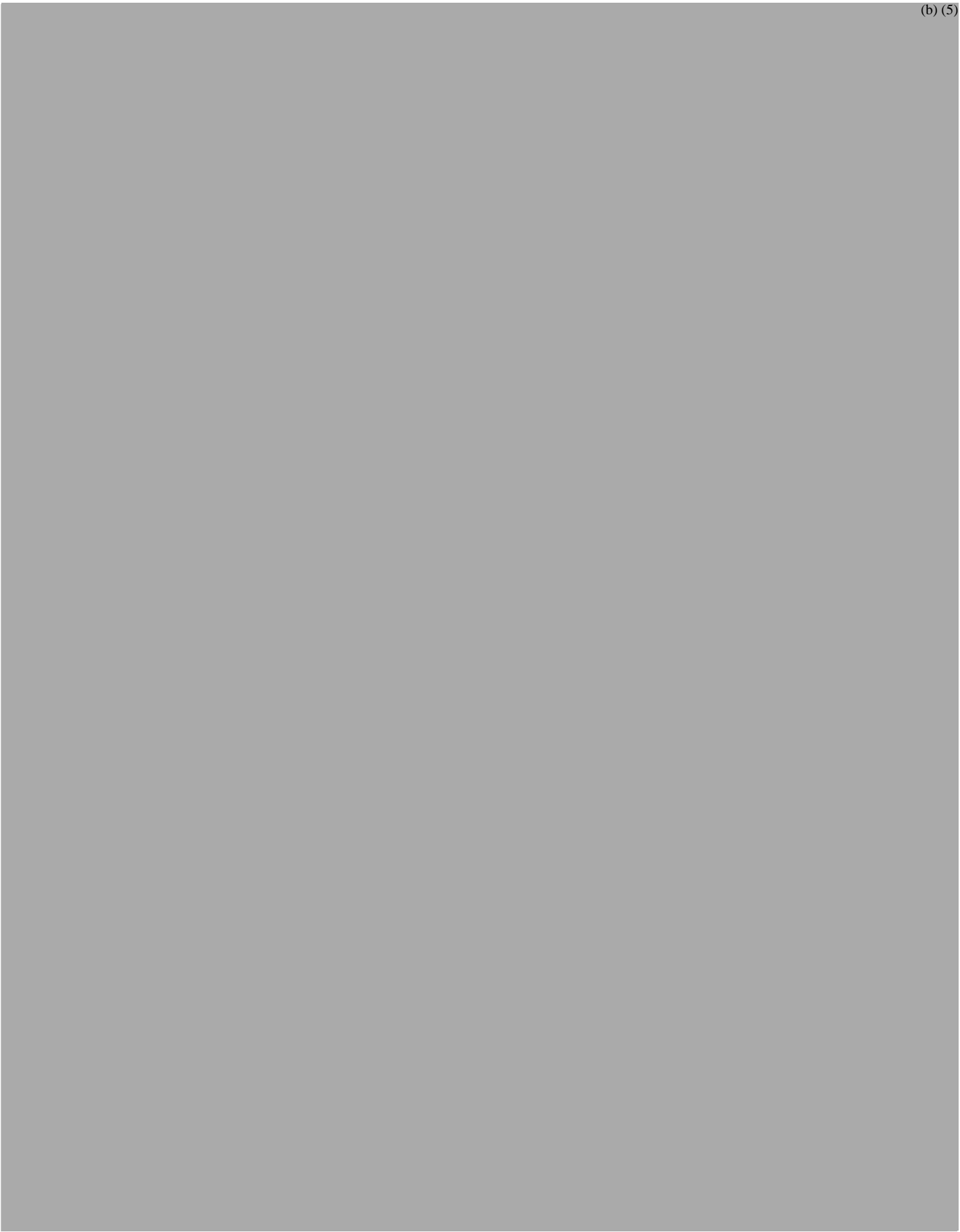
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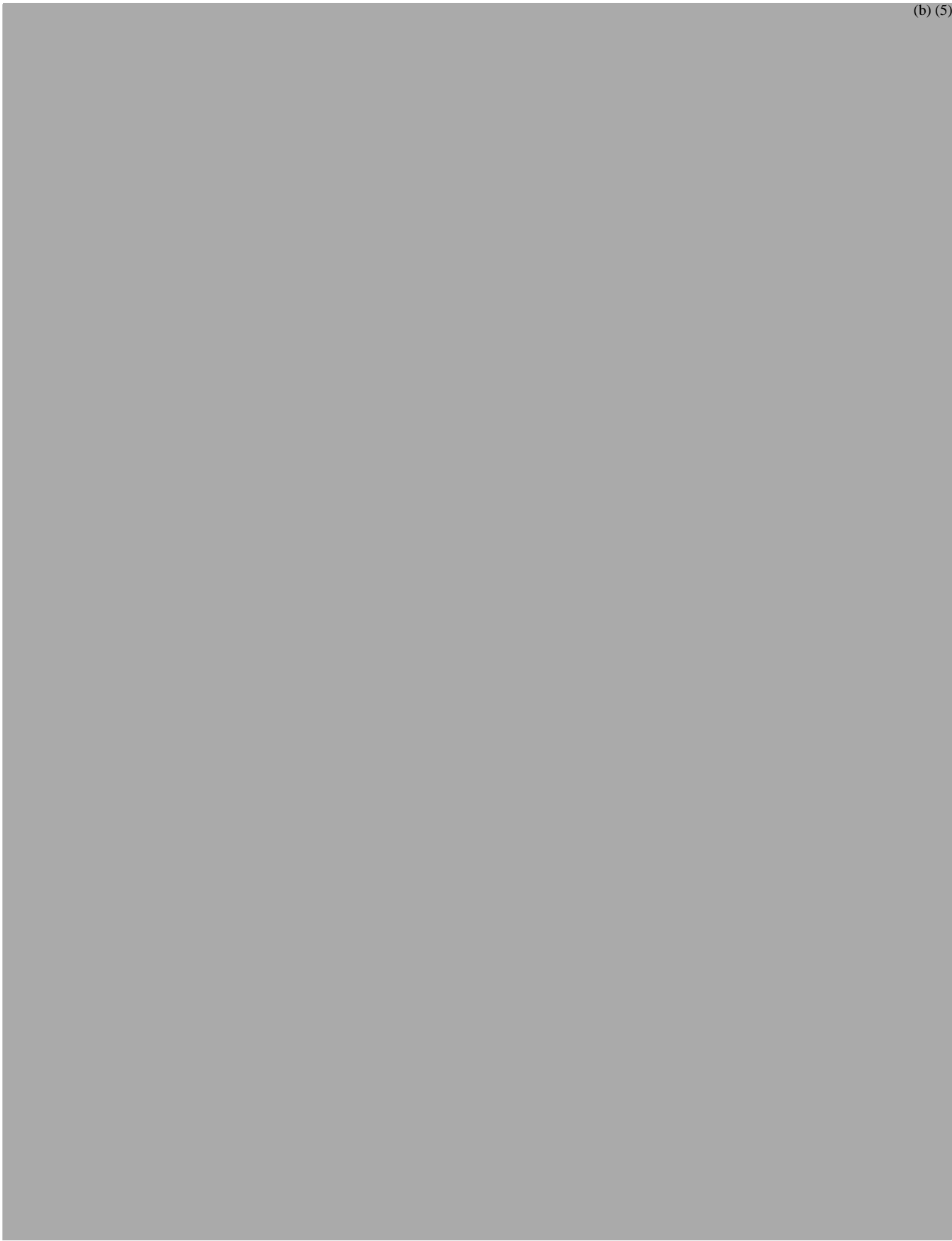


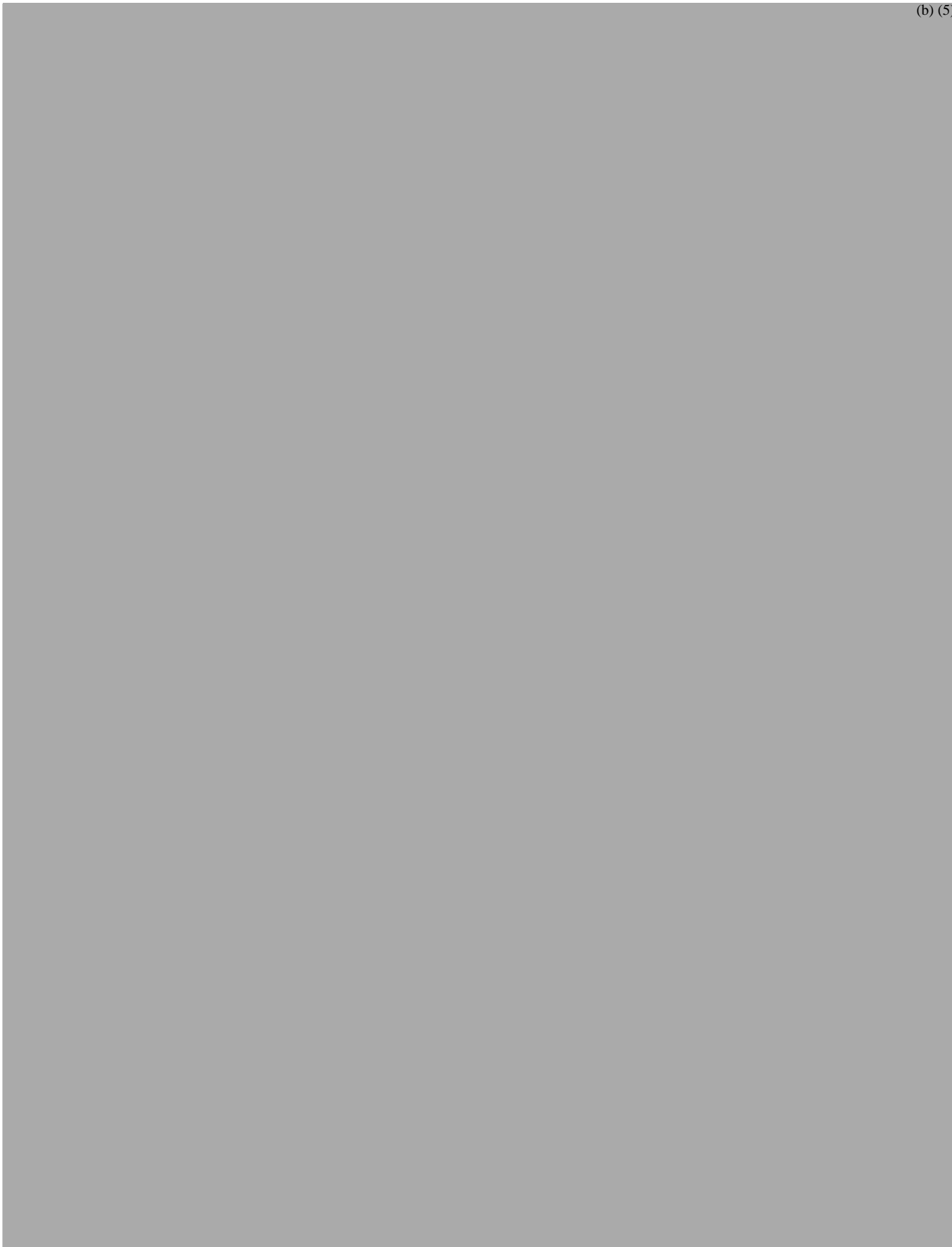




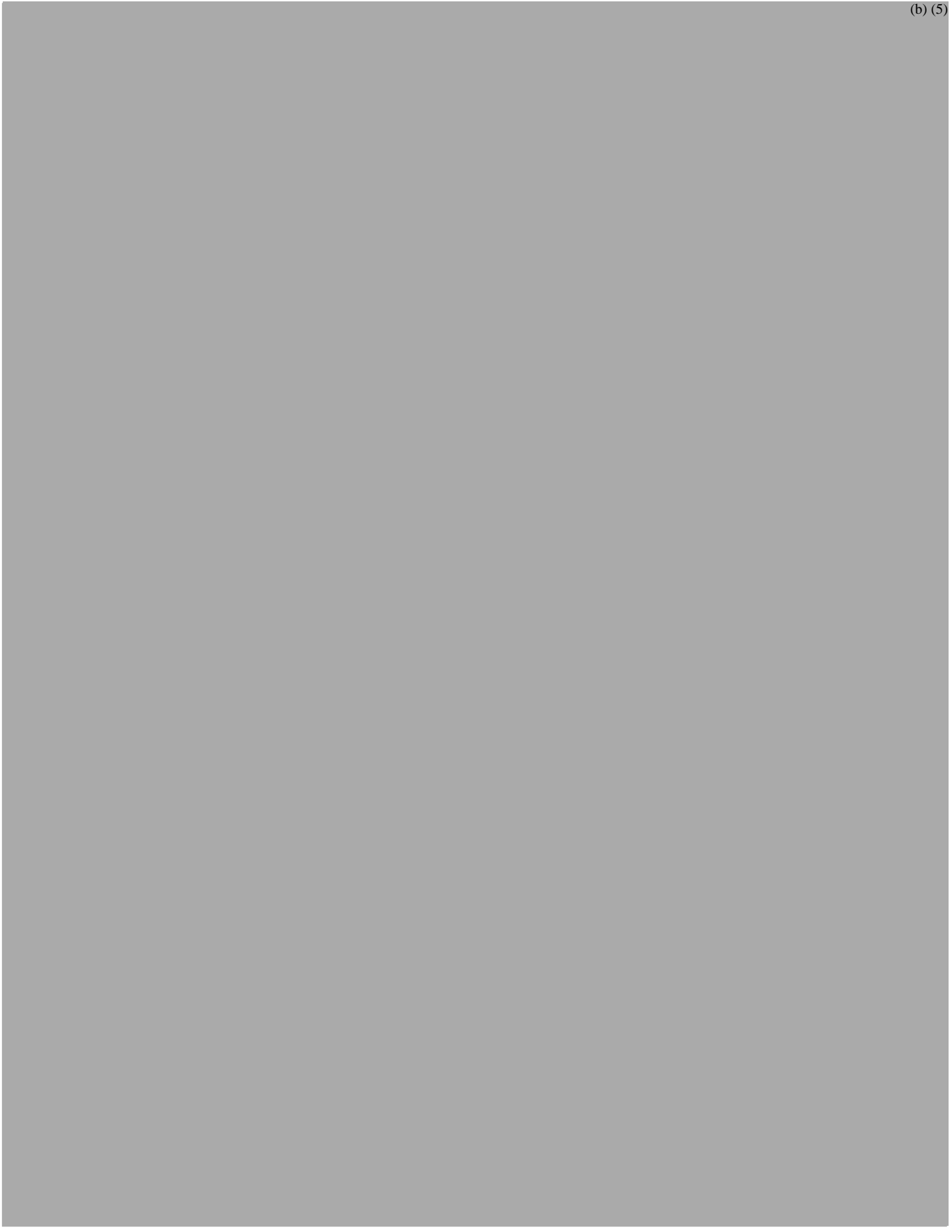




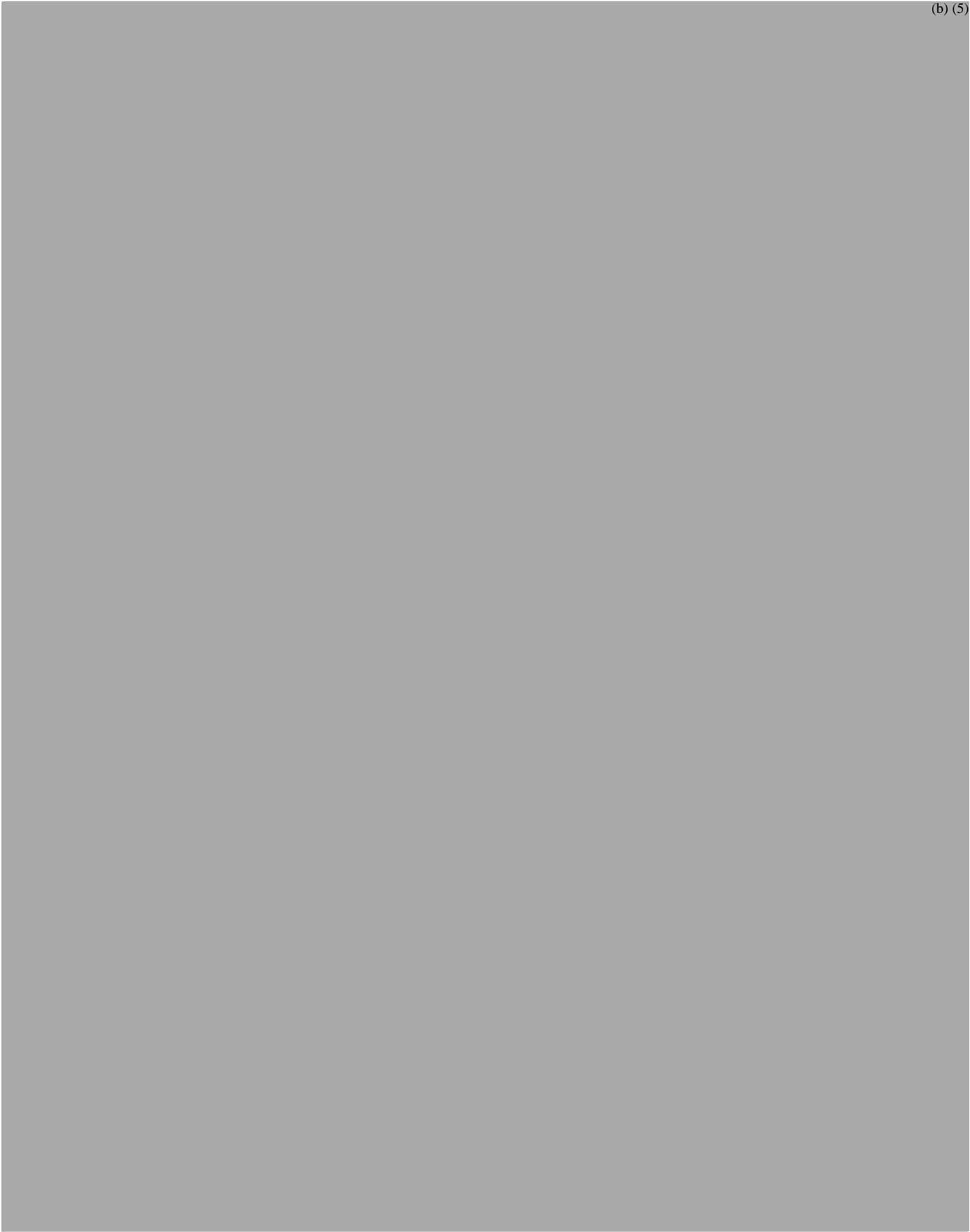




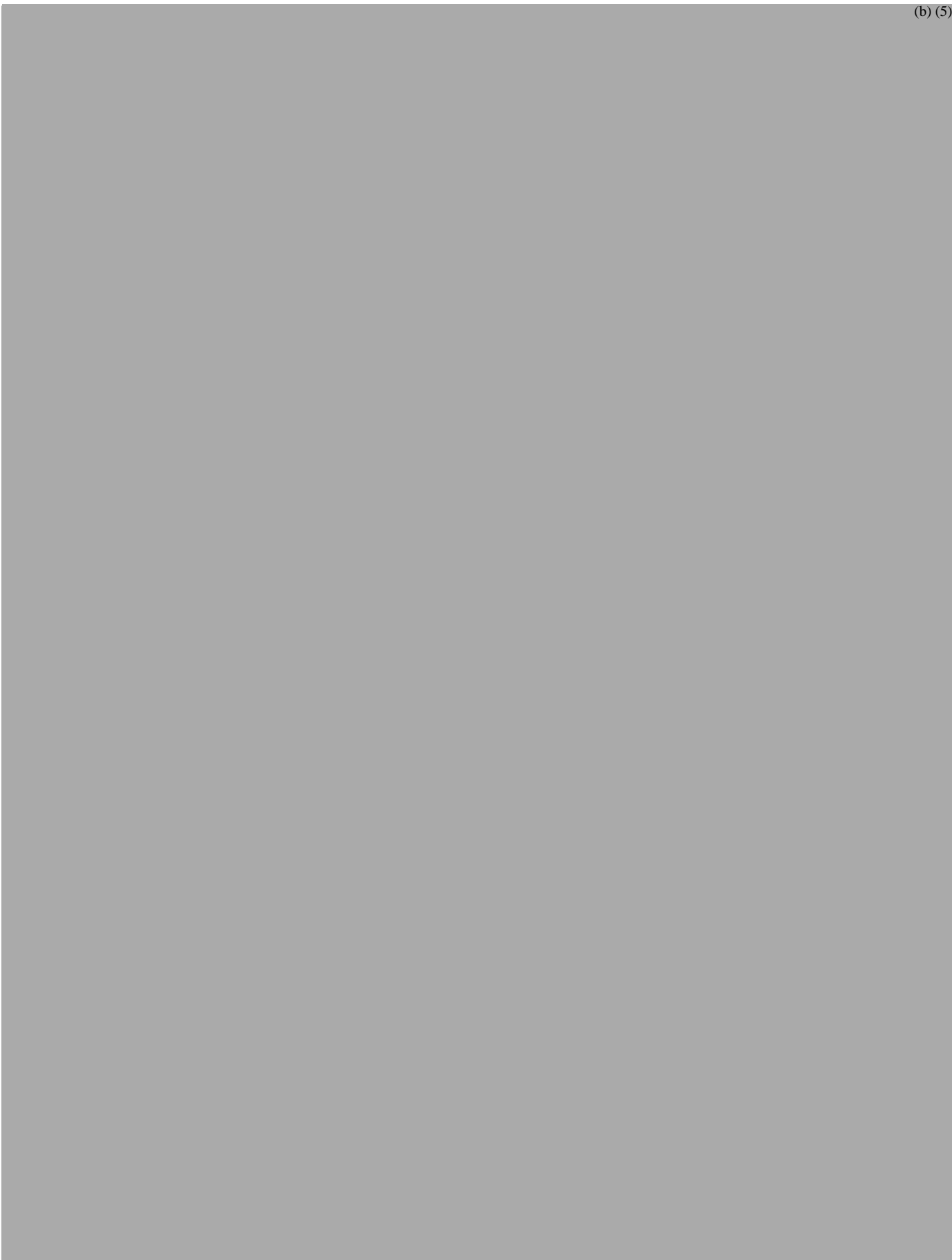


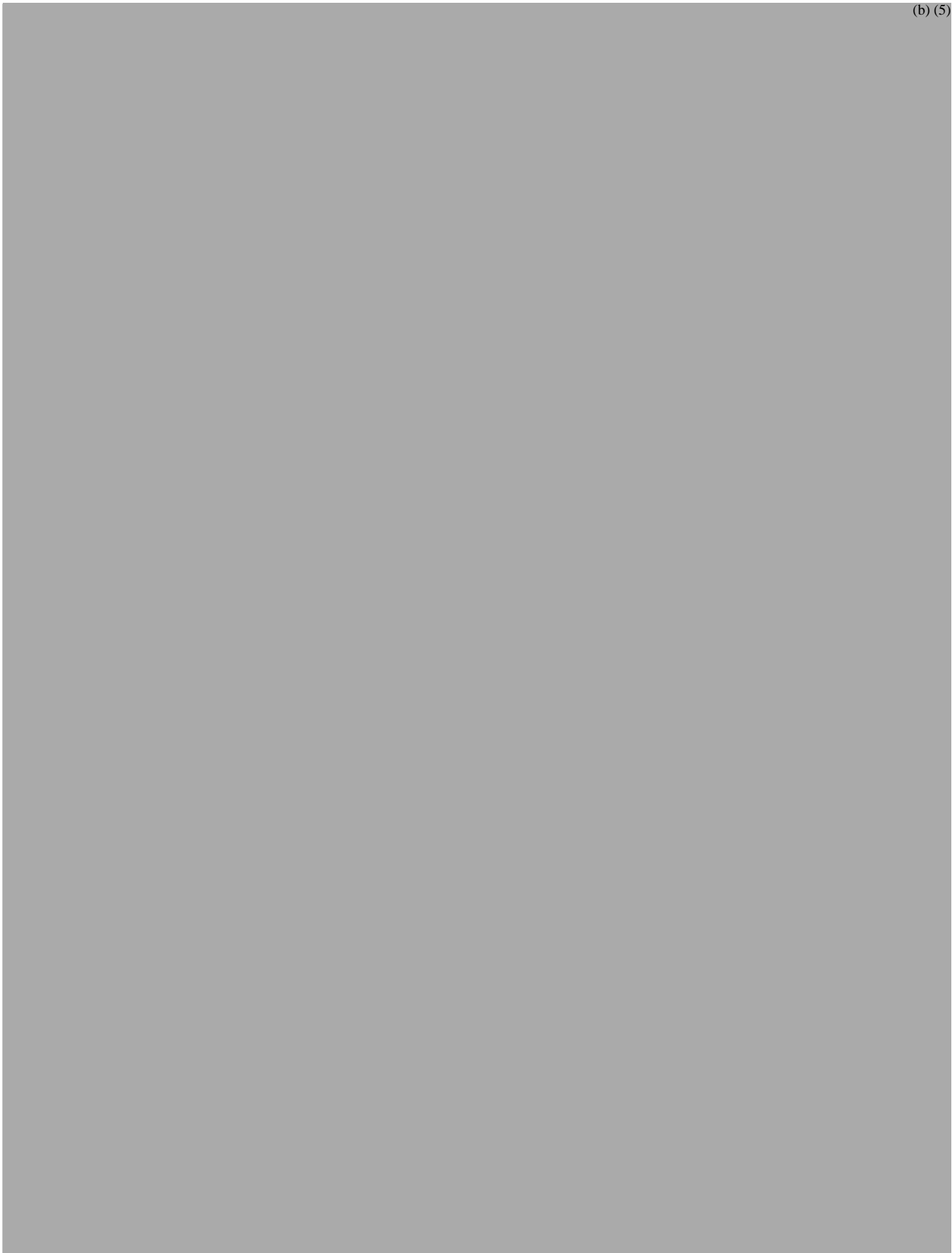


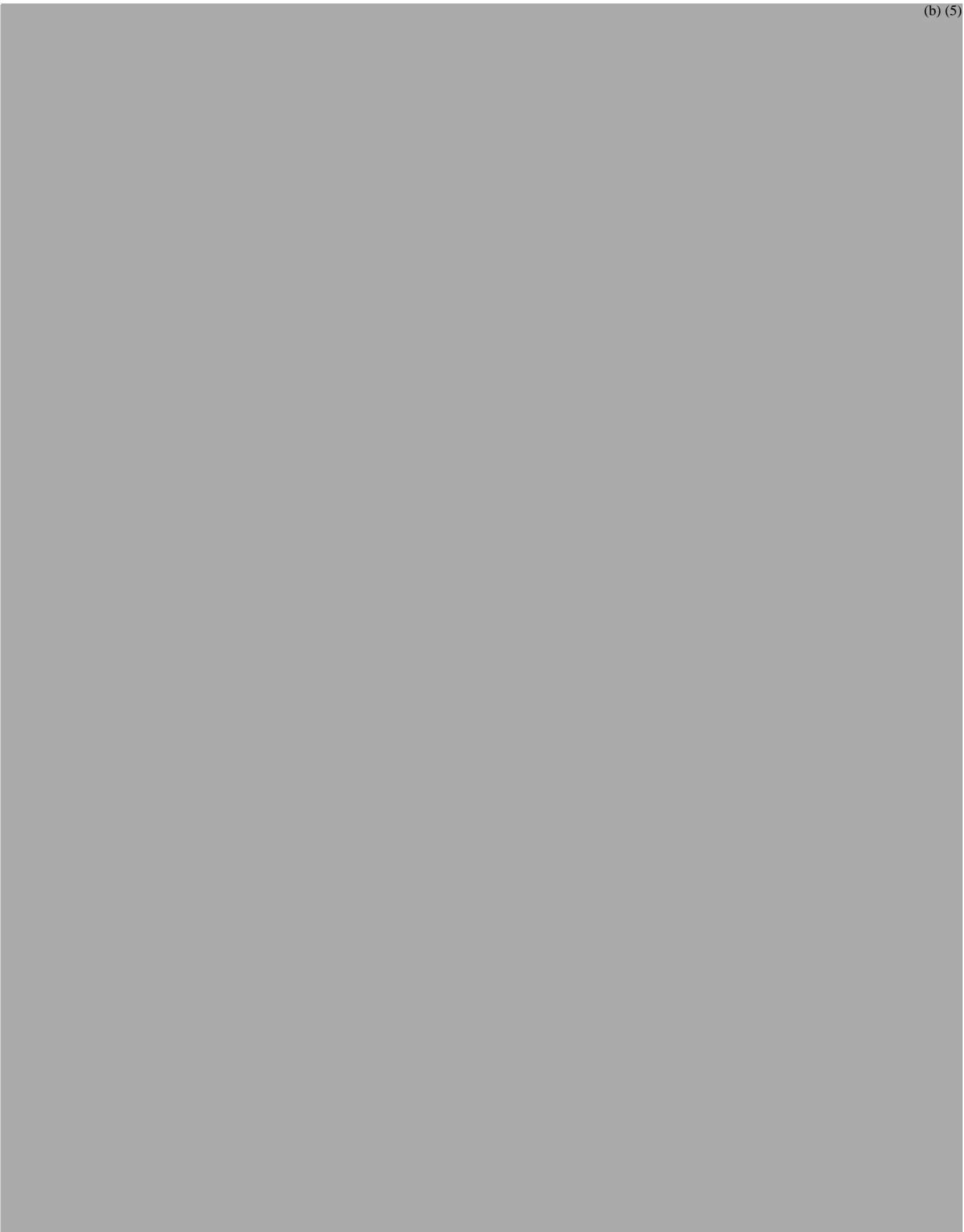




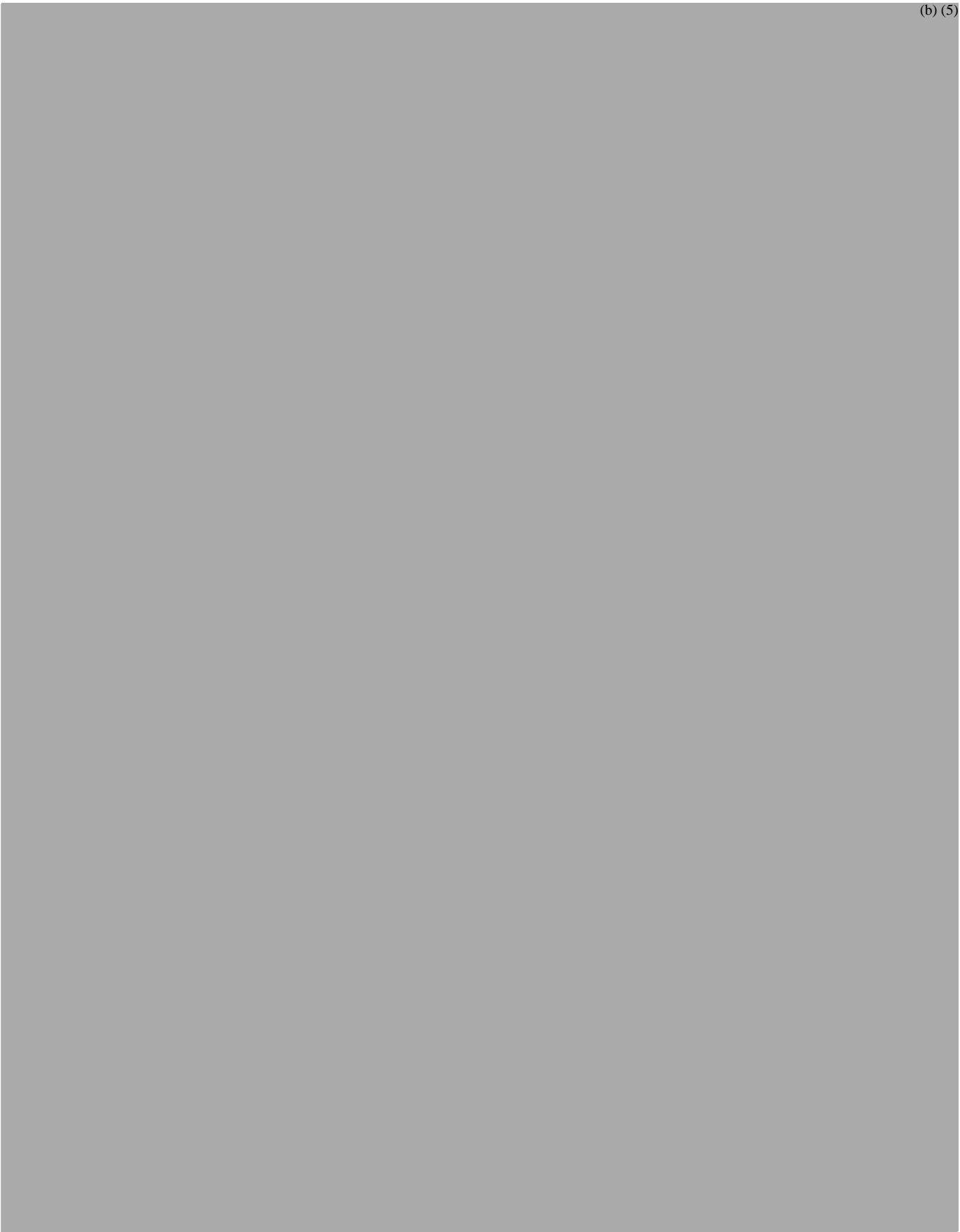


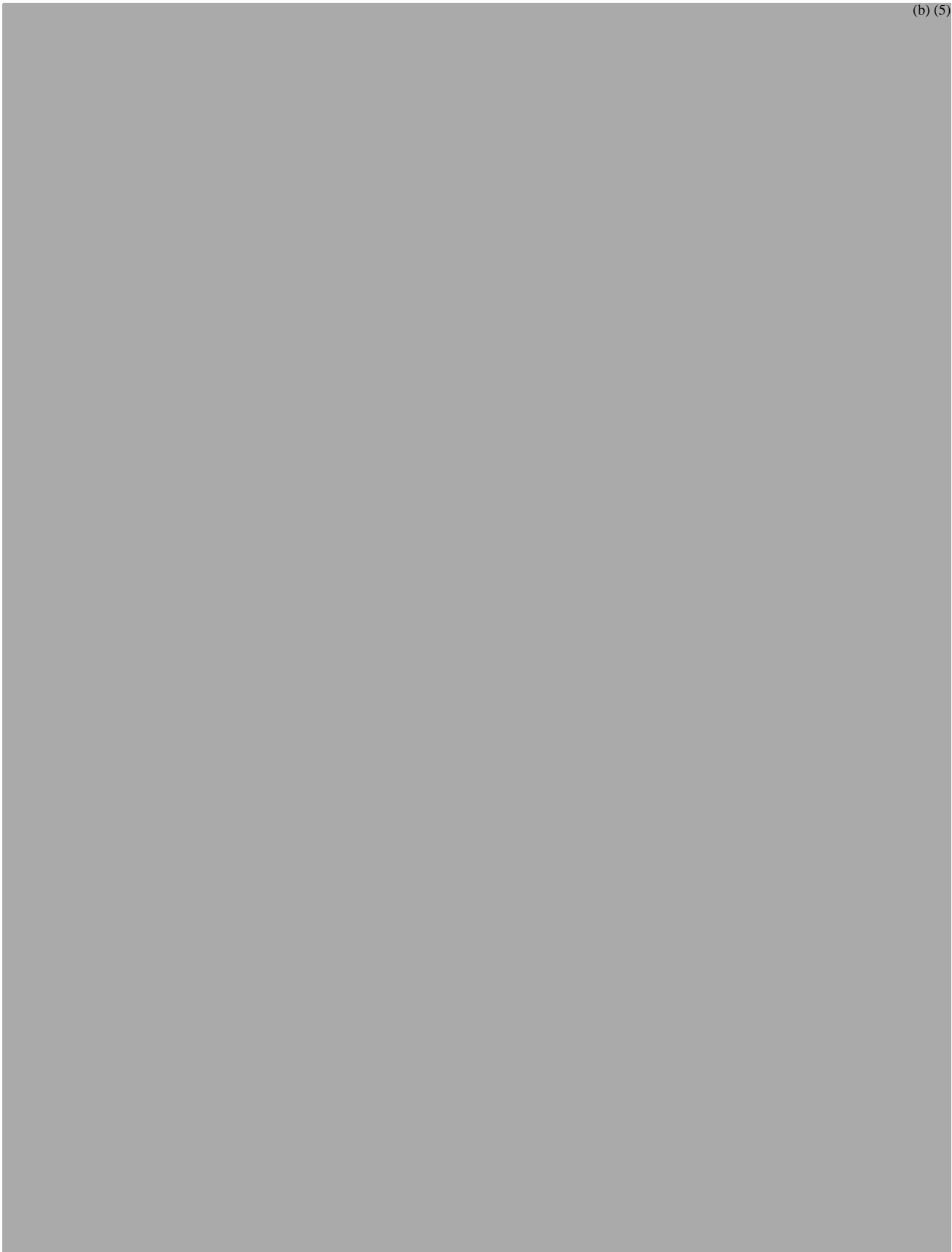


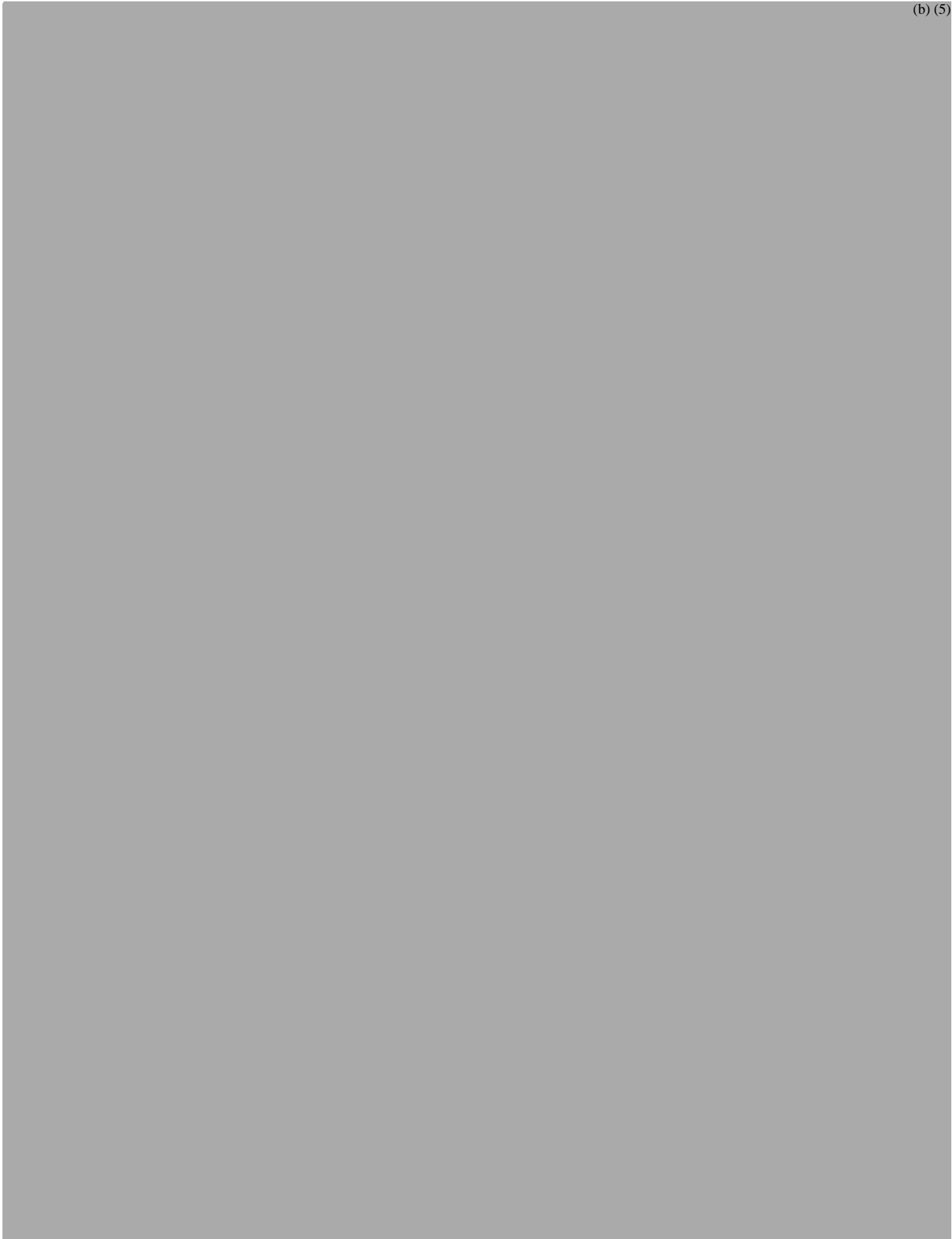


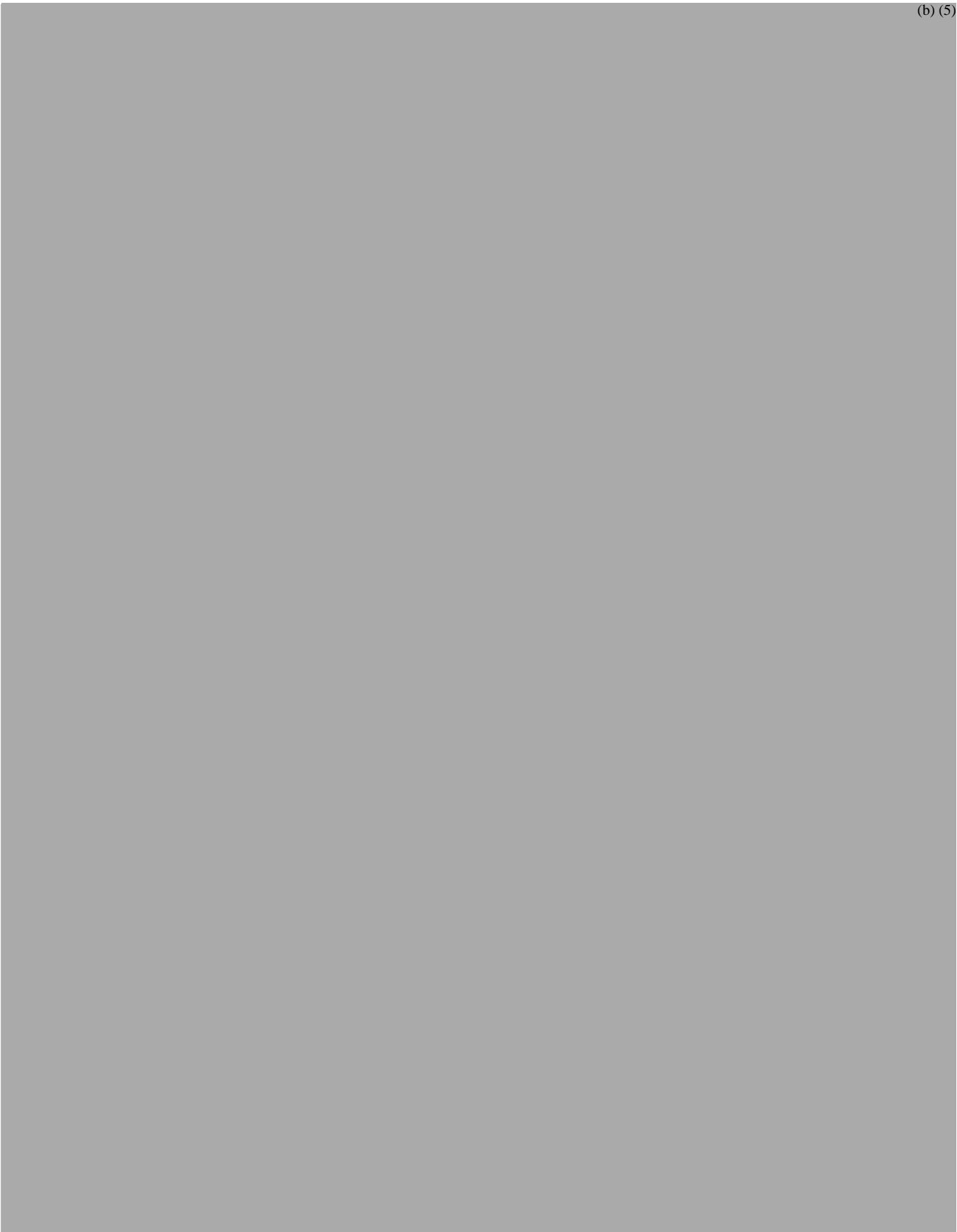


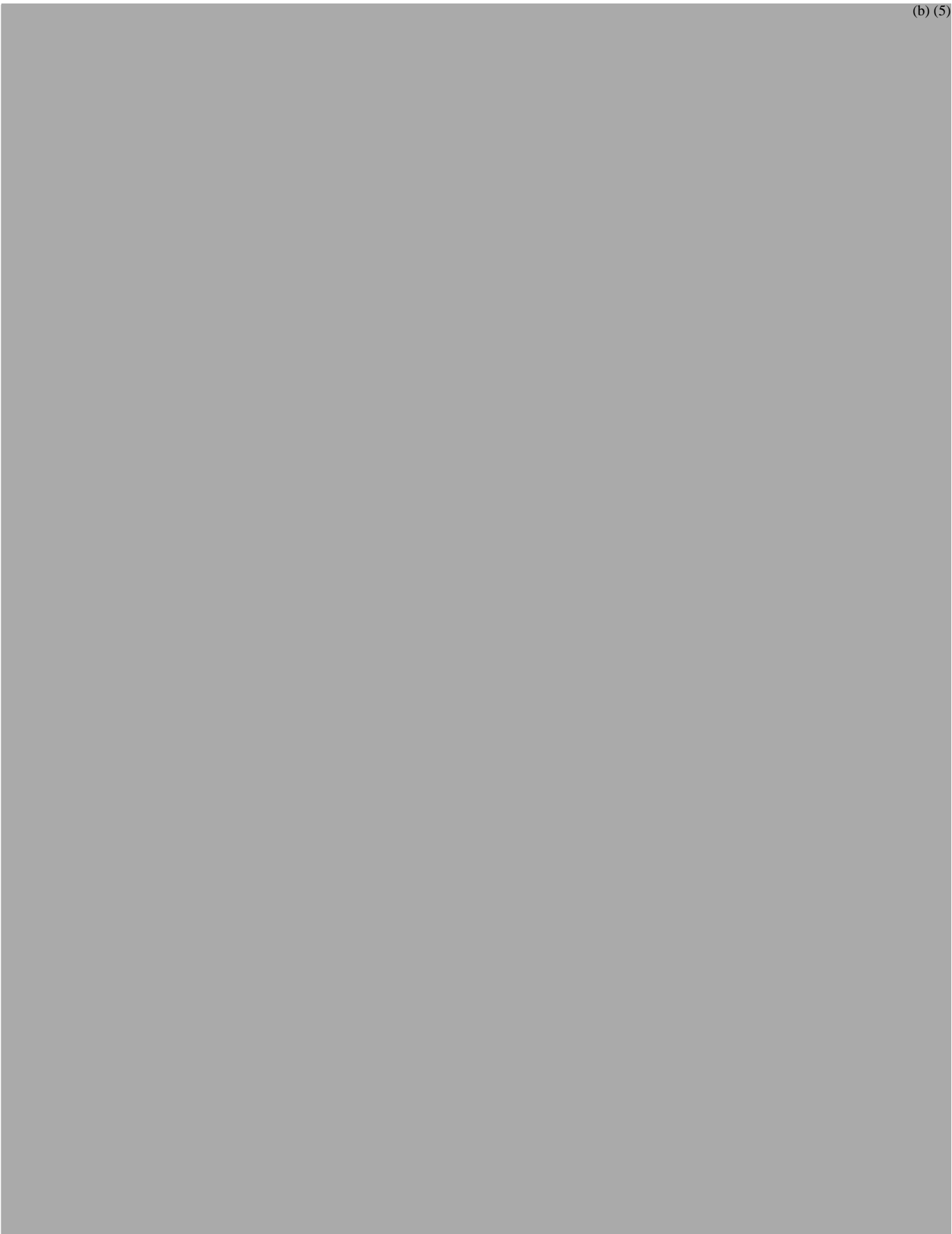


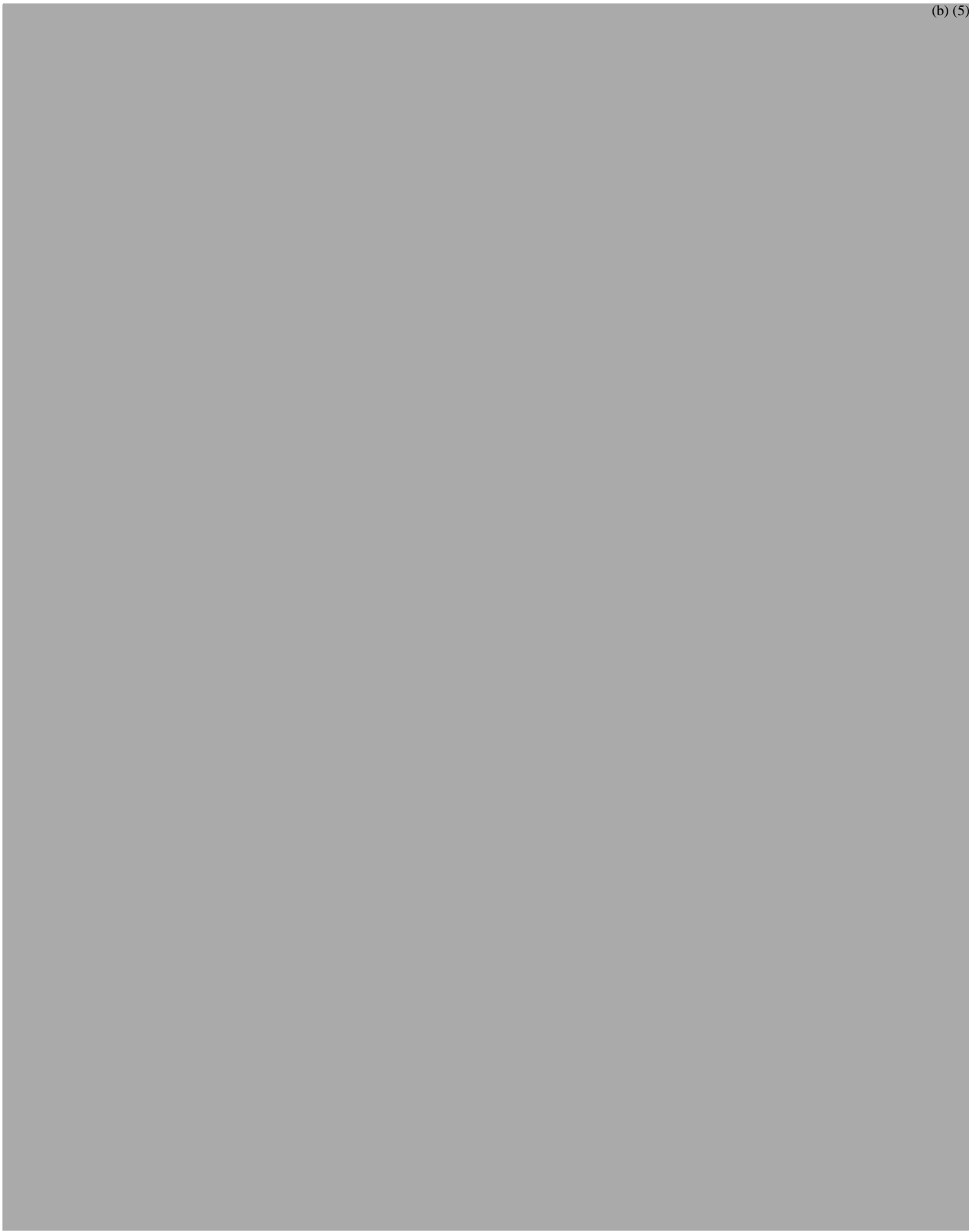


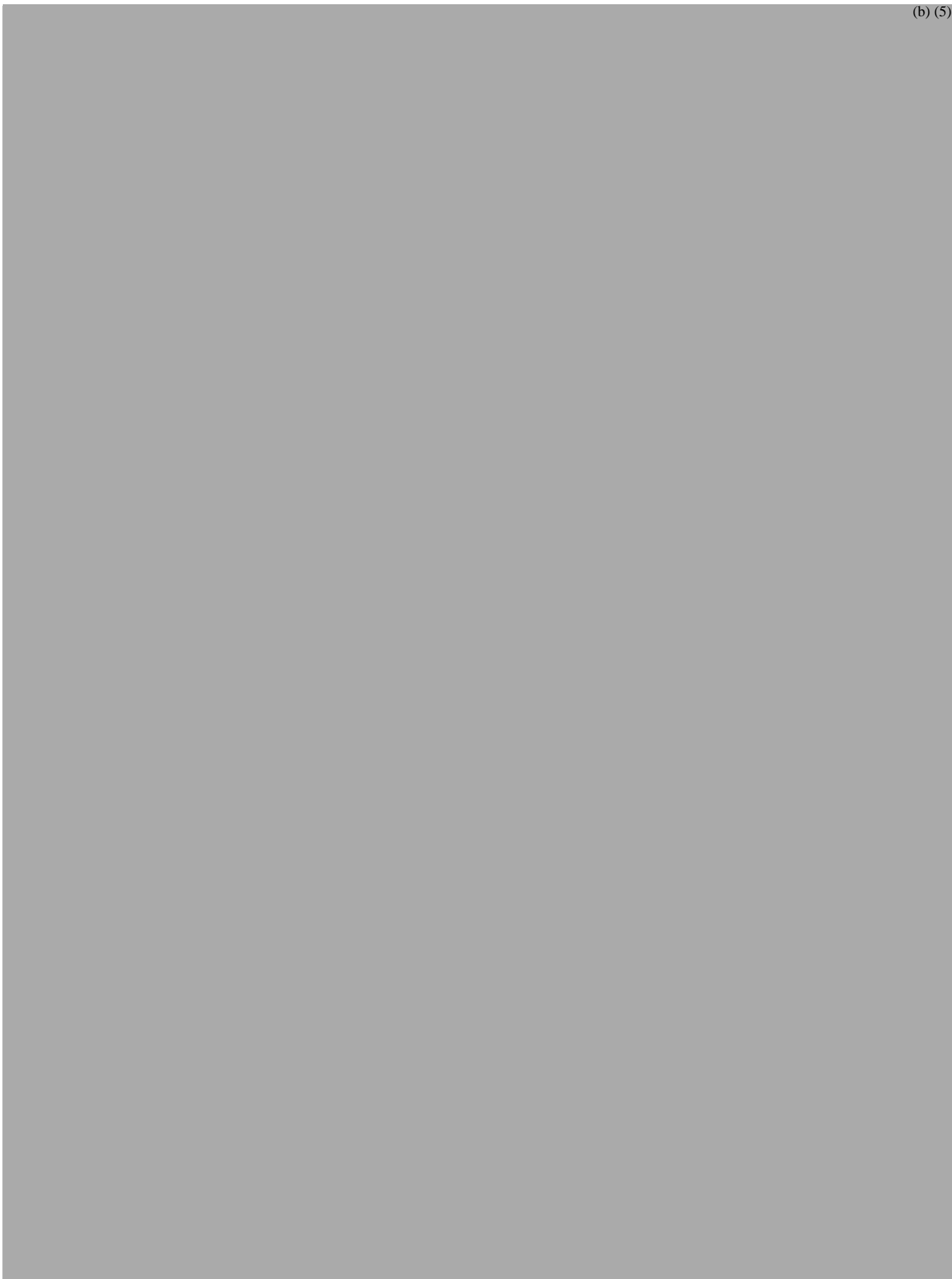




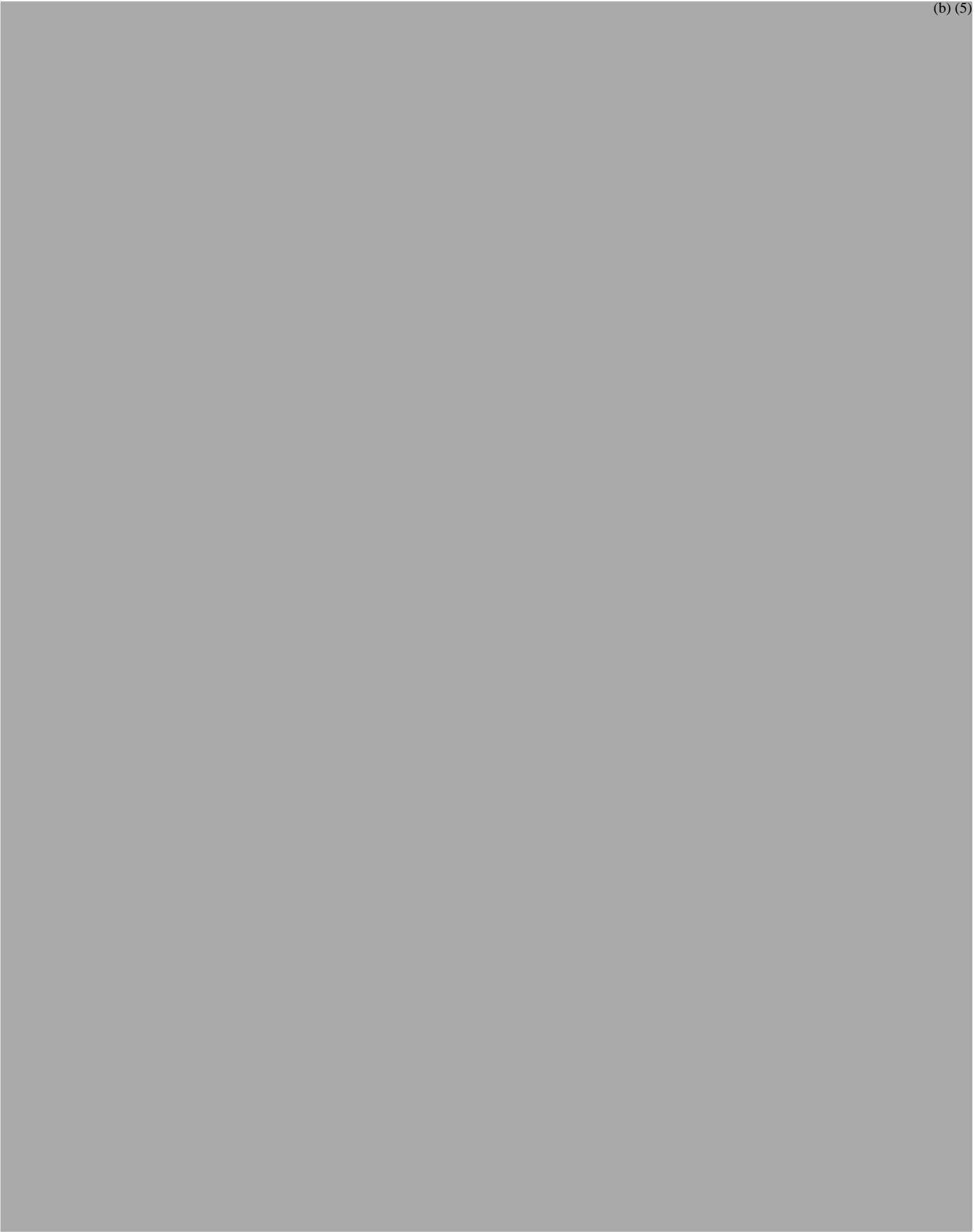


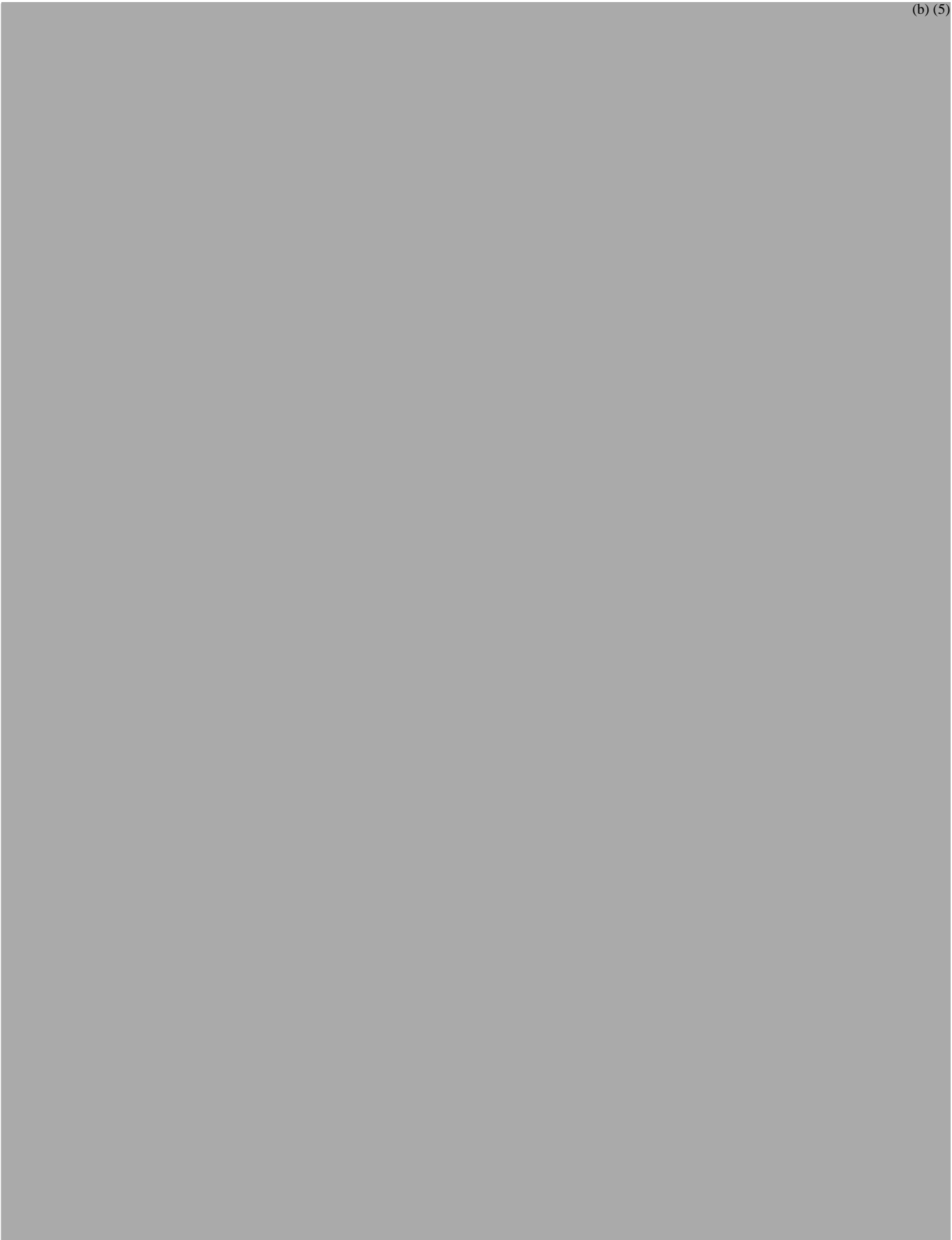






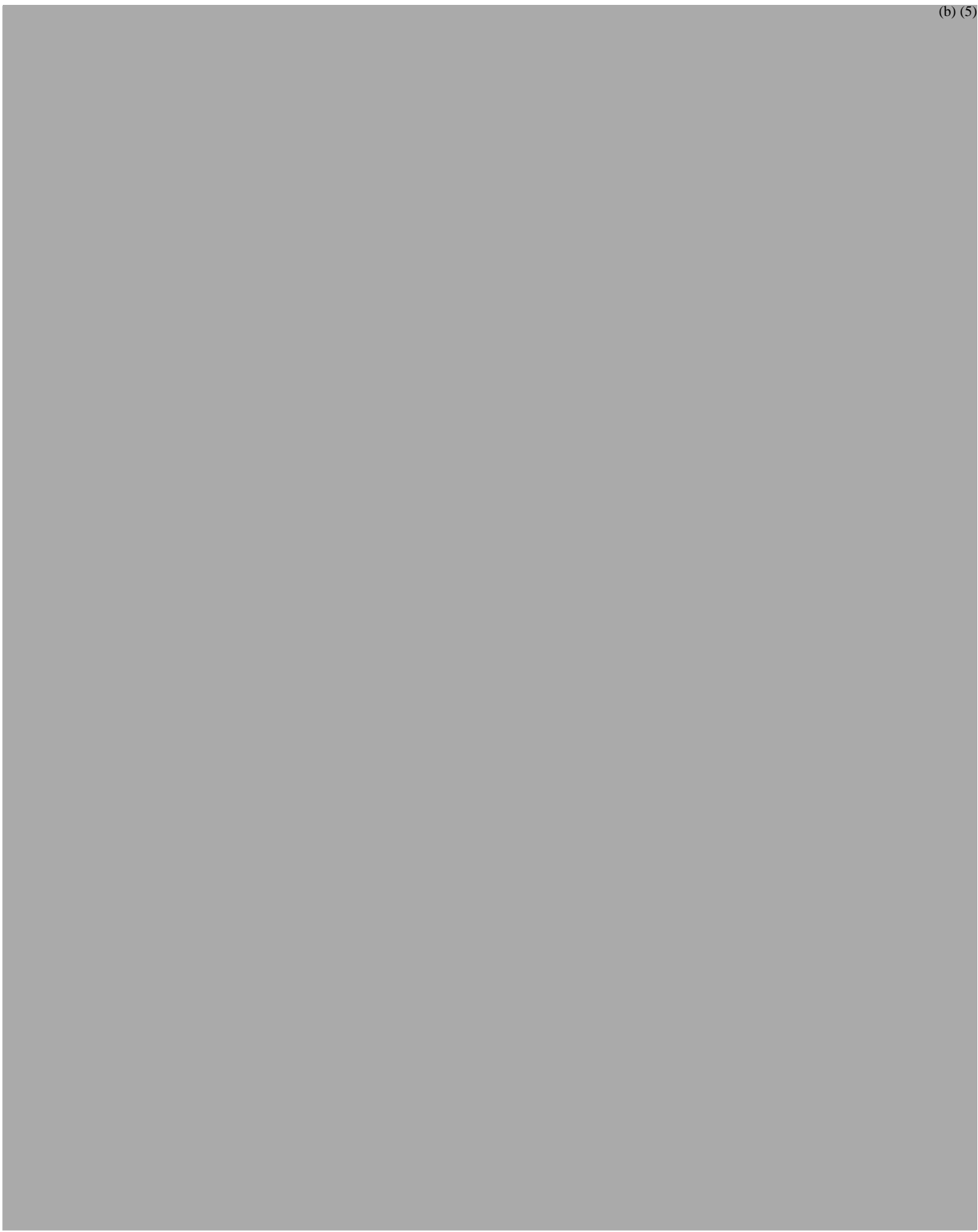










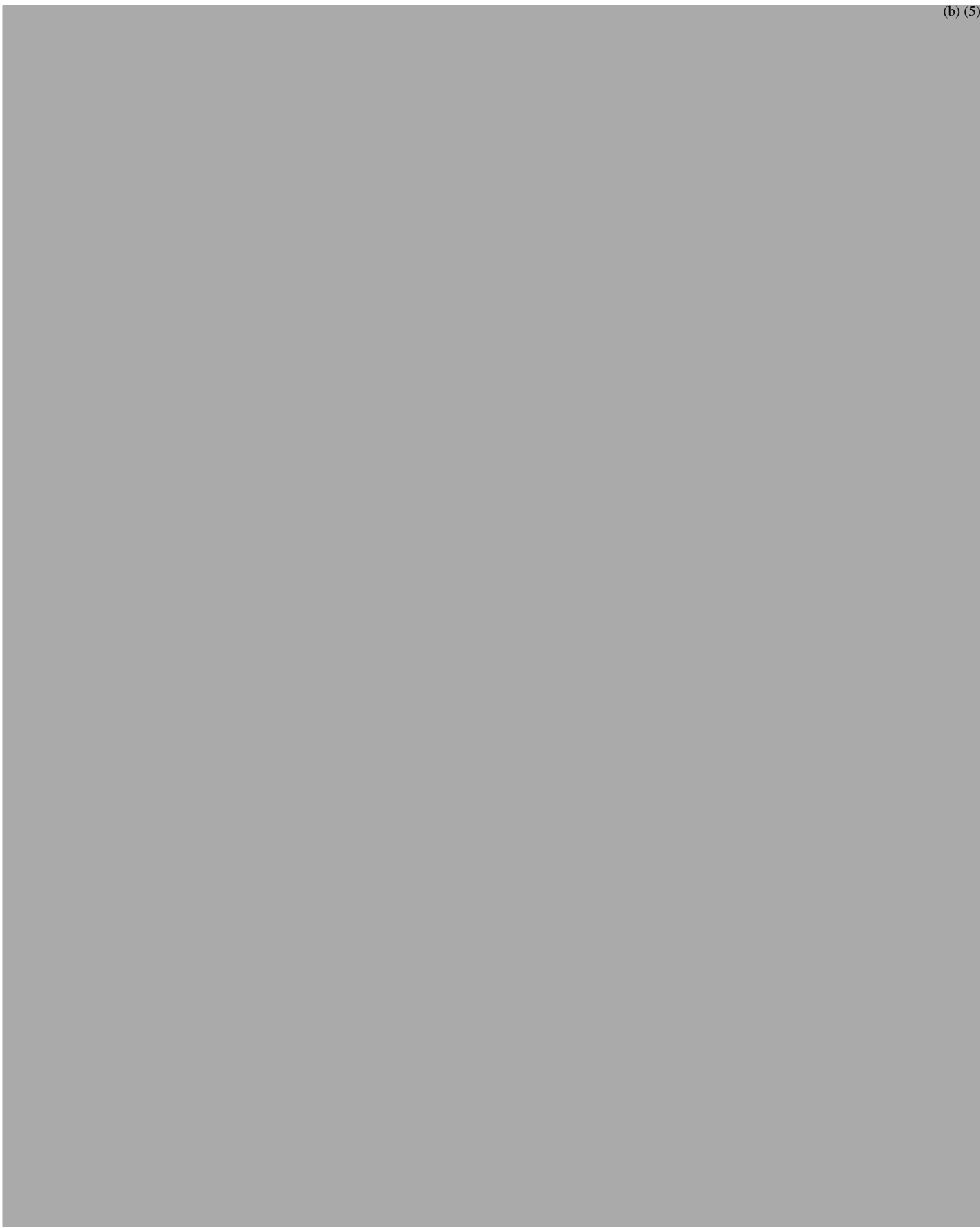










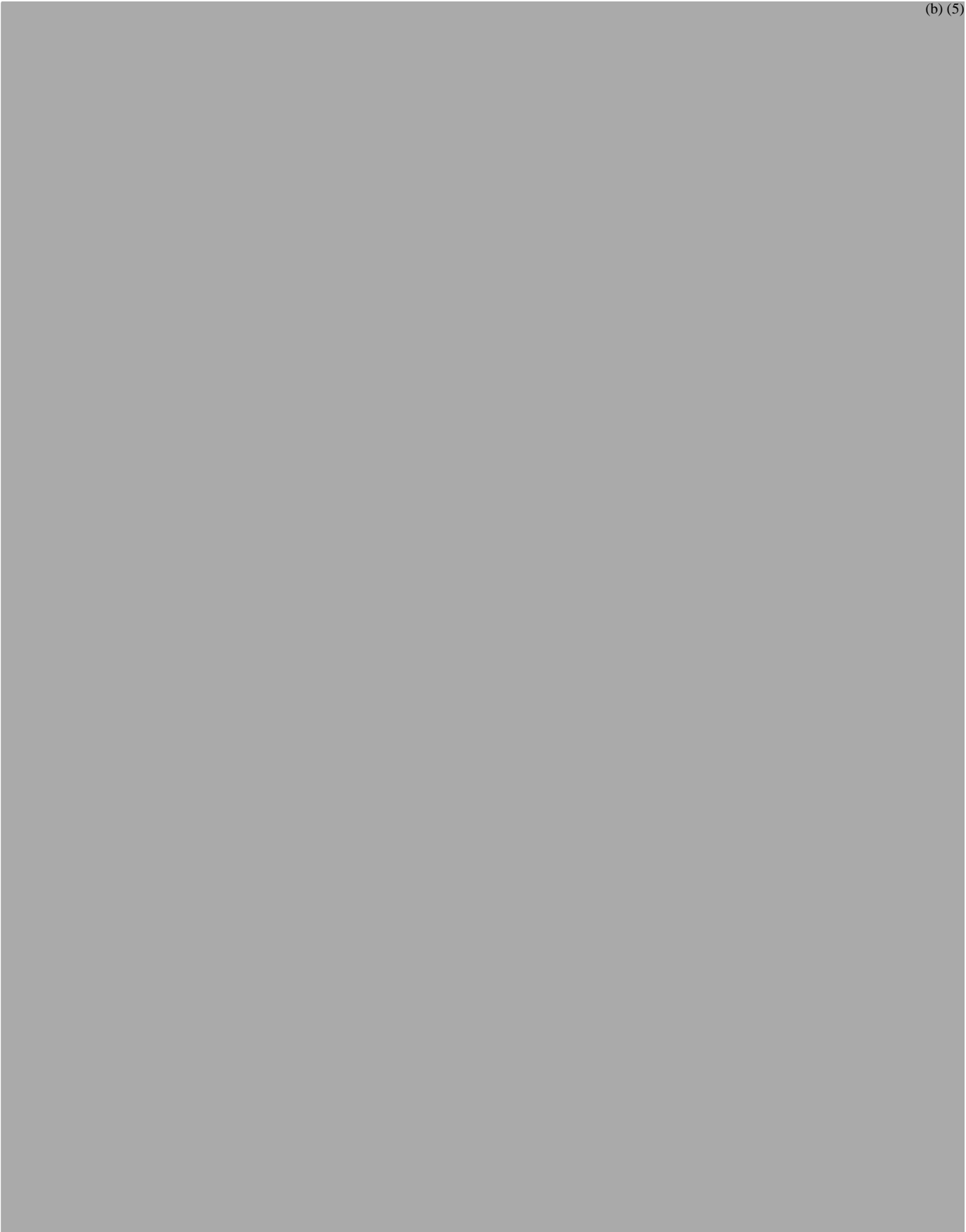


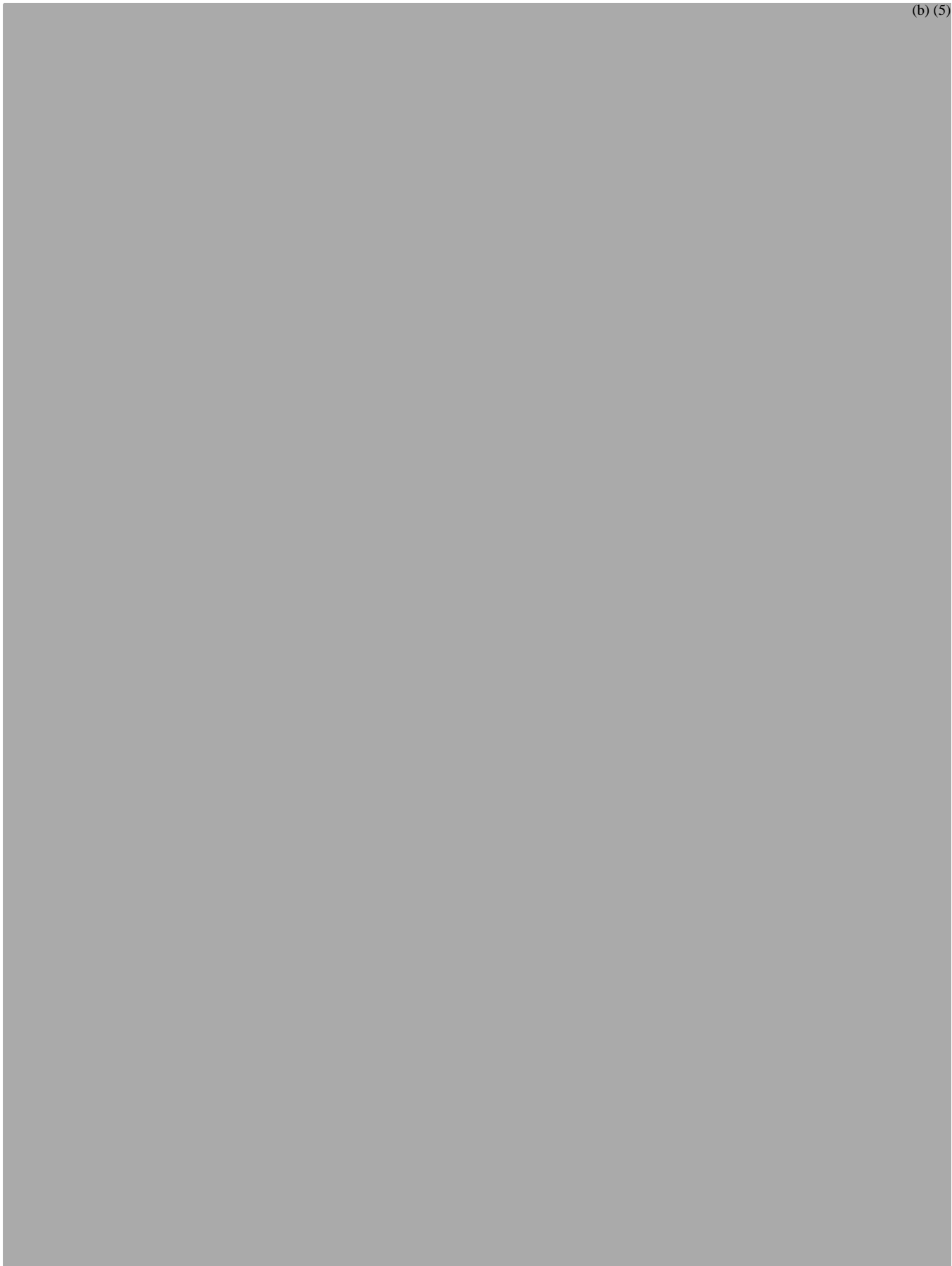




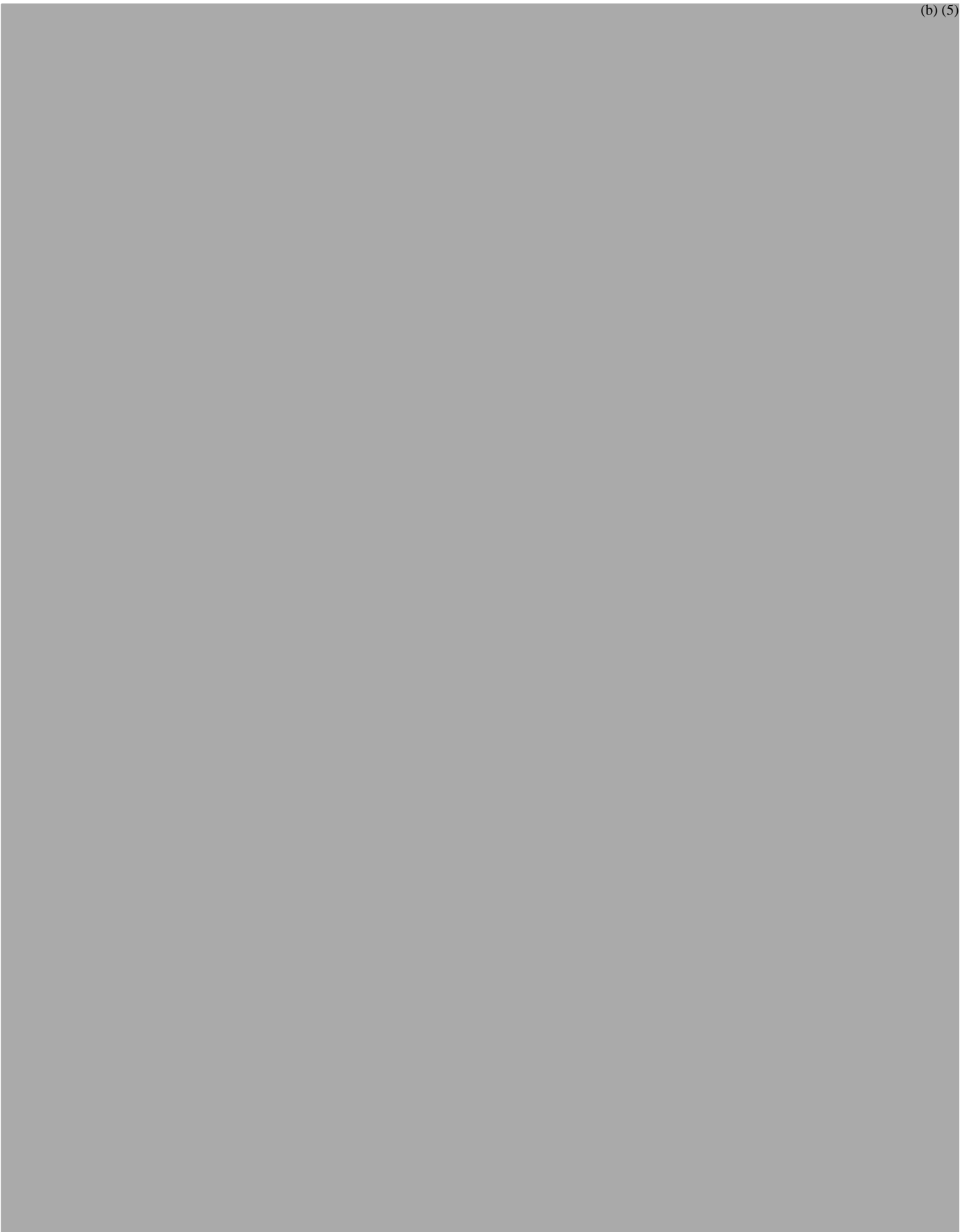


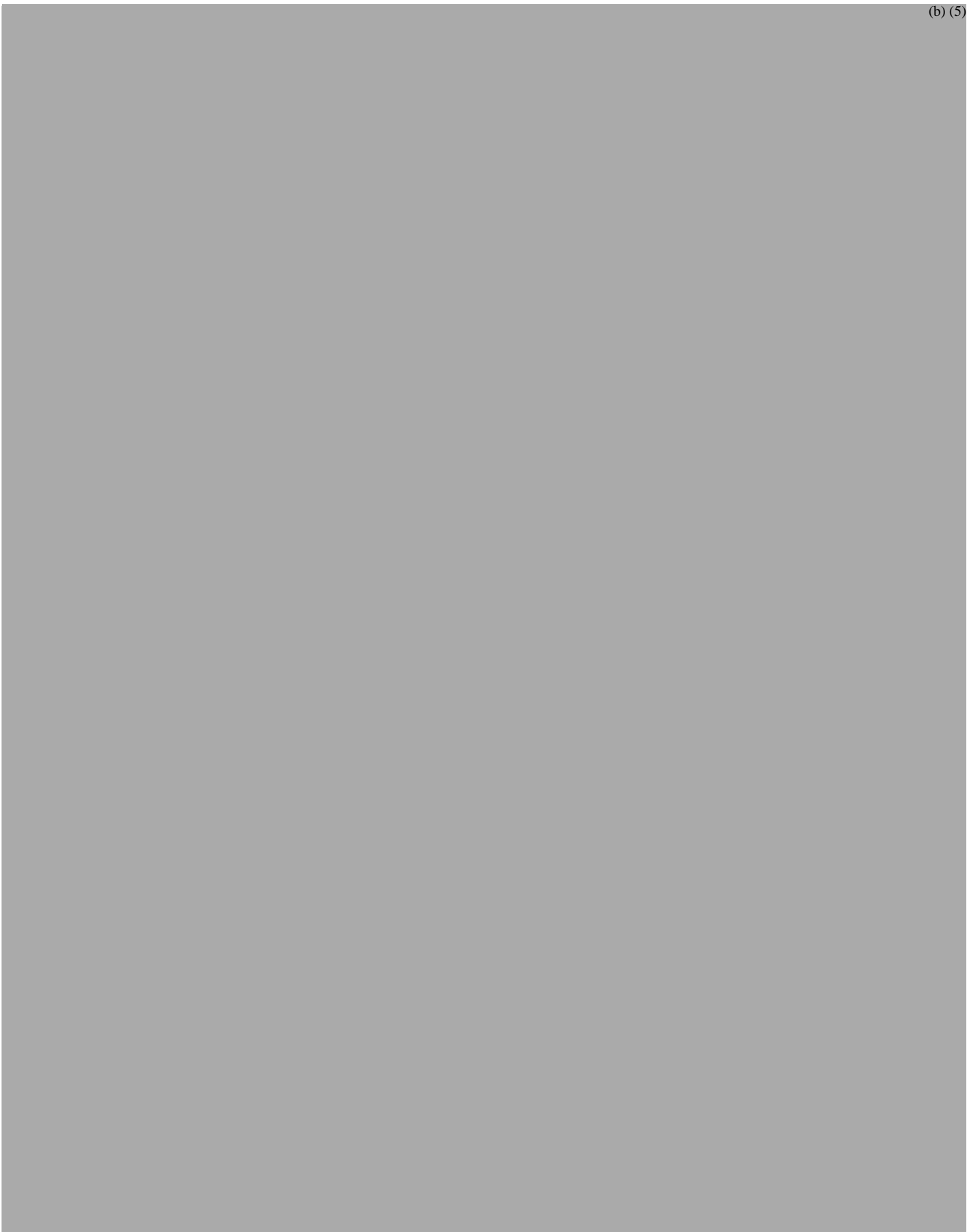


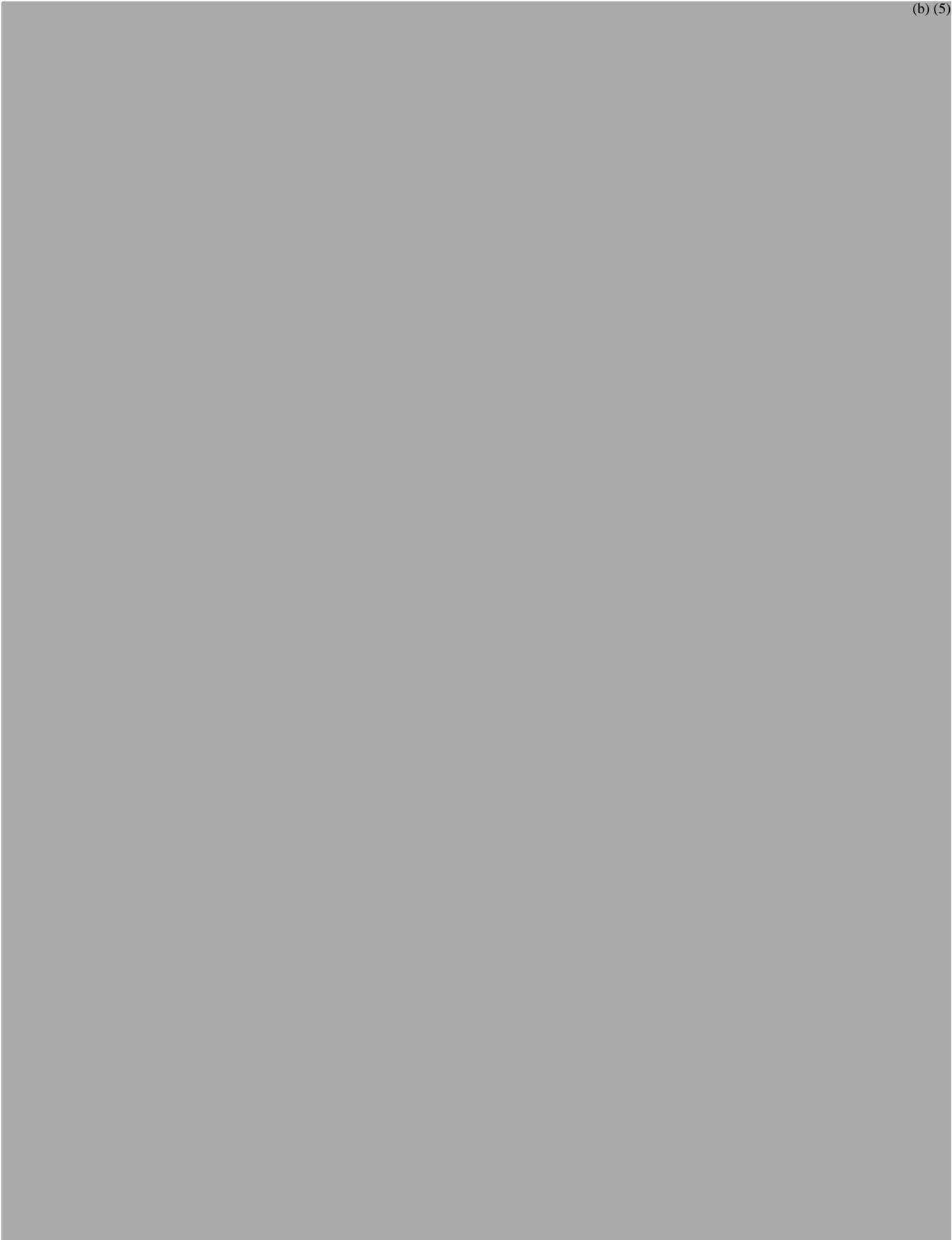


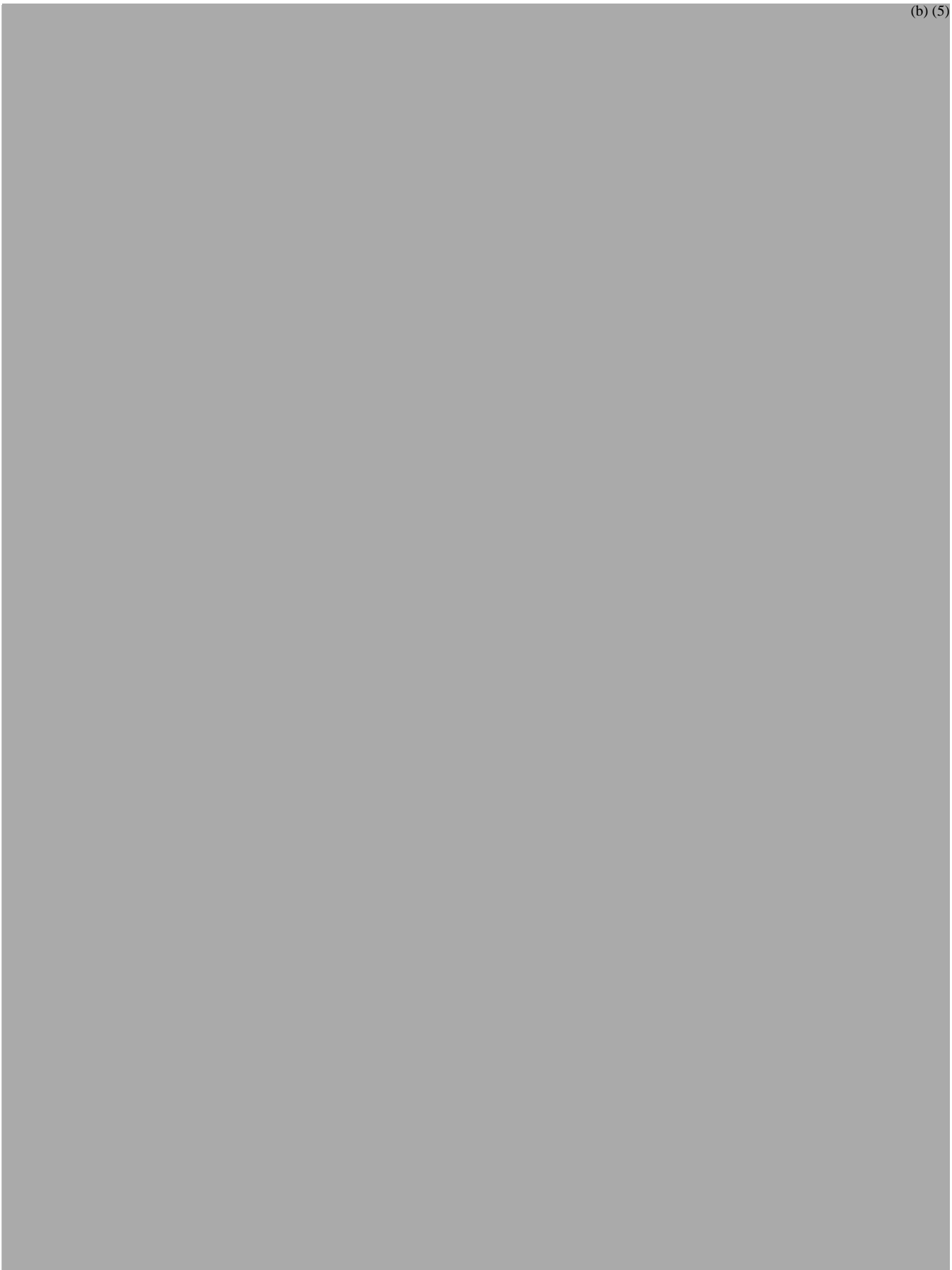




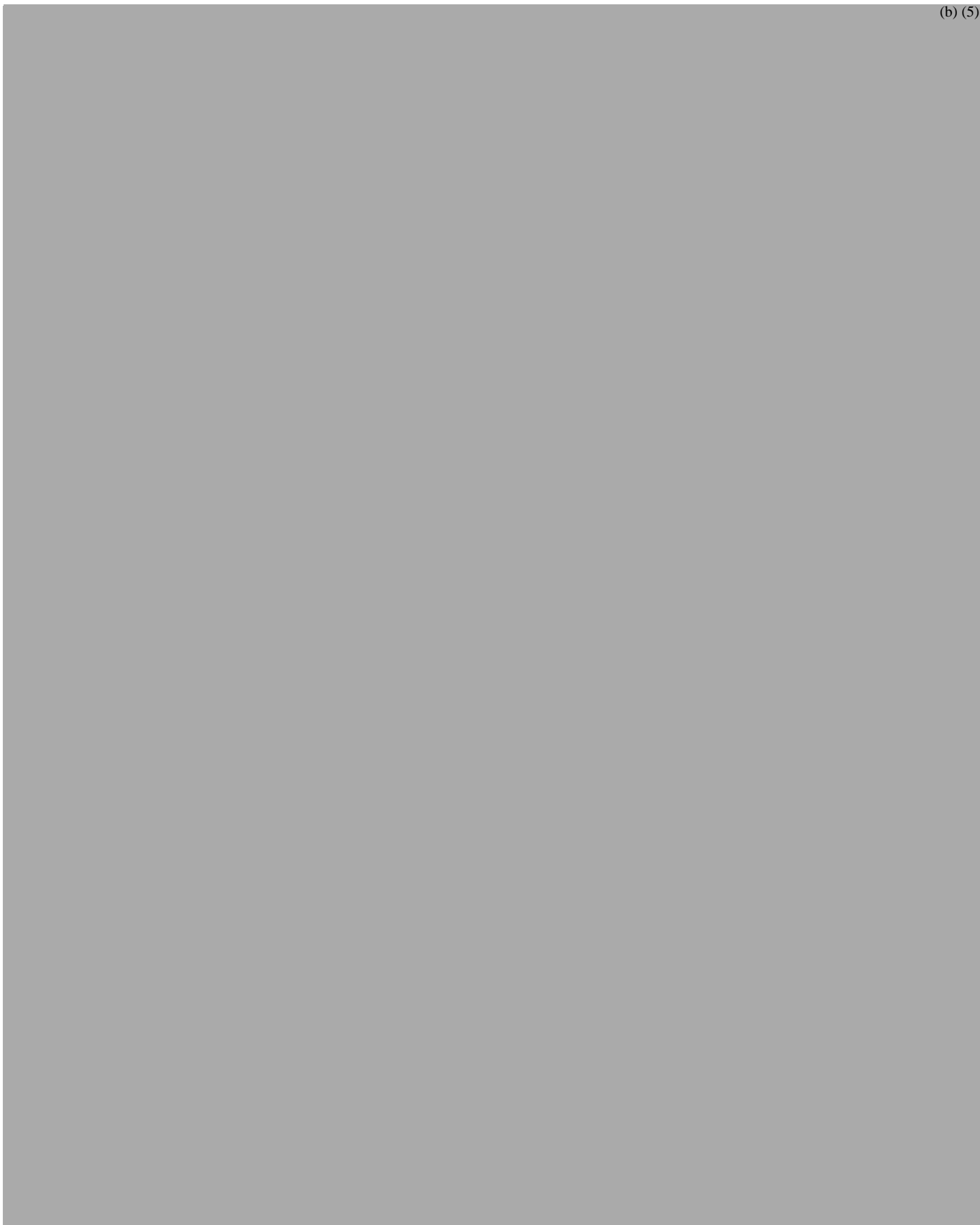




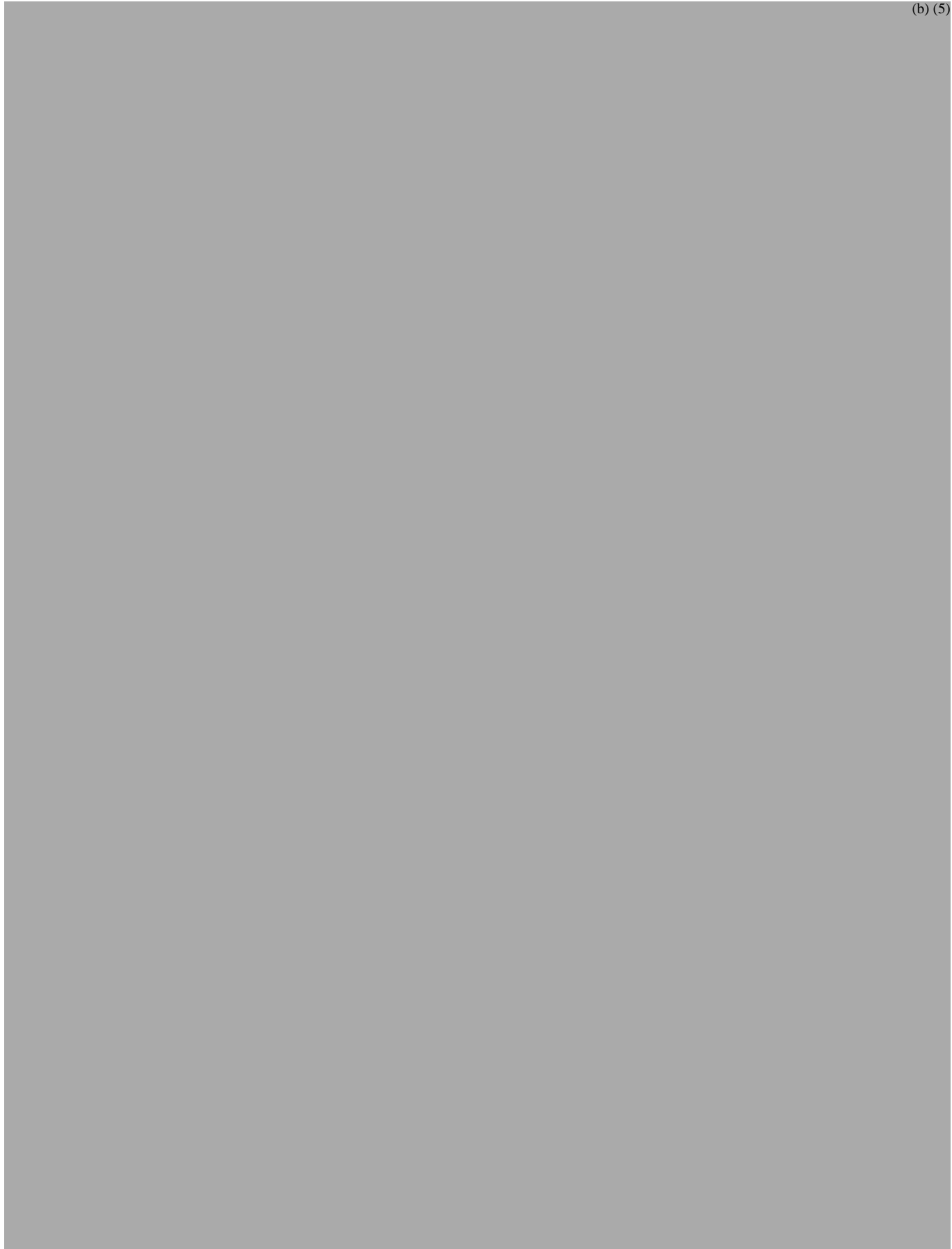




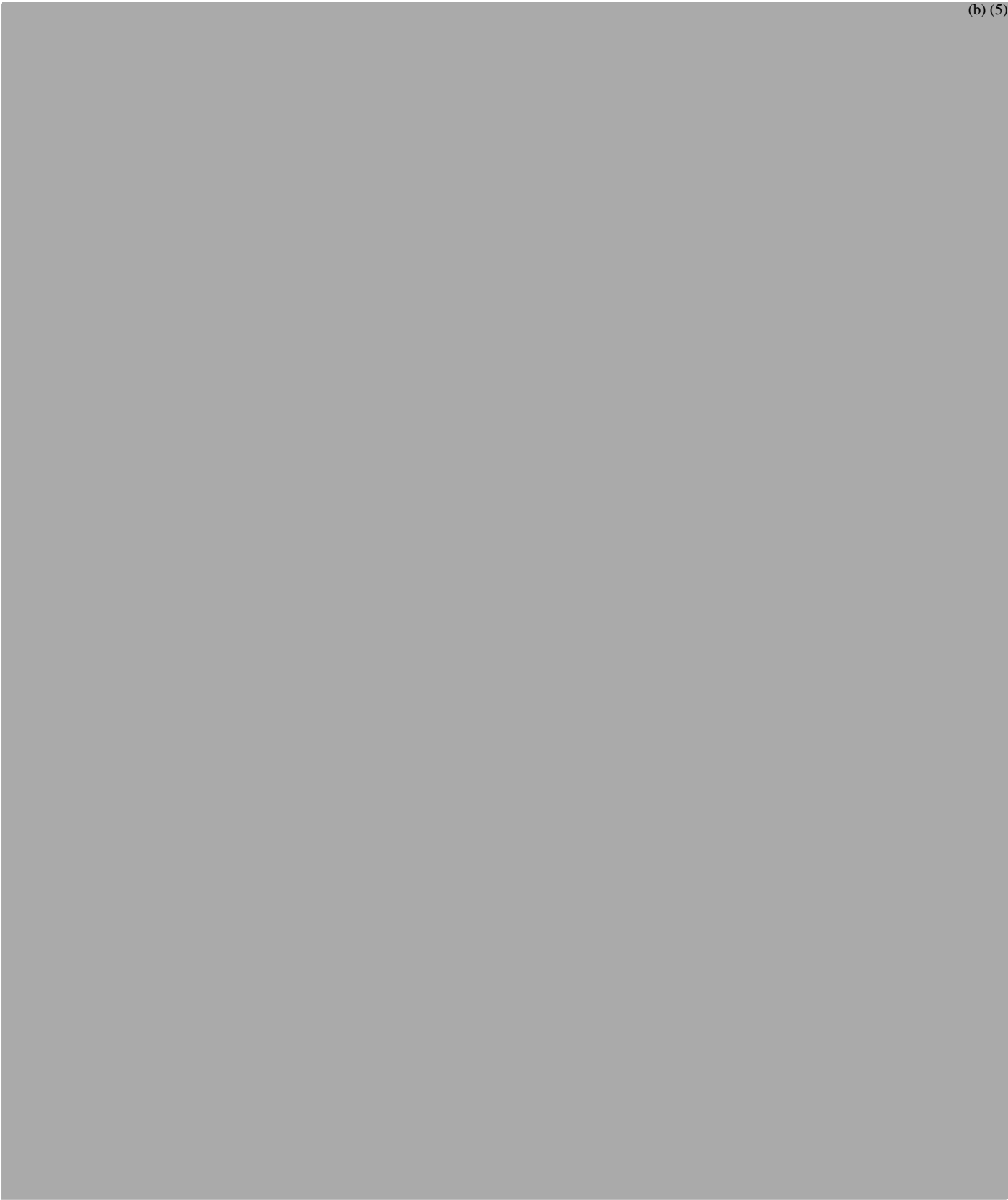


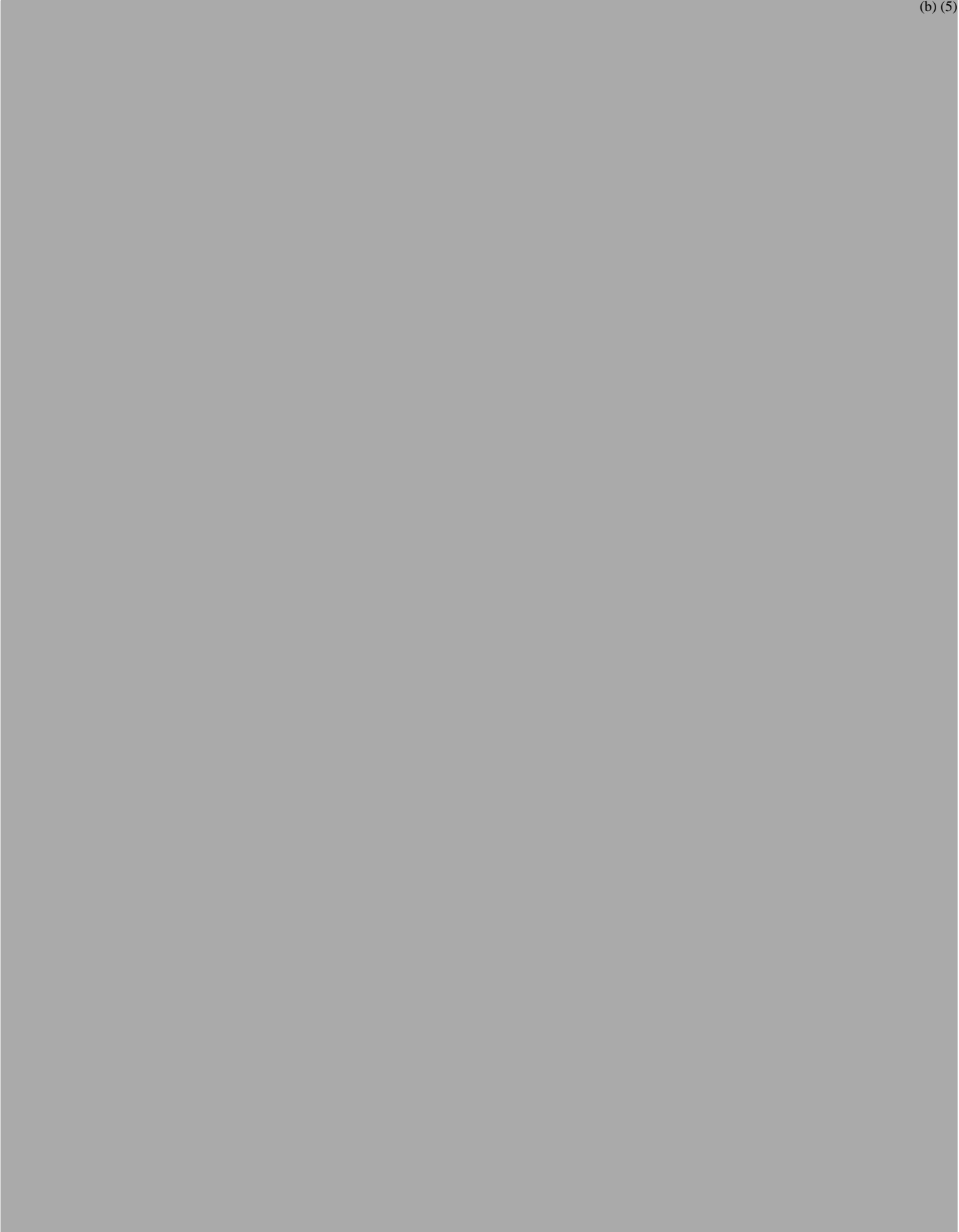










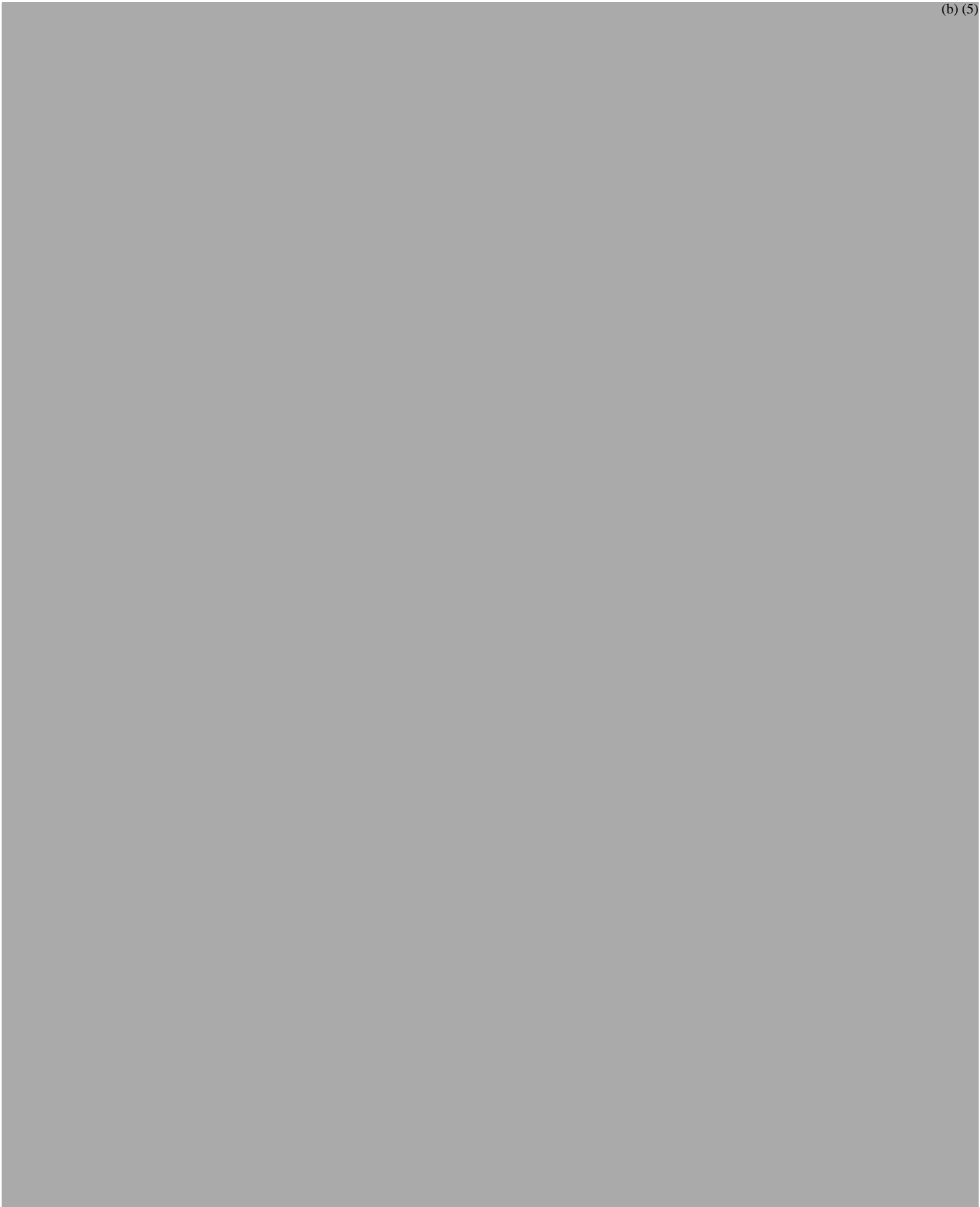




Appendix I:
Funding for Chronic Diseases and Organ Systems



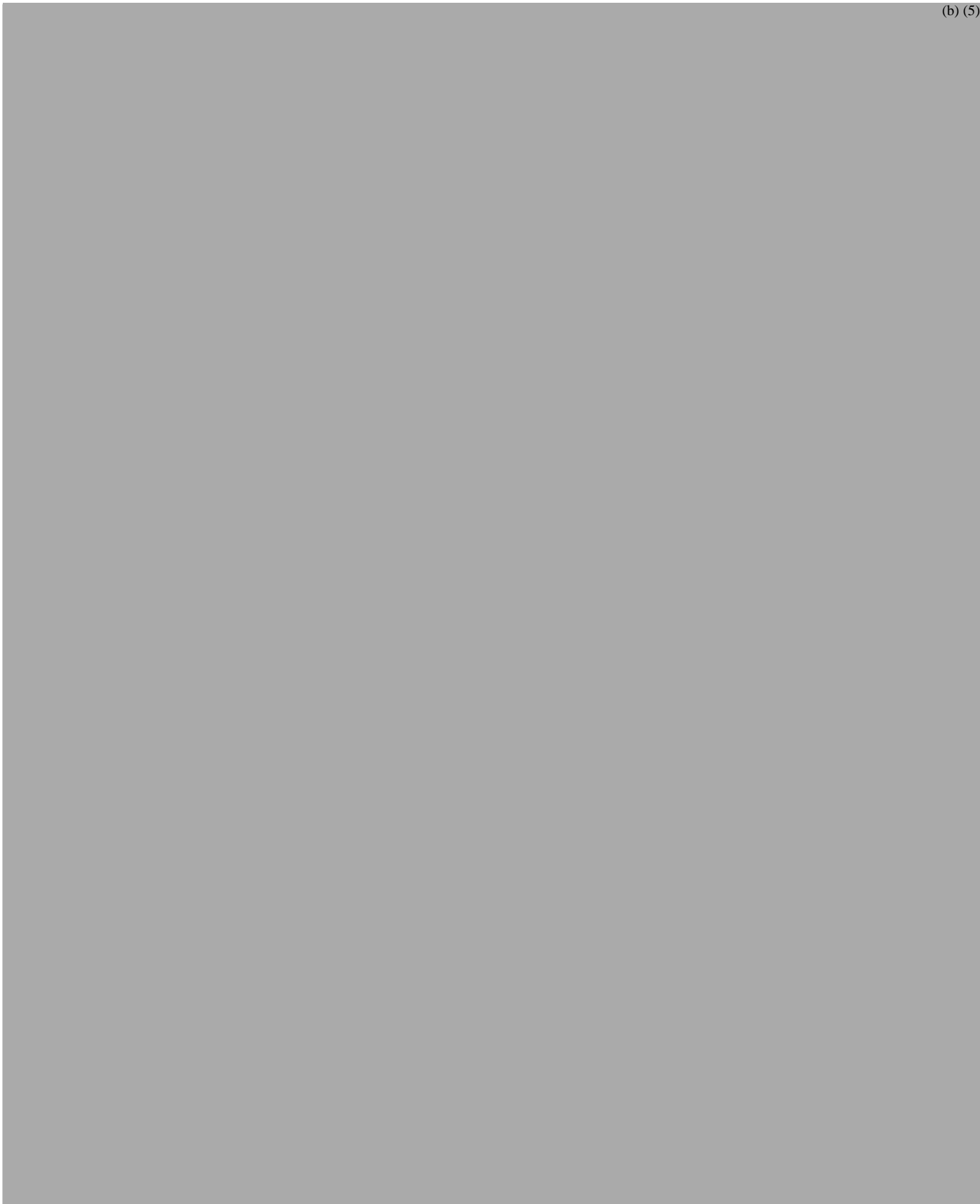












Appendix J:

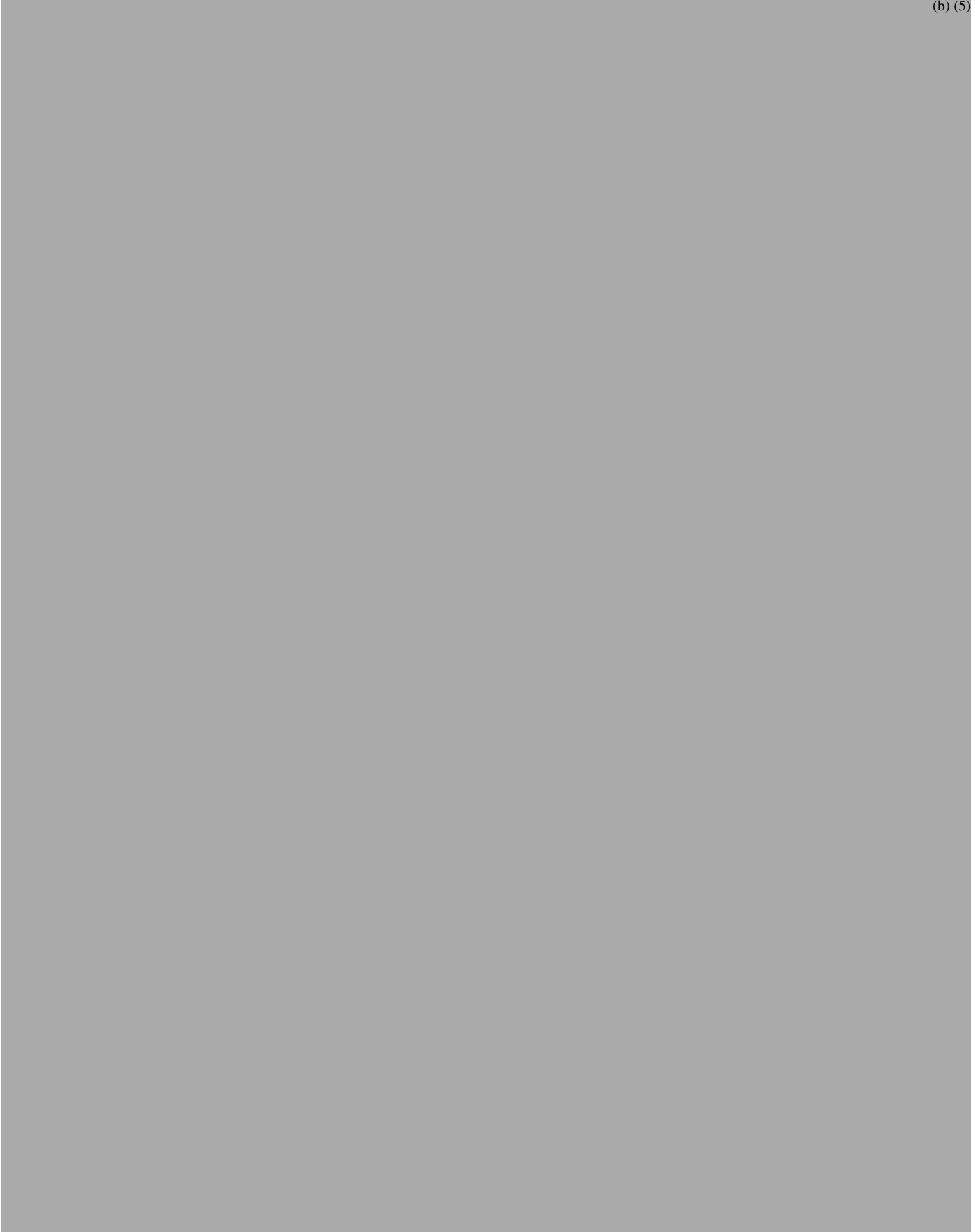
EUREKA Prize Competitions

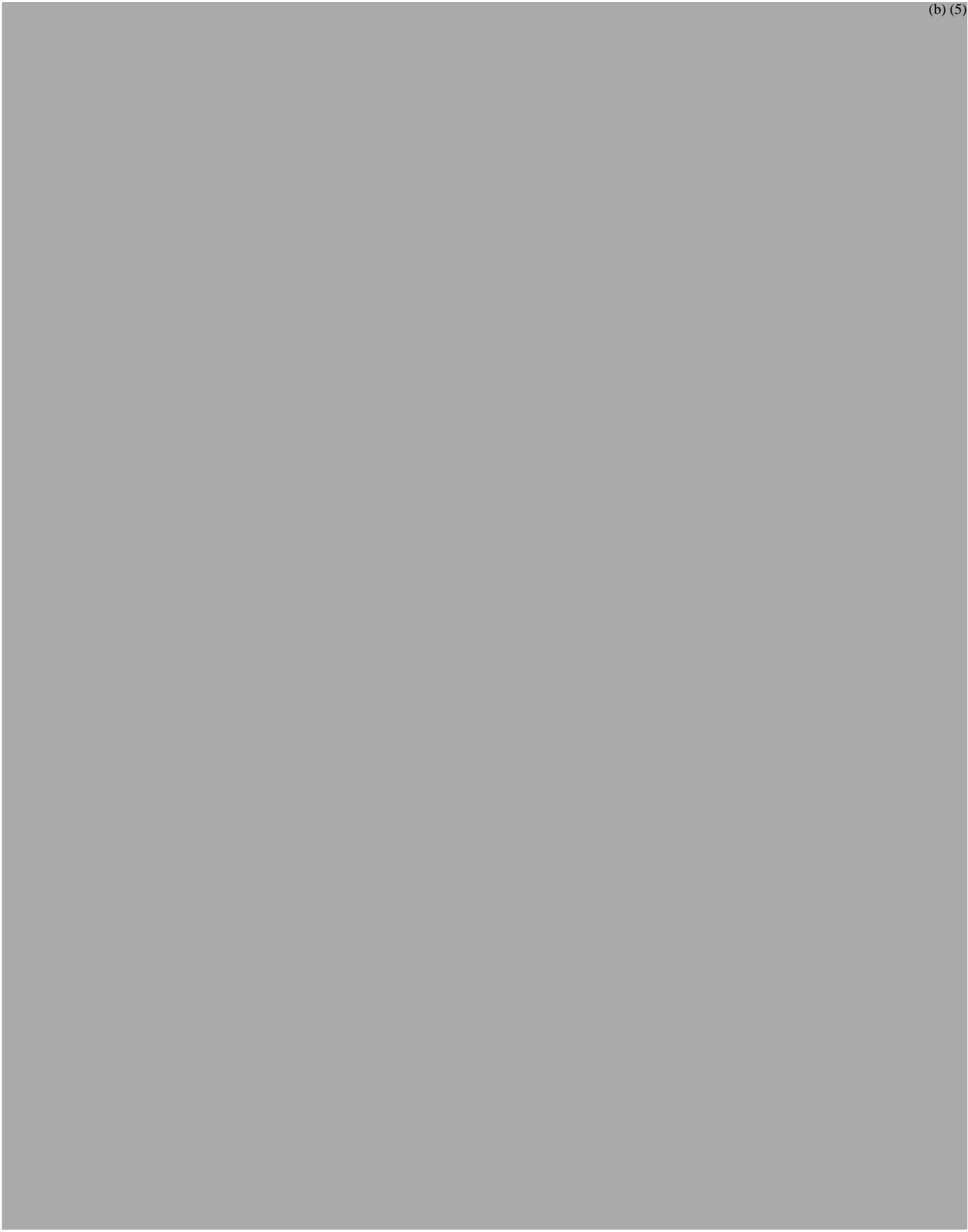
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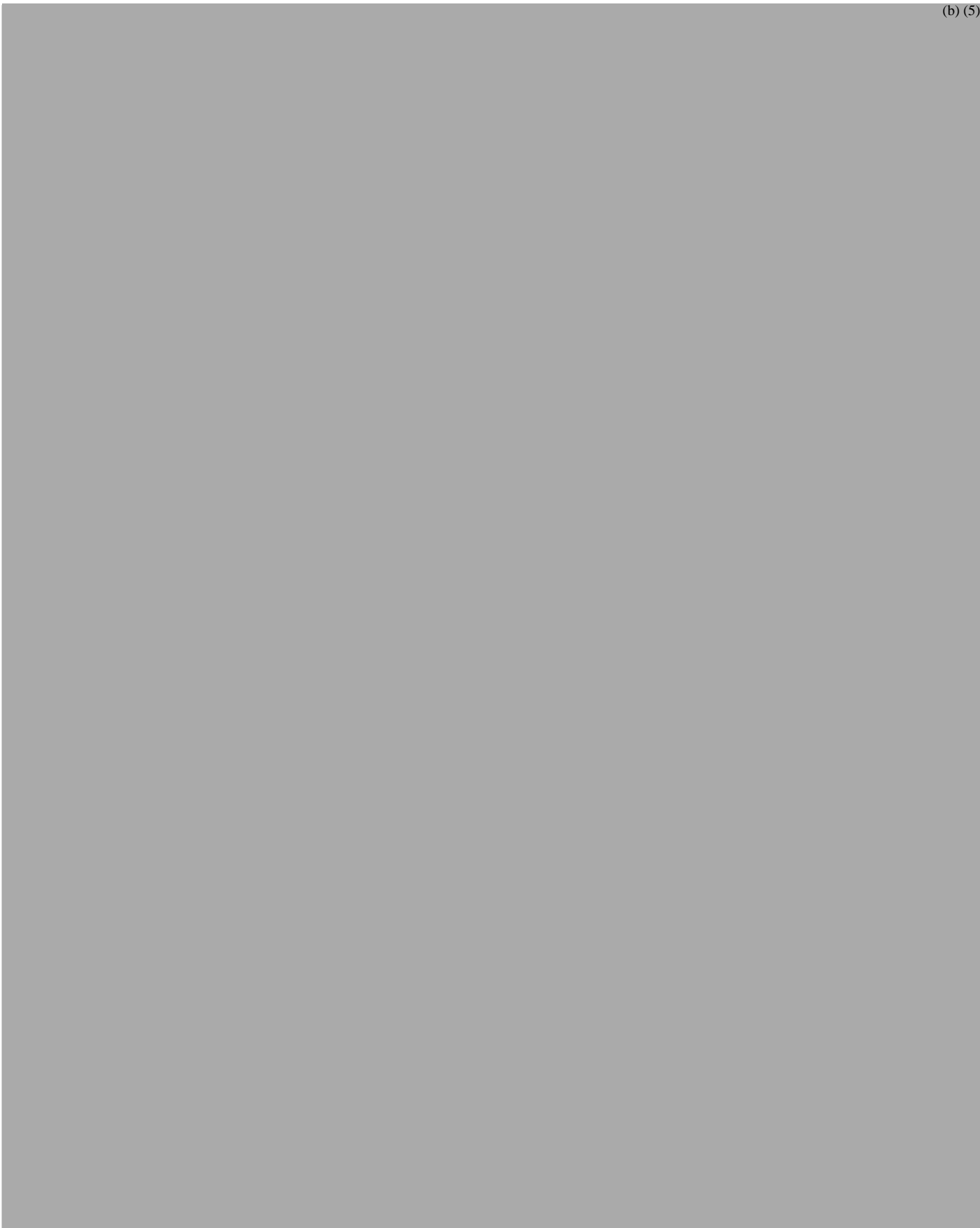


Appendix K: Acronyms

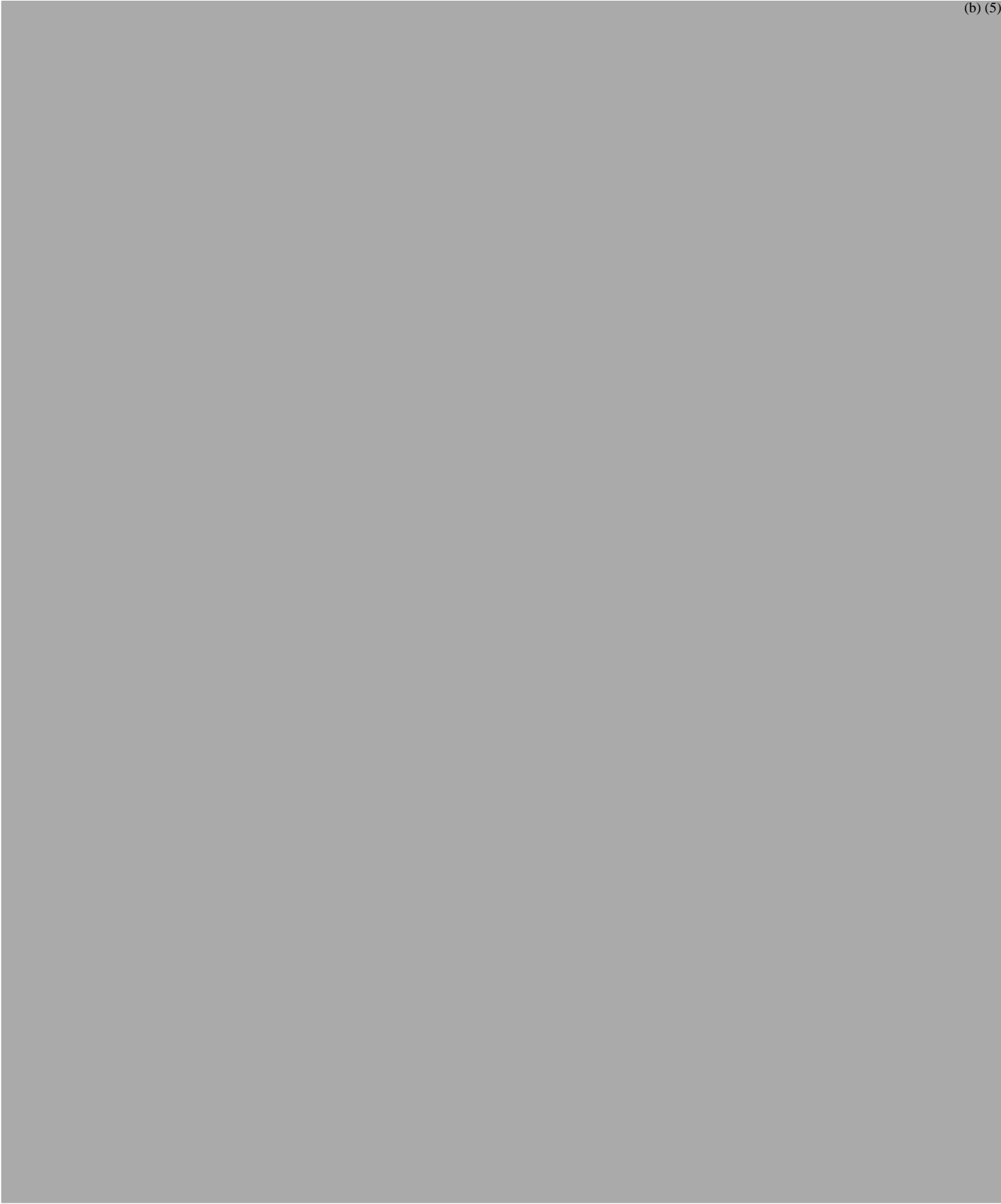
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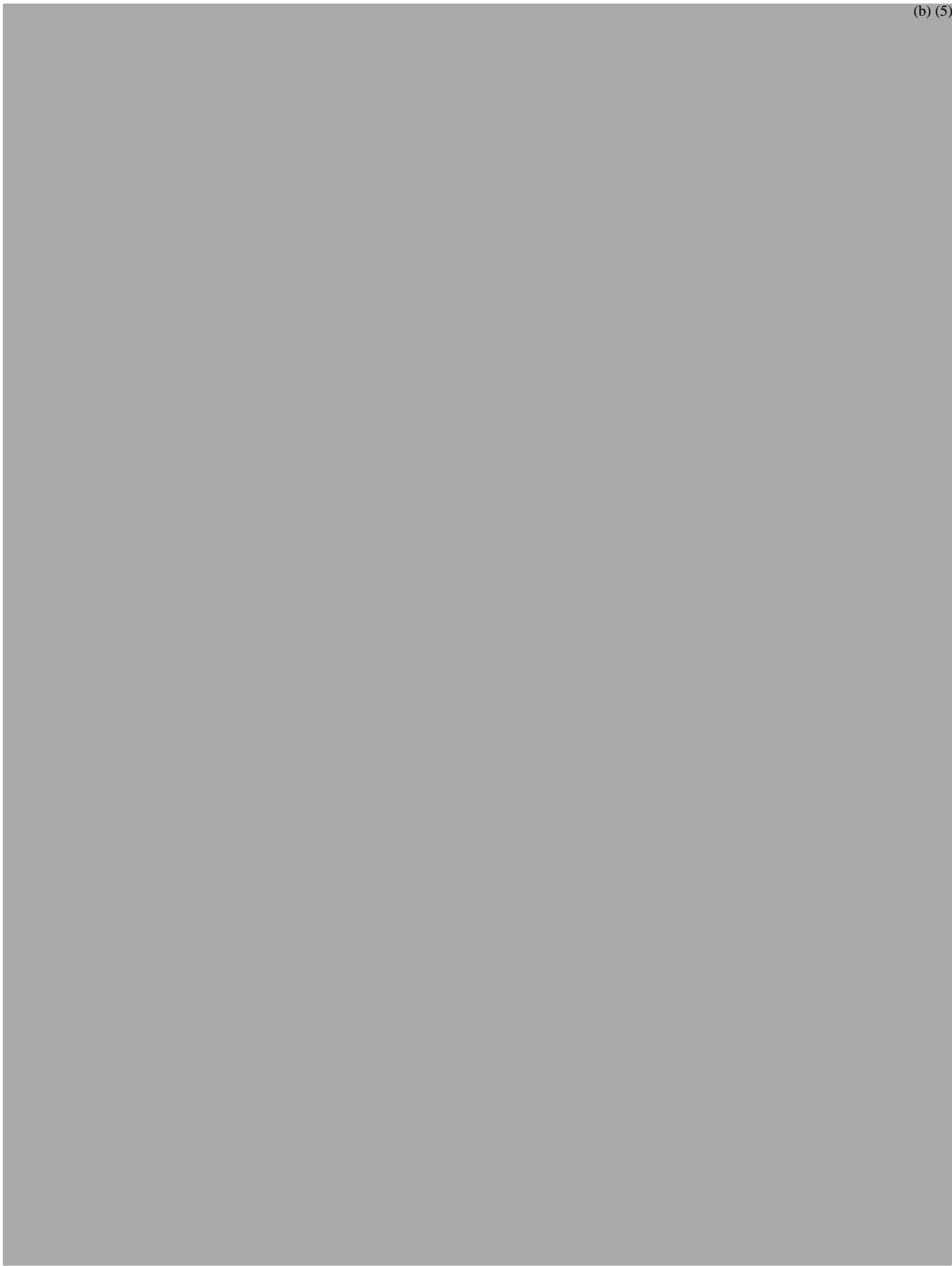










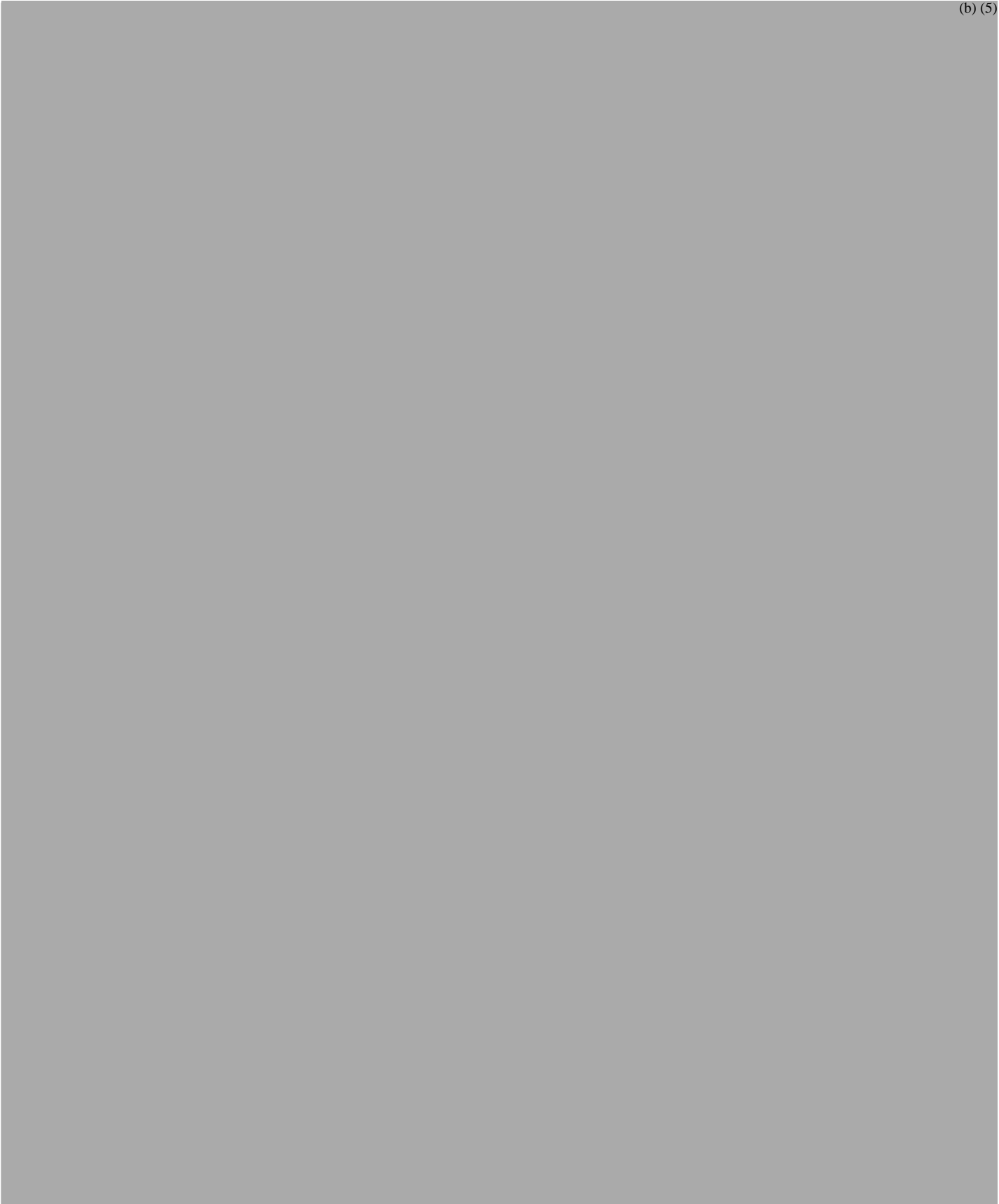


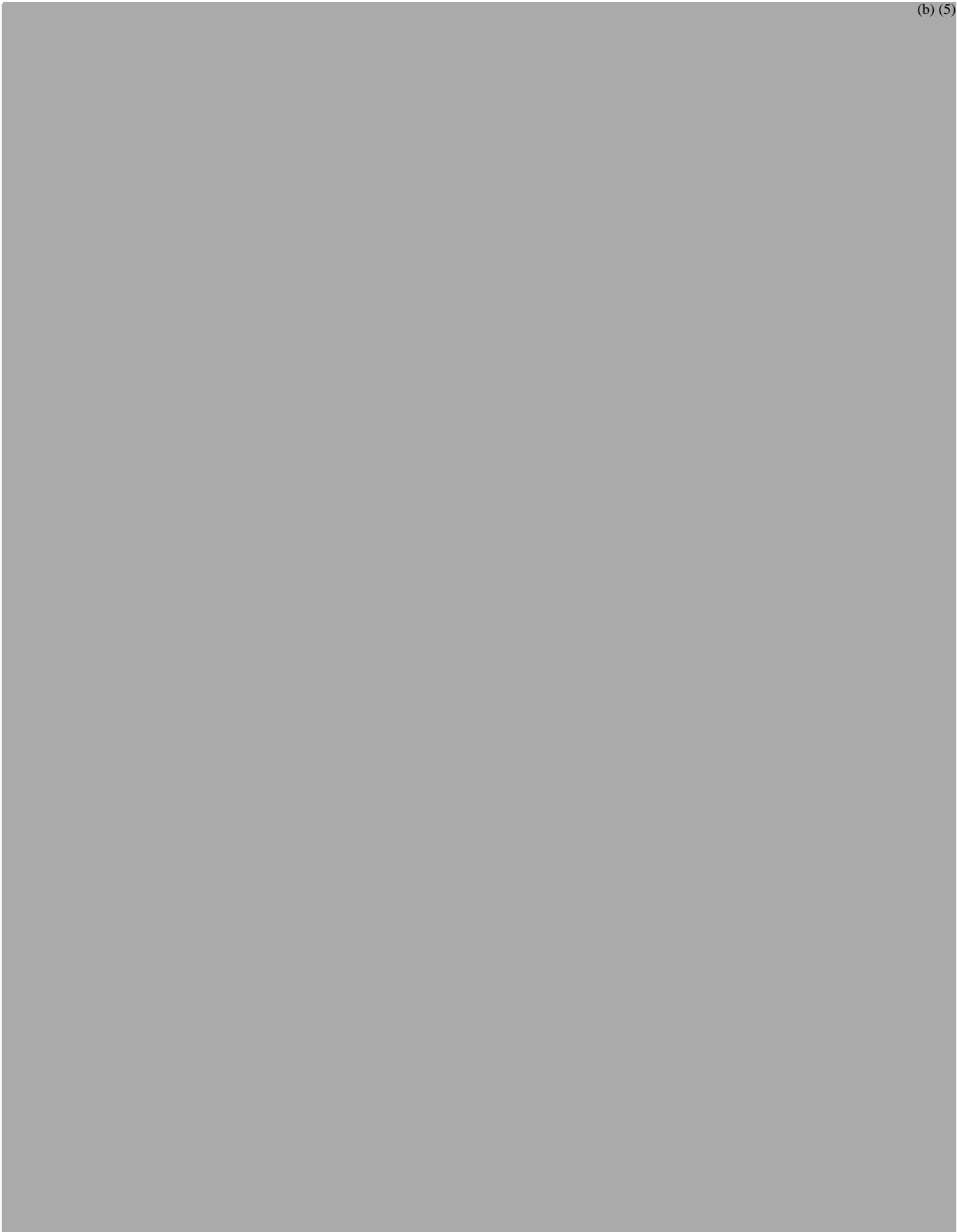












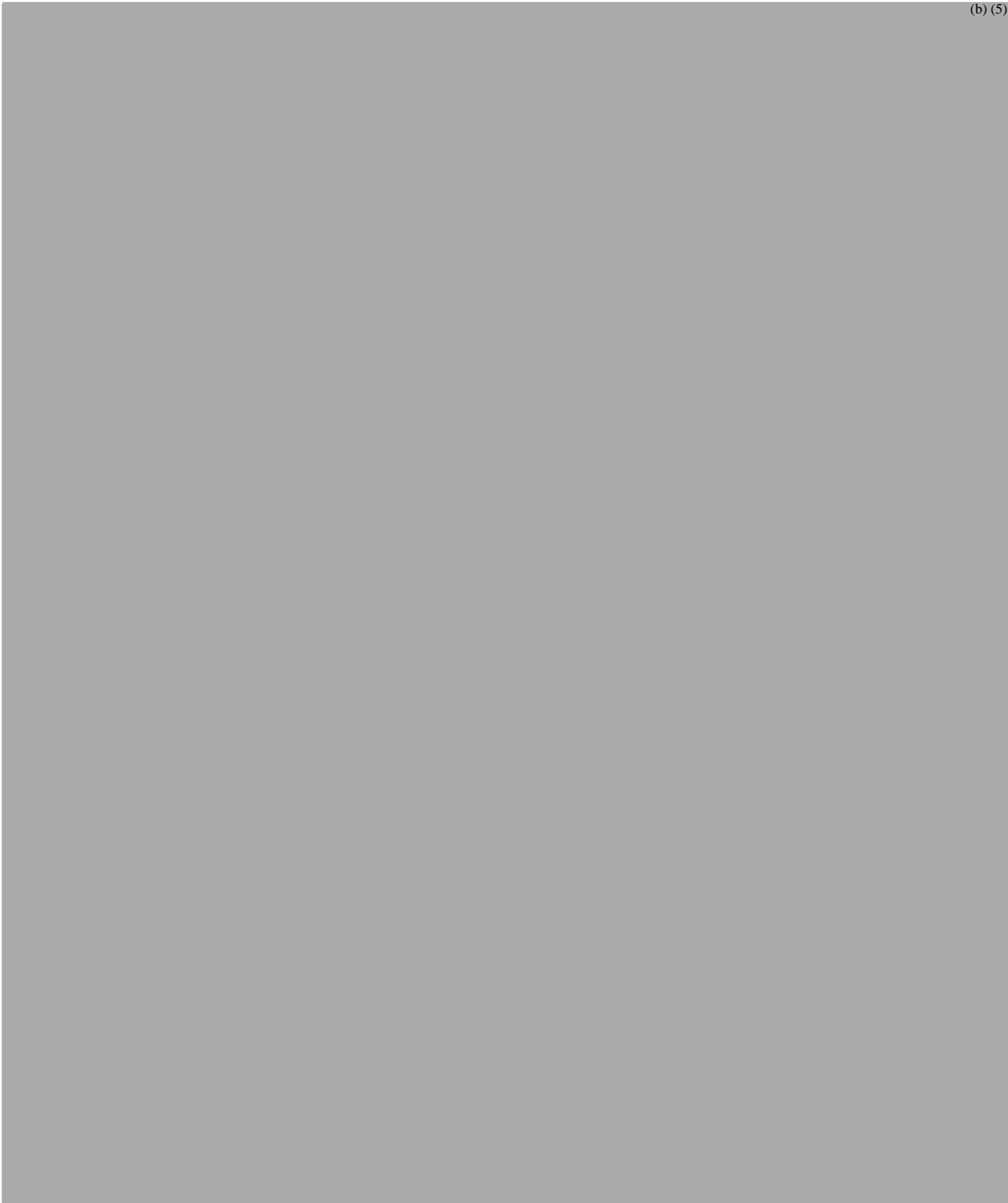


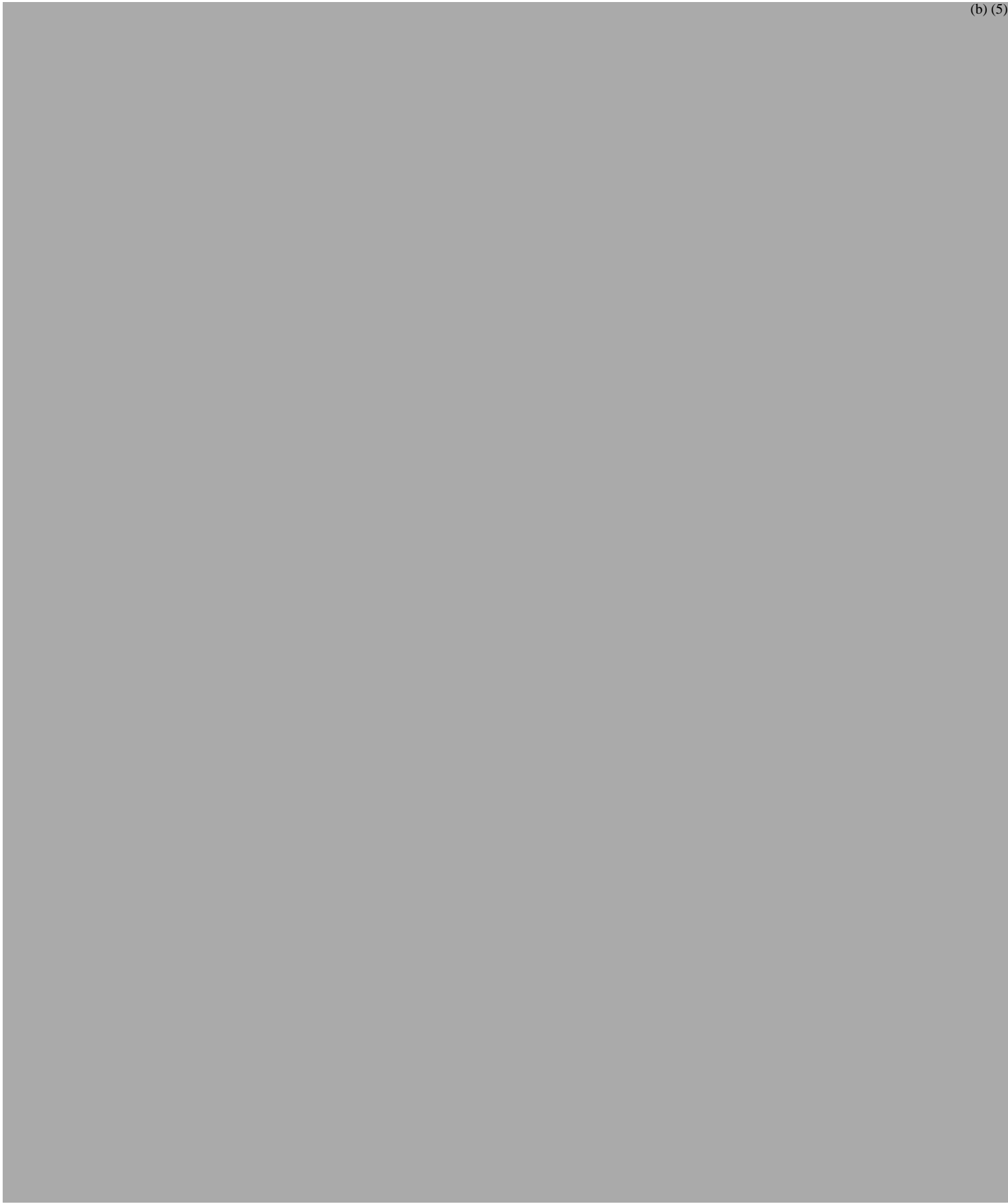


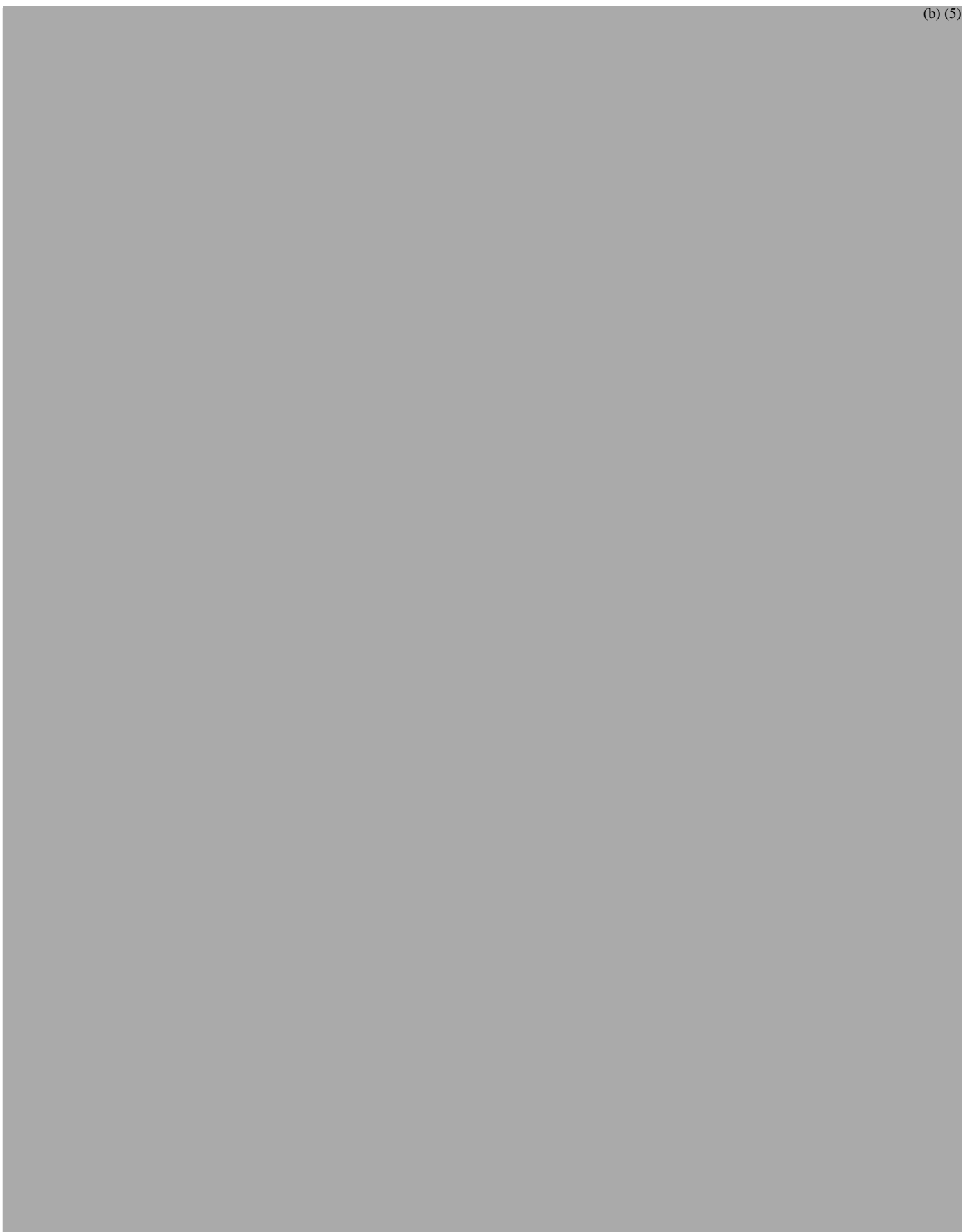














Tab B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Lamar Alexander
Chairman, Committee on Health,
Education, Labor and Pensions
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Patty Murray
Ranking Member, Committee on Health,
Education, Labor and Pensions
United States Senate
Washington, D.C. 20510

Dear Senator Murray:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Richard Shelby
Chairman, Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

(b) (5)

A large, solid grey rectangular box covers the majority of the page, redacting the main body of the letter. The text "(b) (5)" is printed in the top right corner of this redacted area.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Patrick Leahy
Vice Chairman, Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Vice Chairman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Roy Blunt
Chairman, Subcommittee on Labor, Health, and
Human Services, Education, and Related Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Patty Murray
Ranking Member, Subcommittee on Labor, Health, and
Human Services, Education, and Related Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Senator Murray:



(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Frank Pallone, Jr.
Chairman, Committee on Energy
and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Greg Walden
Ranking Member, Committee on Energy
and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Pallone:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Anna Eshoo
Chairwoman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Ms. Chairwoman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Michael Burgess
Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Burgess:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Nita Lowey
Chairwoman, Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Dear Ms. Chairwoman:



(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Kay Granger
Ranking Member, Committee
on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Granger:



(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Rosa DeLauro
Chairwoman, Subcommittee on Labor, Health and
Human Services, Education, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Dear Ms. Chairwoman:

(b) (5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Tom Cole
Ranking Member, Subcommittee on Labor, Health and
Human Services, Education, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Cole:

(b) (5)



From: Barber, Susanna (NIH/NIAID) [E]
Sent: Mon, 9 Mar 2020 13:04:31 +0000
To: Lane, Cliff (NIH/NIAID) [E]; Carver, Trea (NIH) [C]
Cc: Chaitt, Doreen (NIH/NIAID) [E]
Subject: Clearance: 376096 Triennial Report of the Director, FY 16-18 -- deadline is March 11th
Attachments: 376096 Triennial Report clear.doc.pdf

Good morning Cliff,

NIAID OCGR Correspondence would like our clearance on the attached **Triennial Report of the Director of NIH for Fiscal Years 2016, 2017, and 2018.**

The report covers a lot of ground and can only devote space to topics in succinct terms.

There is brief mention of the following topics on the following pages of the report. I refer to the ACTUAL pages of the report, not the PDF pages:

- Influenza B is mentioned on page 9
- Zika is mentioned on page 10
- Clinical research and clinical center activities are described on pages 64 - 66

IMPORTANT: I found an error in the report on Page 10. There is a raised note that says: (b) (5)
[REDACTED] – I have already sent an email about this to NIAID OCGR Correspondence.

Do you clear the report? **Our deadline is March 11th**

Thanks,
Susanna

From: Barber, Susanna (NIH/NIAID) [E] [REDACTED] (b) (6)
Sent: Friday, March 6, 2020 9:50 AM
To: Lane, Cliff (NIH/NIAID) [E] [REDACTED] (b) (6); Carver, Trea (NIH) [C] [REDACTED] (b) (6)
Cc: Chaitt, Doreen (NIH/NIAID) [E] [REDACTED] (b) (6); Barber, Susanna (NIH/NIAID) [E] [REDACTED] (b) (6)
Subject: Clearance: 376096 Triennial Report of the Director, FY 16-18

Cliff –

NIAID OCGR Correspondence would like our clearance on the attached **Triennial Report of the Director of NIH for Fiscal Years 2016, 2017, and 2018.**

The report covers a lot of ground and can only devote space to topics in succinct terms.

There is brief mention of the following topics on the following pages of the report. I refer to the ACTUAL pages of the report, not the PDF pages:

- Influenza B is mentioned on page 9
- Zika is mentioned on page 10
- Clinical research and clinical center activities are described on pages 64 - 66

IMPORTANT: I found an error in the report on Page 10. There is a raised note that says: (b) (5)

– here is the paragraph and error note:

(b) (5)

I will mention this error in our DCR response to NIAID OCGR Correspondence.

Other than this, do you clear the report? Our deadline is March 11th

Thanks,
Susanna

Susanna Barber, Ph.D., J.D., CEP

Clinical Research Oversight Manager
Office of Clinical Research Policy and Regulatory Operations (OCRPRO)
Division of Clinical Research (DCR)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fisher's Lane – Room 5B11
Mail Stop Code: 9820
Phone: (b) (6) or (b) (6)1
E-mail: (b) (6)

Confidentiality Notice and Disclaimer:

The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statement made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Harris, Kara (NIH/NIAID) [E] (b) (6) >
Sent: Friday, March 6, 2020 8:31 AM
To: NIAID DCR-OCGR <NIAIDDCR-OCGR@mail.nih.gov>; NIAID DivCoord <divcoord@niaid.nih.gov>
Cc: NIAID OCGR Correspondence <NIAIDOCGRCorrespondence@mail.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: RE: Clearance: 376096 Triennial Report of the Director, FY 16-18

Correction - COB Wednesday, March 11.

From: Harris, Kara (NIH/NIAID) [E] (b) (6)
Sent: Friday, March 6, 2020 8:30 AM
To: NIAID DCR-OCGR <NIAIDDCR-OCGR@mail.nih.gov>; NIAID DivCoord <divcoord@niaid.nih.gov>
Cc: NIAID OCGR Correspondence <NIAIDOCGRCorrespondence@mail.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>
Subject: Clearance: 376096 Triennial Report of the Director, FY 16-18

Good morning –

Clearance due to NIAID OCGR Correspondence by **COB Wednesday, March 12.**

Background: Attached for clearance is the NIH Triennial Report of the Director, FY 16-18. This report, mandated by the Public Health Service Act, is to serve as a reference for understanding NIH's activities and operations.

As you may recall, PP&E had reached out to NIAID Divisions to obtain information for the report. All of the information appears to have been included, except for text on CIVICS, OMiCC, and basic research on group 2 H7N9 vaccination (may be too technical).

Action: Please provide your clearance on the report and submit it to NIAID OCGR Correspondence by **COB Wednesday.** Please submit any comments in narrative form. Once this report has been cleared, it will be professionally copy edited. Also, the images have been removed from this report to keep the file size down, but they will be added once the report is finalized. All other IC's are clearing.

Thank you,
Kara



DATE:

TO: Acting Assistant Secretary for Legislation

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Director, NIH

SUBJECT: Recommendation to Approve the Triennial Report of the Director, National Institutes of Health, Fiscal Years 2016, 2017, and 2018 – DECISION

BACKGROUND

Section 403 of the Public Health Service Act requires the Director of the National Institutes of Health (NIH) to submit a triennial report to Congress.

DISCUSSION

The Triennial Report of the Director describes NIH activities for fiscal years 2016, 2017, and 2018 and provides:

- An assessment of the state of biomedical and behavioral research;
- An overview of the NIH structure, operations, and policies;
- Summaries and highlights of NIH research activities in areas specified by Congress; and
- Reviews of the NIH center of excellence programs that were established by congressional mandate.

RECOMMENDATION

I recommend you approve the transmittal of the Triennial Report of the Director, NIH, to Congress (see the letters at Tab B).

Francis S. Collins, M.D., Ph.D.

DECISION

Sending the Triennial Report of the Director, NIH, to Congress is

Approved _____ Disapproved _____ Need More Information _____

Sarah Arbes

Date

Page 2 – The Secretary

Attachments

Tab A – Triennial Report of the Director, NIH, FYs 2016, 2017, and 2018

Tab B – Letters to Congress

Tab A

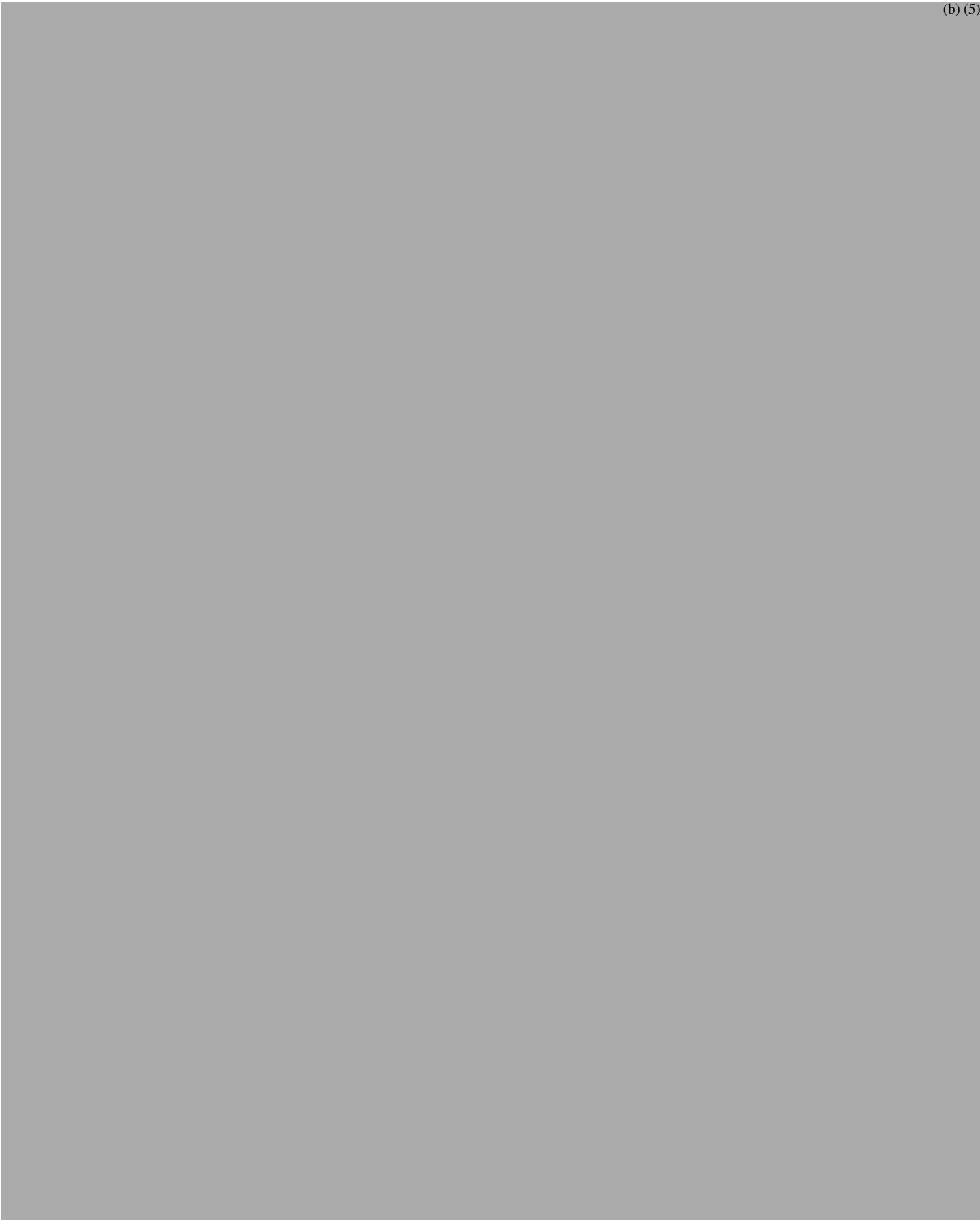
Report of the Director

National Institutes of Health

Fiscal Years 2016, 2017, and 2018

Preface

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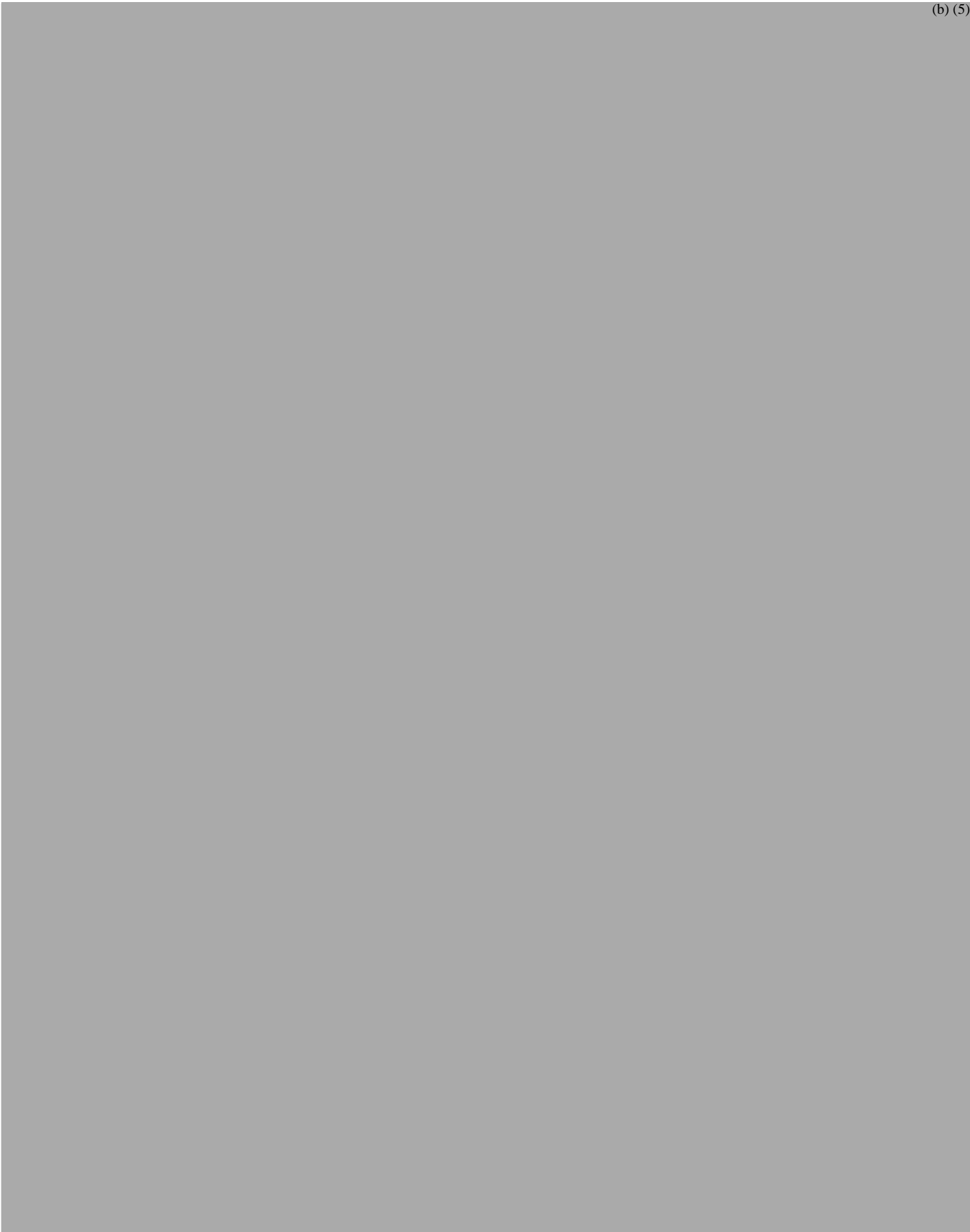
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Chapter 1 About NIH

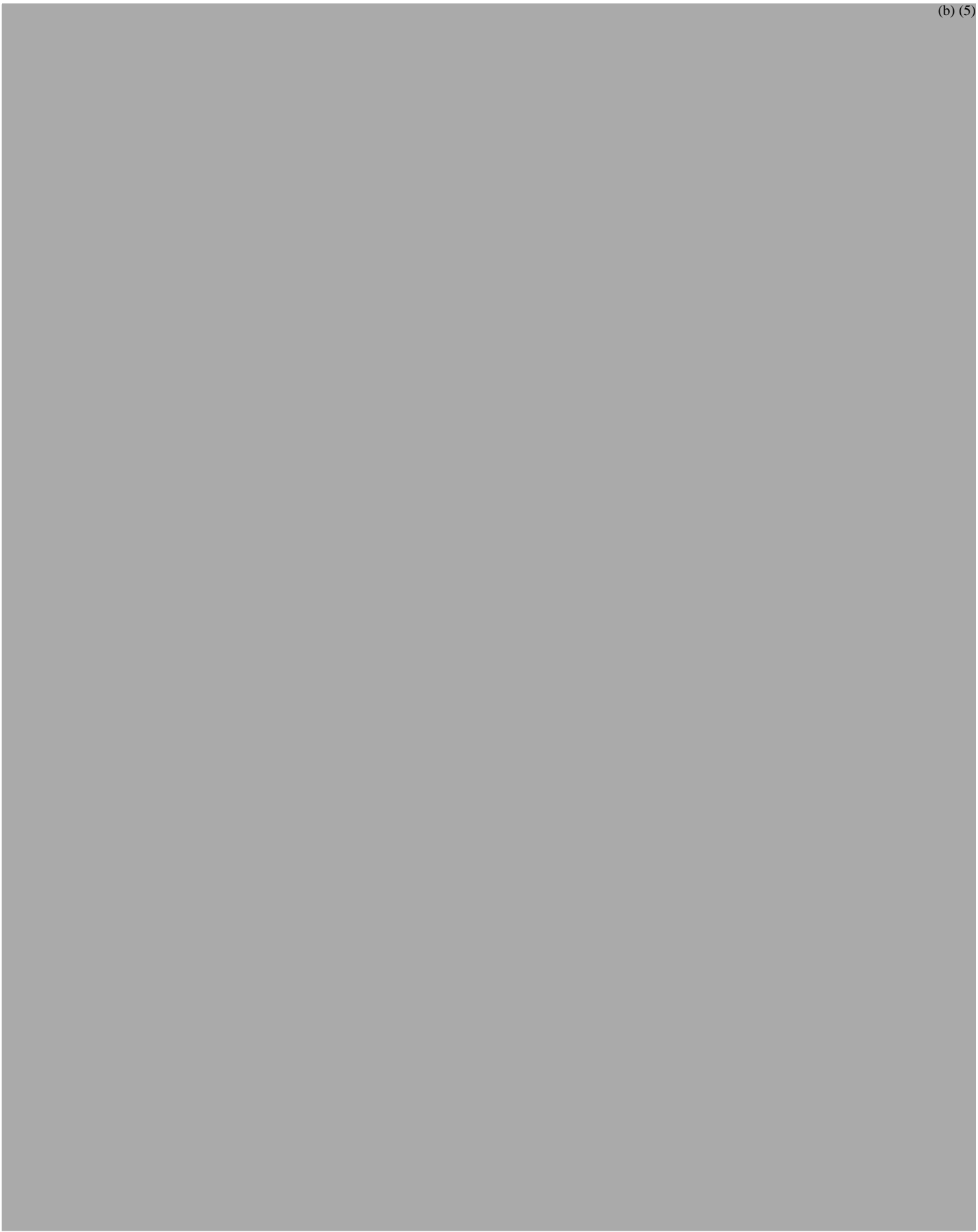
Statement of the Director

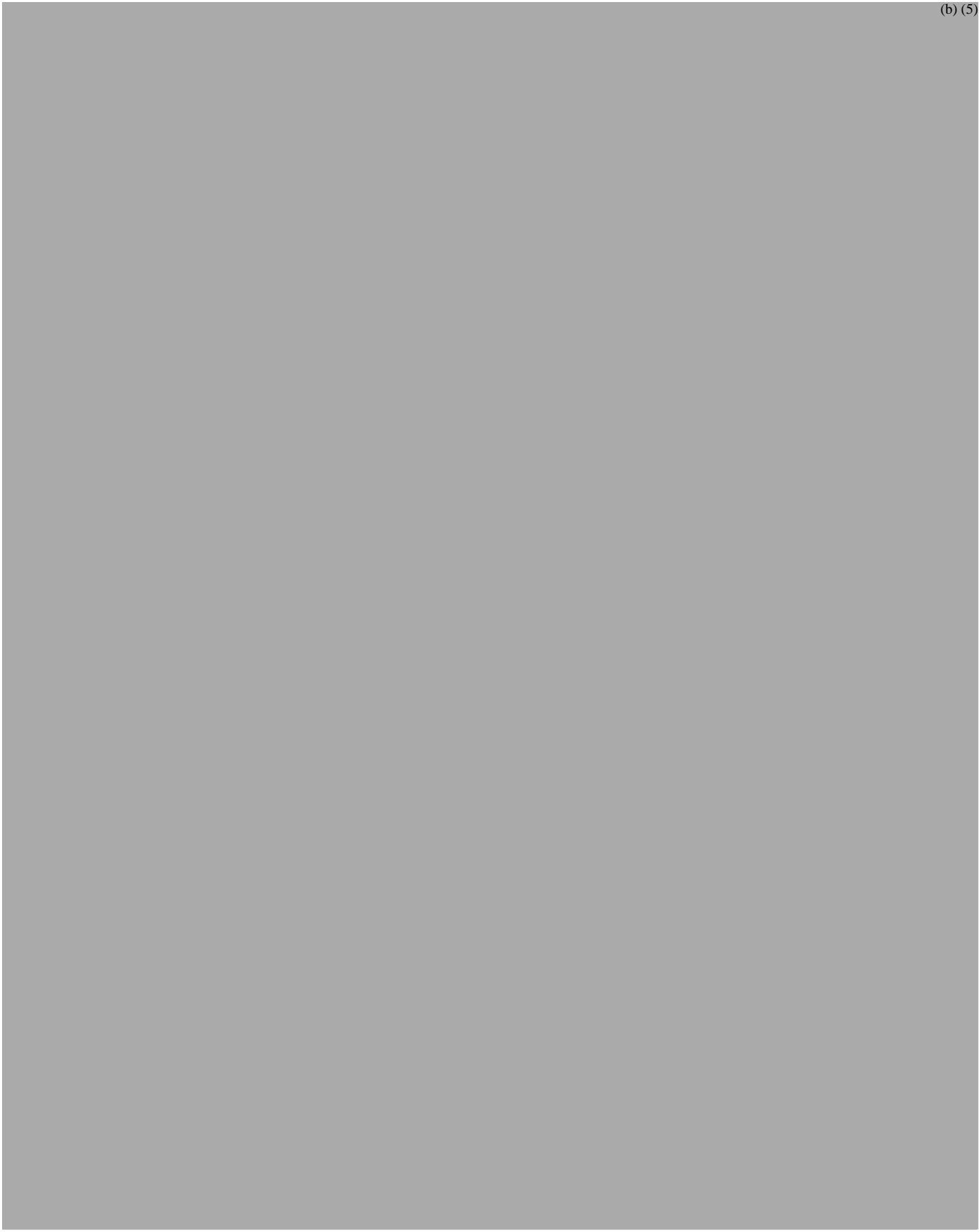
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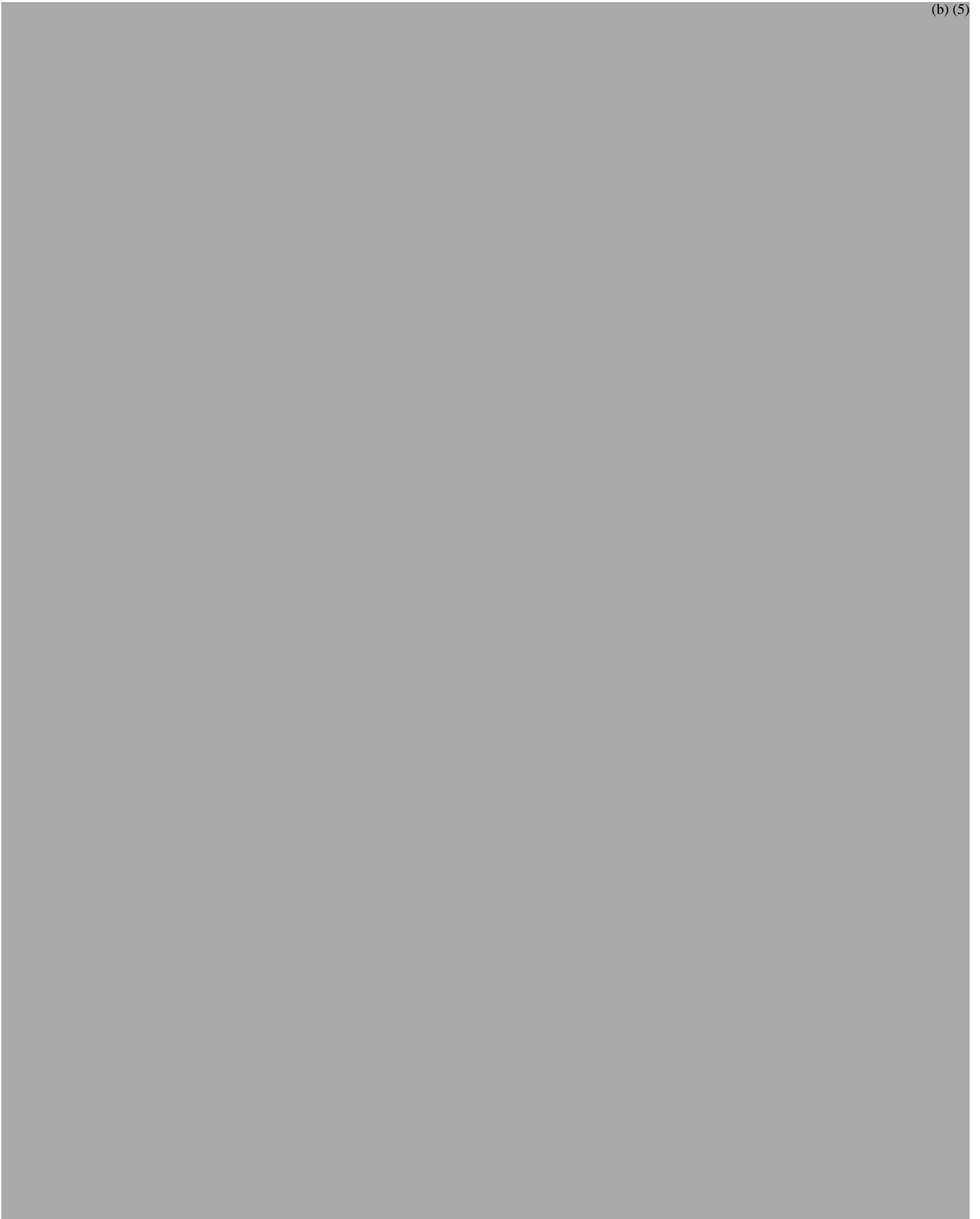


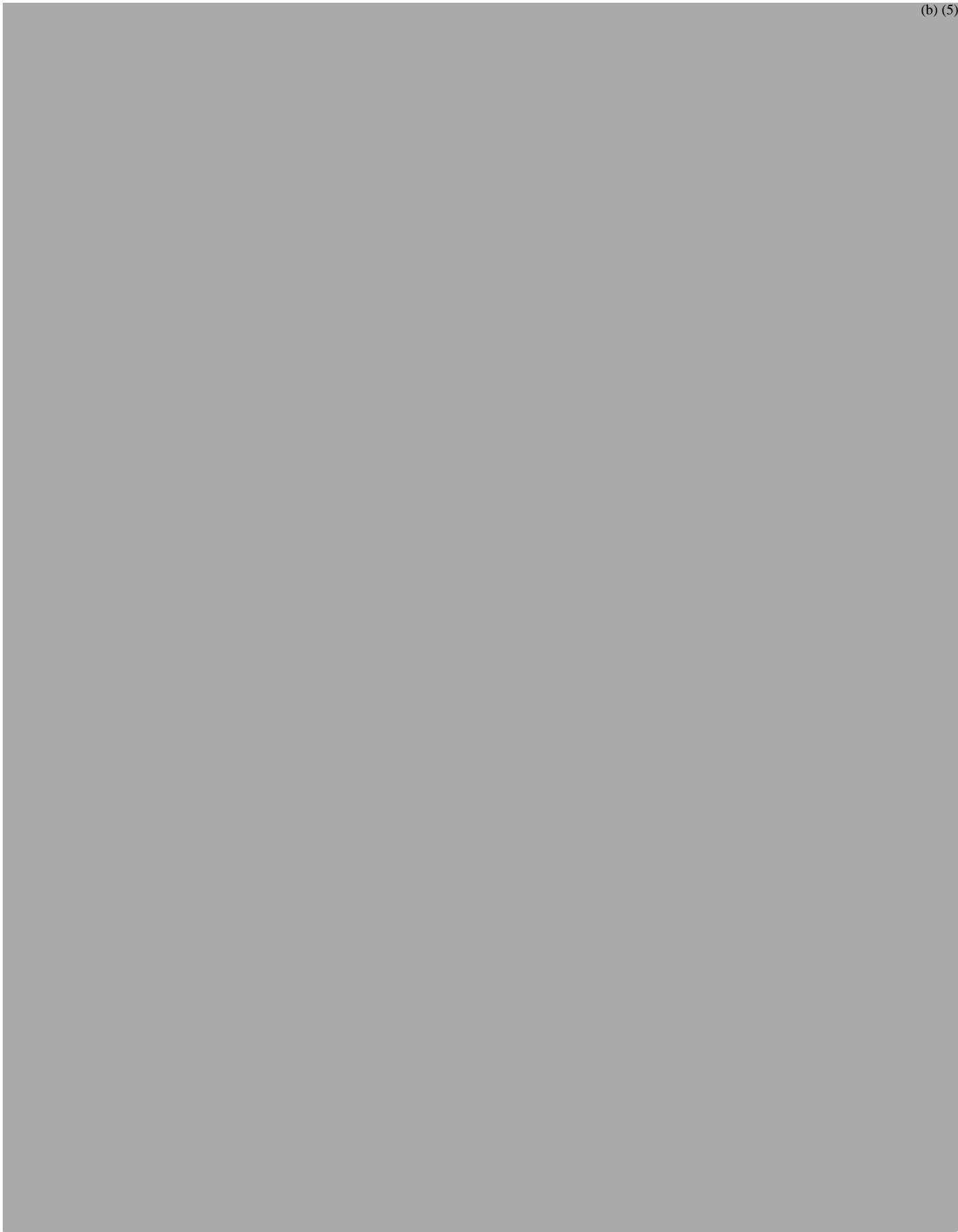
NIH's Mission

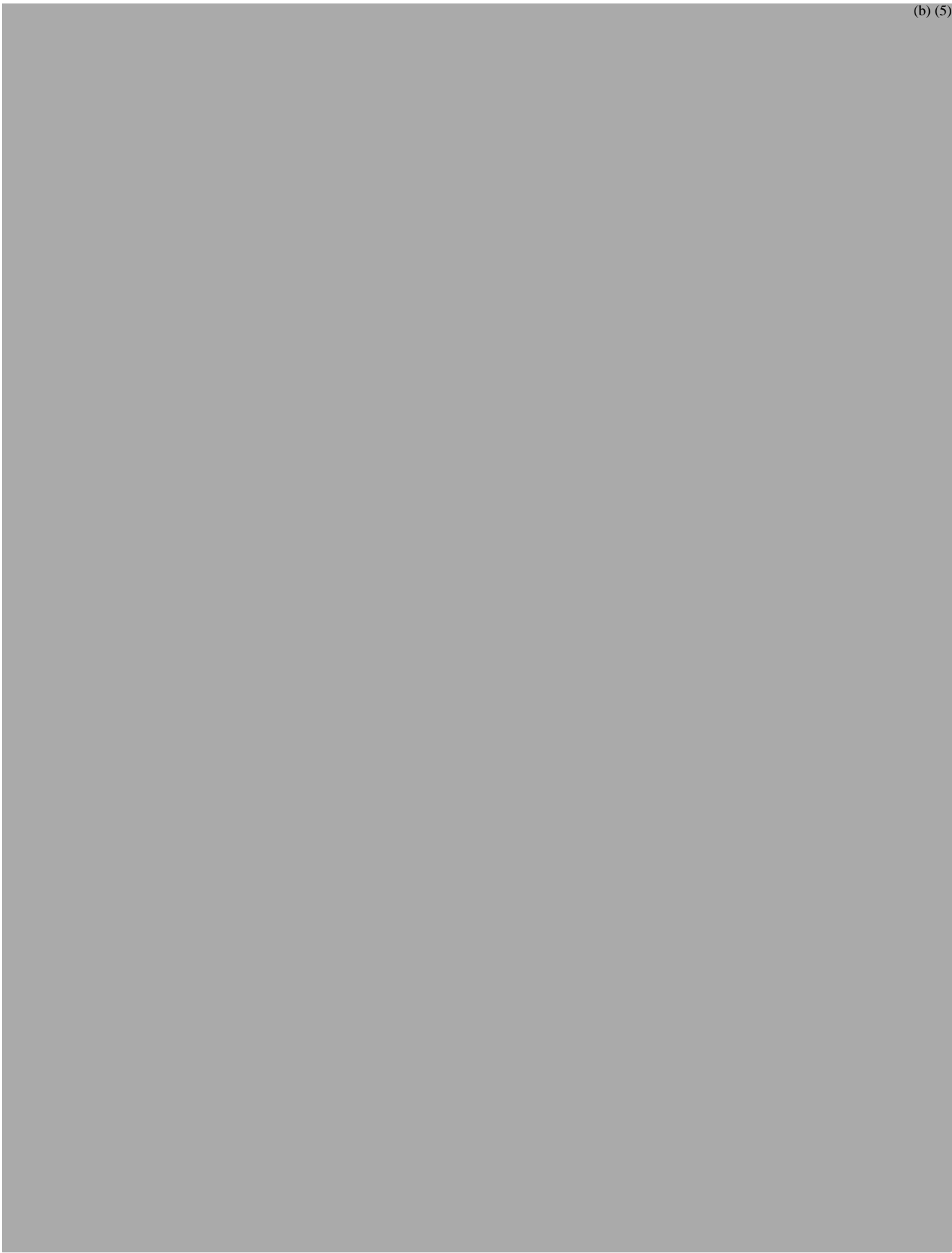
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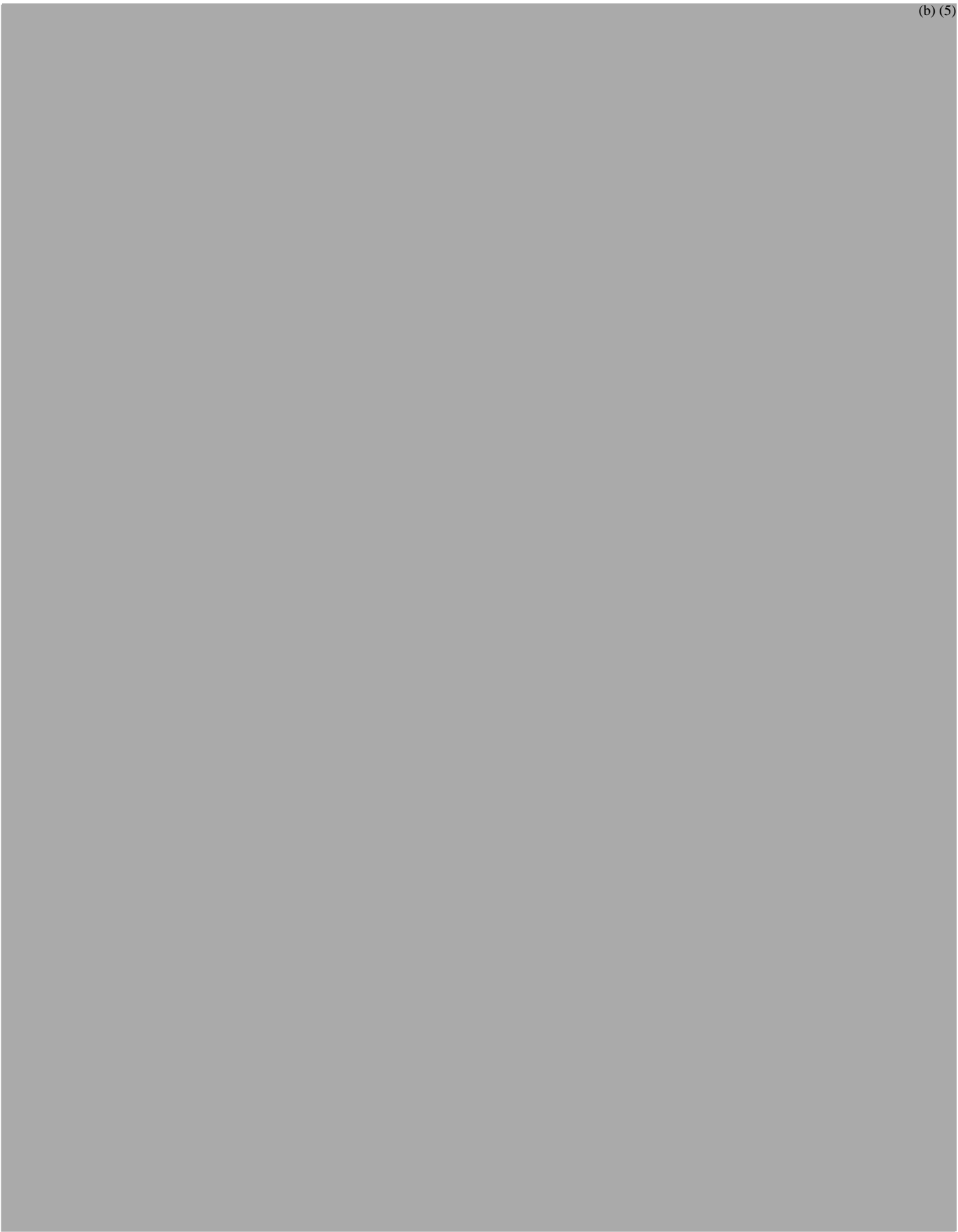
Overview of NIH Structure and Organization

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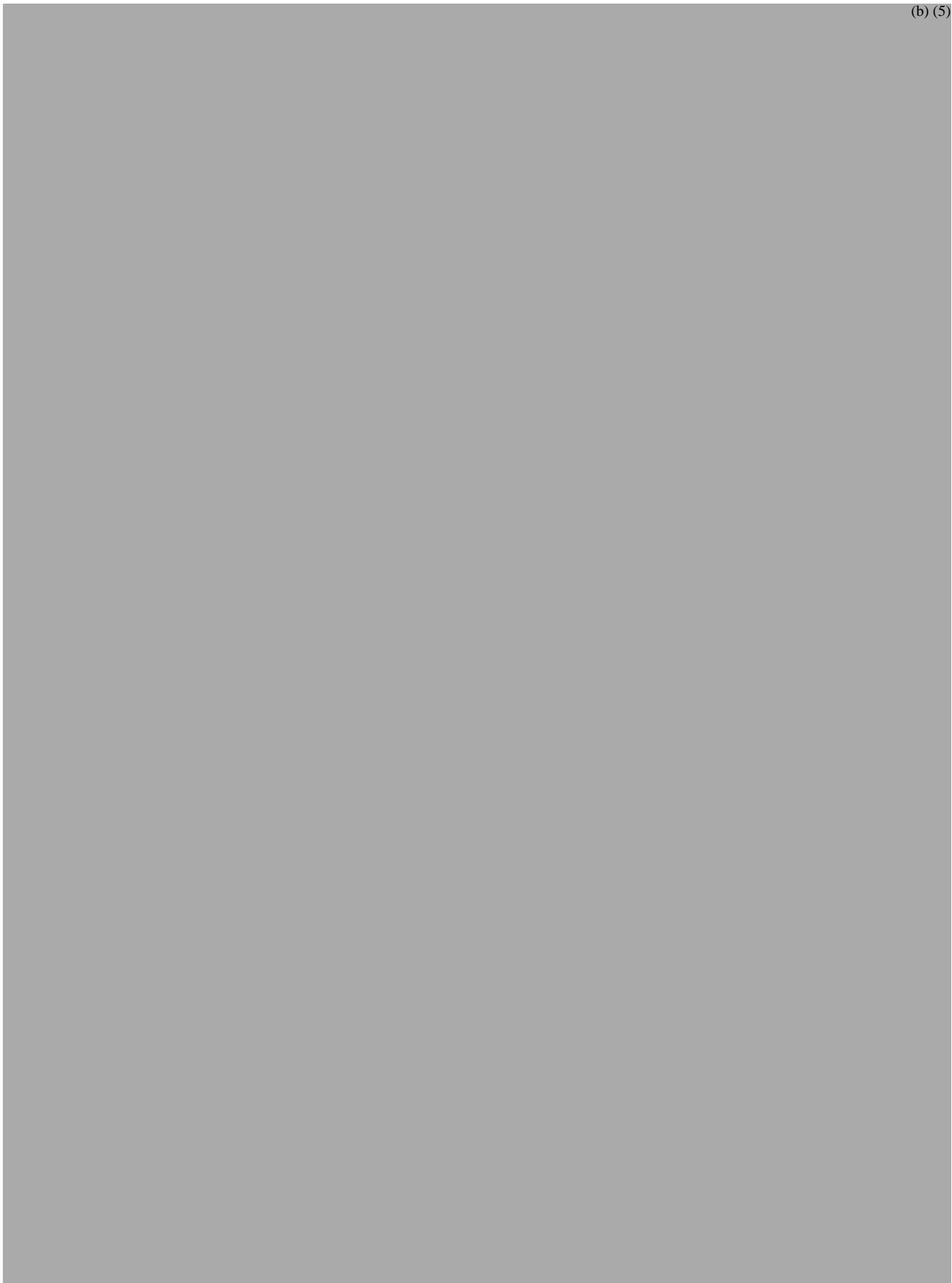




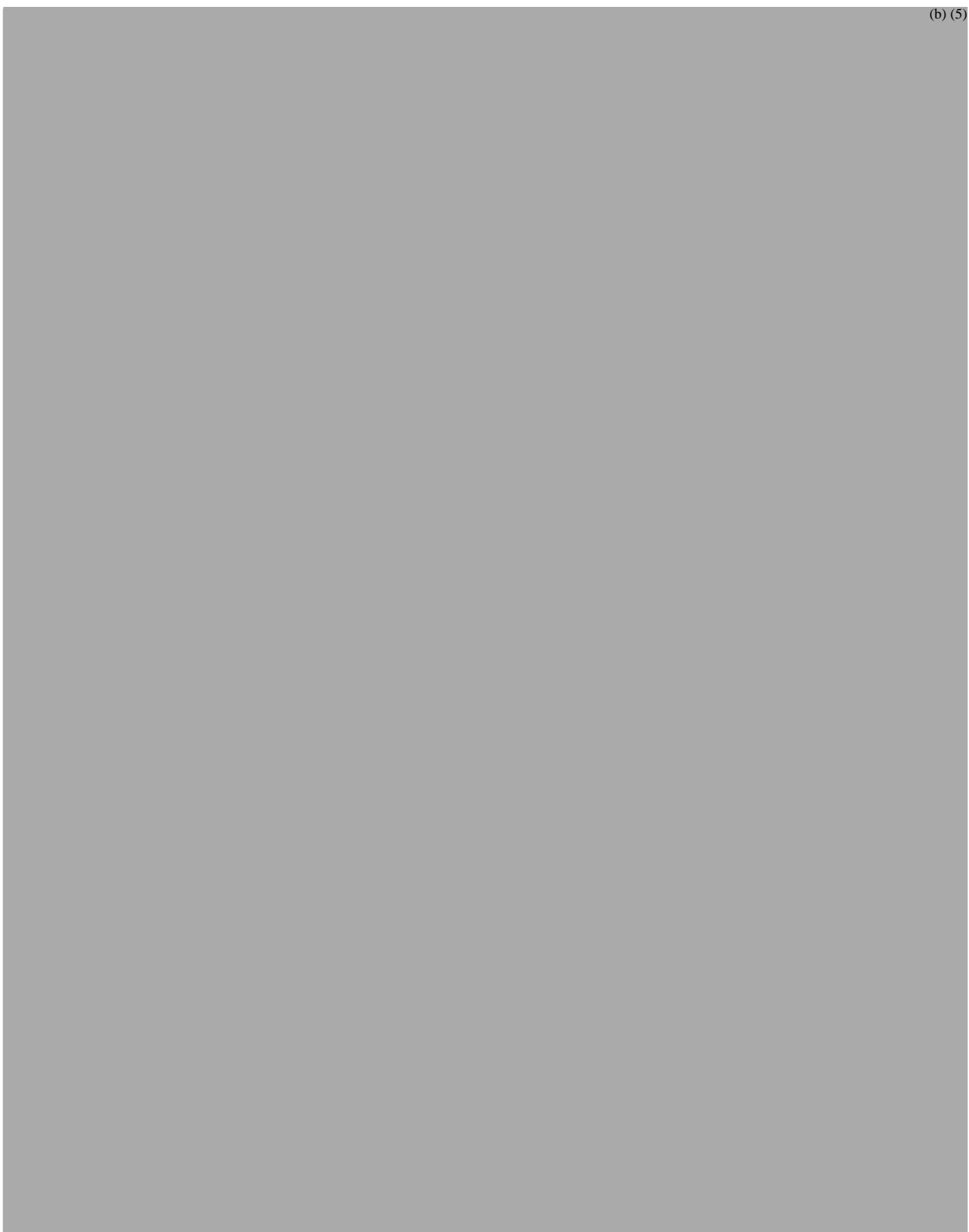


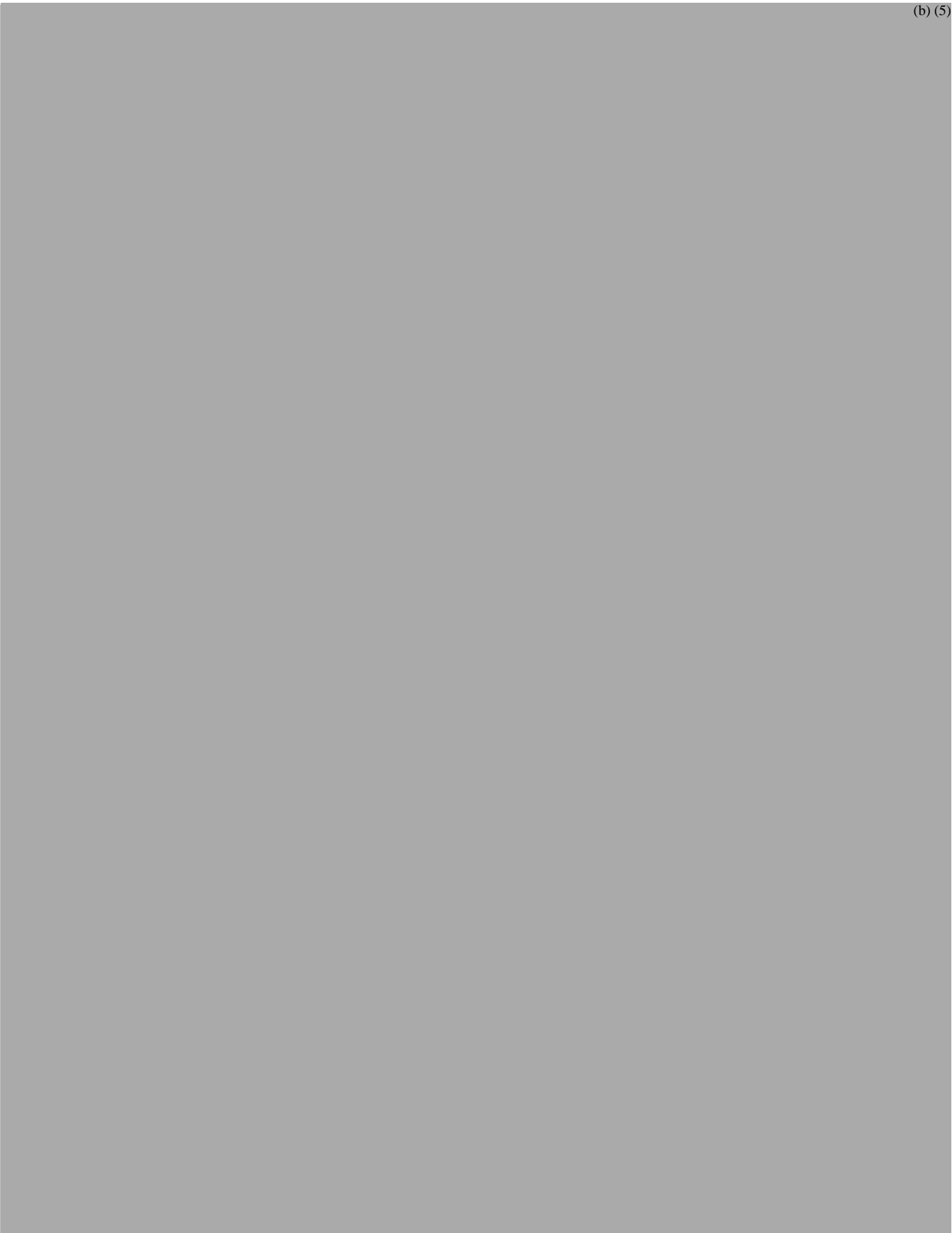










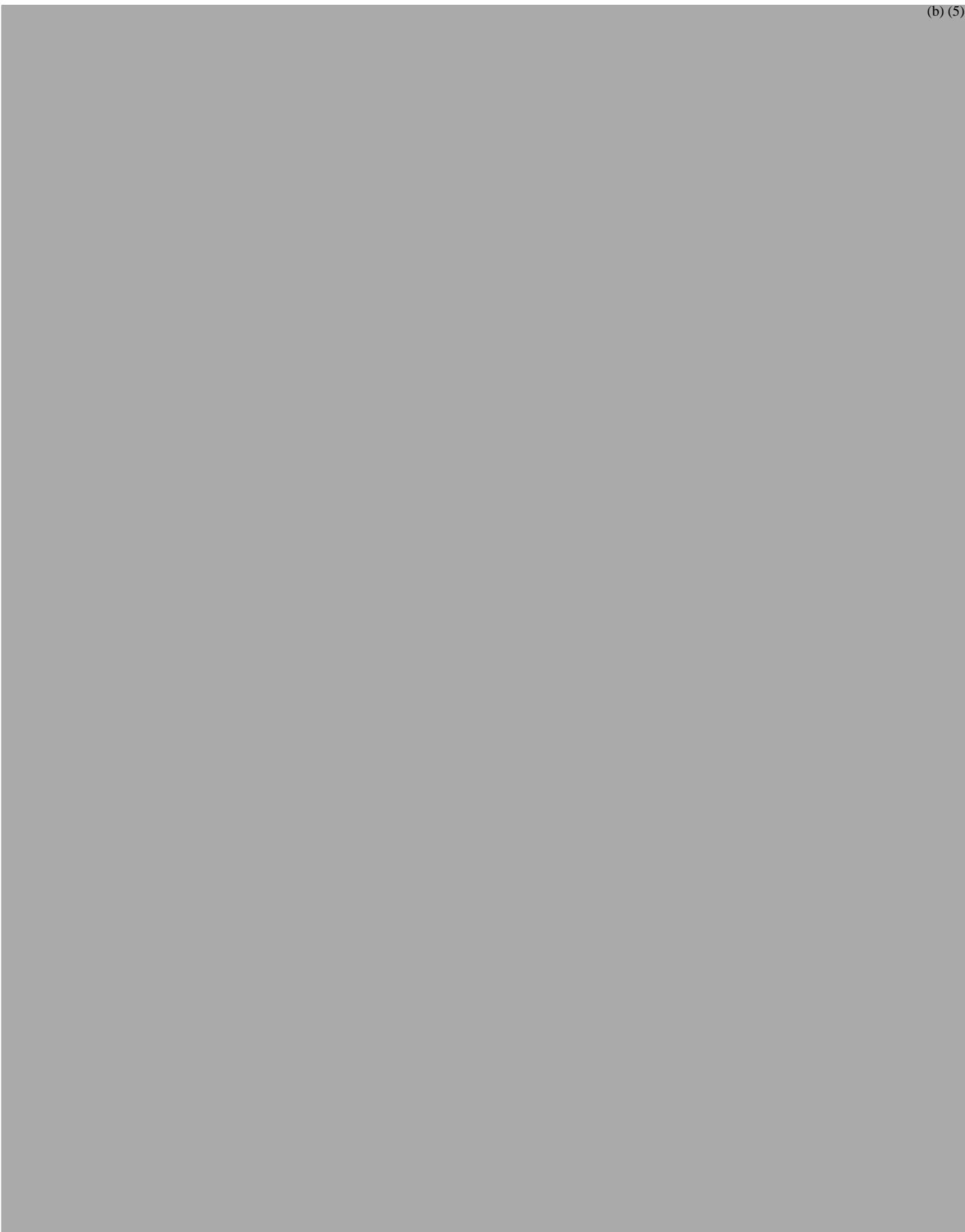


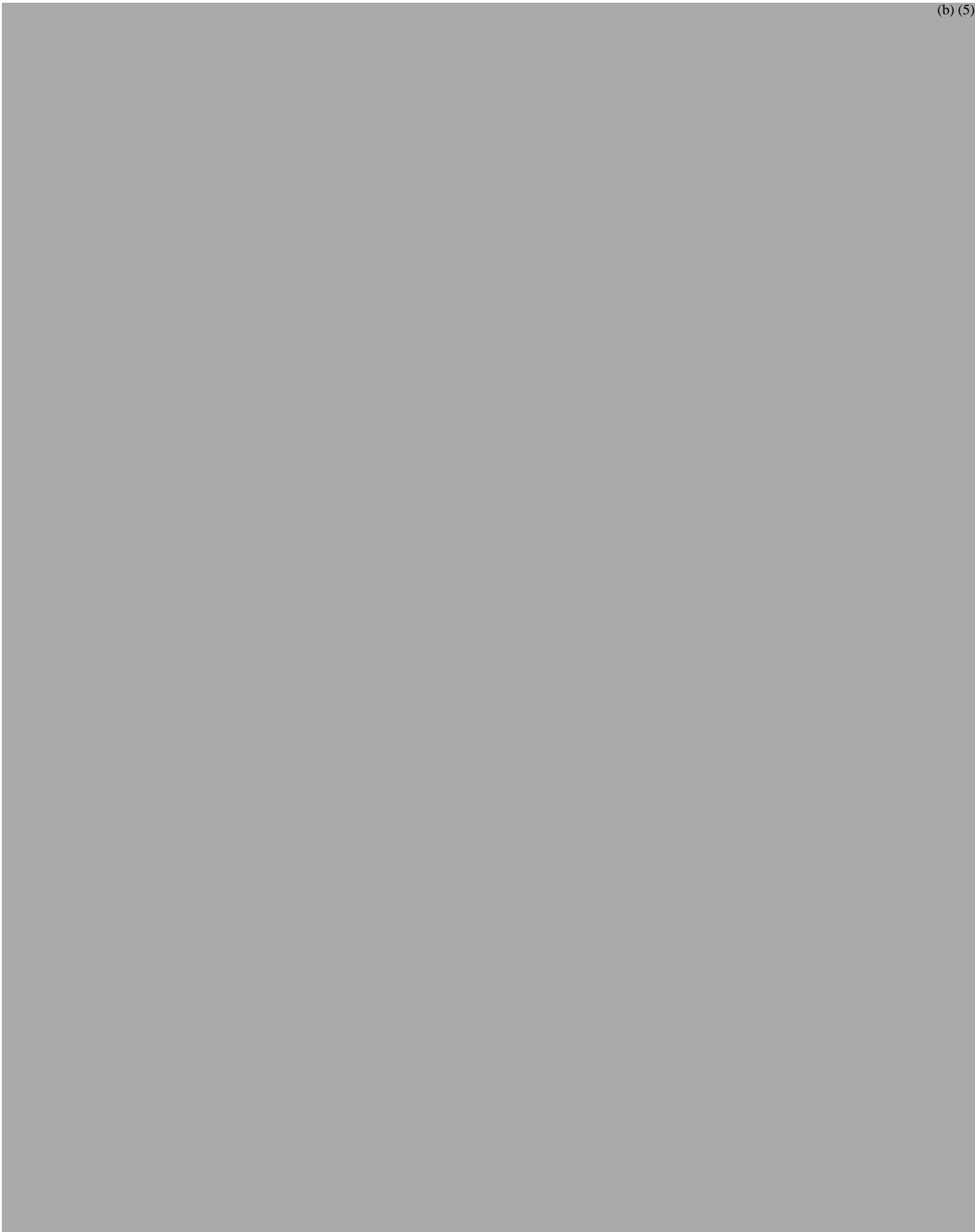


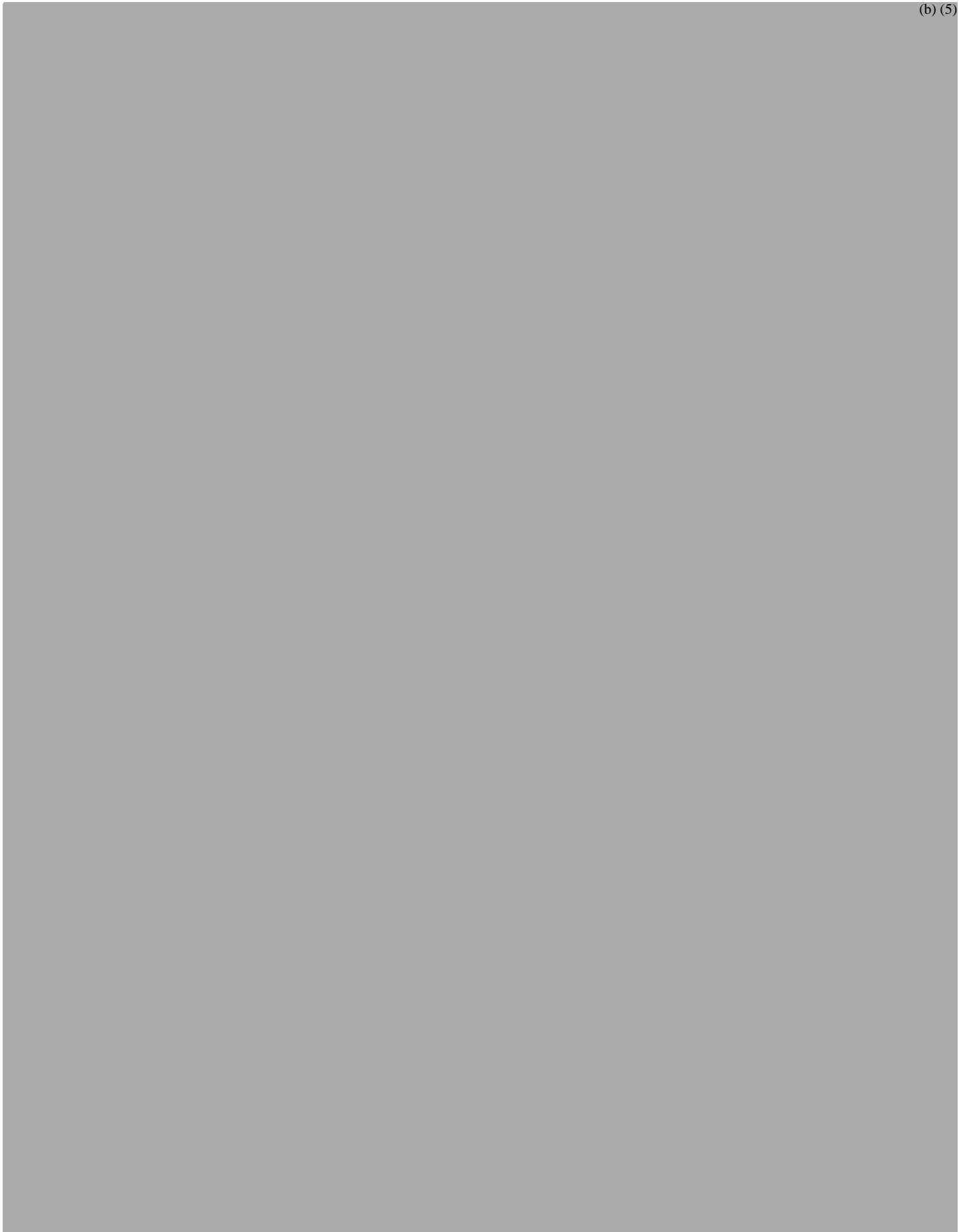
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Fostering Commitment to Science

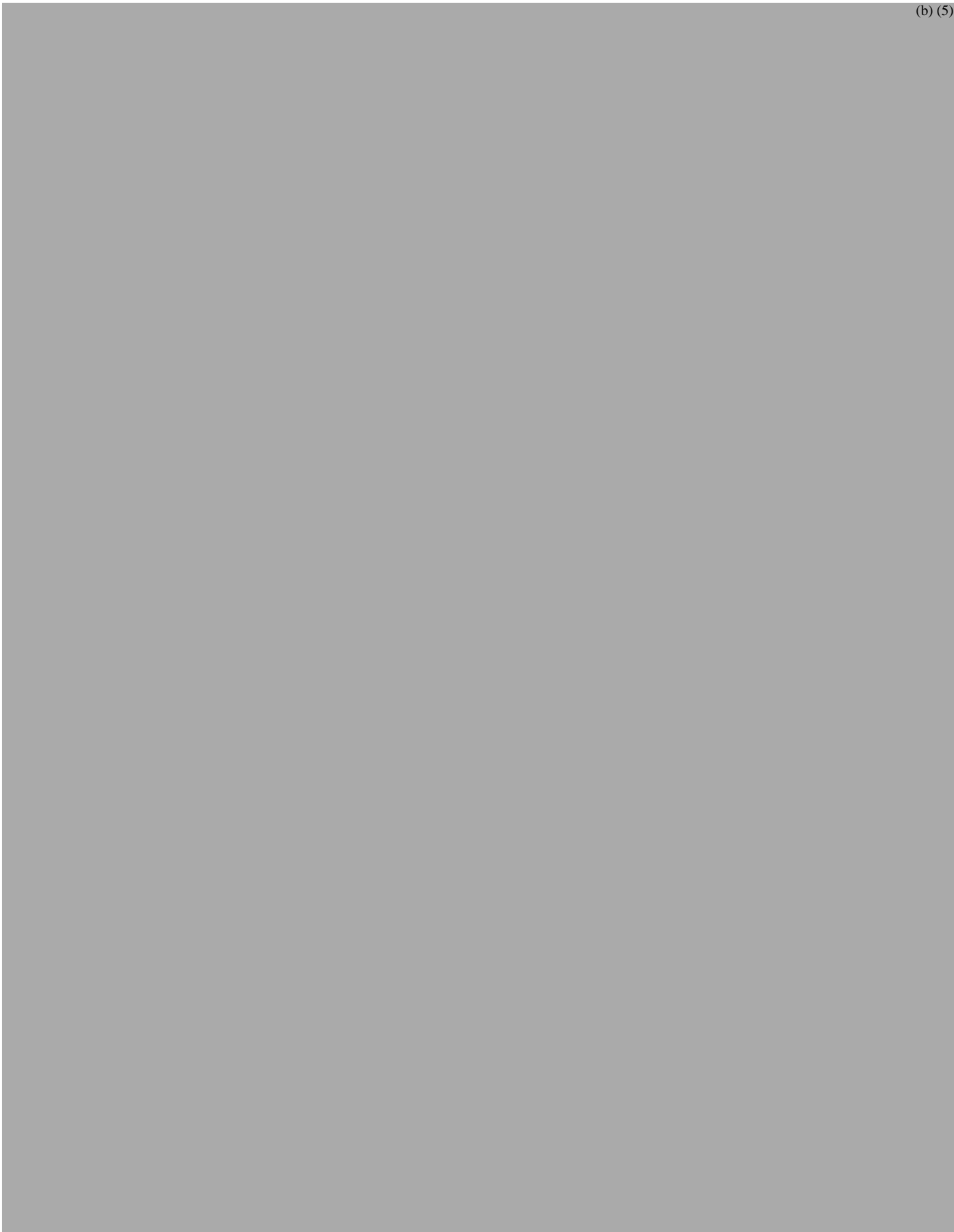
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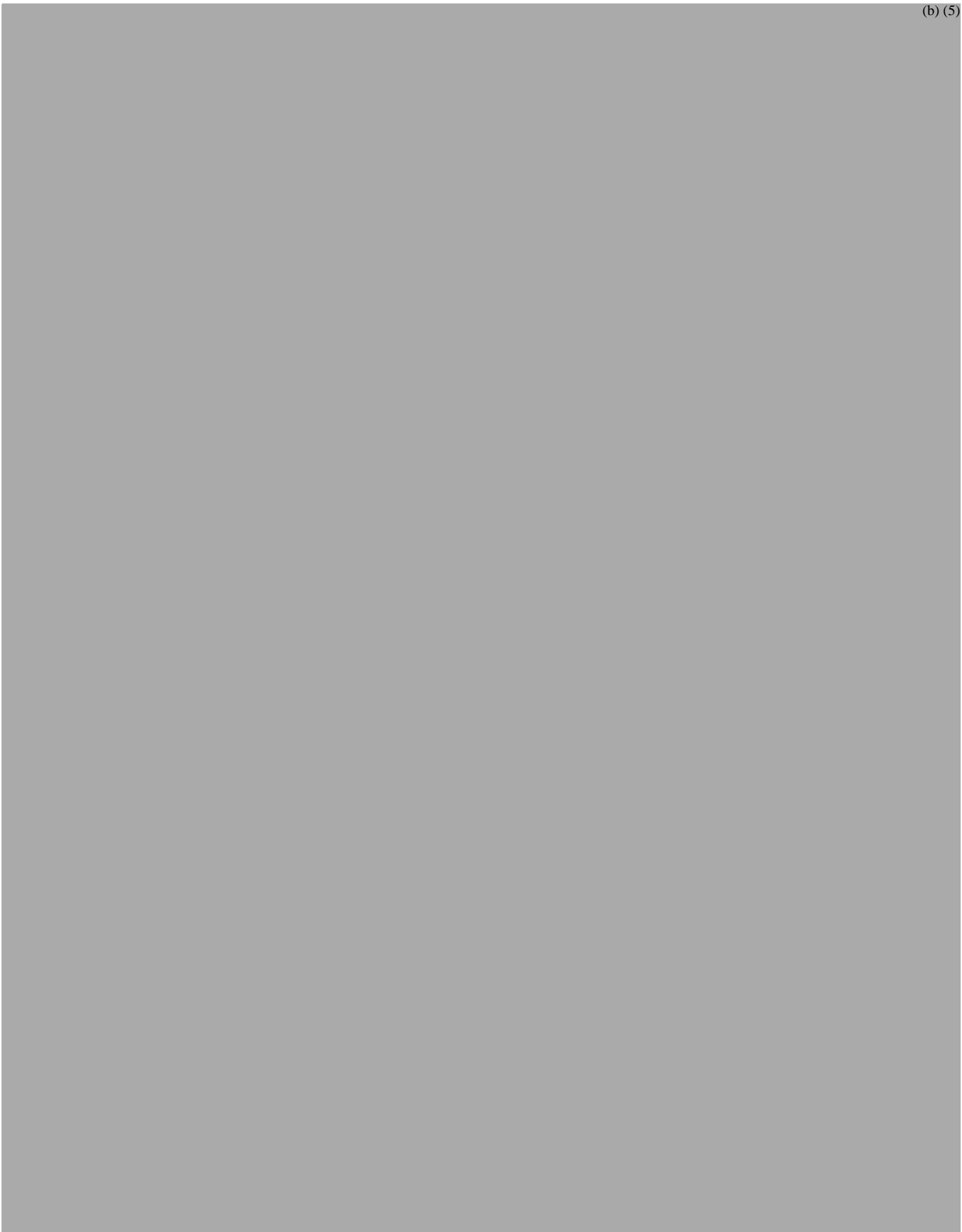


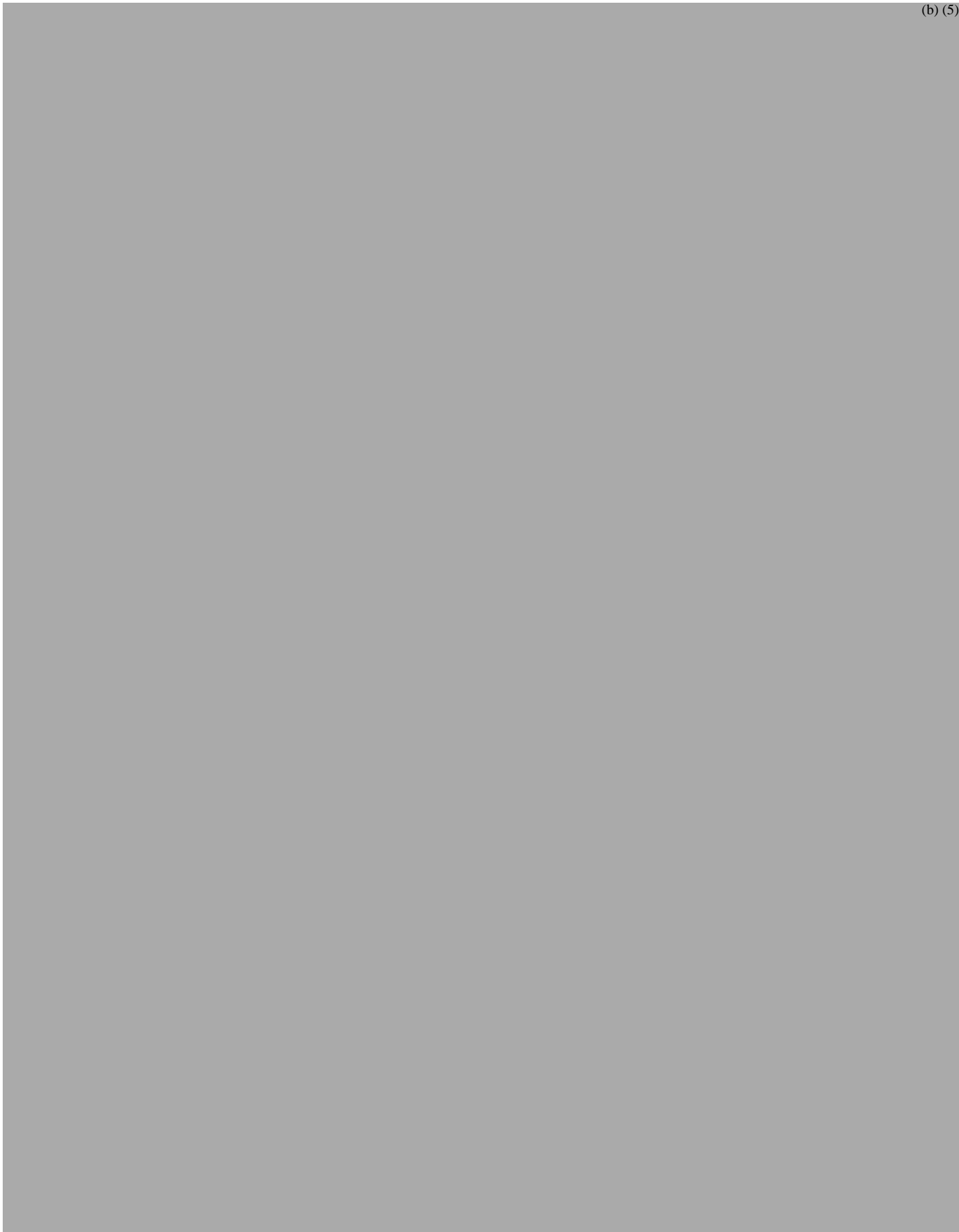






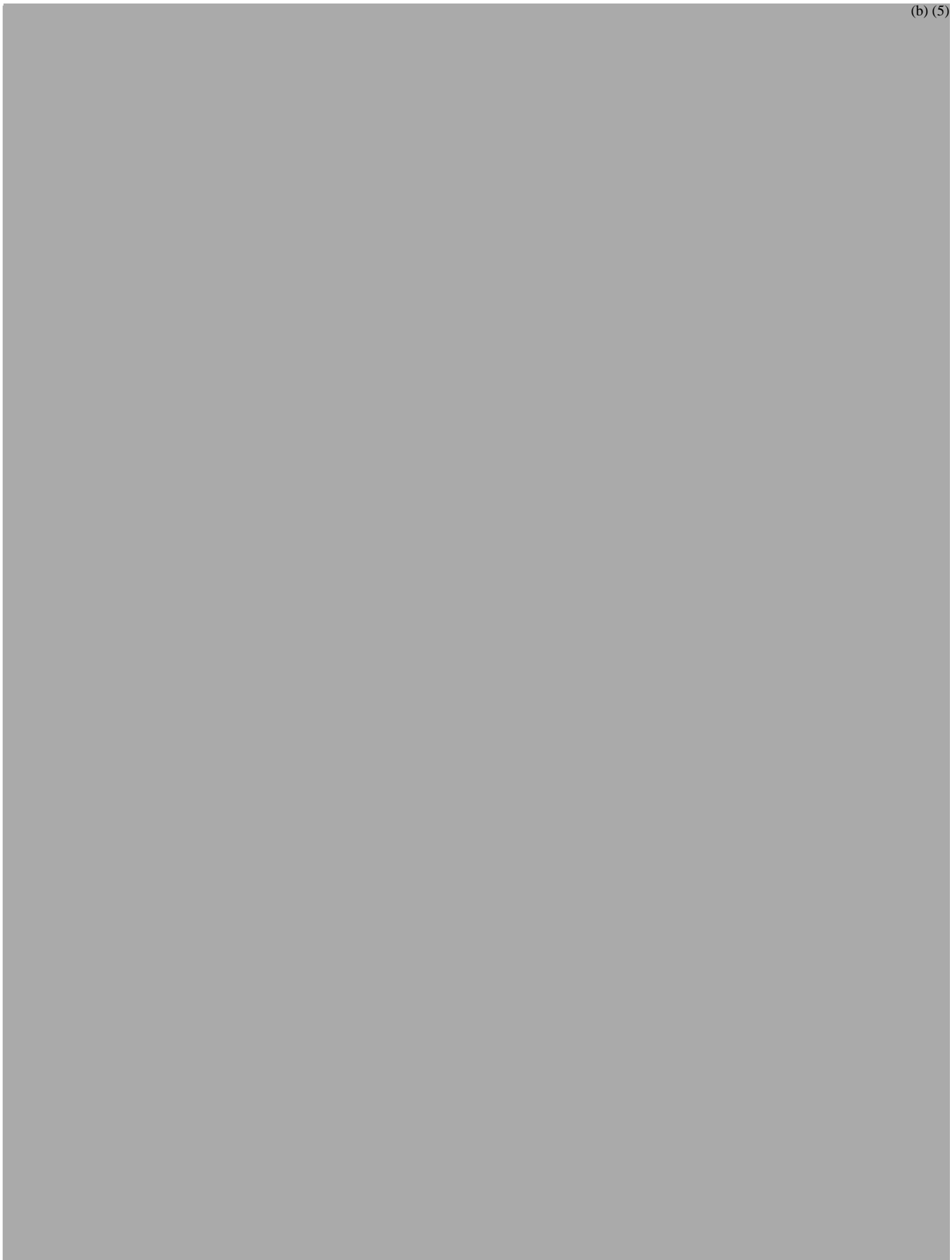






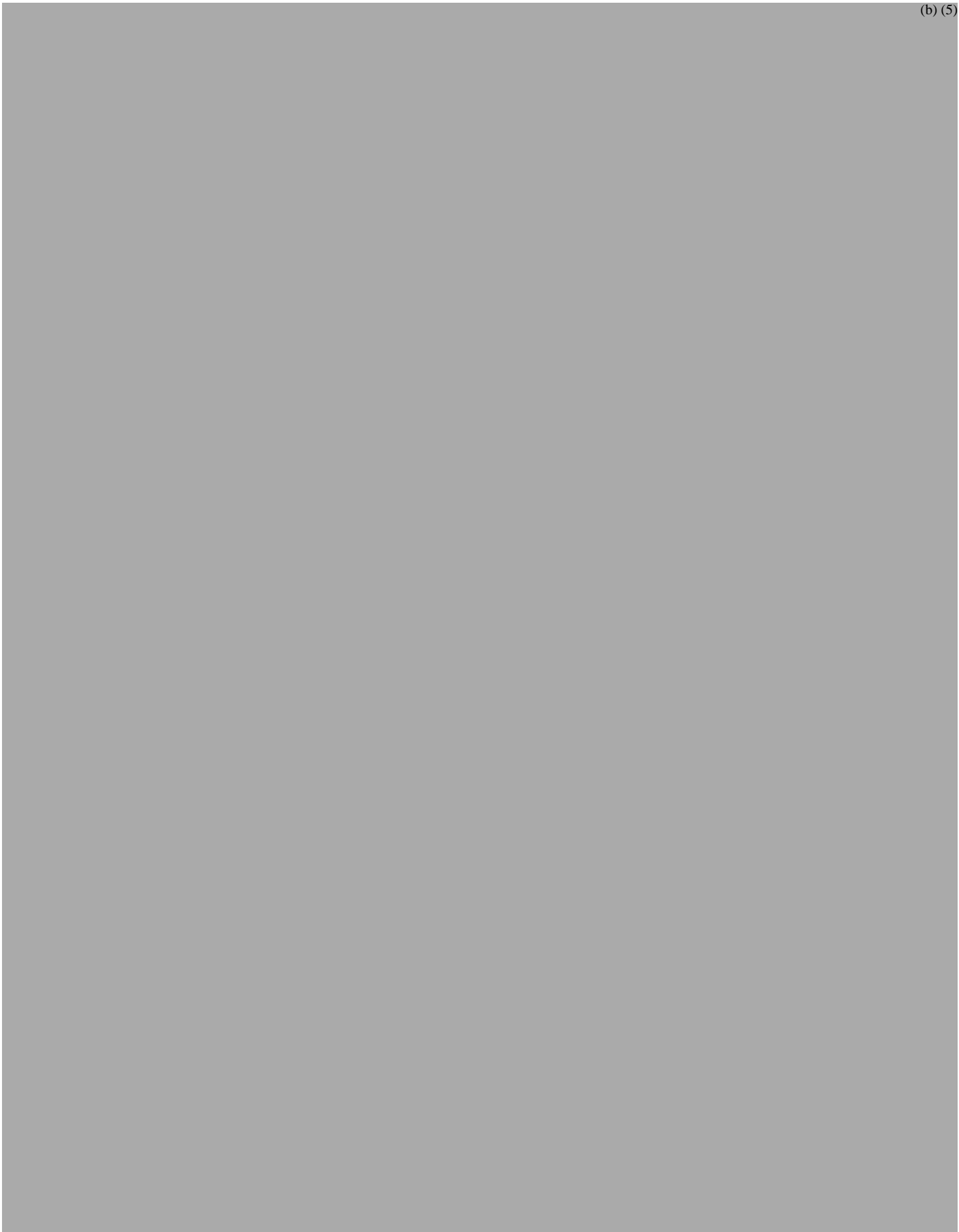






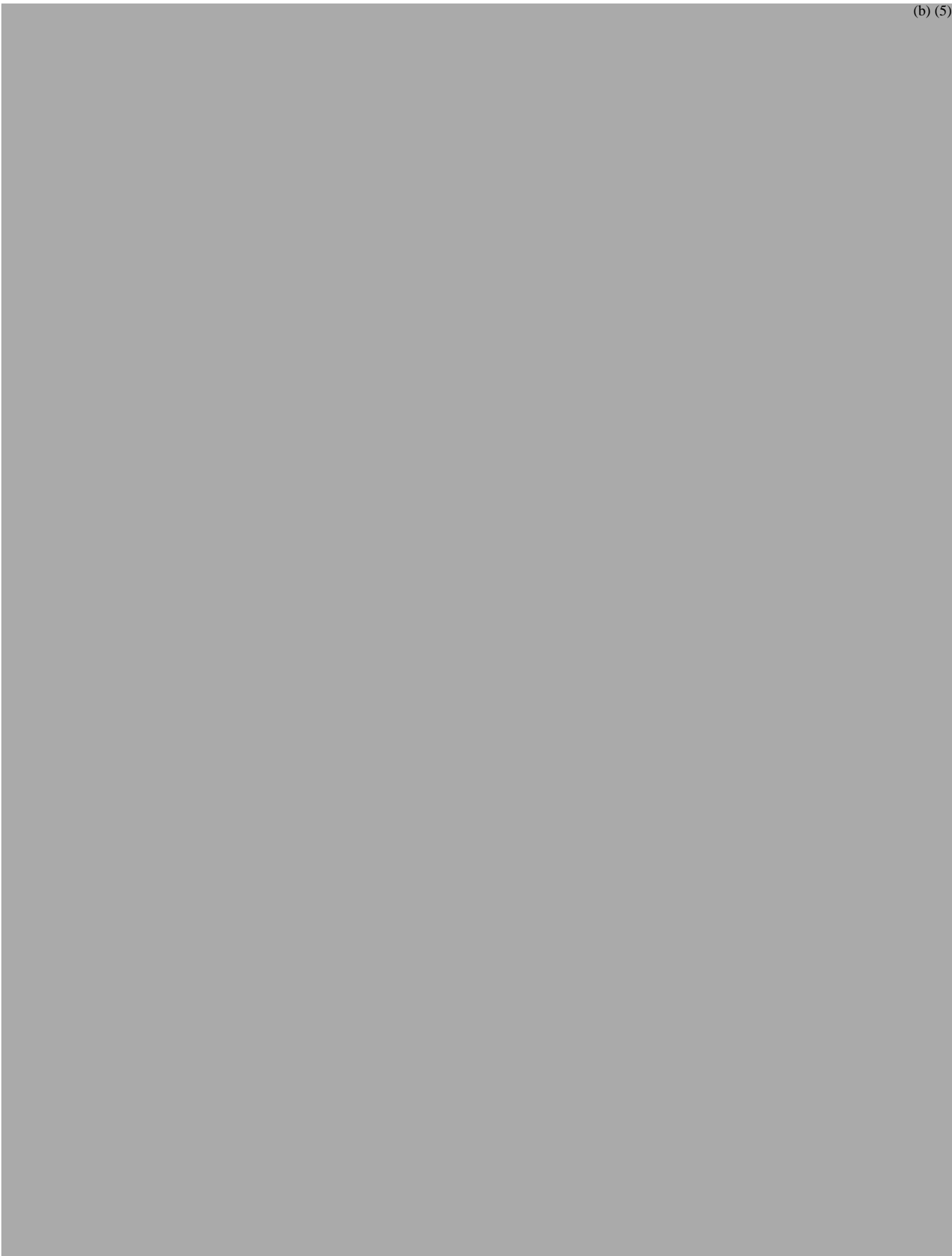


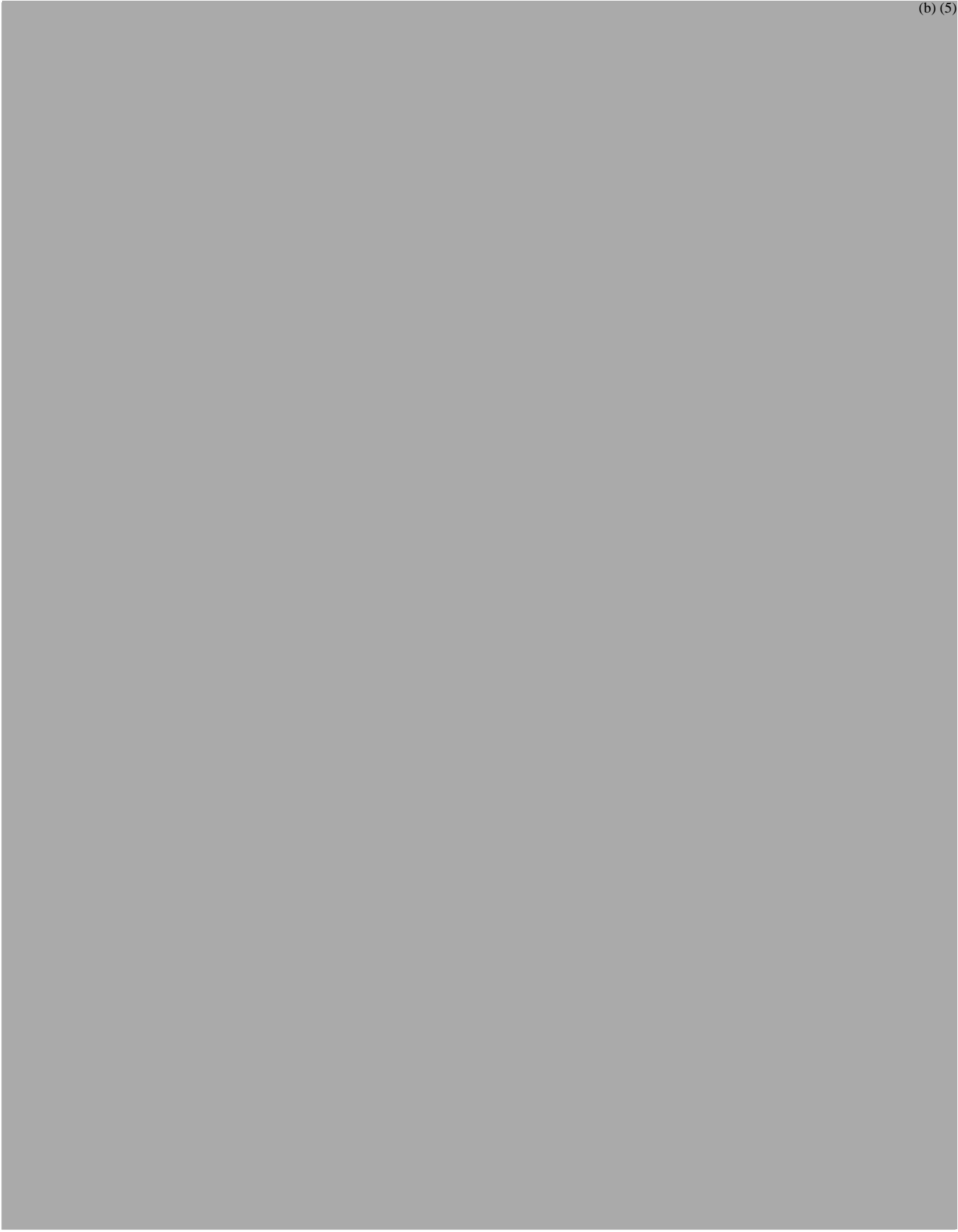


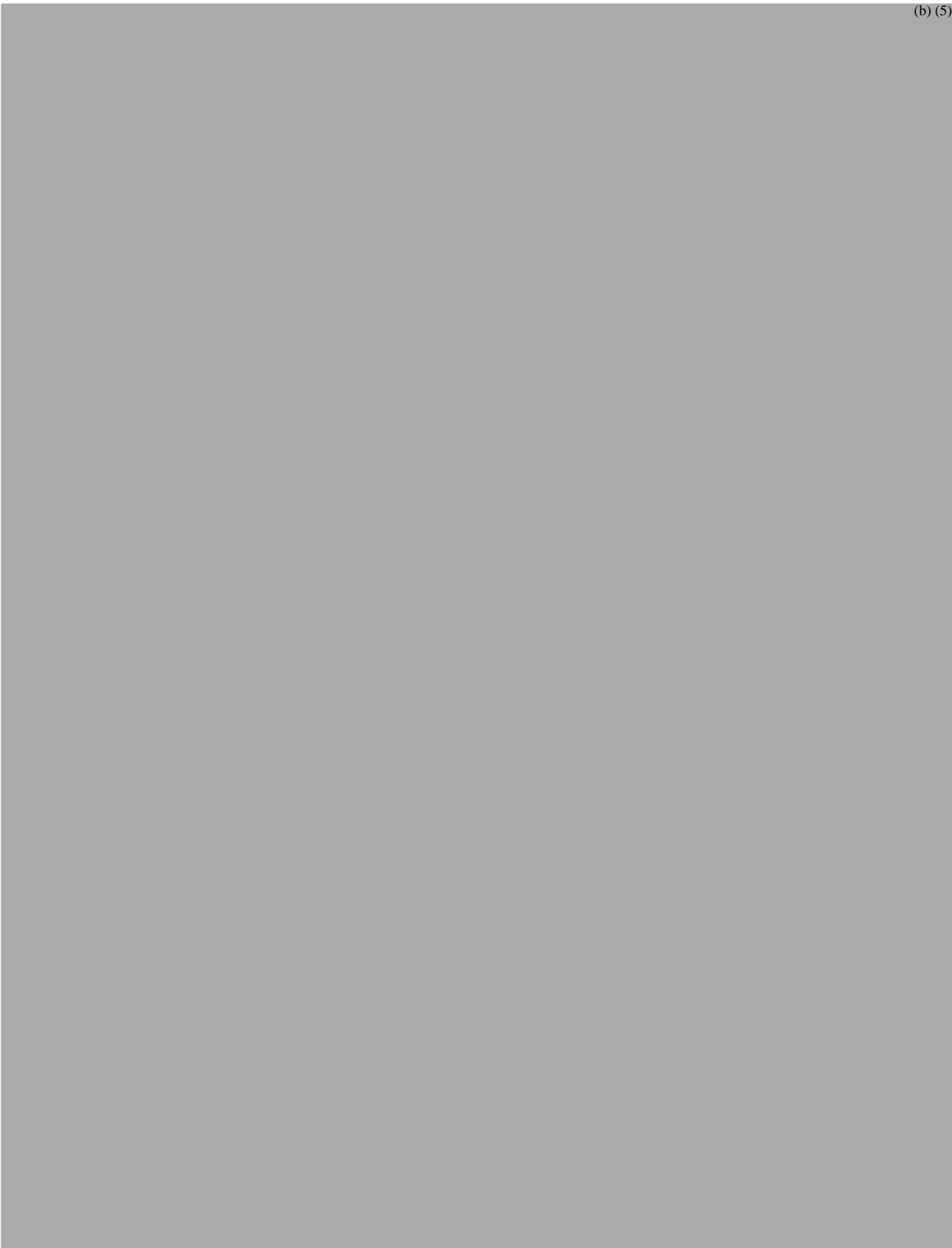


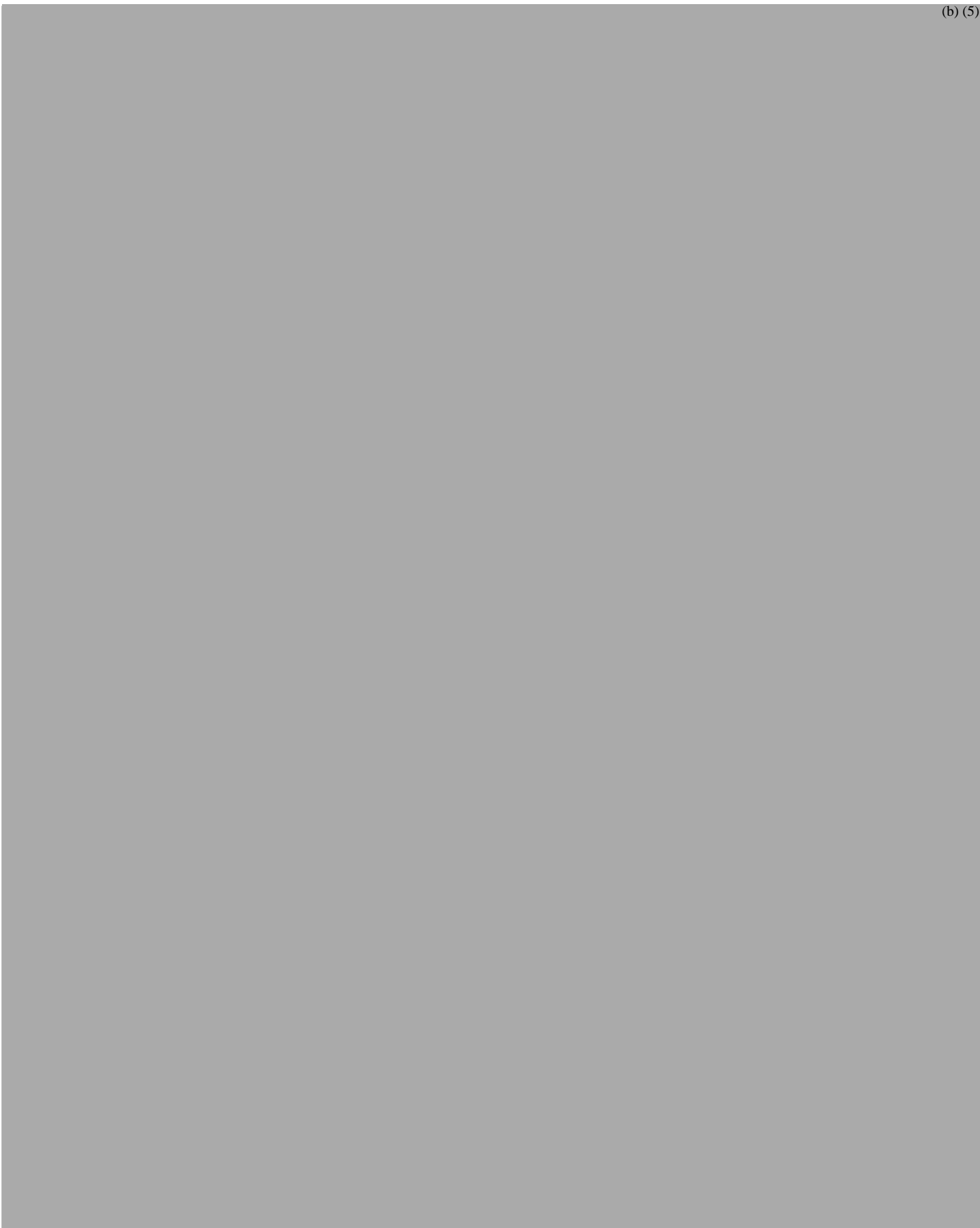














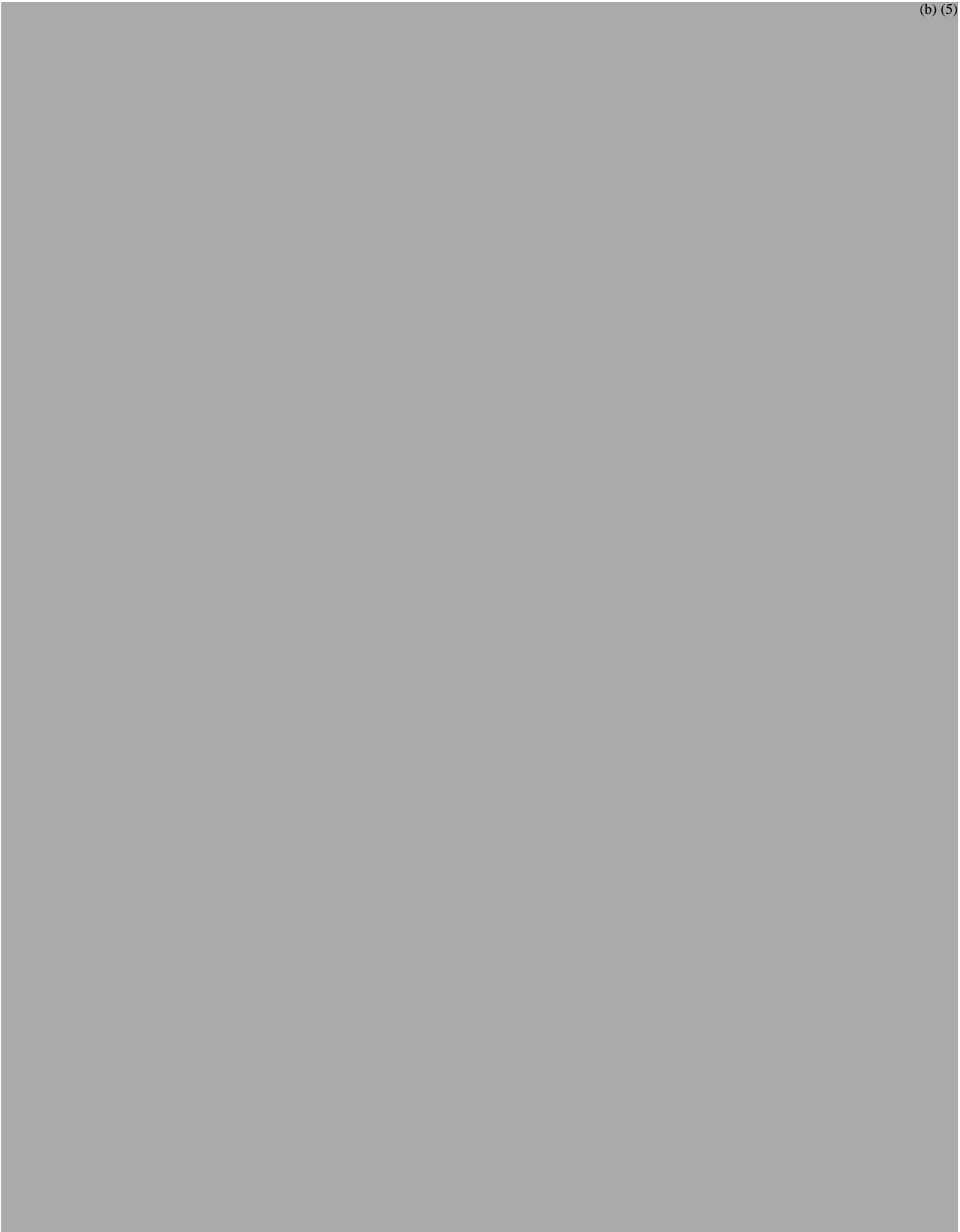
Summary

Chapter 2 Overview of NIH Research

Introduction

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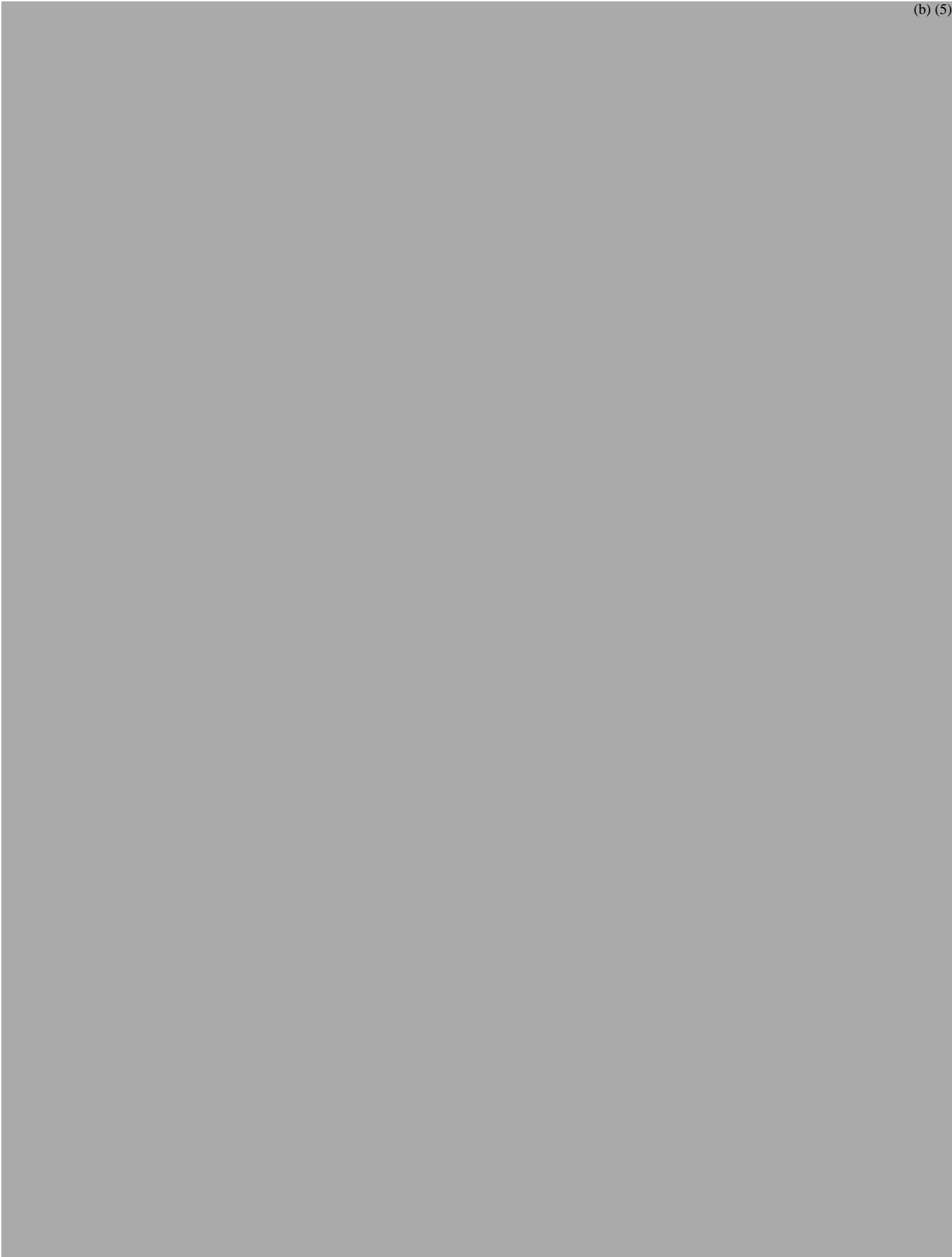
Basic Research

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Preclinical Translational Research



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Clinical Research

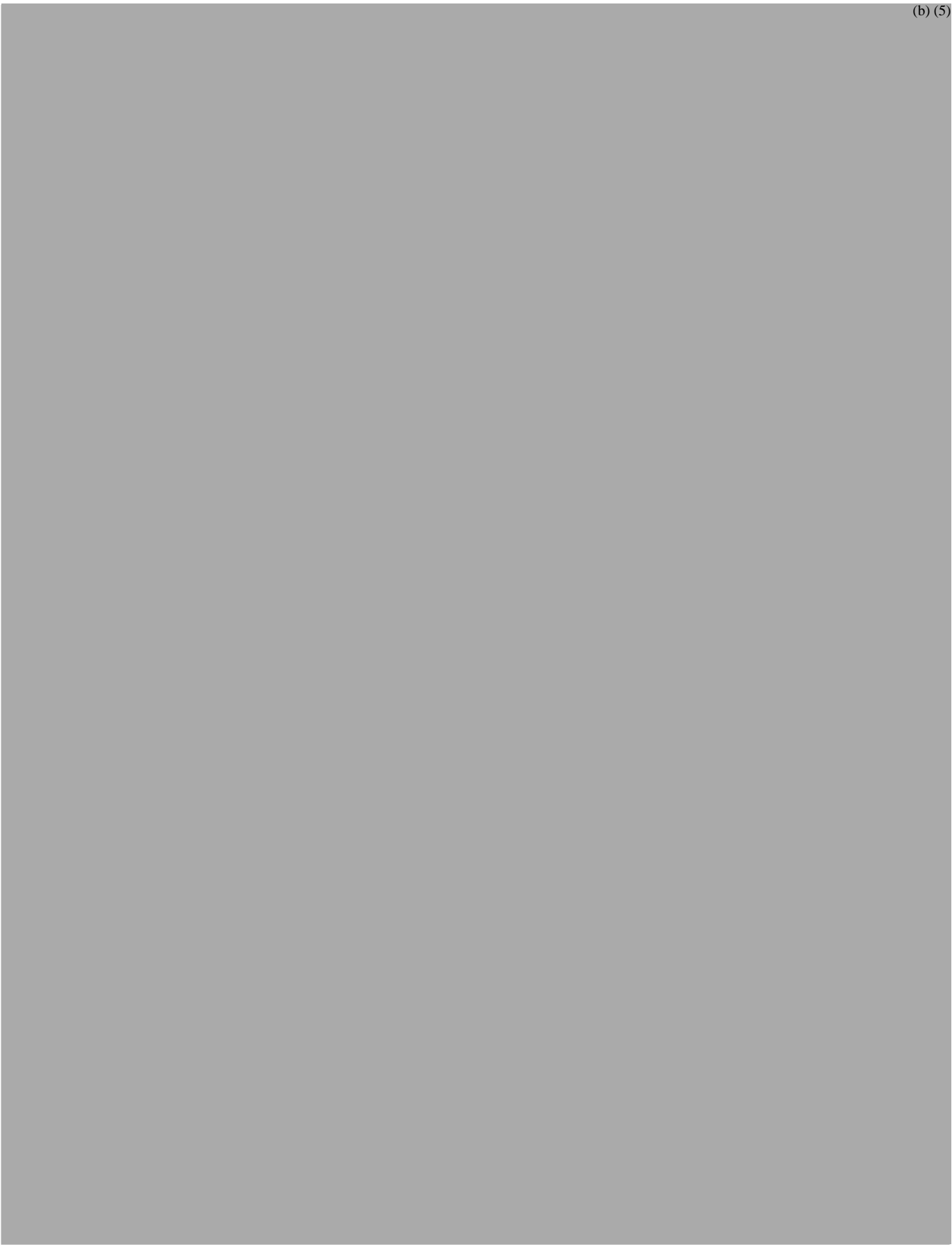
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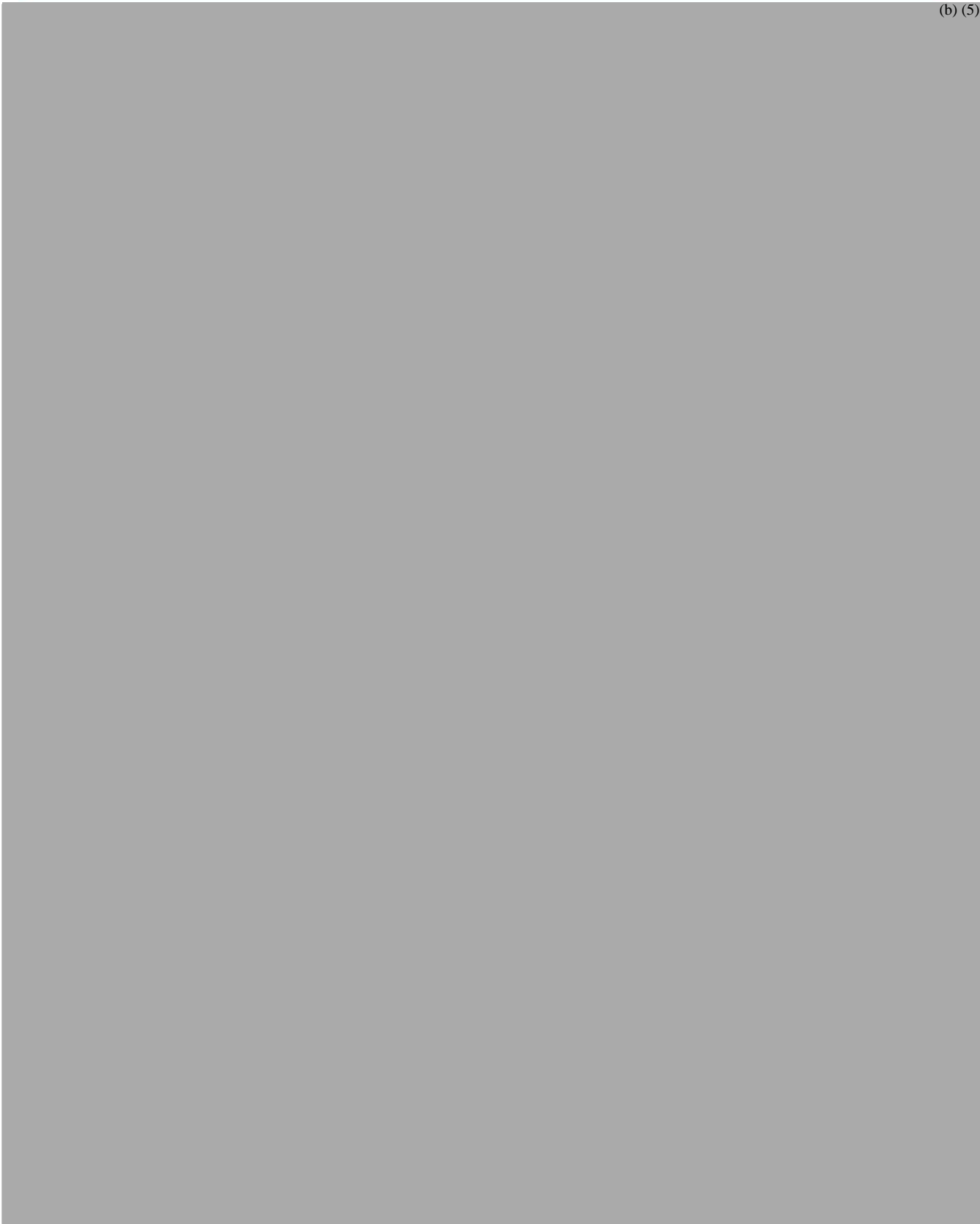














Identifying Public Health Needs (Epidemiology)

The mission of NIH, along with the rest of the PHS, is to address ongoing and newly emerging public health needs. The 27 NIH ICs and OD collectively house expertise on a broad spectrum of diseases, populations, and research support methods. Large-scale epidemiological studies provide an ideal opportunity for researchers from various NIH components to work together on innovative studies that examine the frequency, pattern, and determinants of health events in a population. Our investments in epidemiology and public health continue to pay off as NIH contributes to the nation's ability to detect emerging and re-emerging diseases quickly, mitigate their health impacts, and improve the nation's resilience to future disease threats.

NIH Epidemiological Research Activities

Epidemiological studies examine the distribution of and the factors that contribute to health and disease in human populations using a broad range of approaches. Epidemiological research, a cornerstone of public health, helps us understand how many people have a disease or disorder, whether those numbers are changing, and how the disorder affects our society and our economy. Groups can be followed over time in longitudinal (cohort) studies, or a snapshot of information can be collected at a single point in time (cross-sectional studies). Studies can be done retrospectively, examining outcomes that already have occurred and factors that may have contributed to health or disease, or they can be done prospectively, by beginning to monitor a population of interest before a particular disease-related outcome occurs. Epidemiological research can be experimental, but many epidemiological studies are observational in nature, collecting information about and comparing groups' individuals who share a characteristic of interest (e.g., tobacco use, age, educational status).

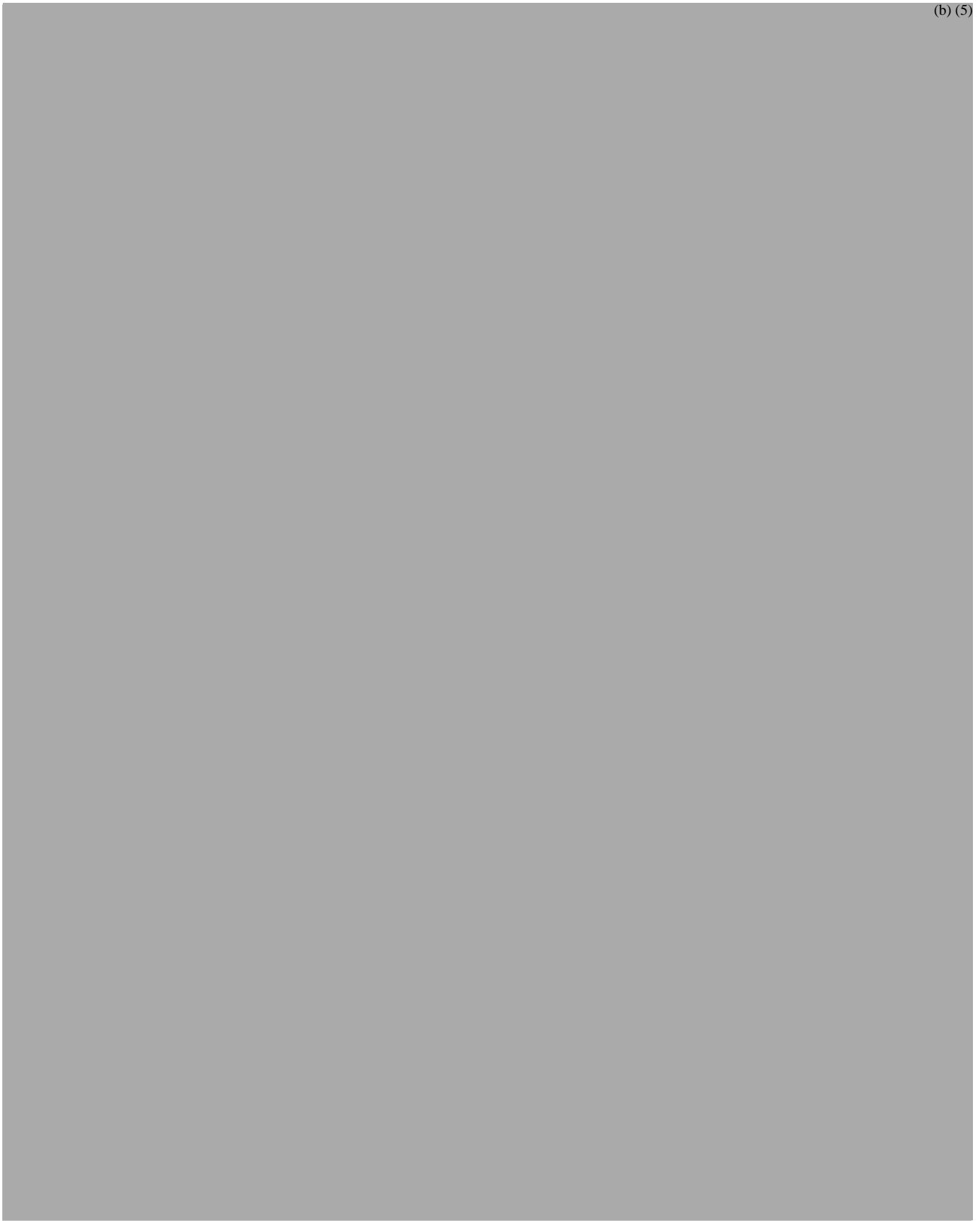
Providing major influence across the continuum from basic to applied research, epidemiological studies often test the findings of laboratory or clinical research at the population level. Additionally, observations made through epidemiological studies often result in the formulation of new or modified hypotheses that spur new basic, translational, and clinical studies. For example, epidemiological studies in the 1950s showing that tobacco smoking increases risk of lung cancer led to extensive research to identify the carcinogens and mechanisms involved. Epidemiological studies are essential for linking results from the bench to the patient bedside to the general population.

²³⁰ <http://www.nih.gov/icd/od/ocpl/resources/campaigns/>.



Infrastructure, Research Resources, and Technology Development







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Summary

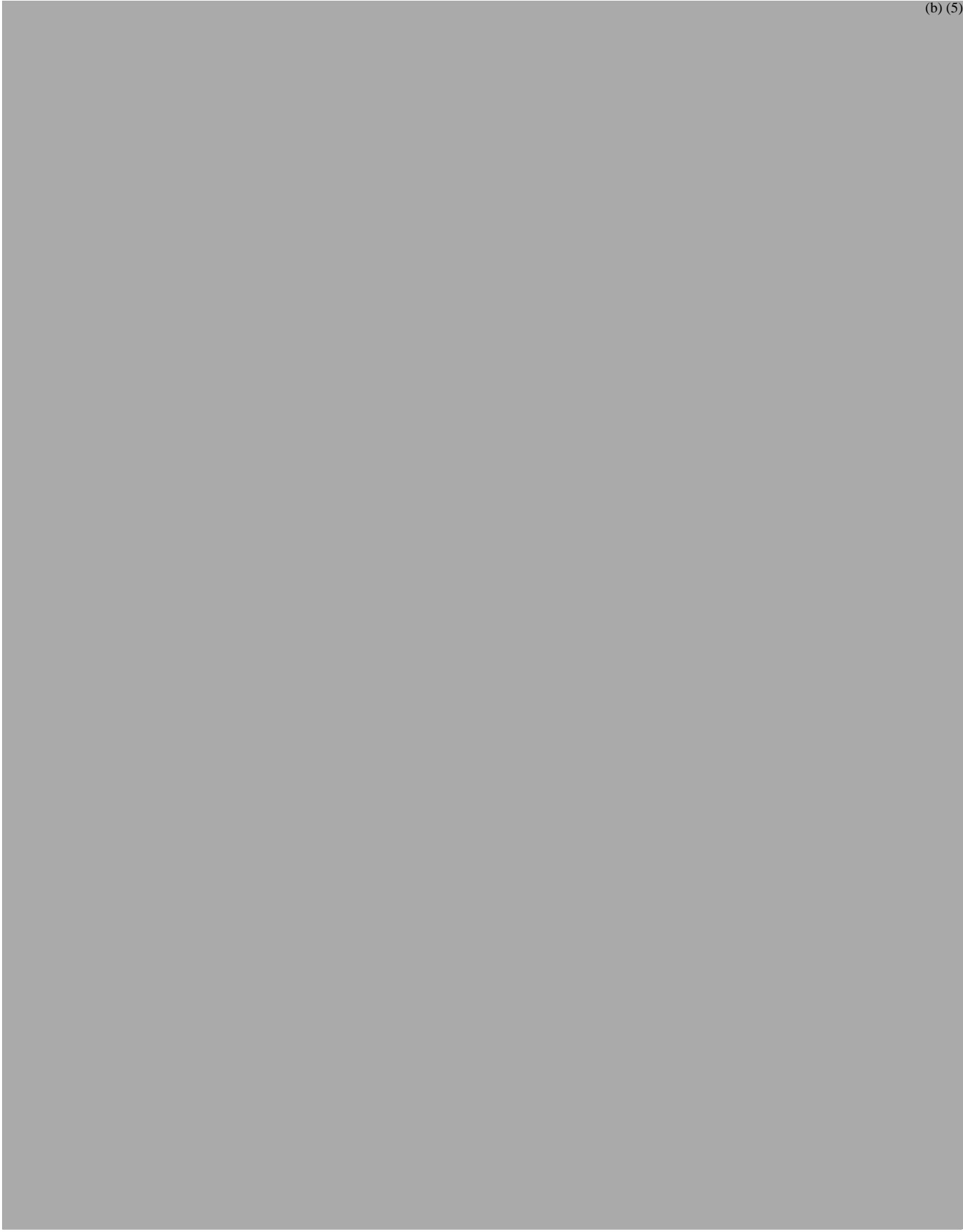
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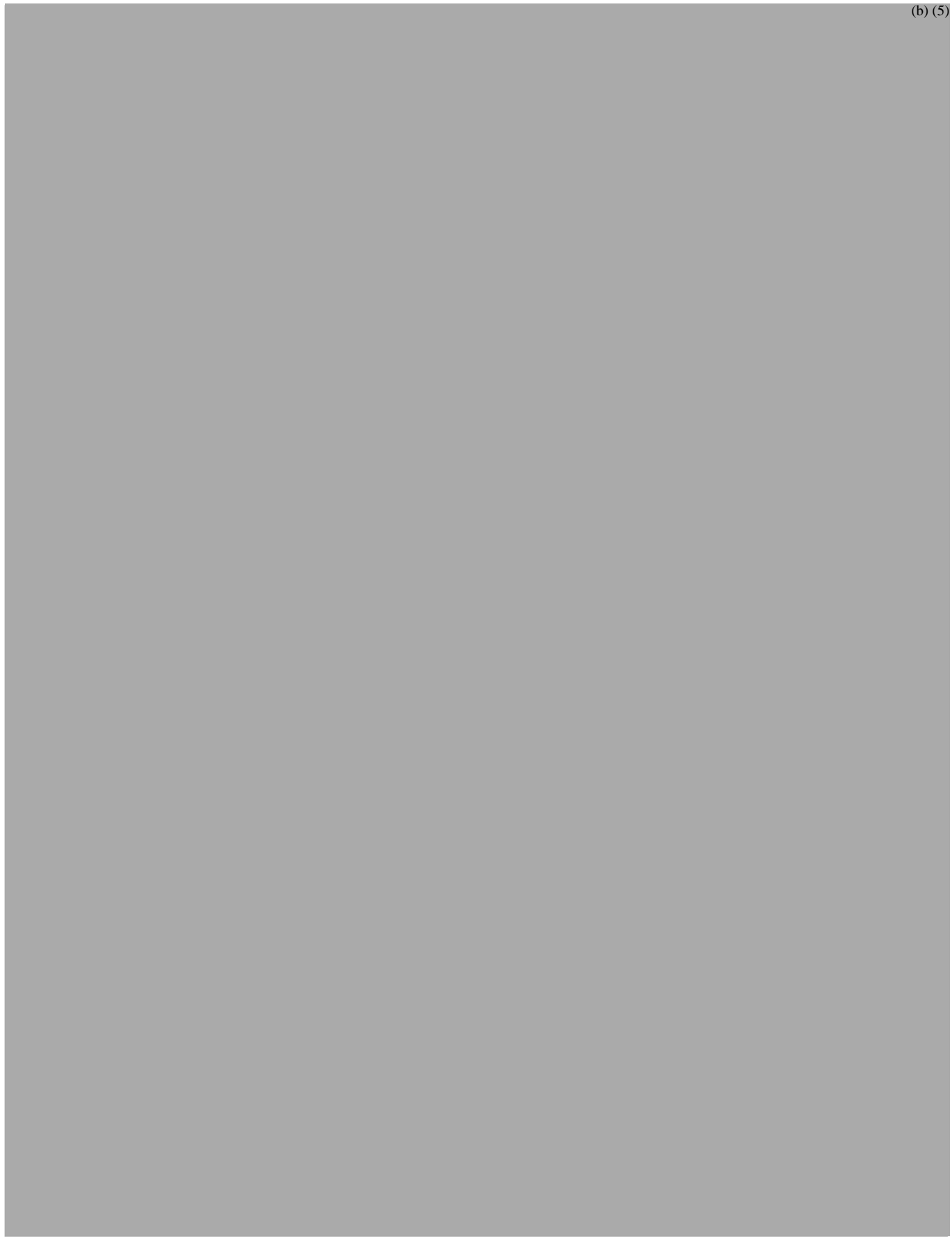
Chapter 3 NIH Research Activities in FY 2016, 2017, and 2018

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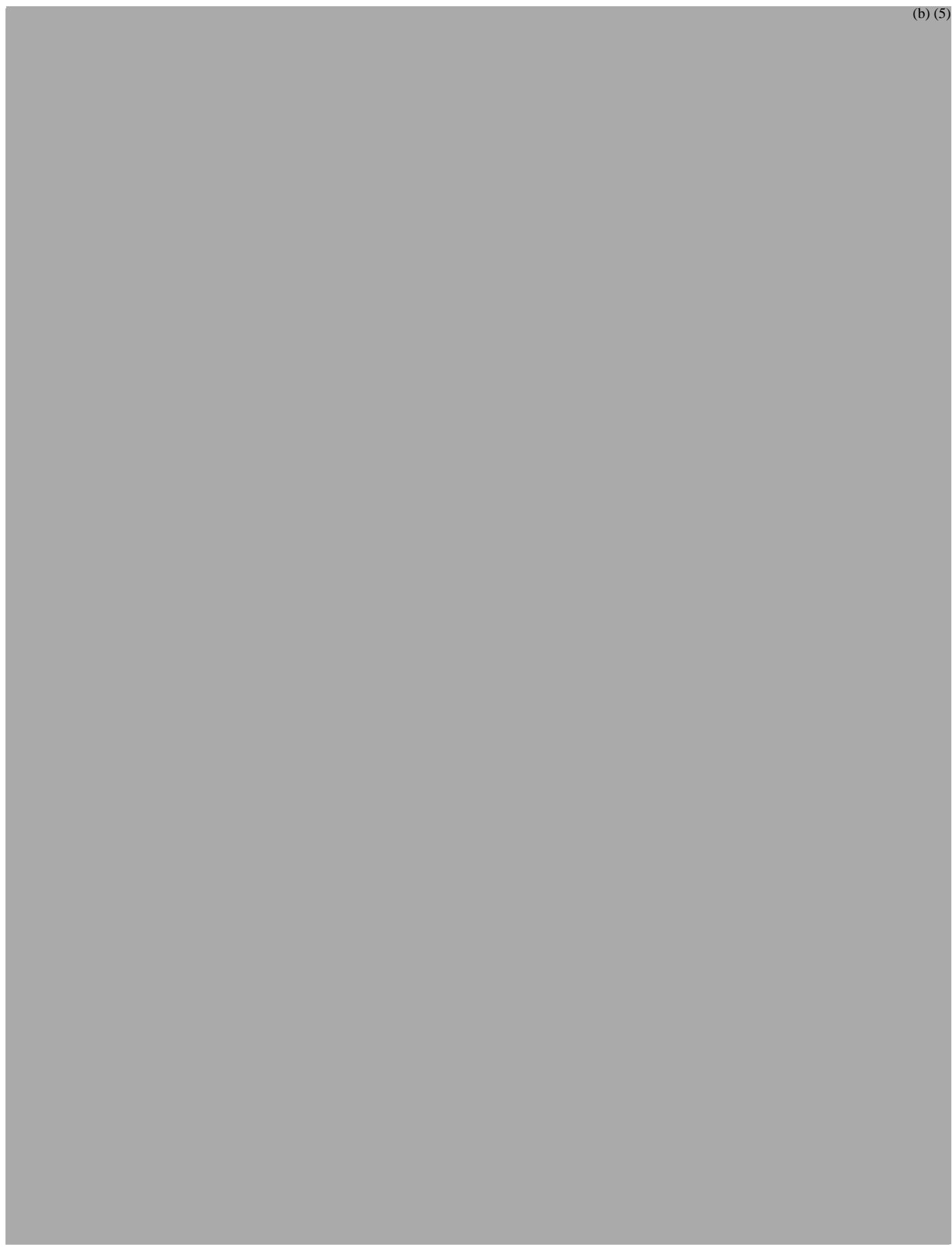
Cancer

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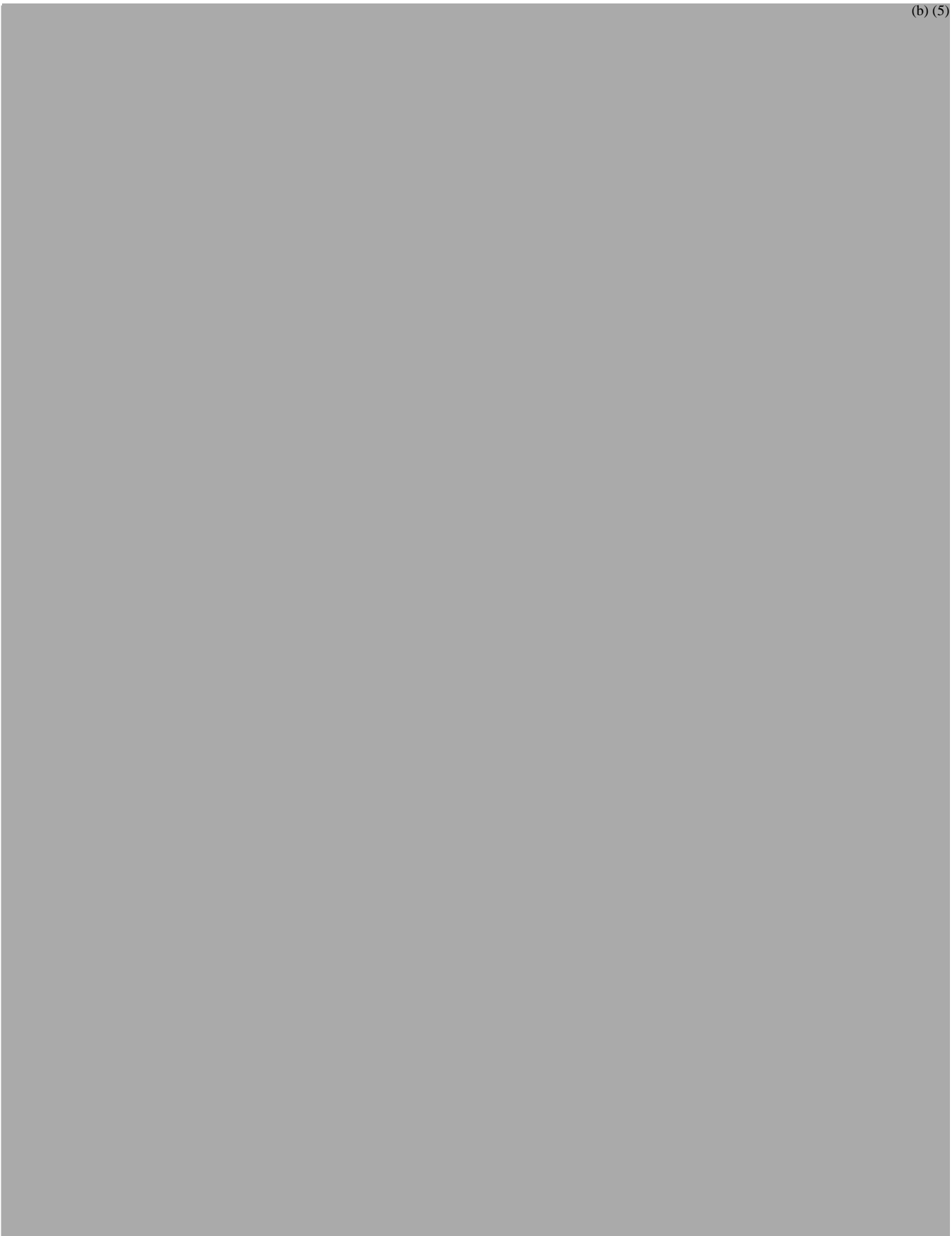


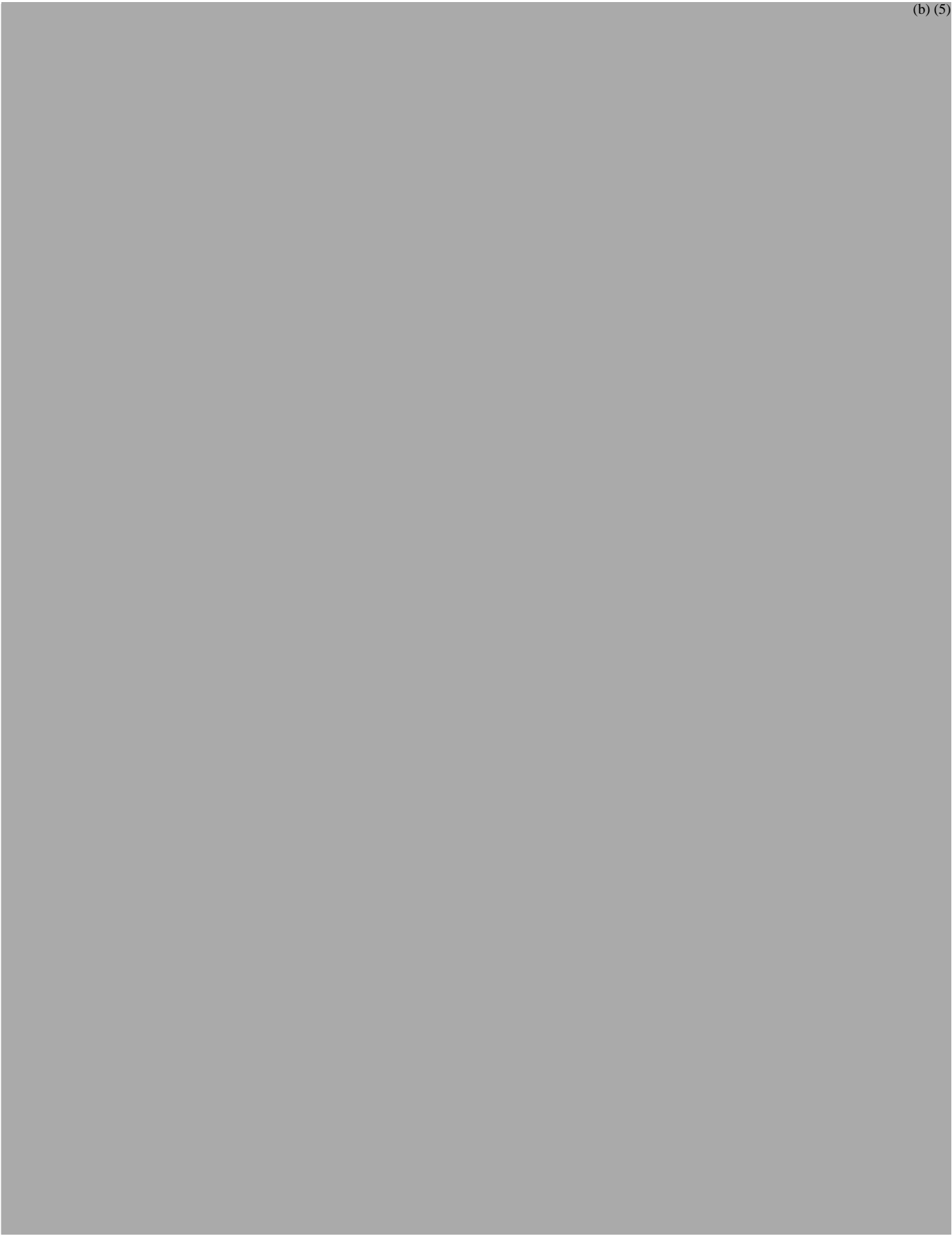




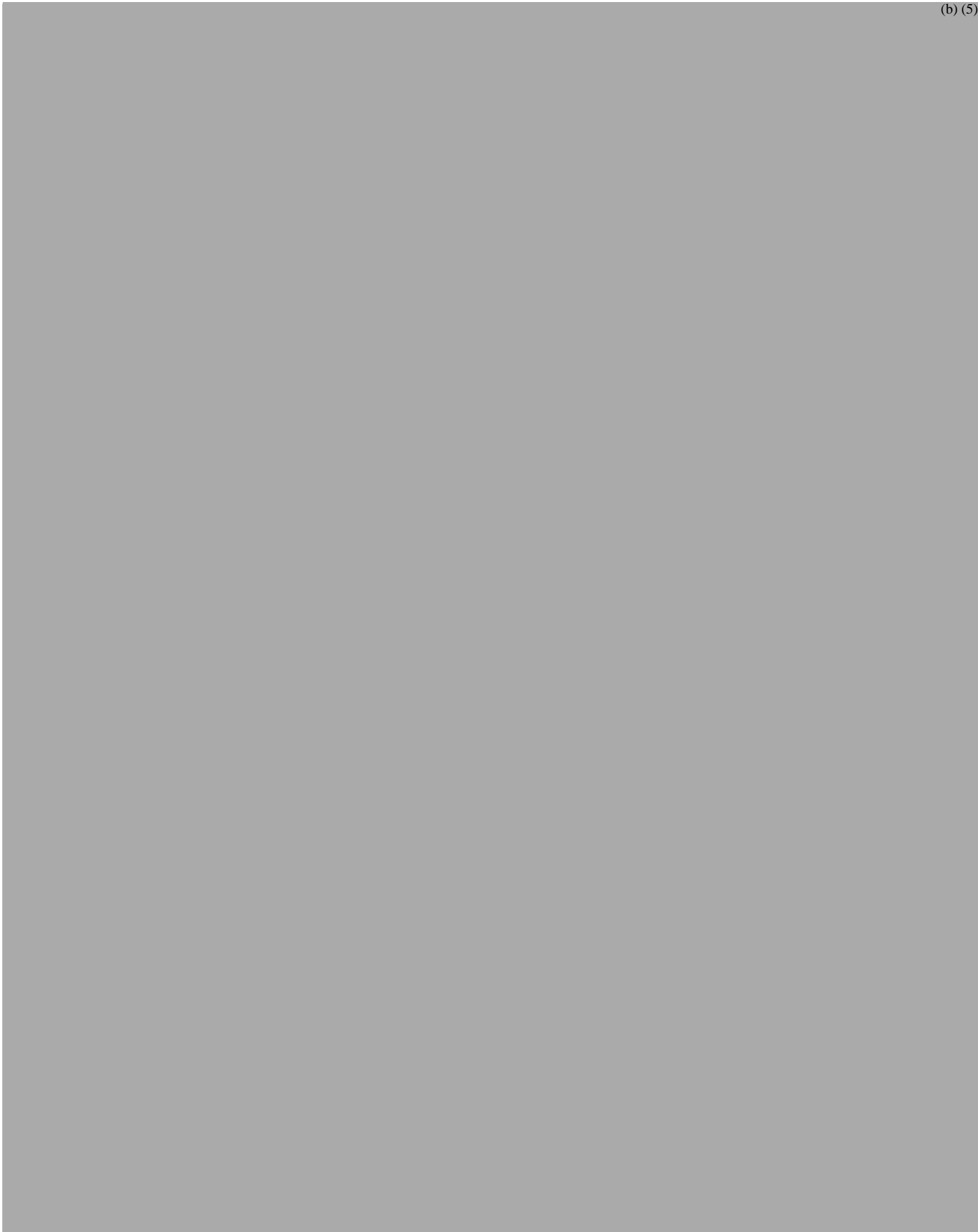




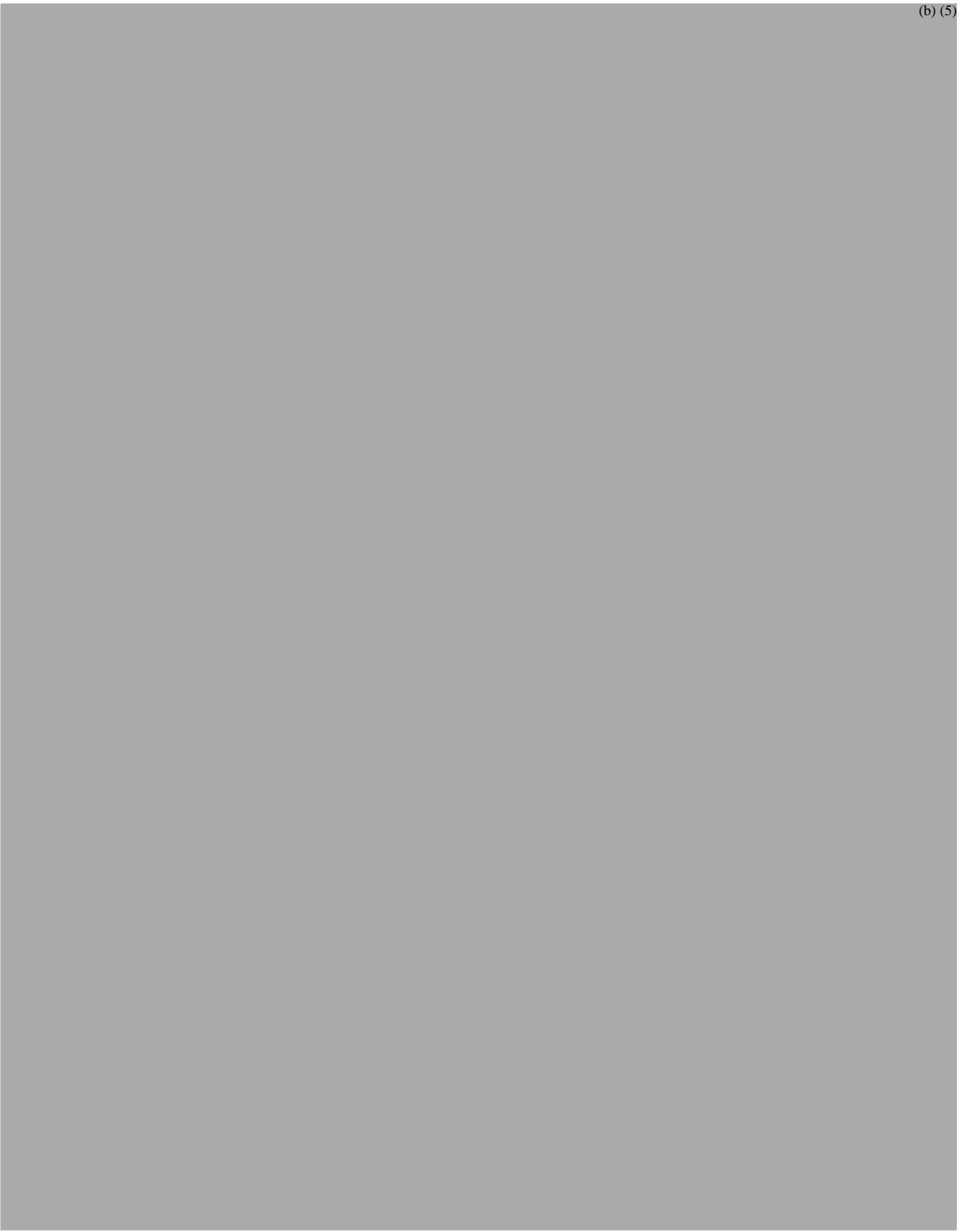


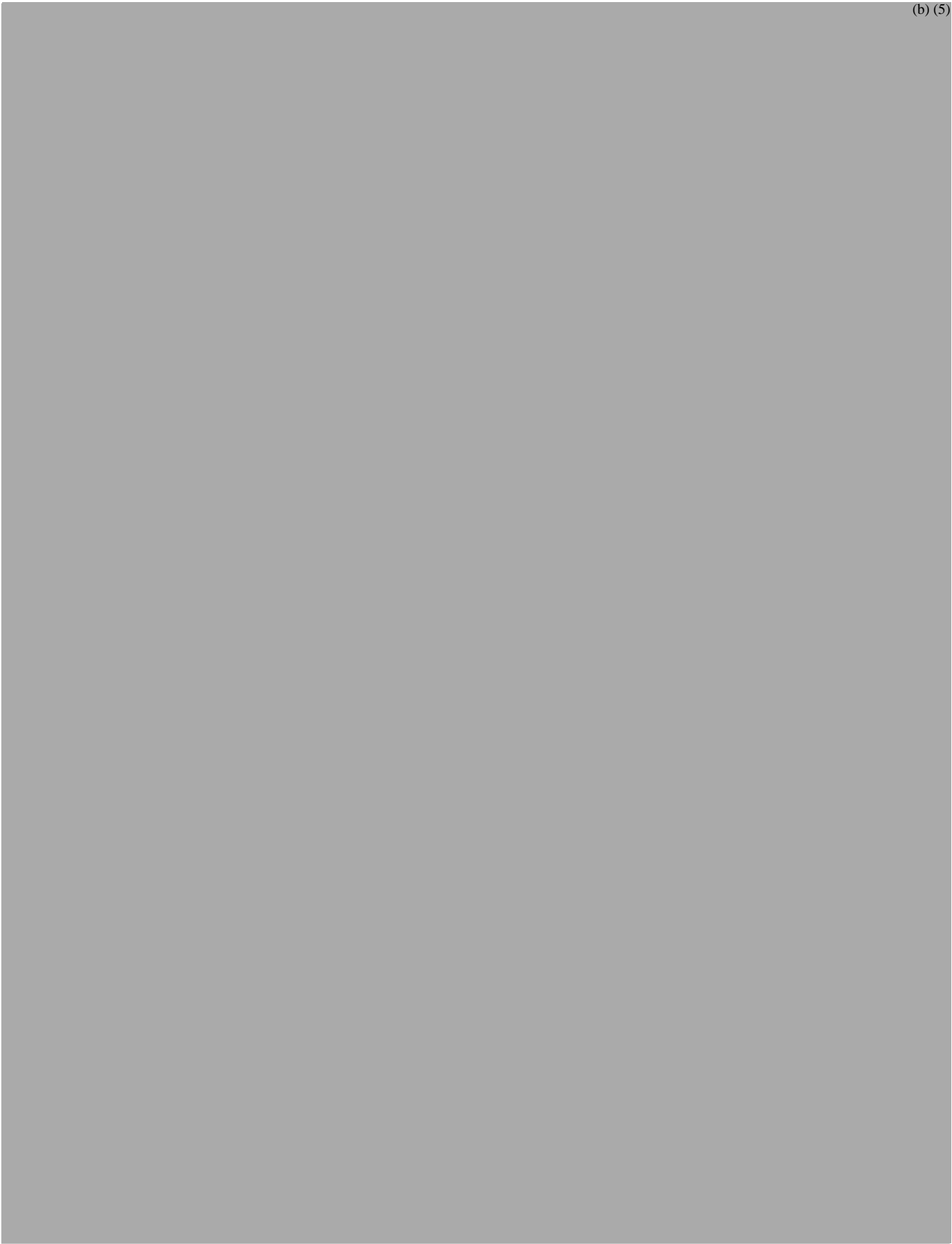






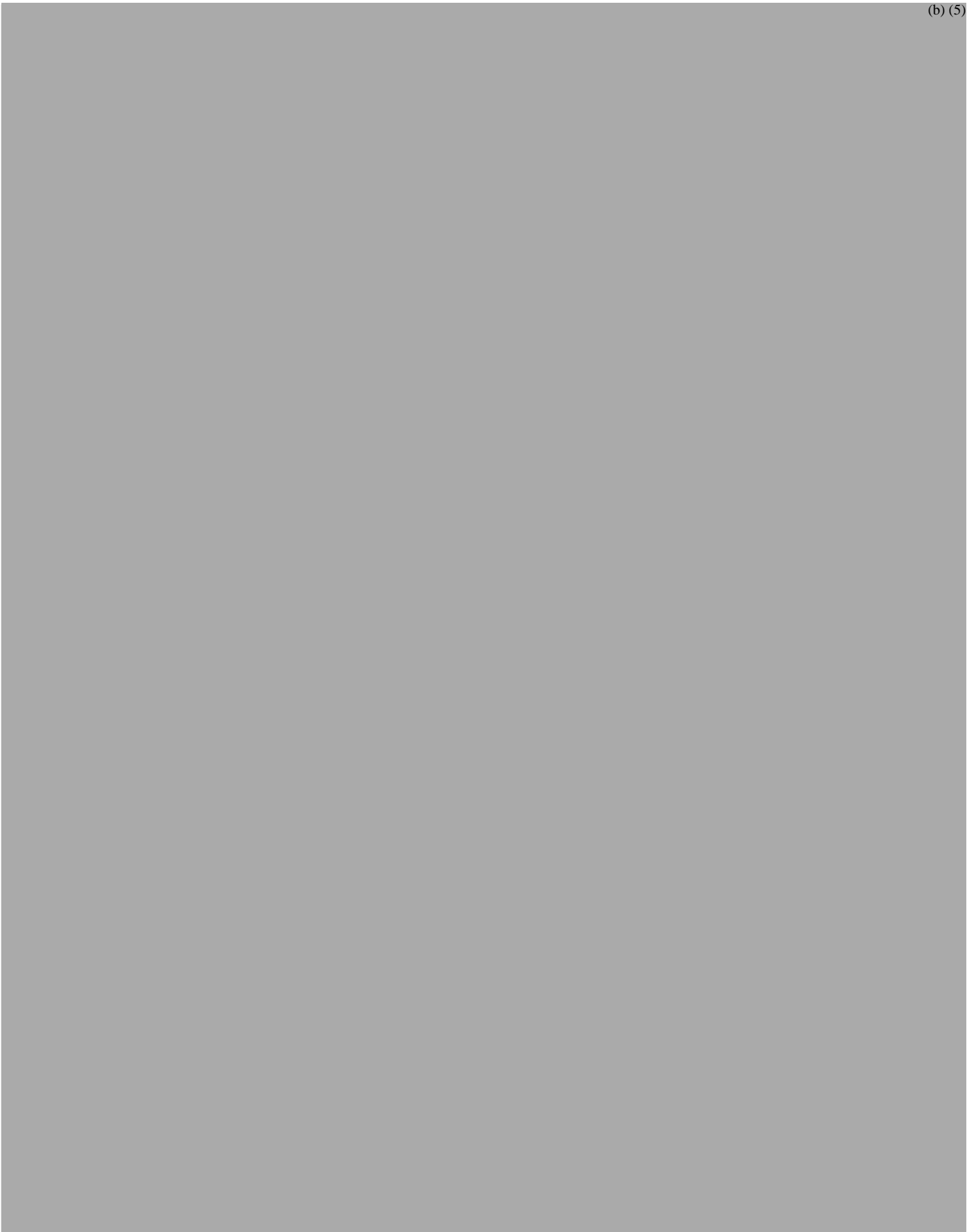
























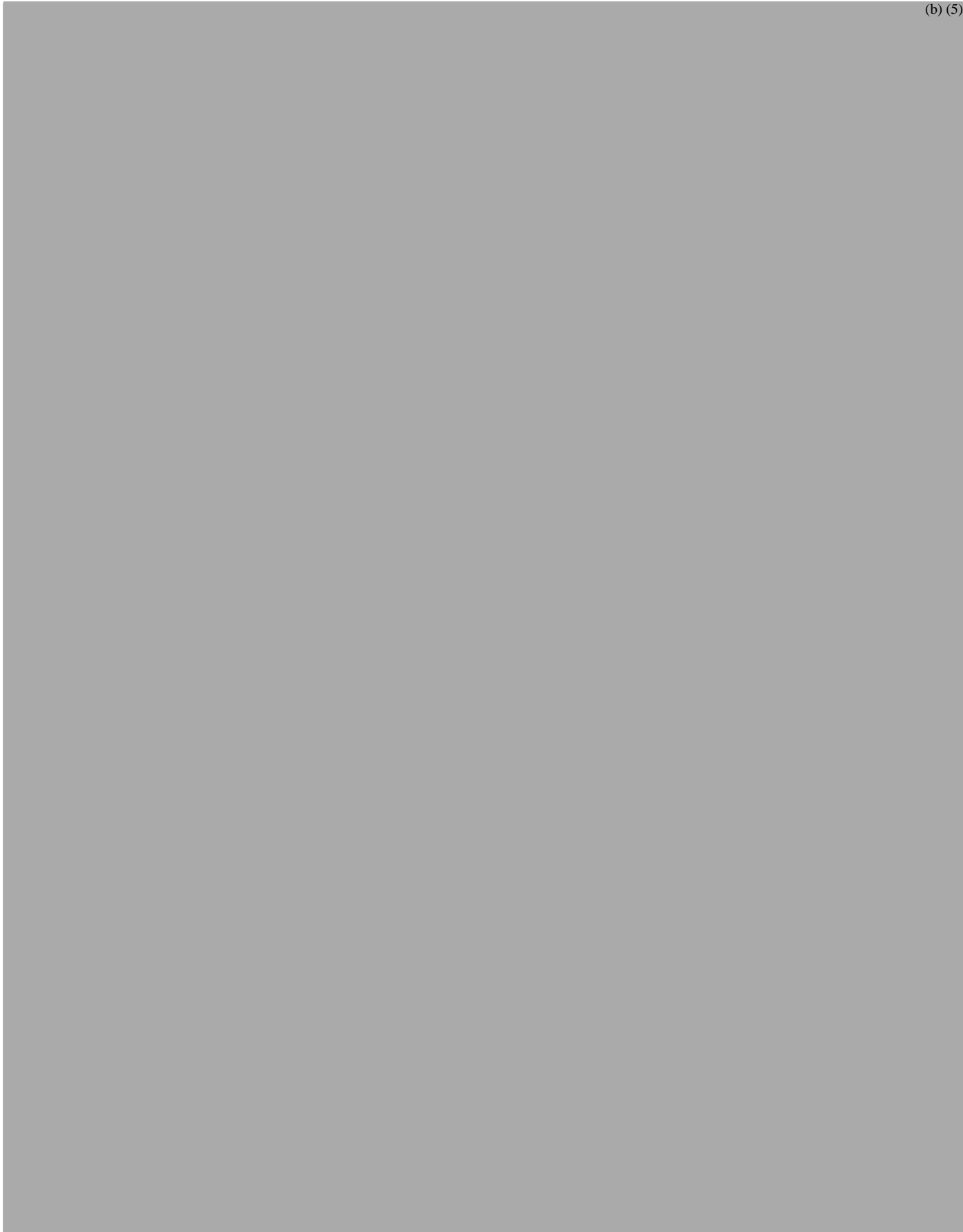








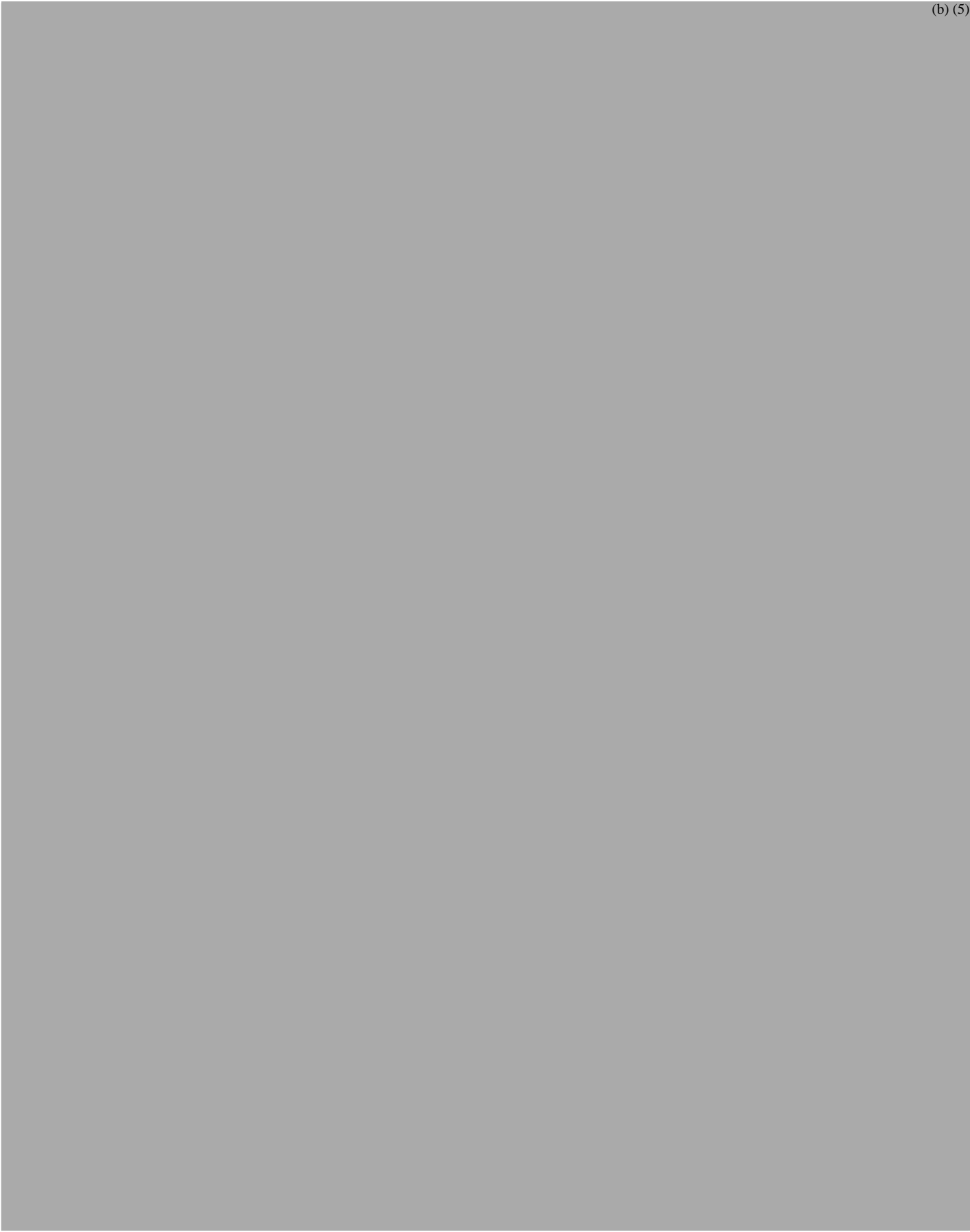












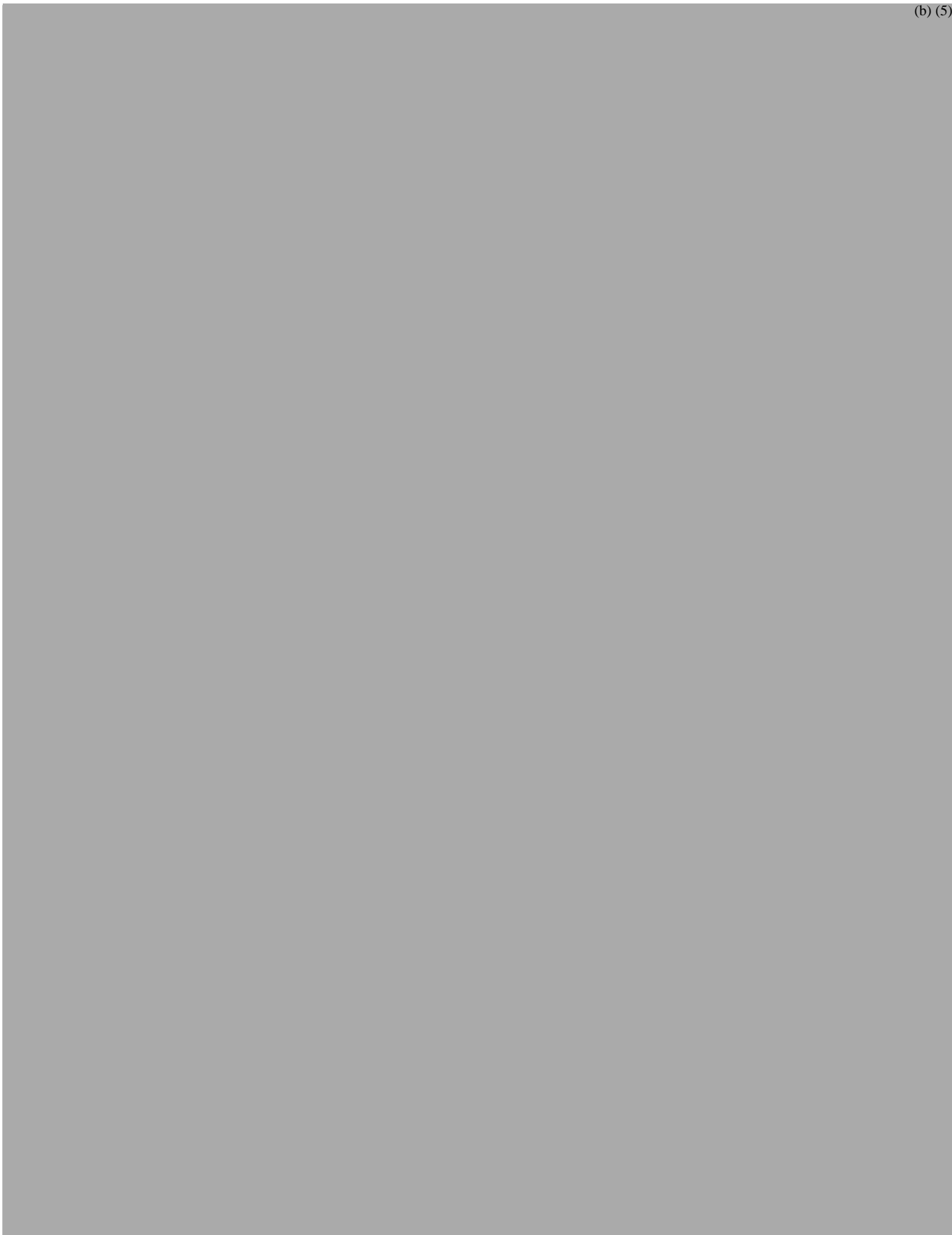


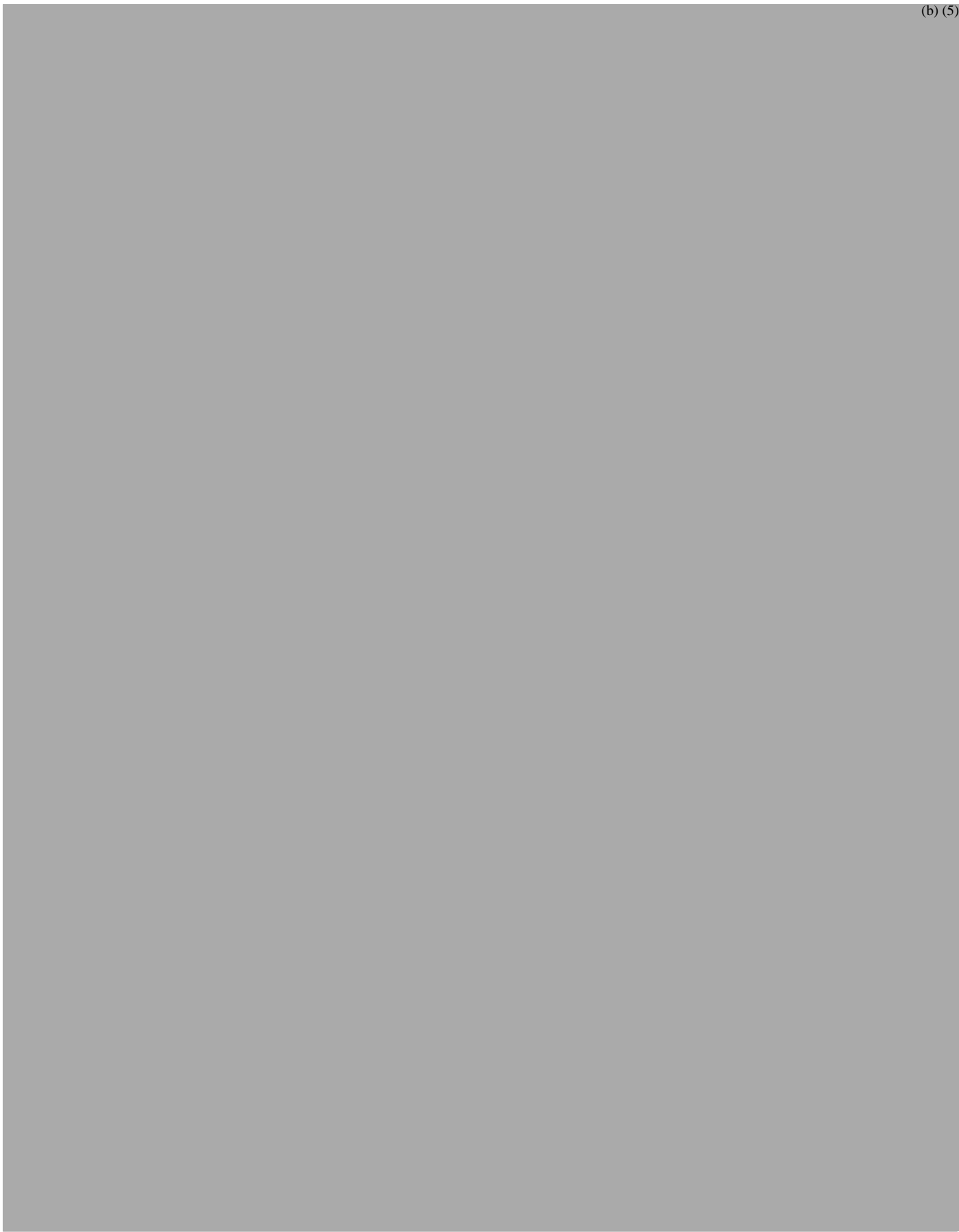


Neuroscience



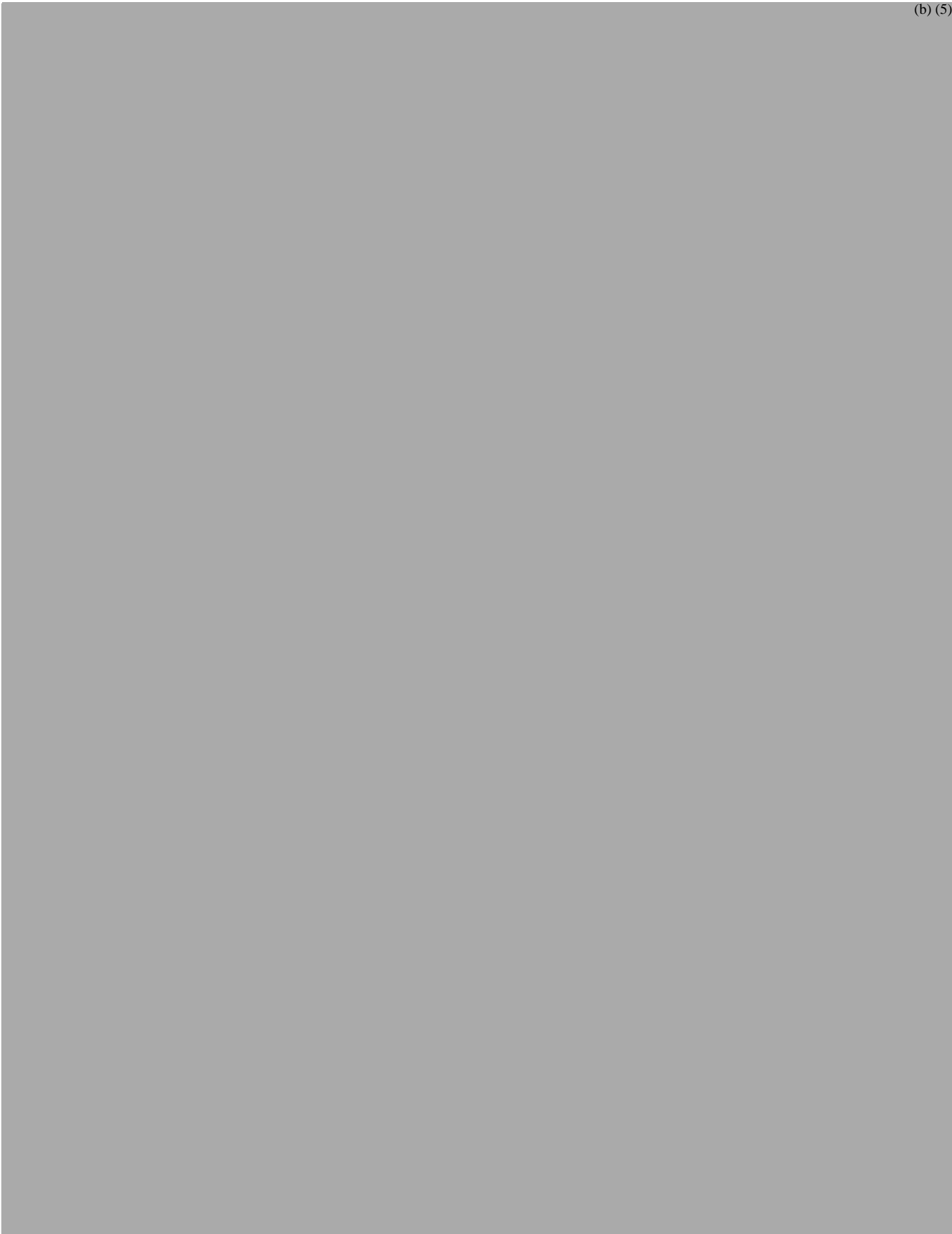




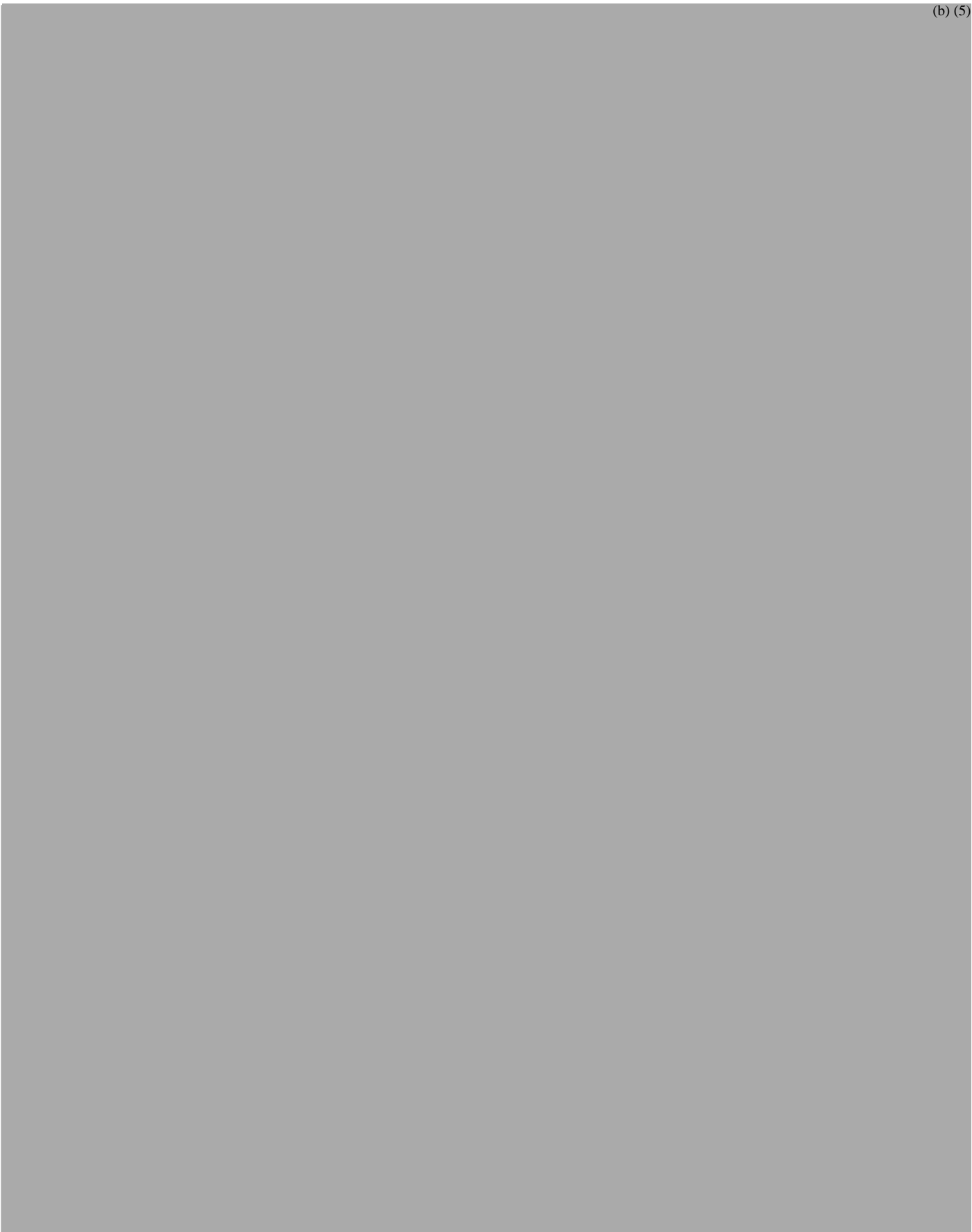






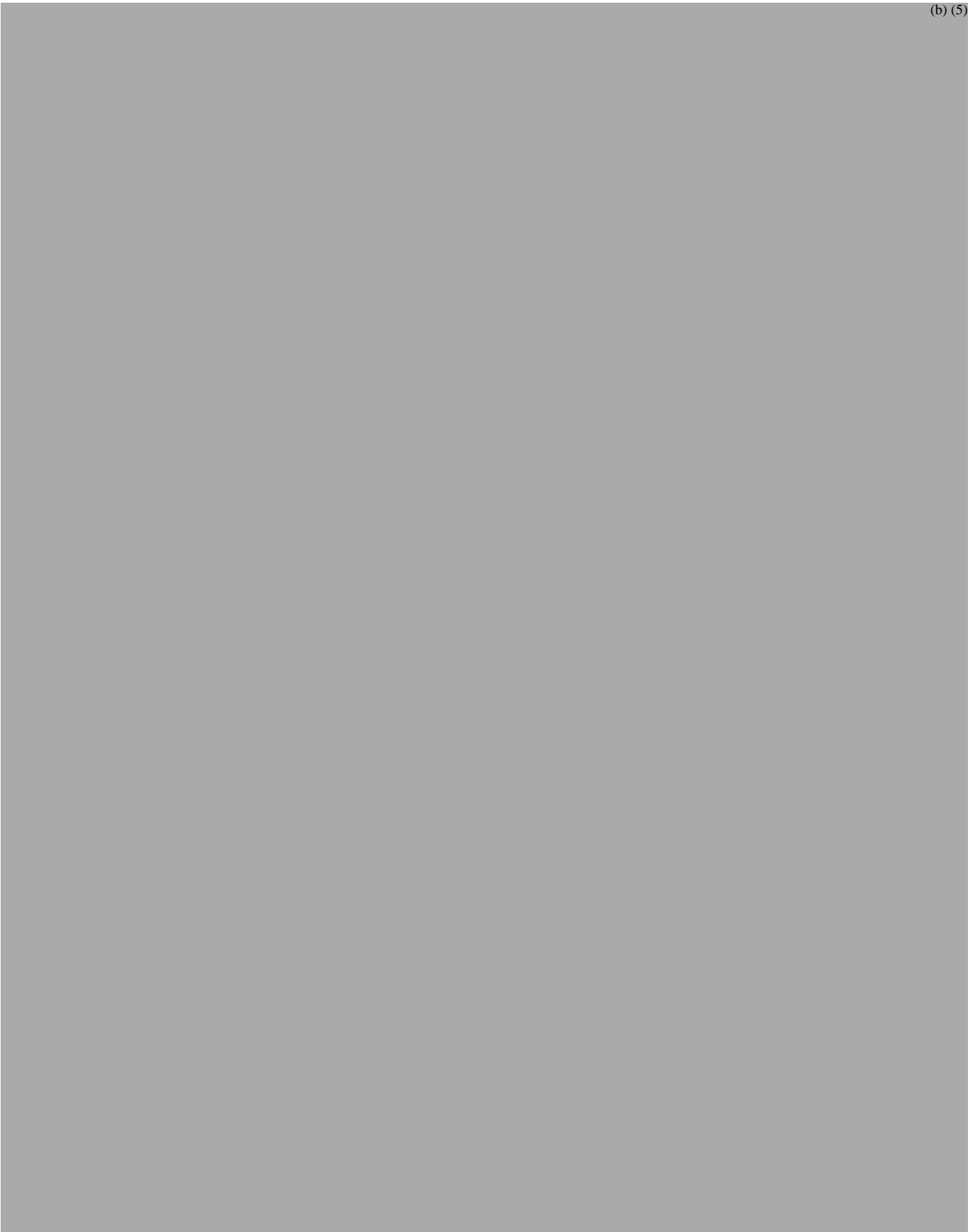






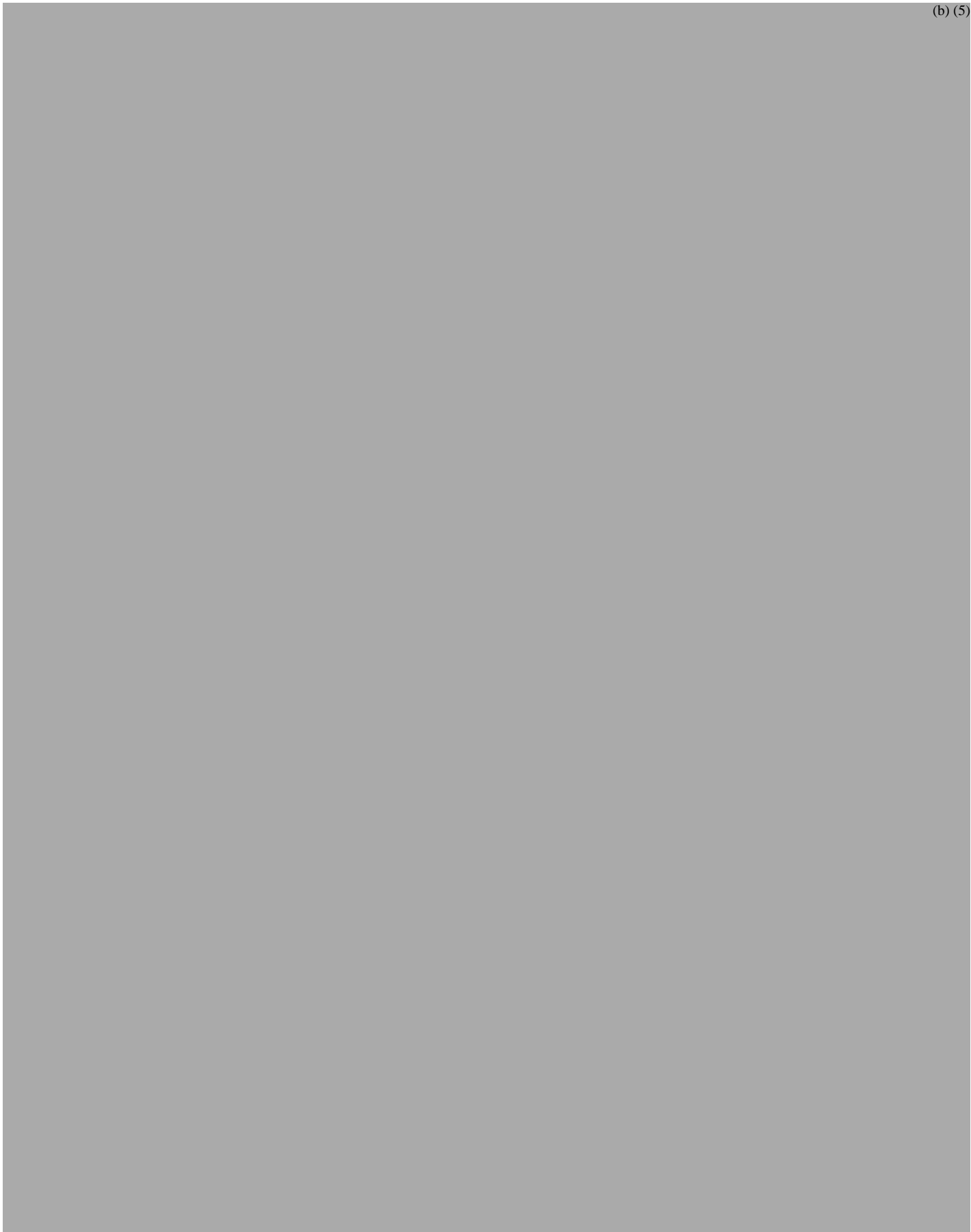


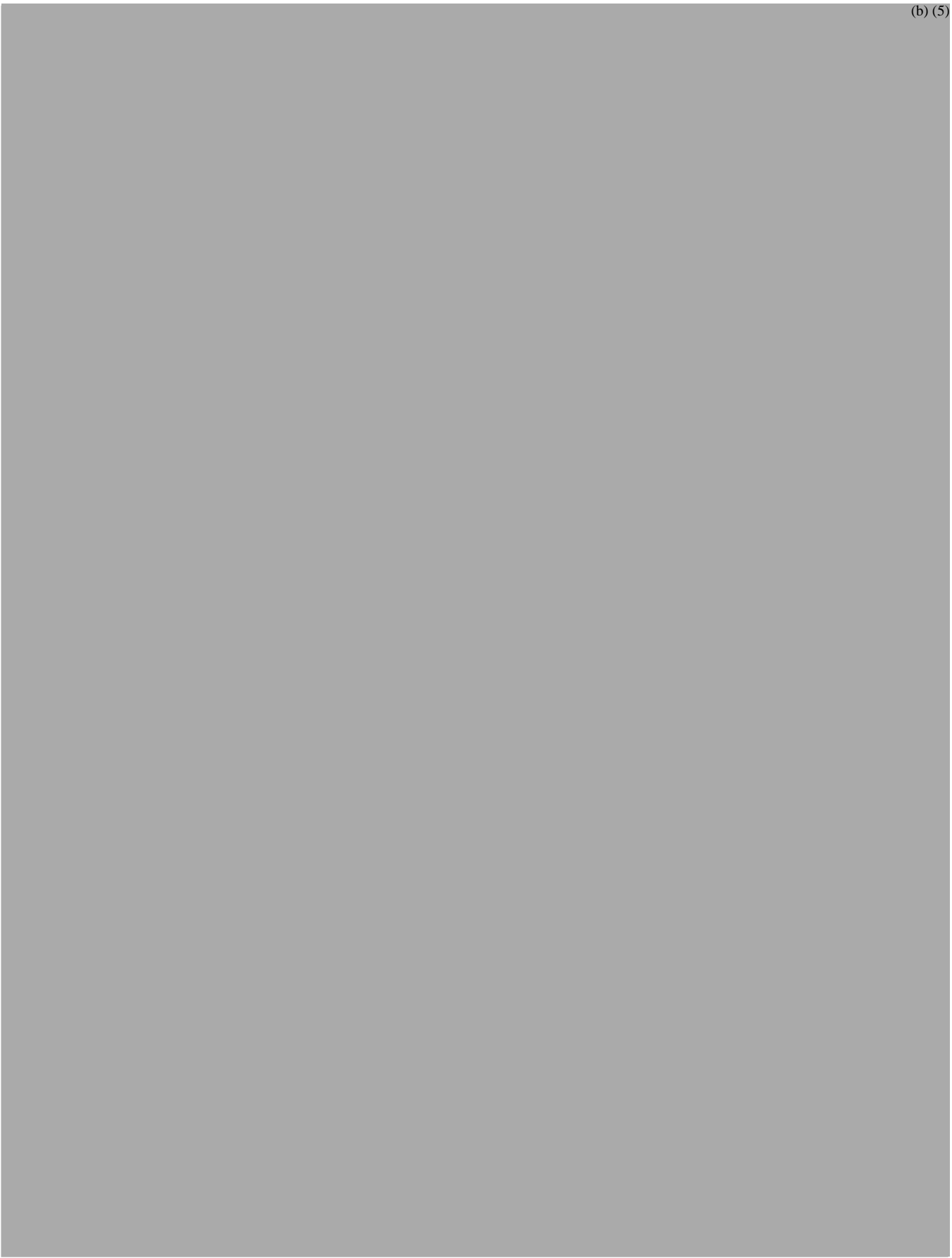


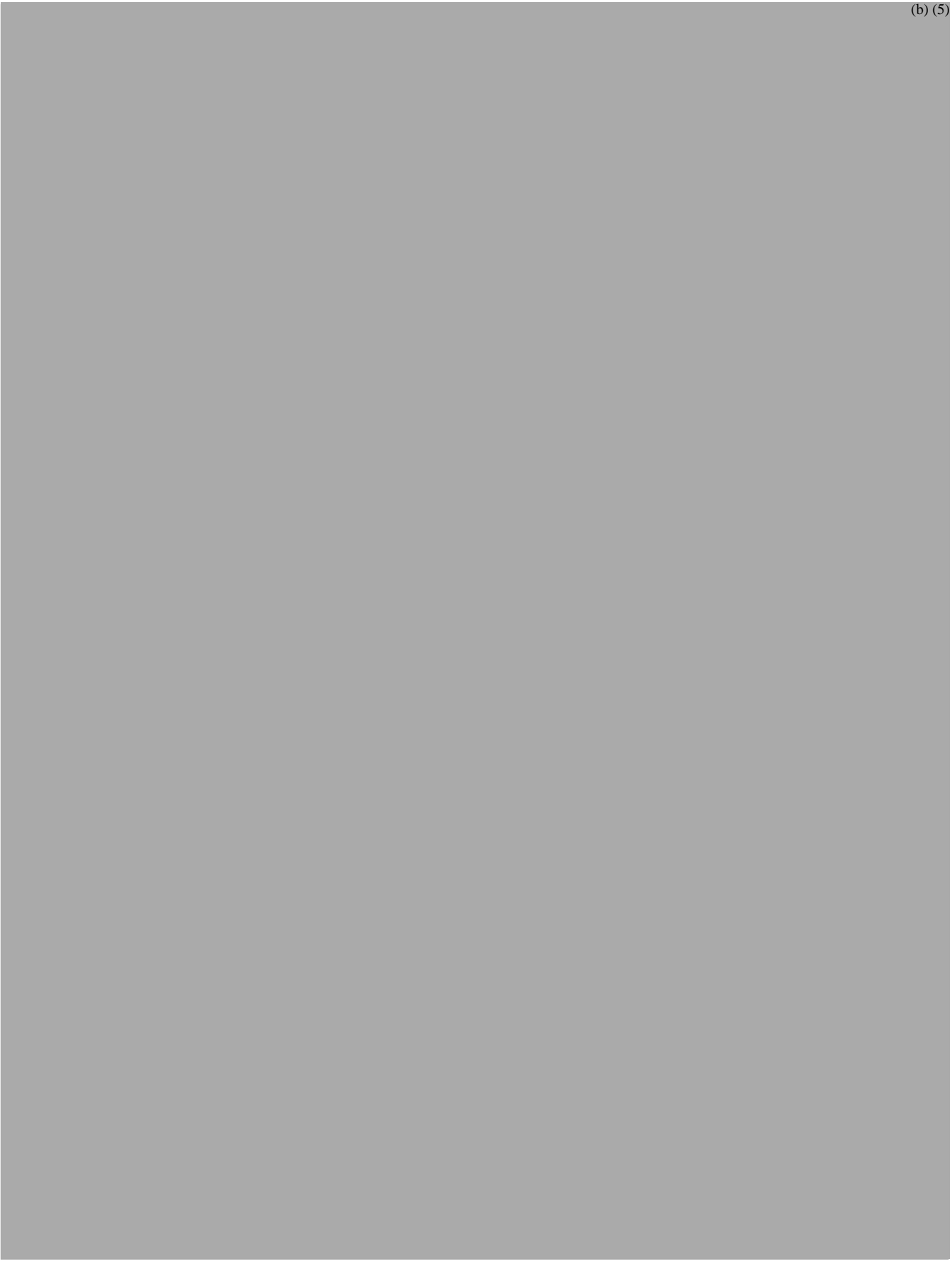


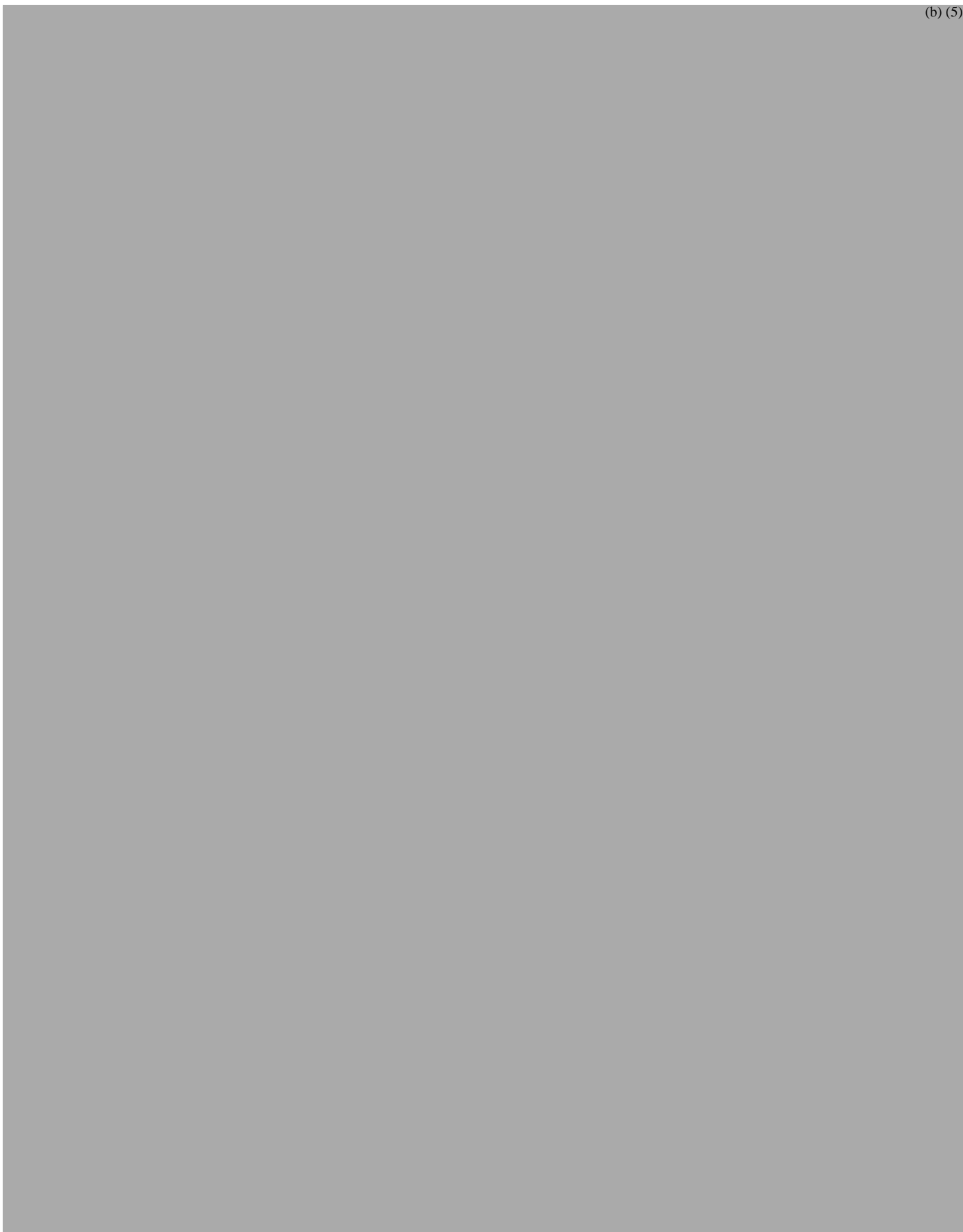


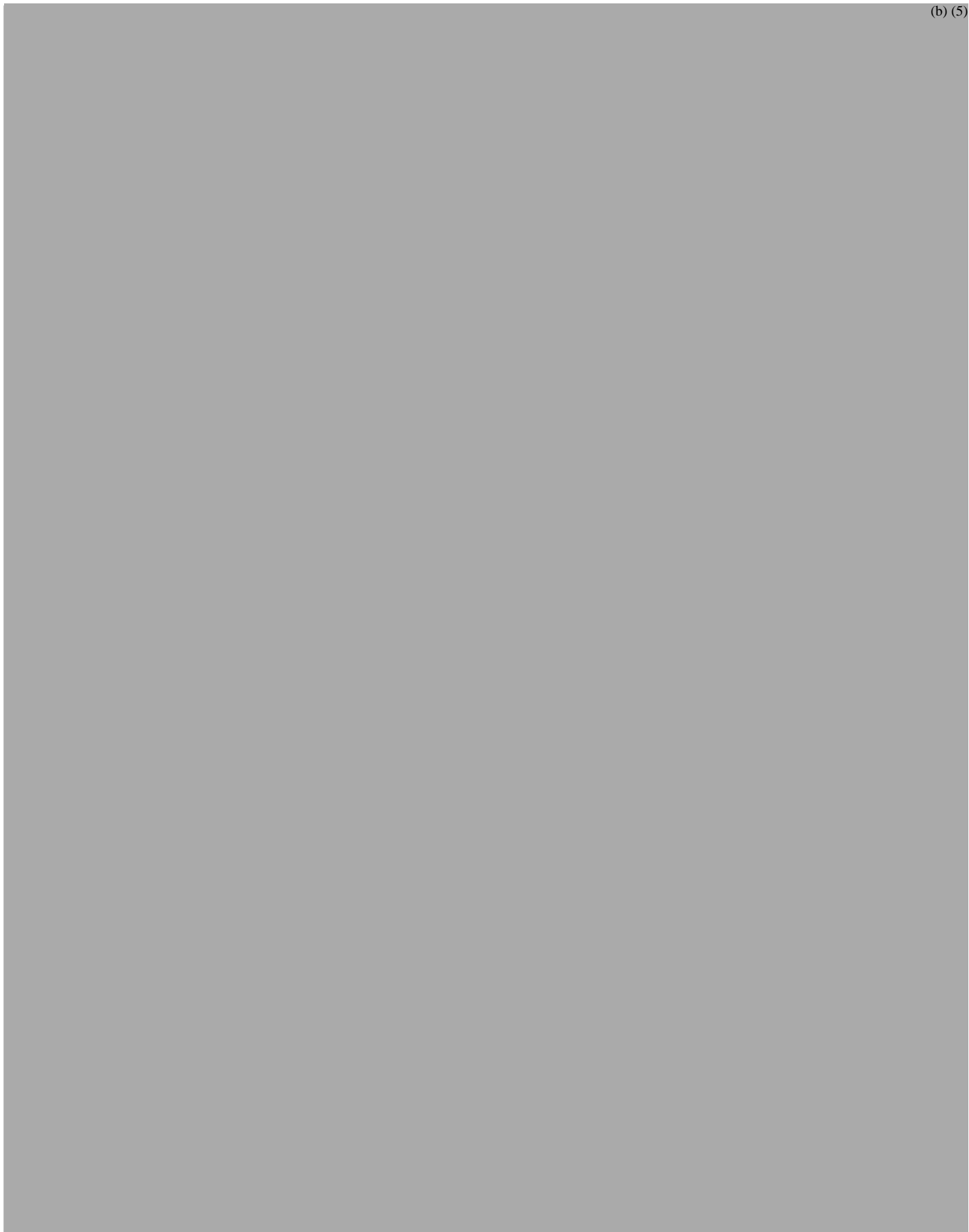


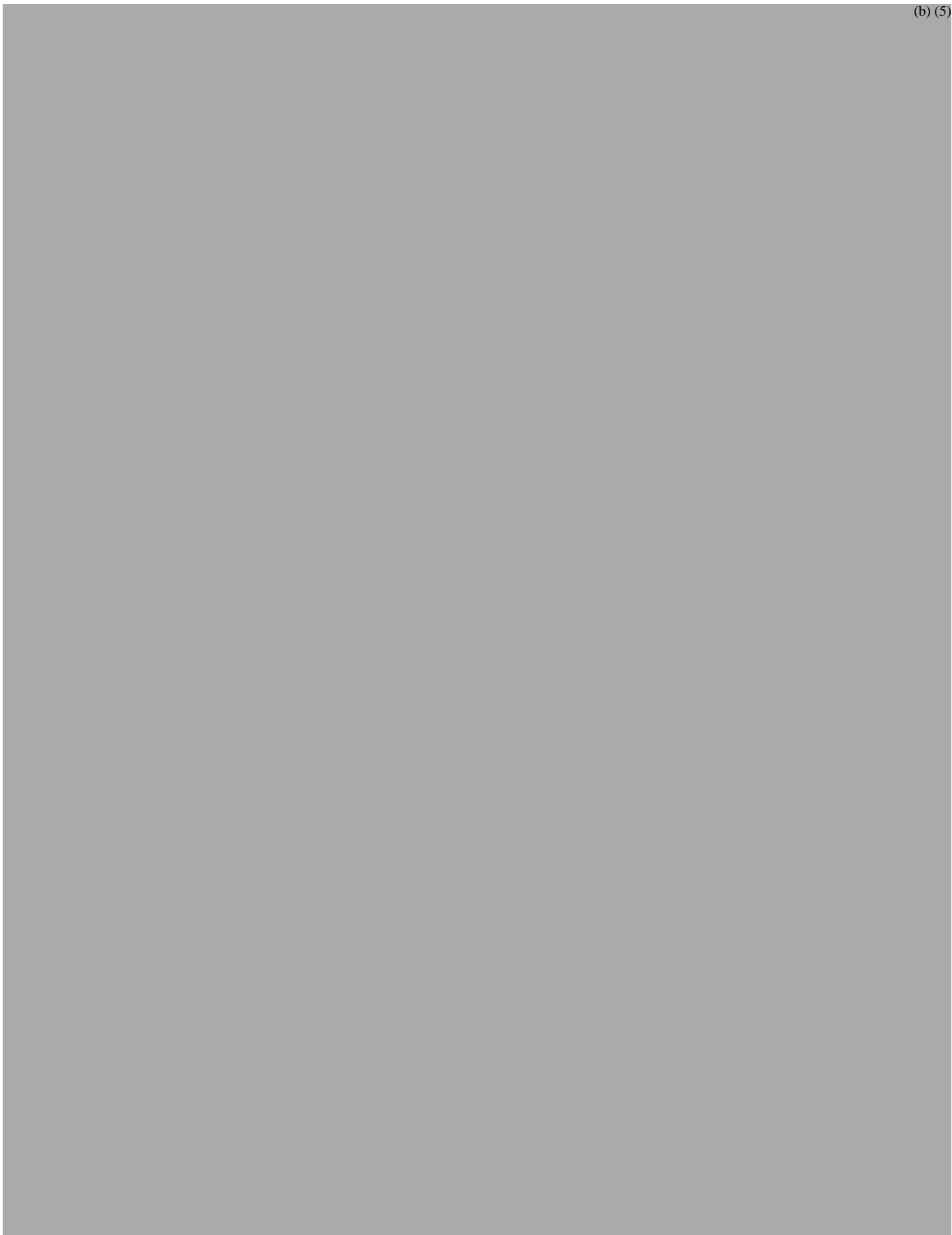


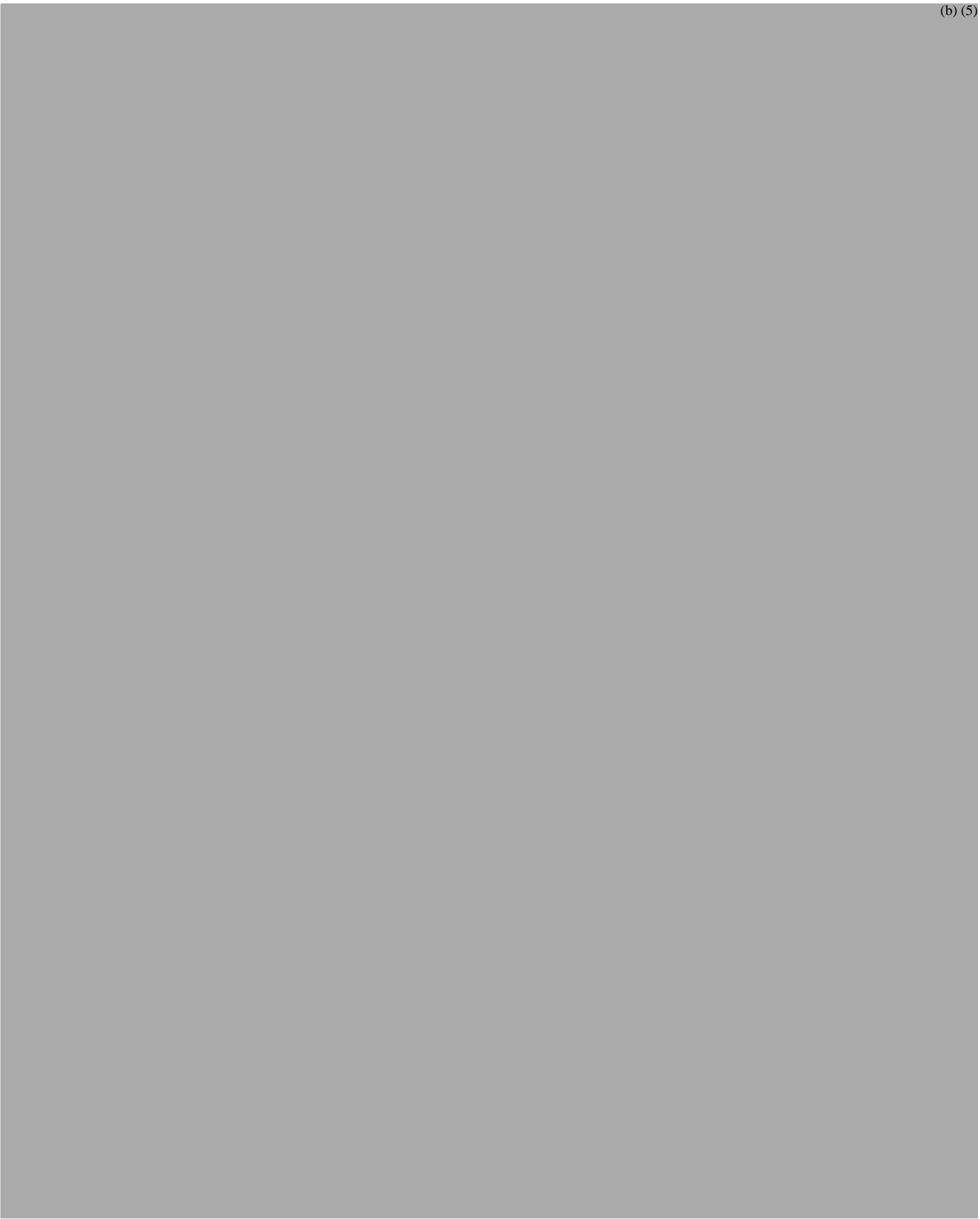


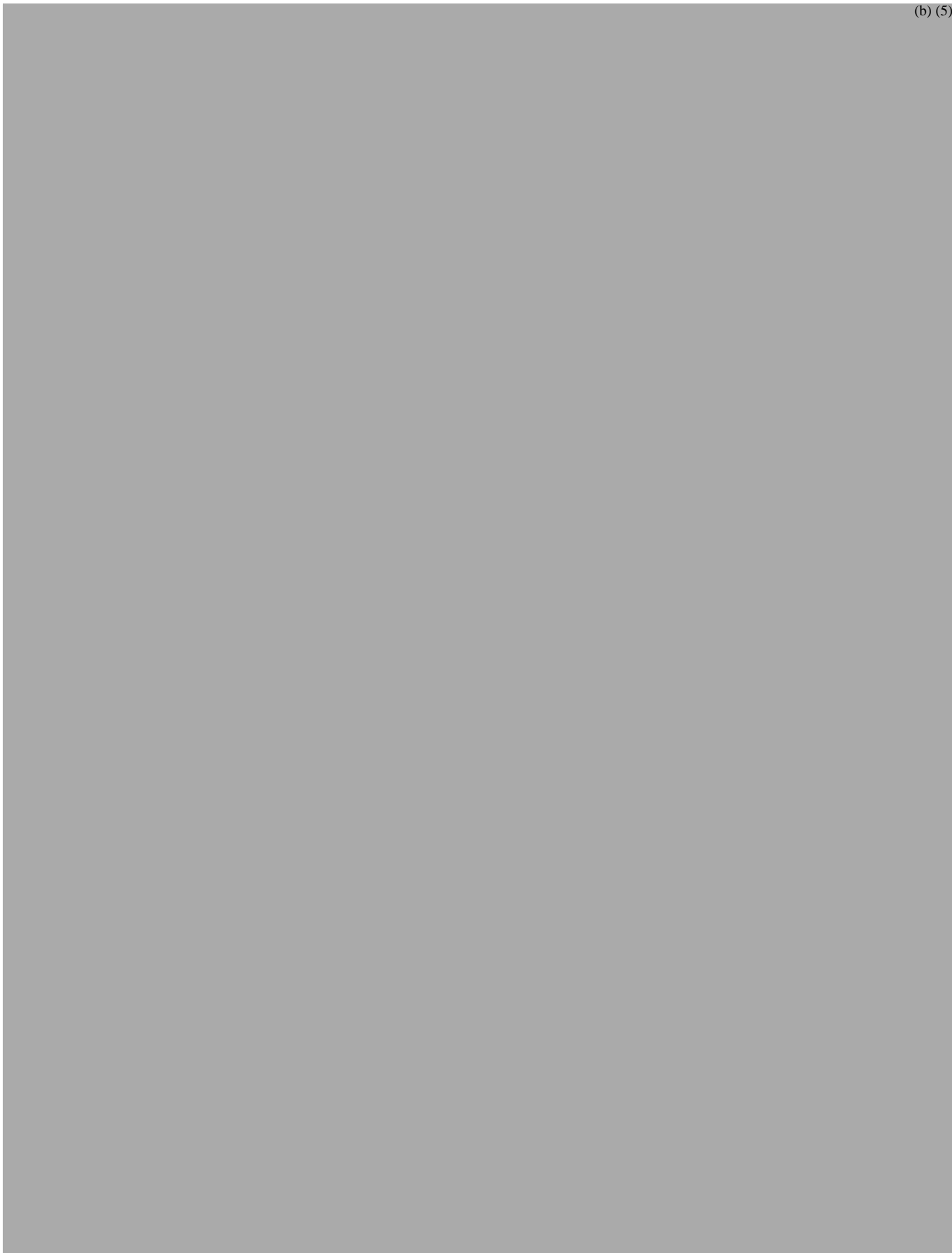


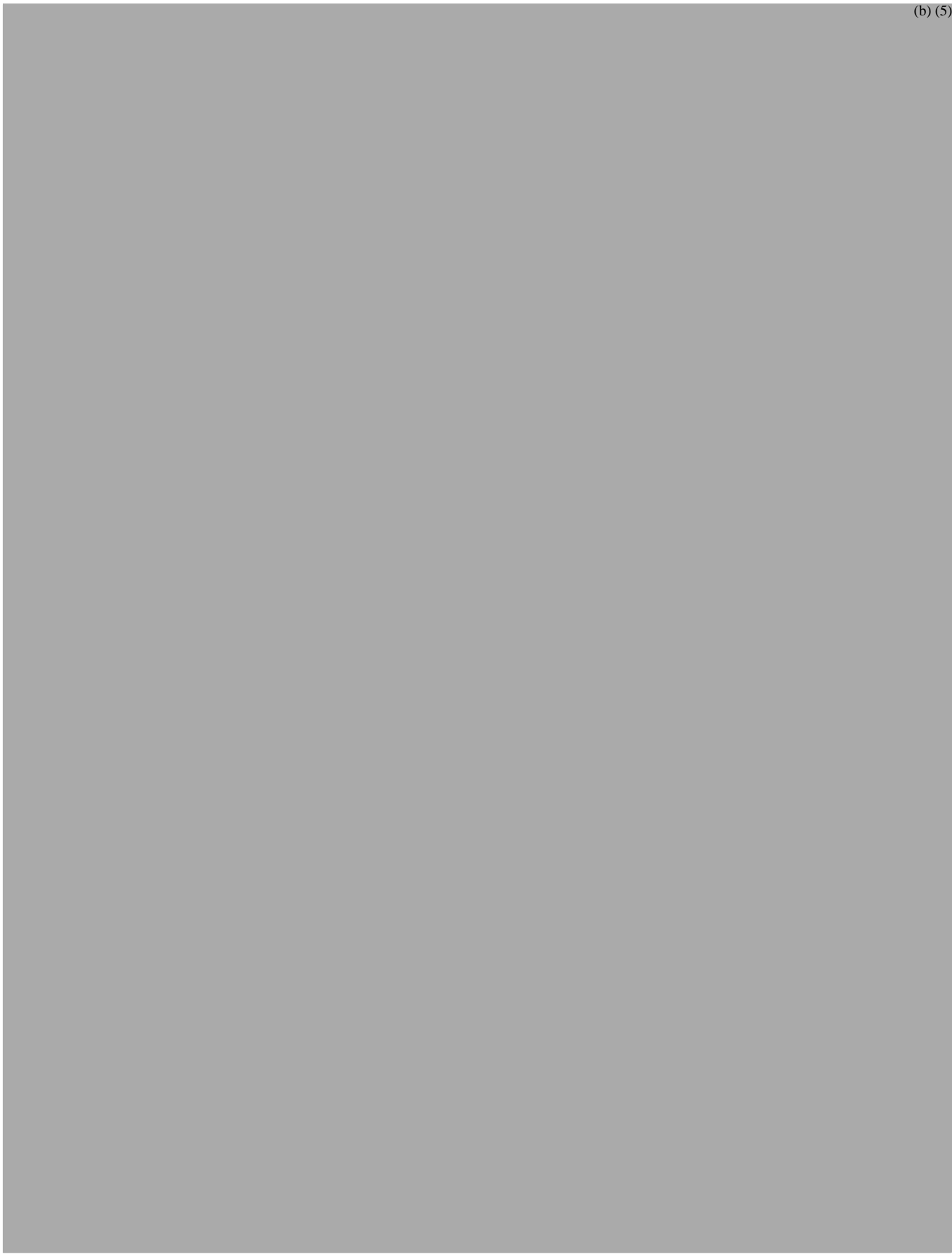


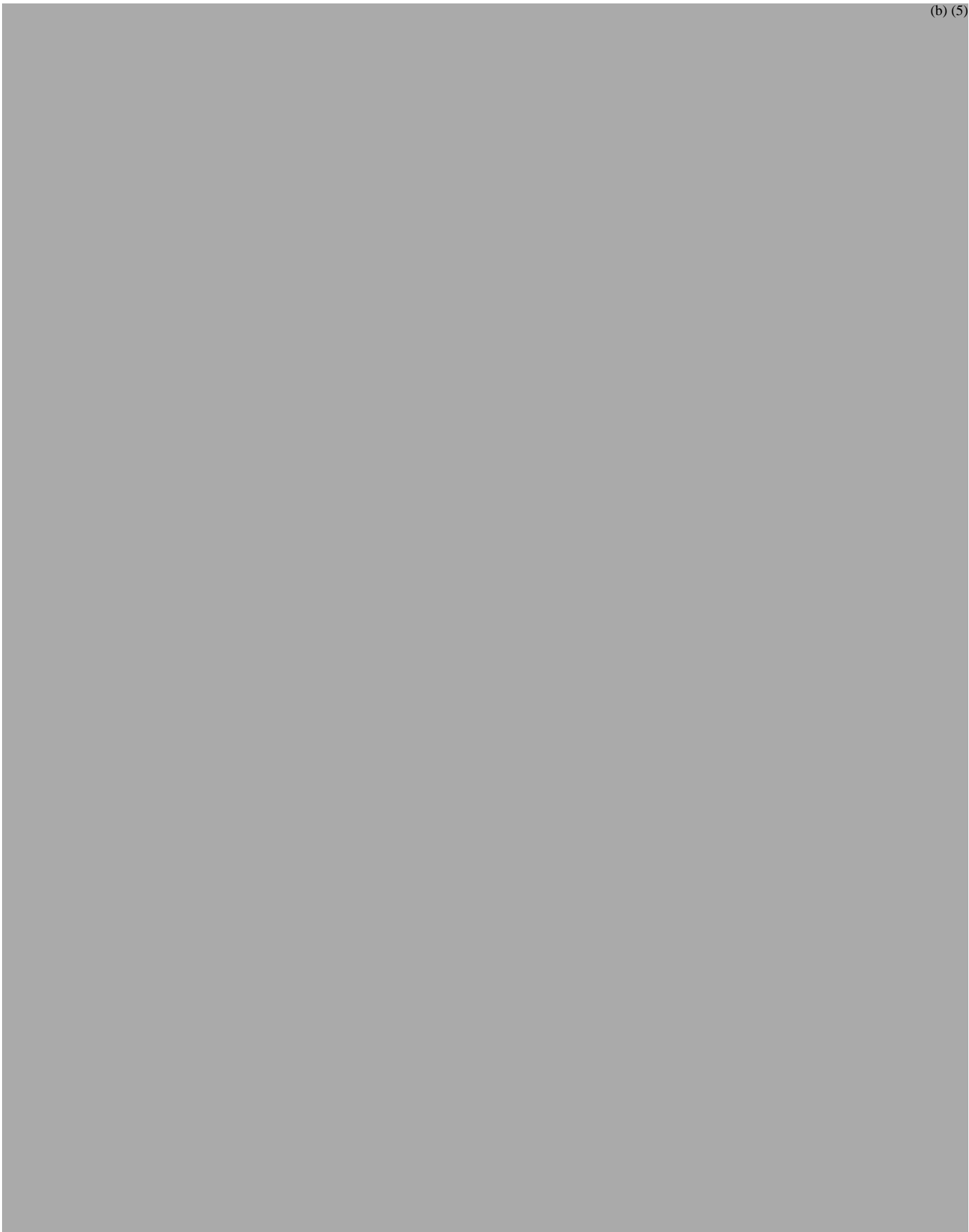


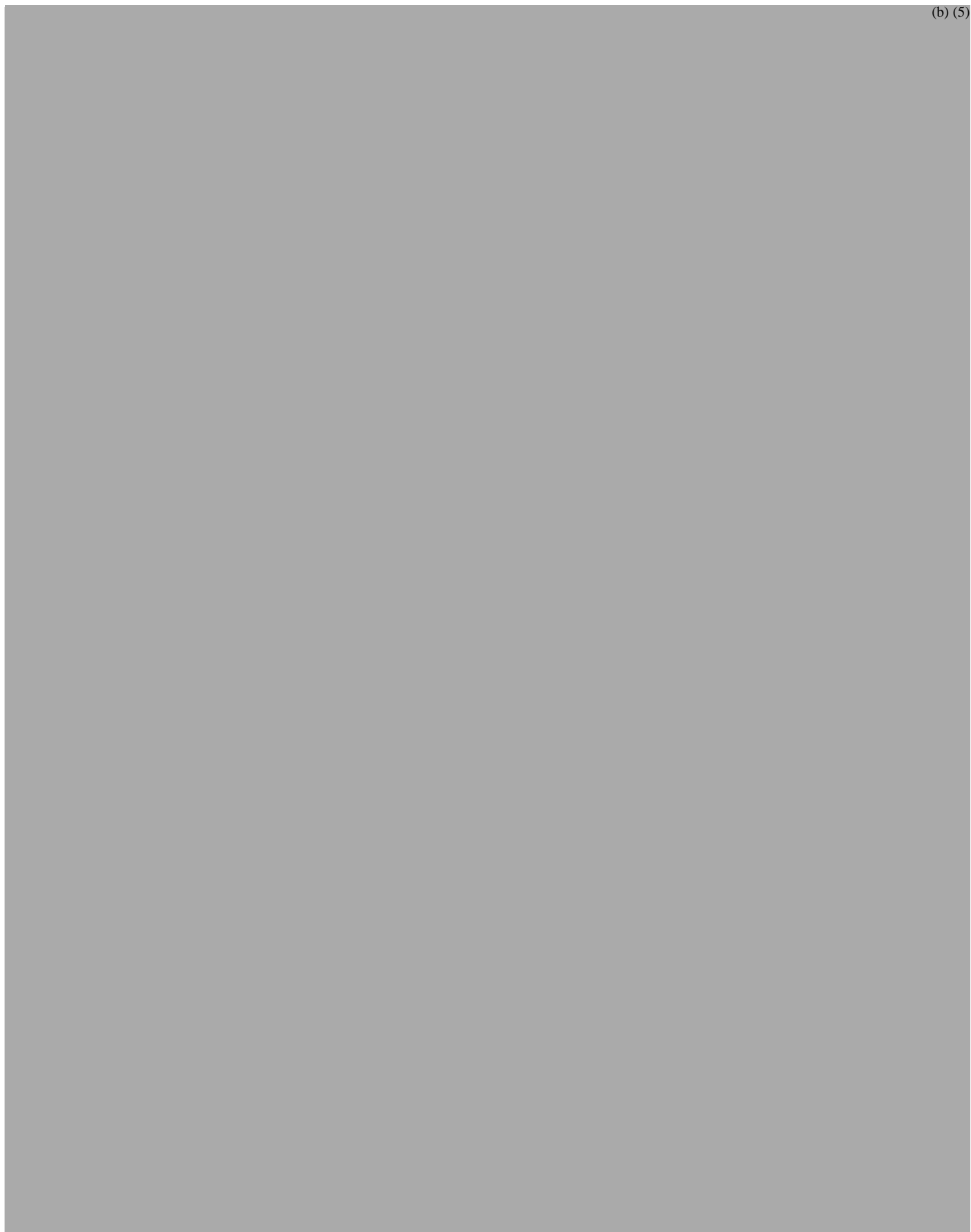


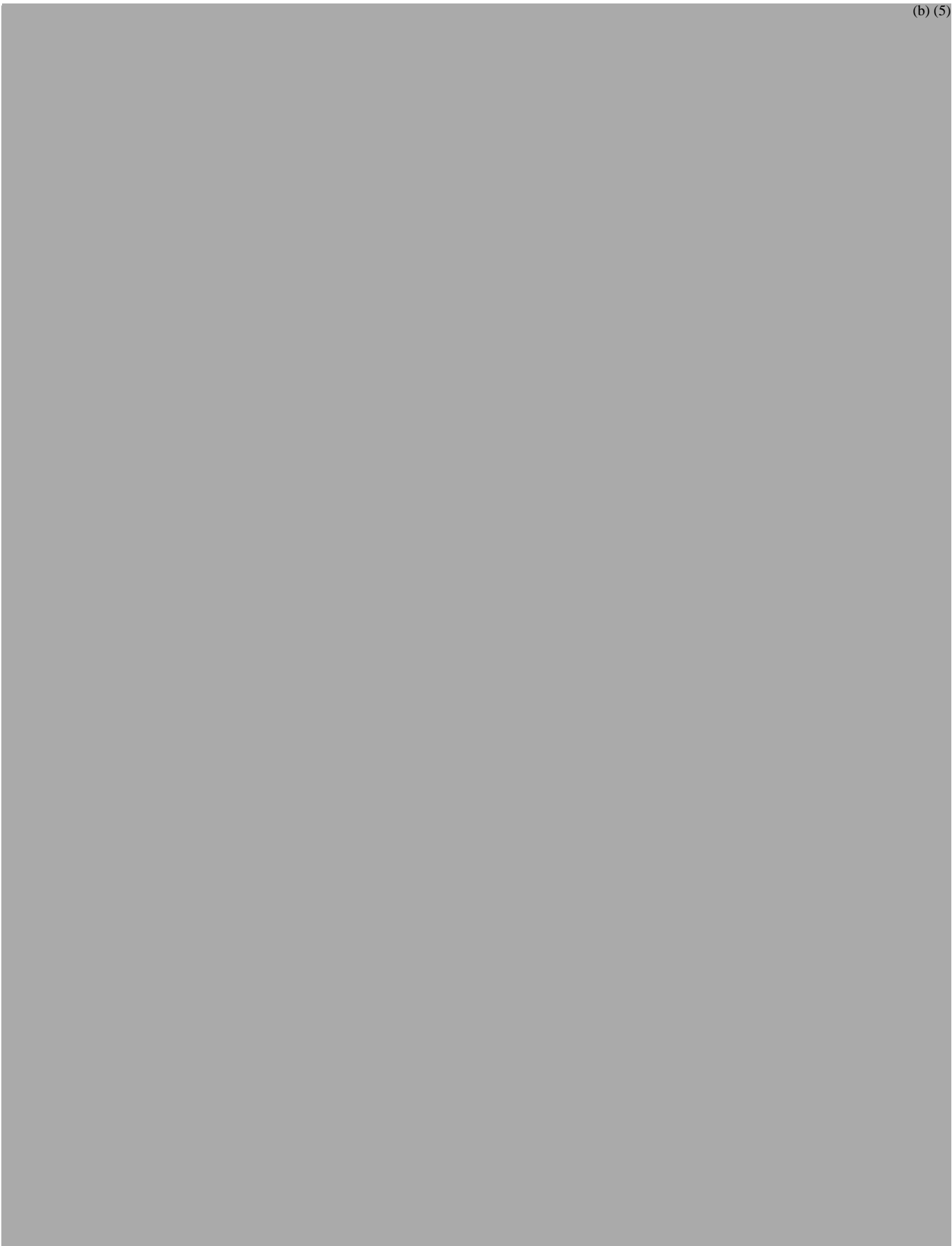






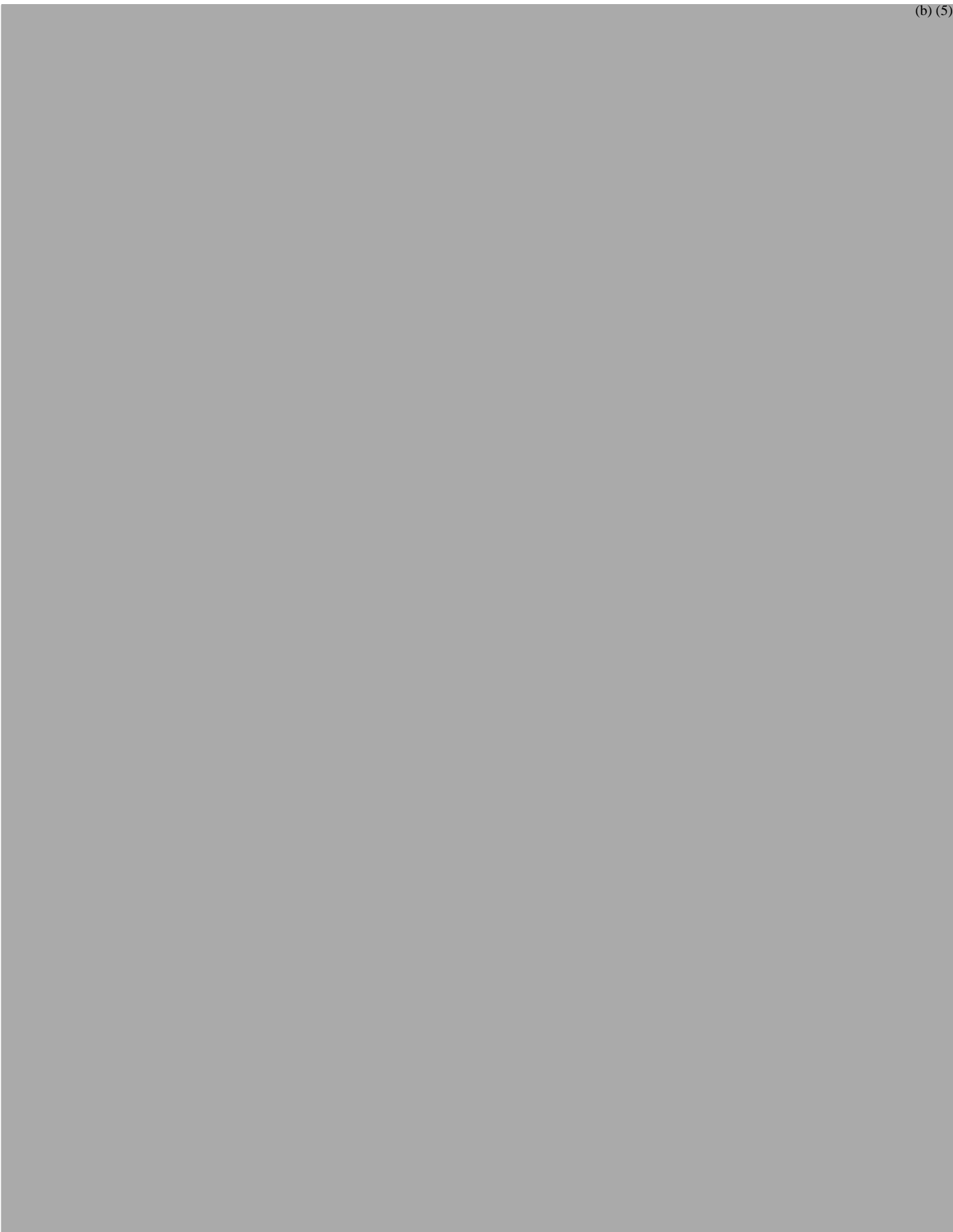


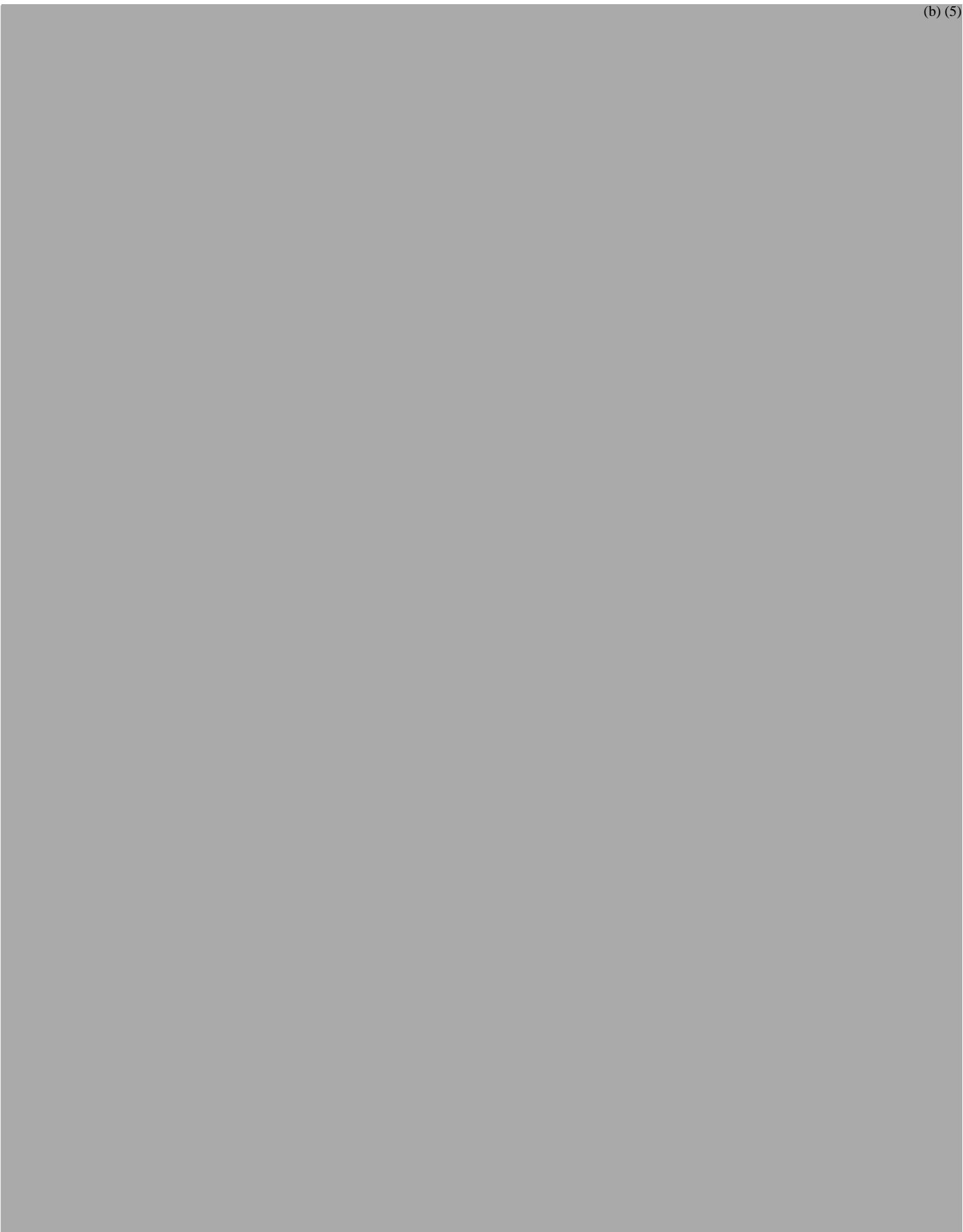


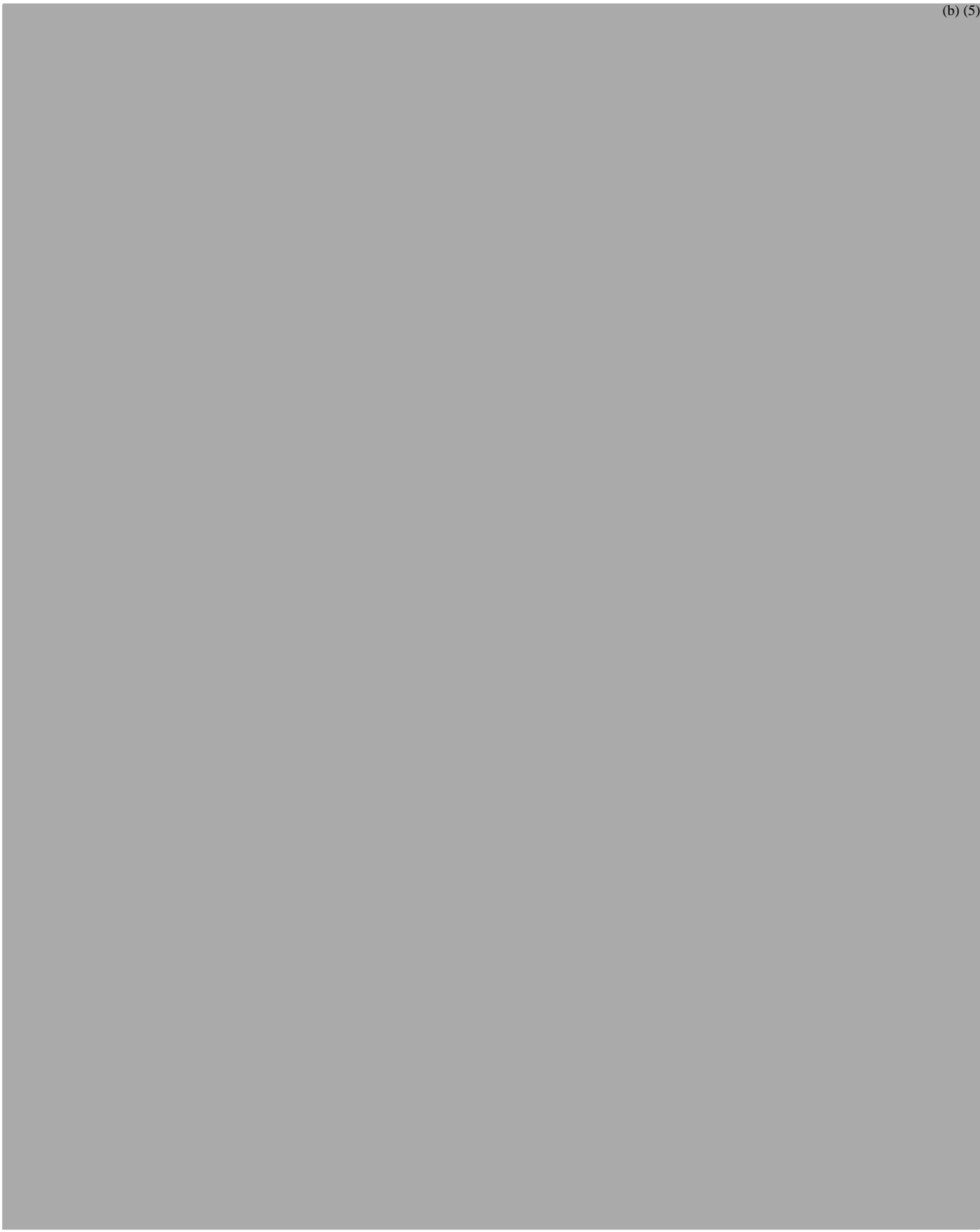


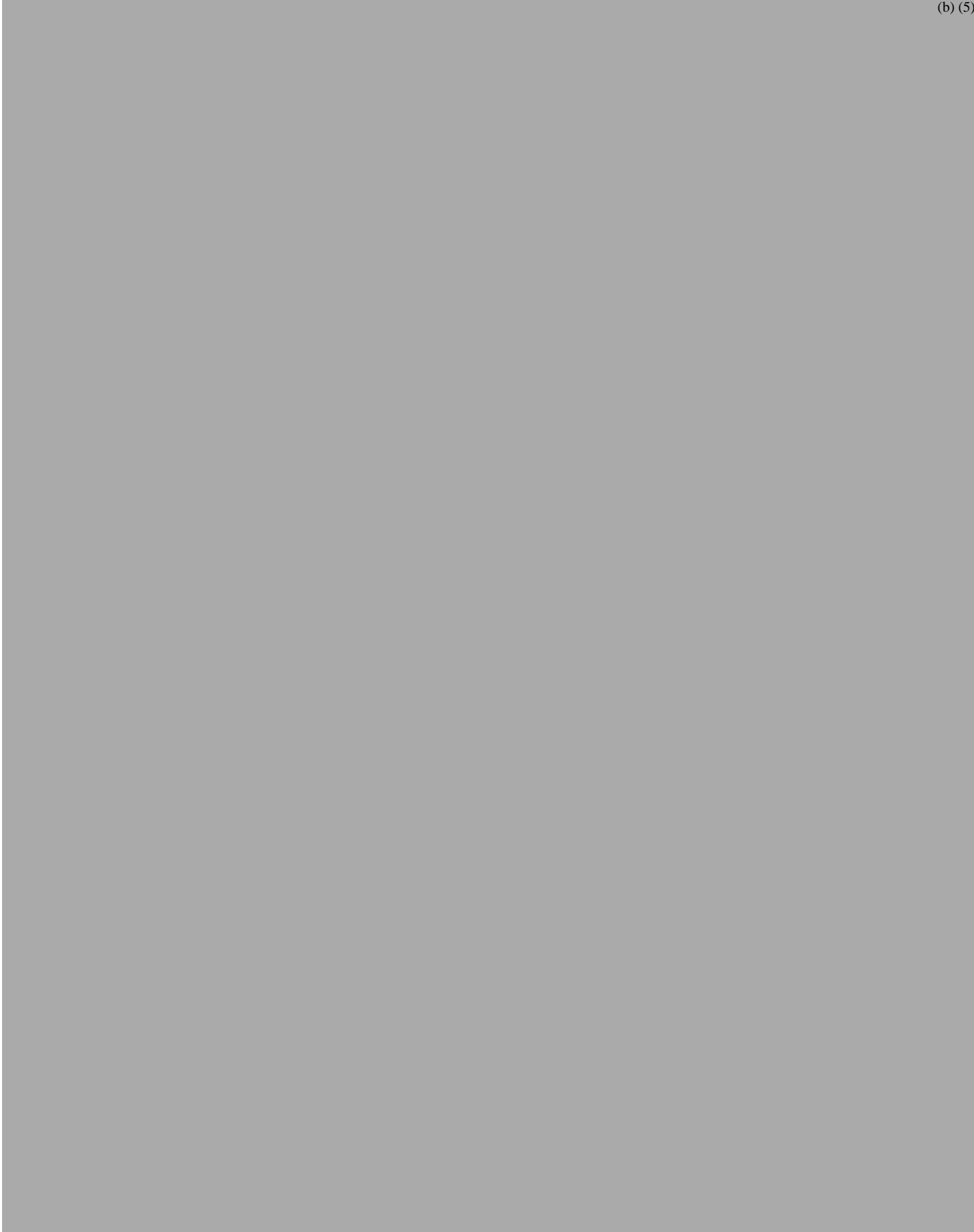






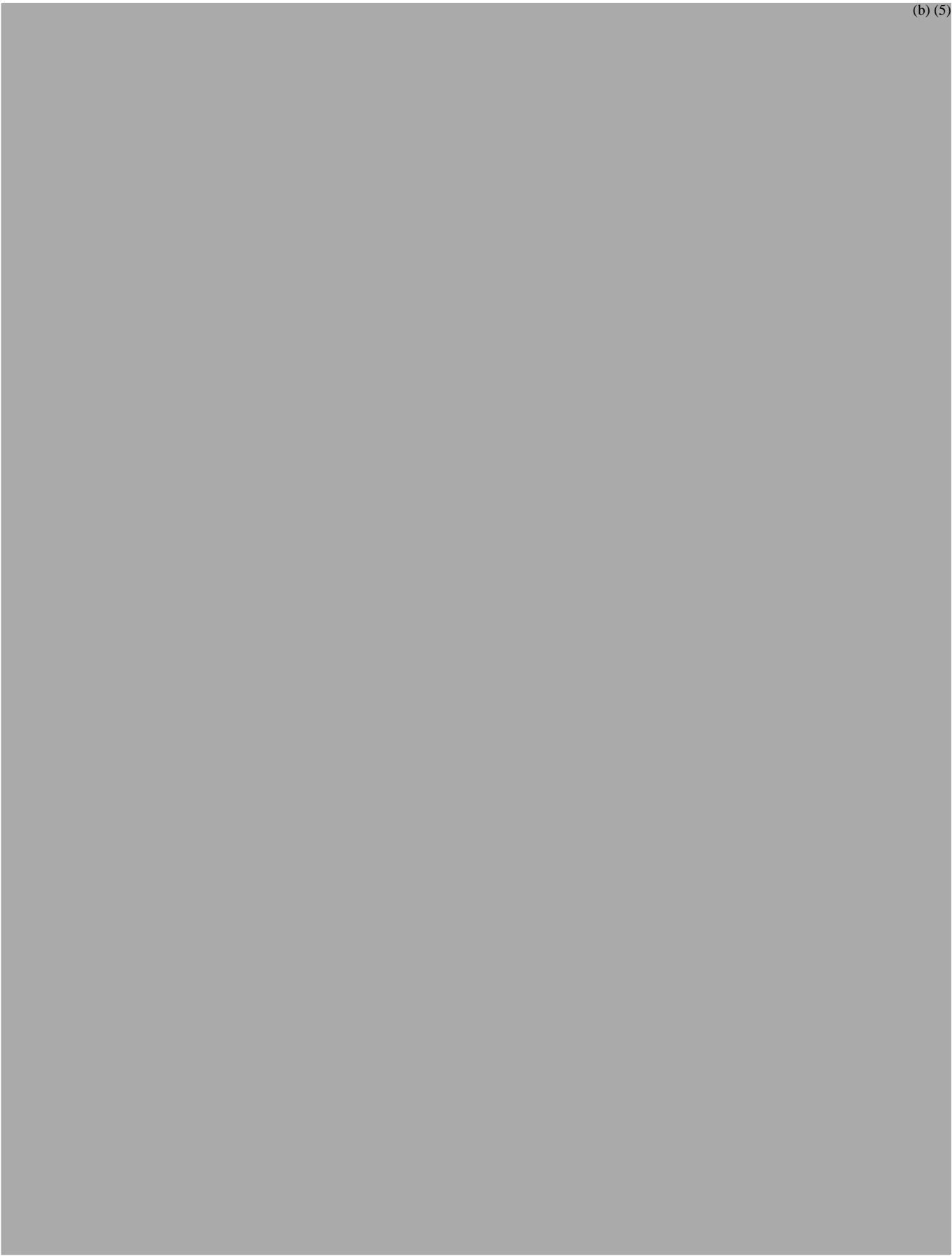


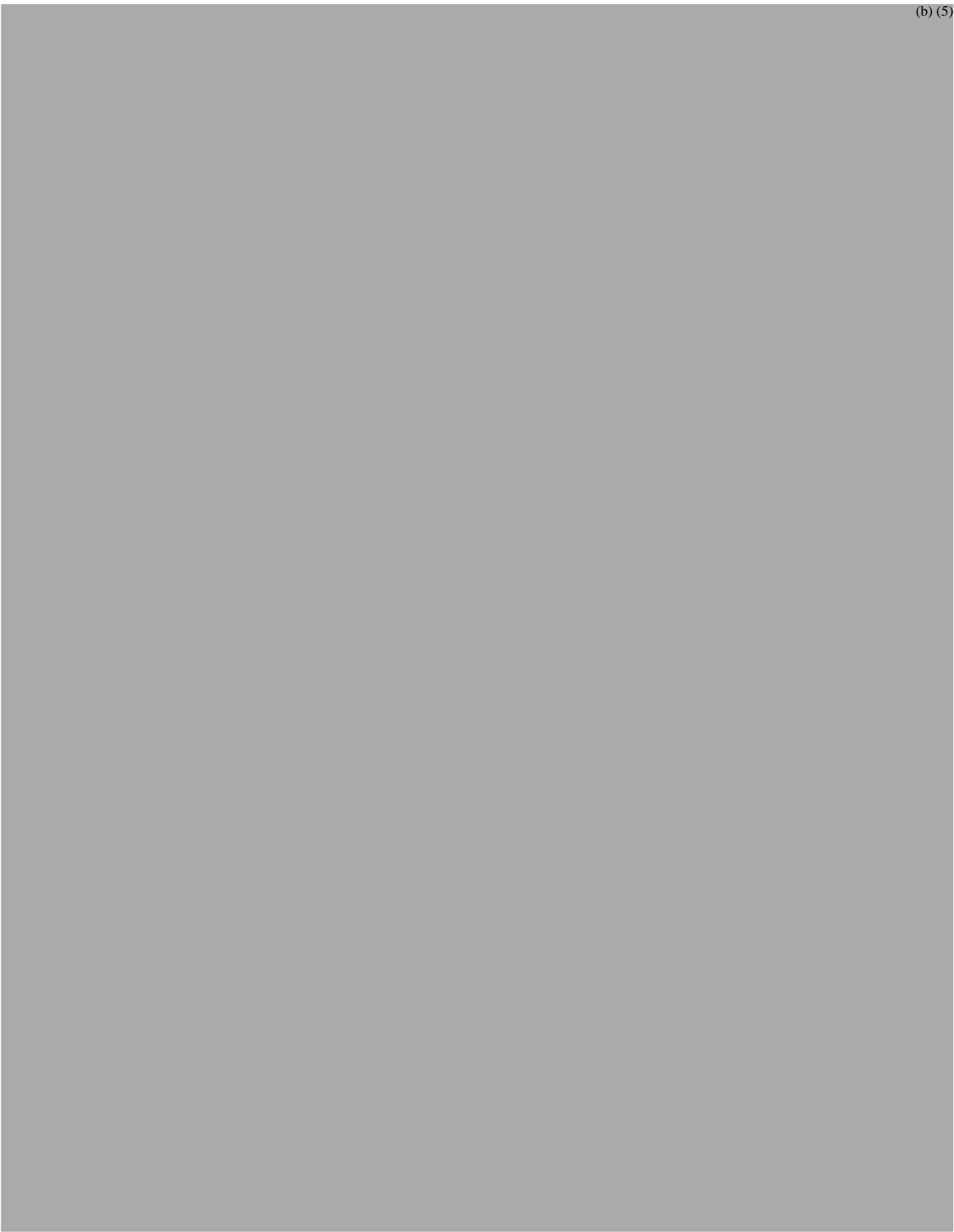


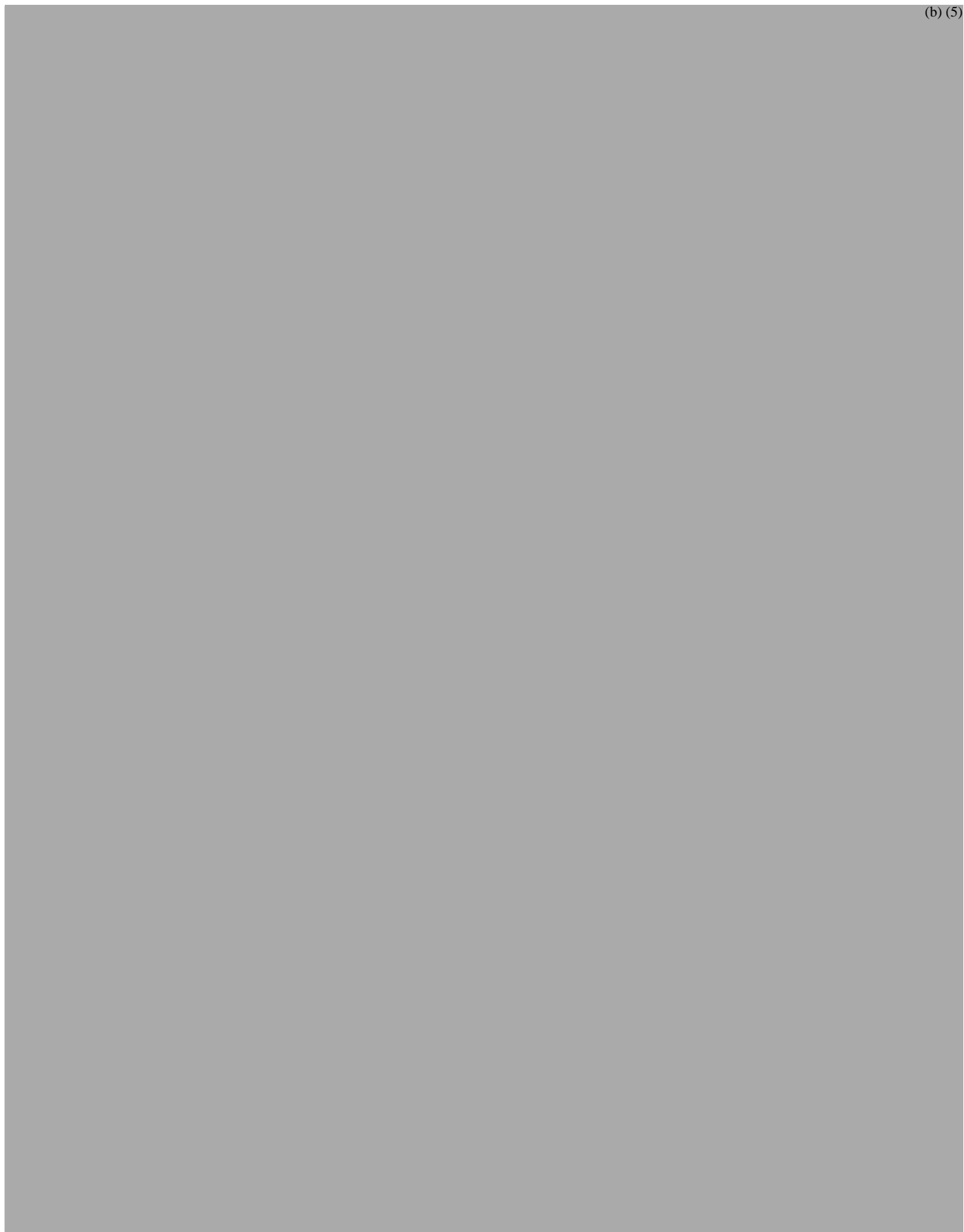




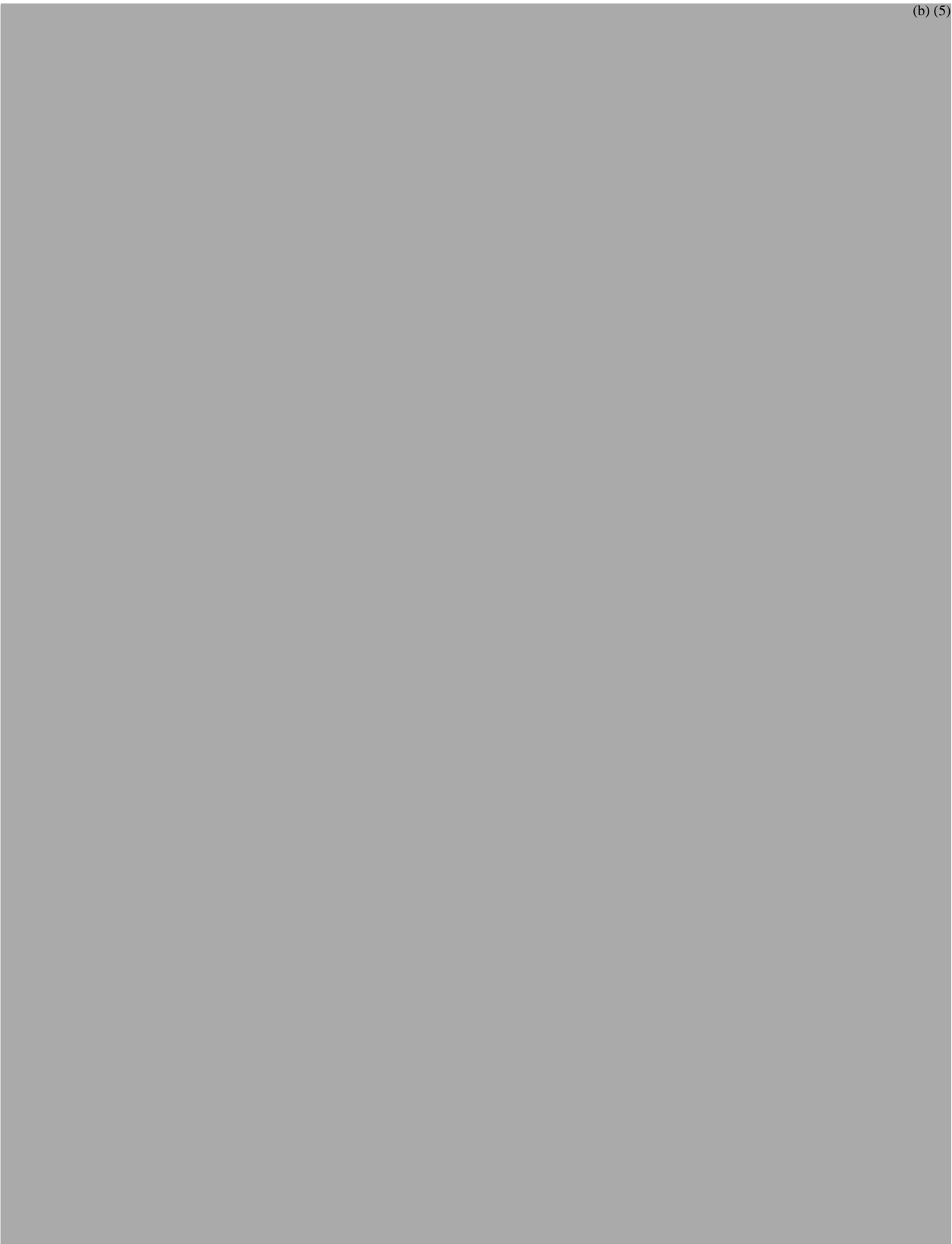


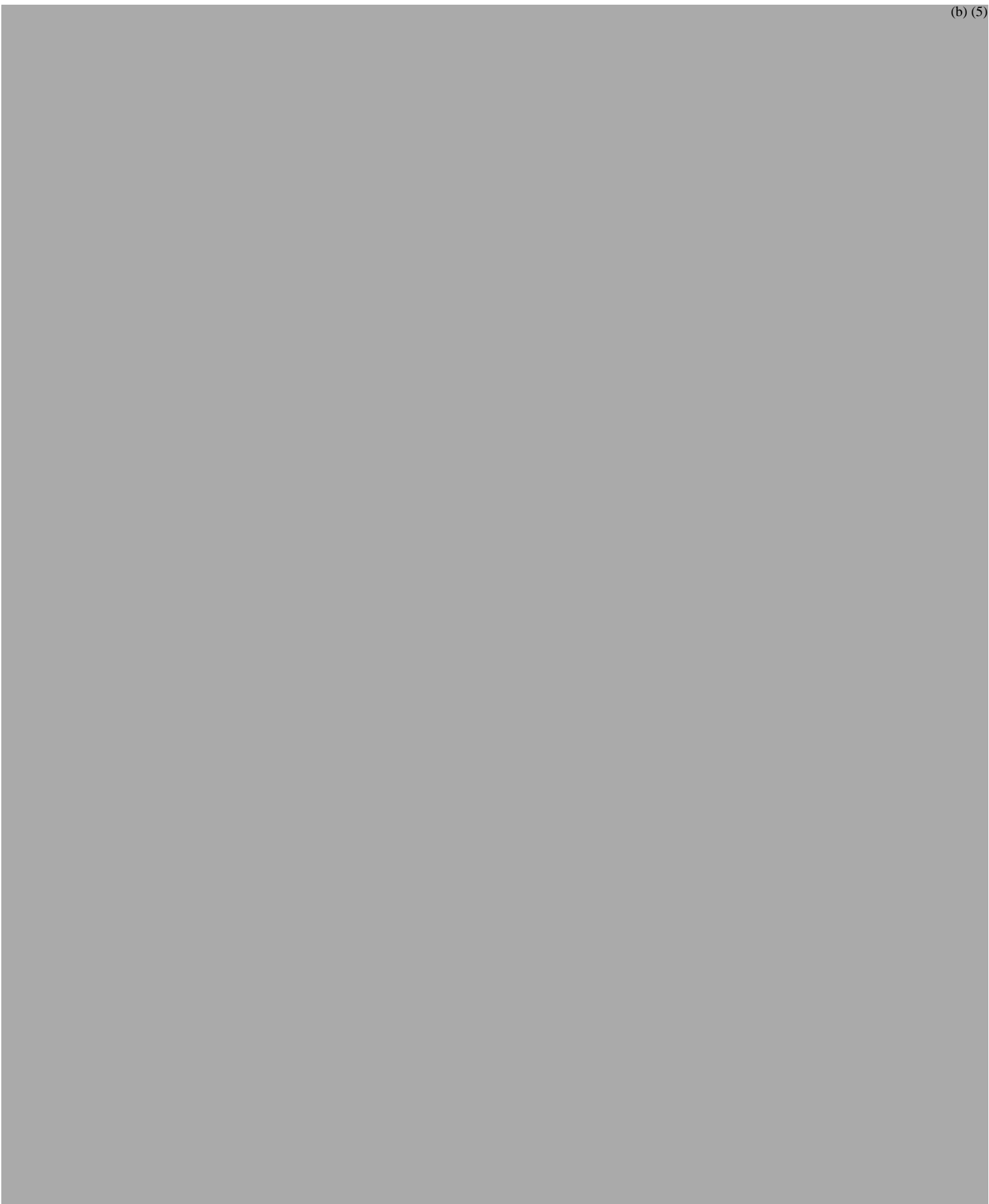




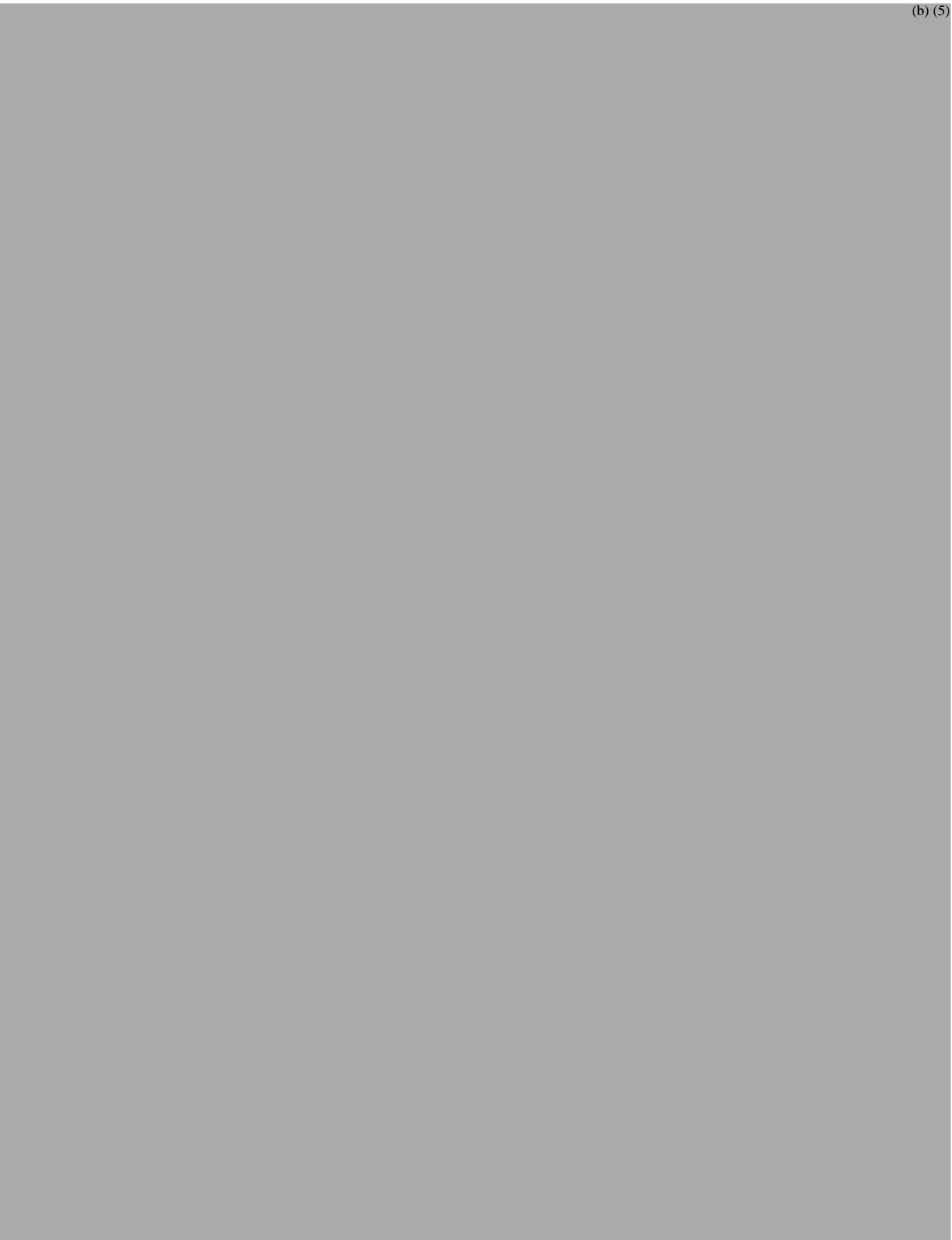










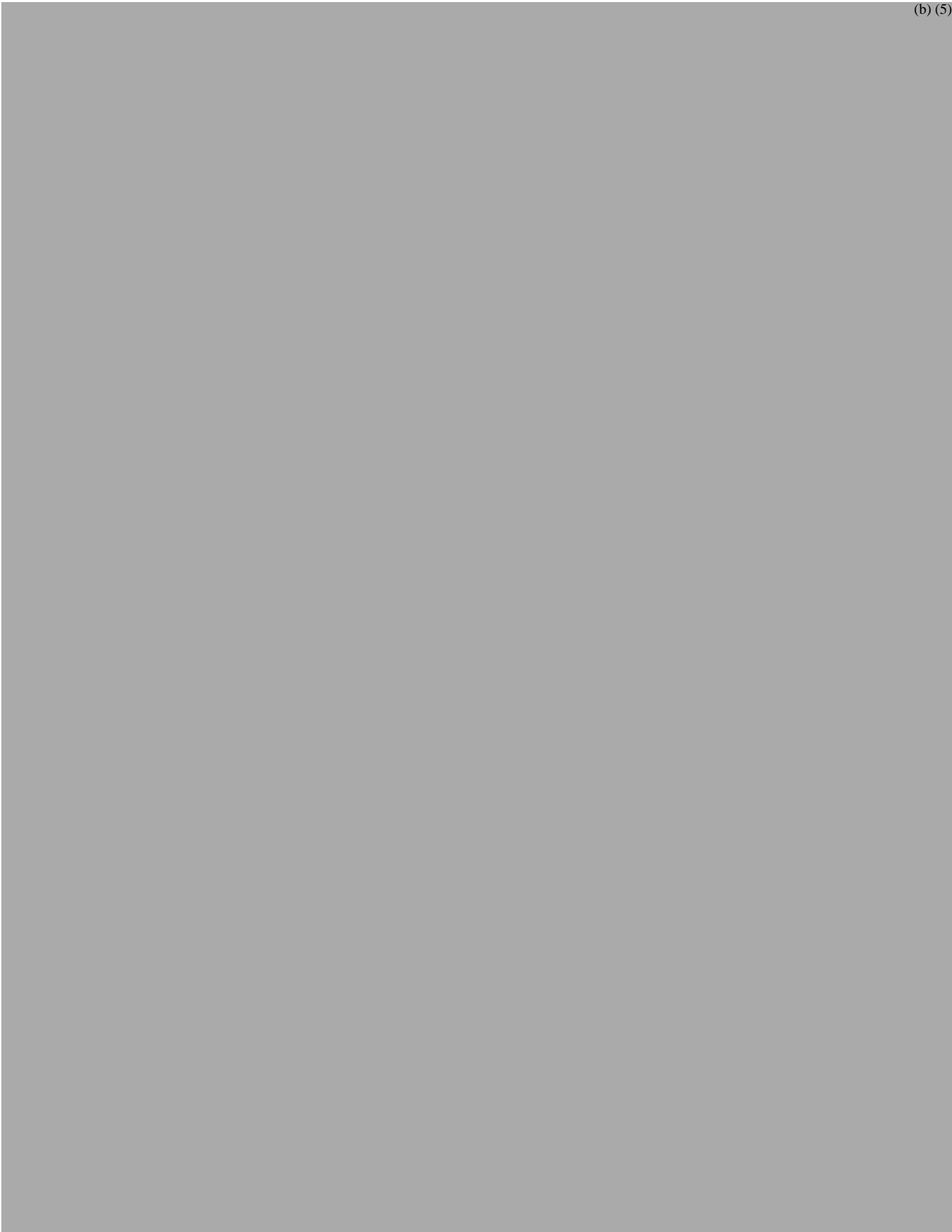




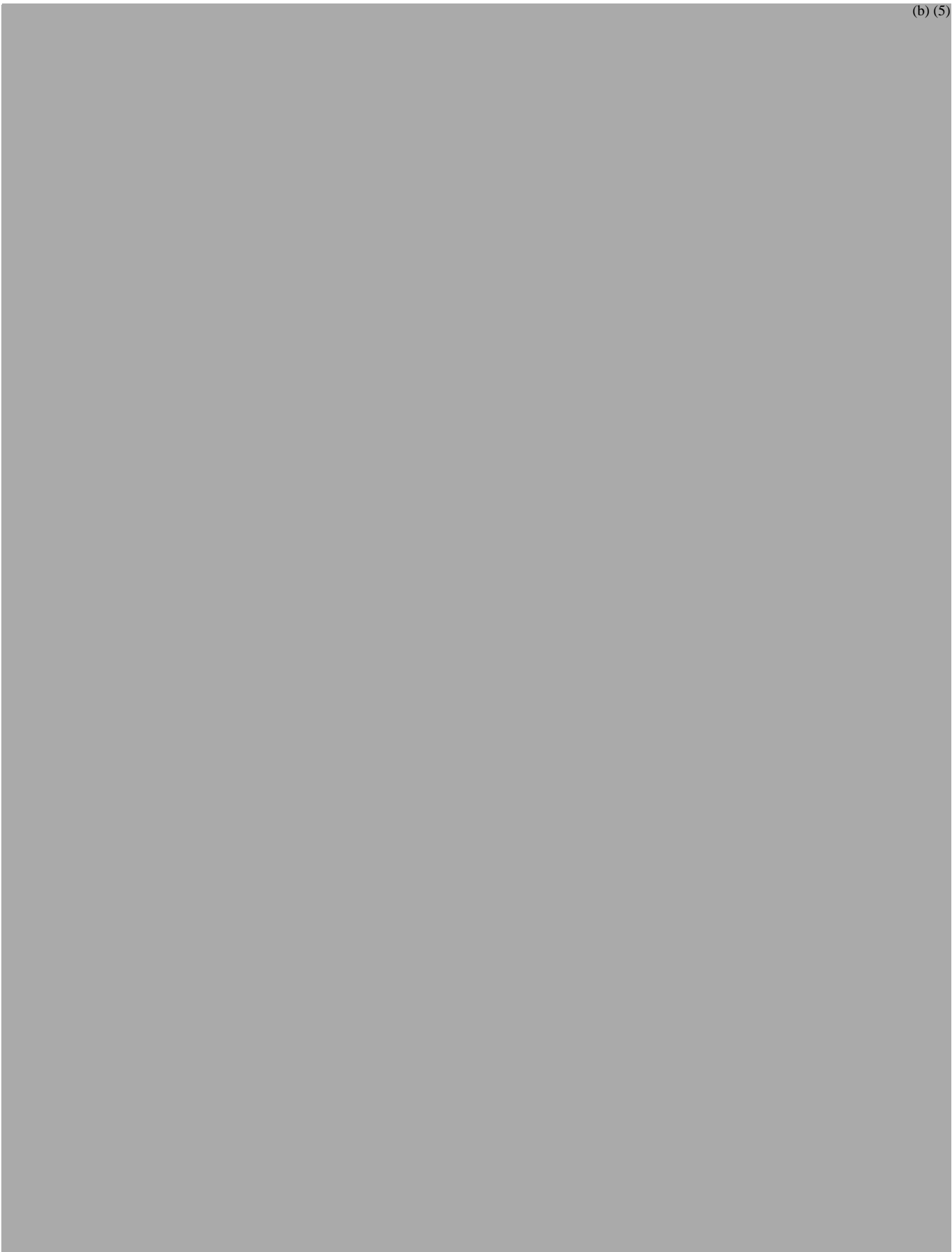


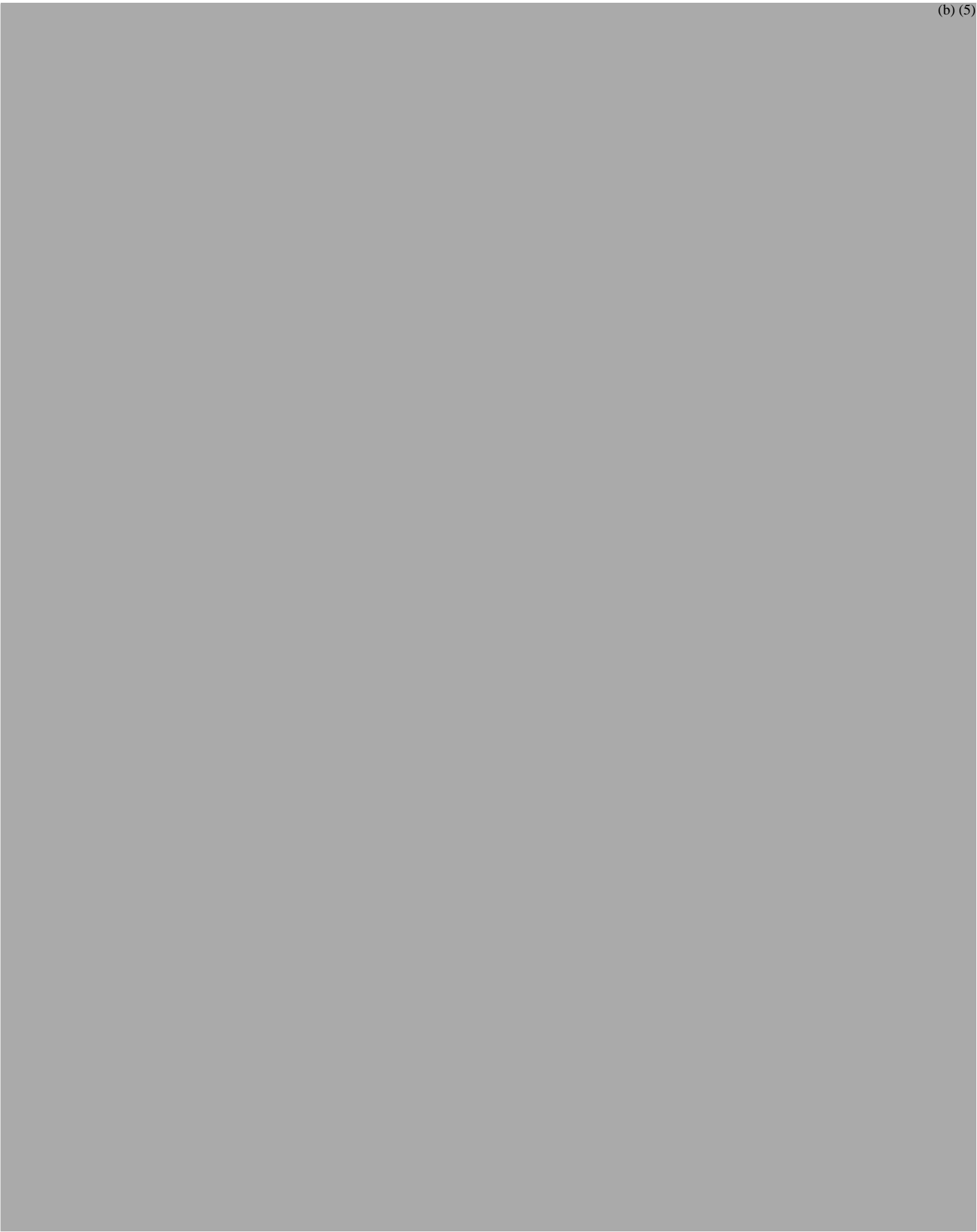


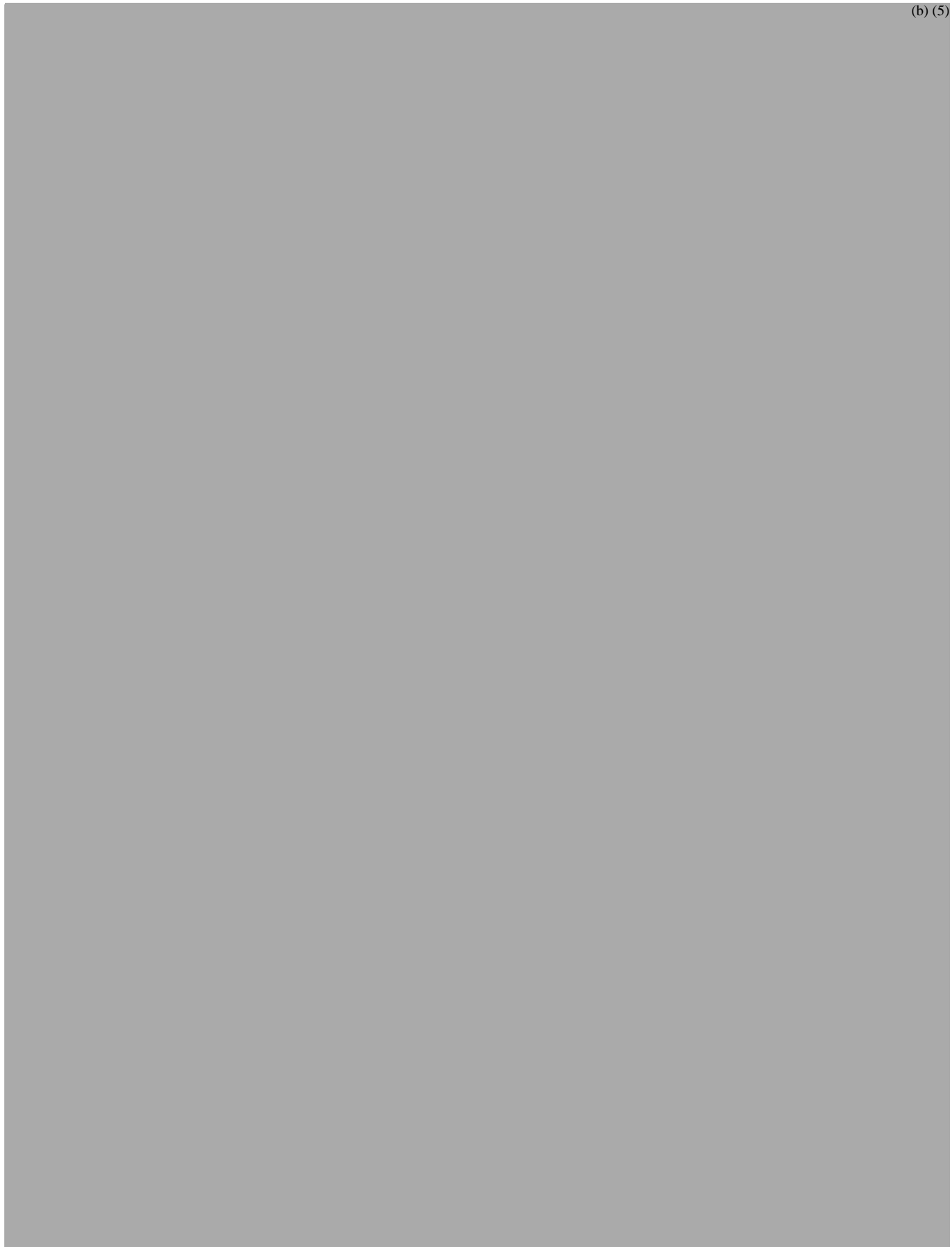










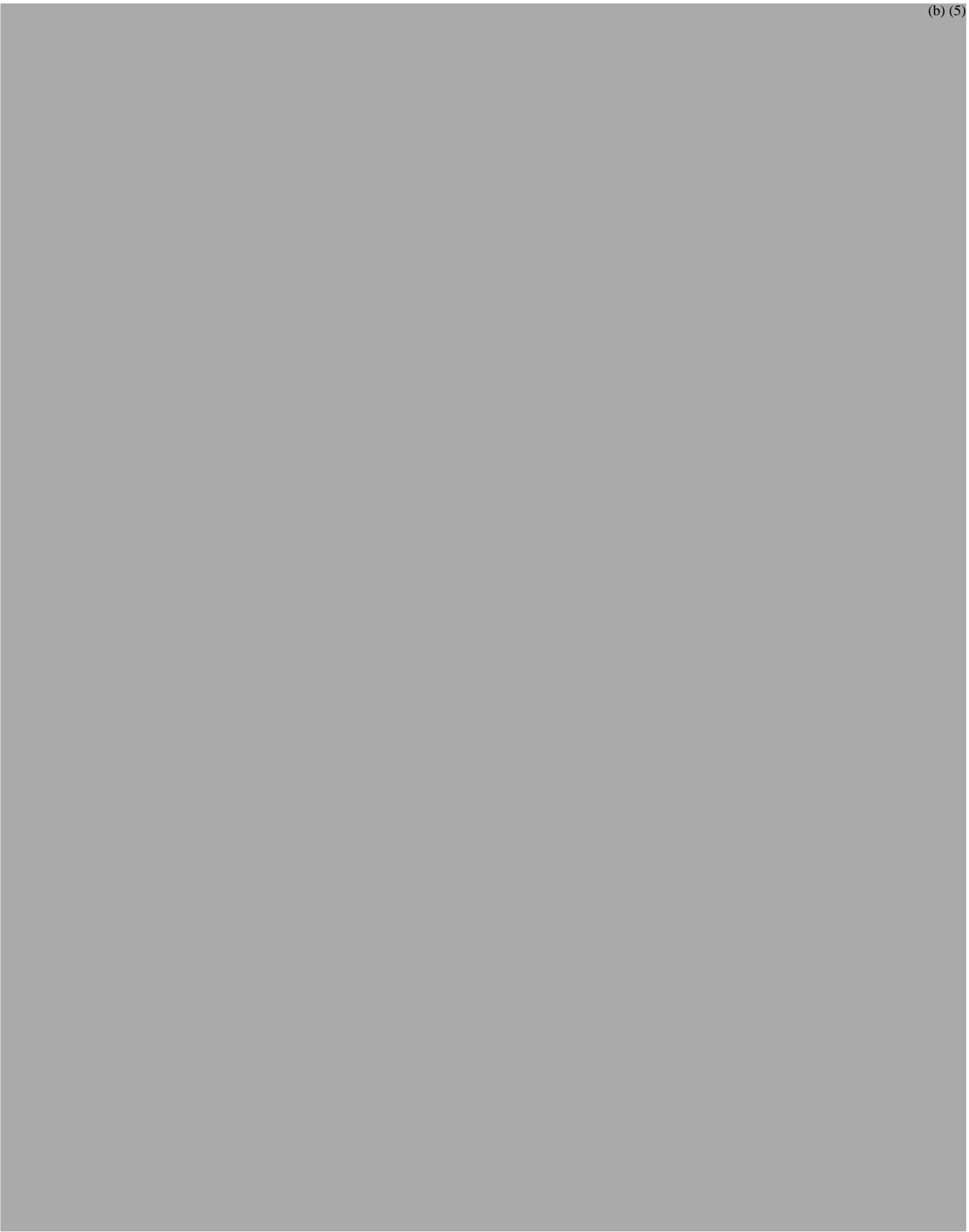




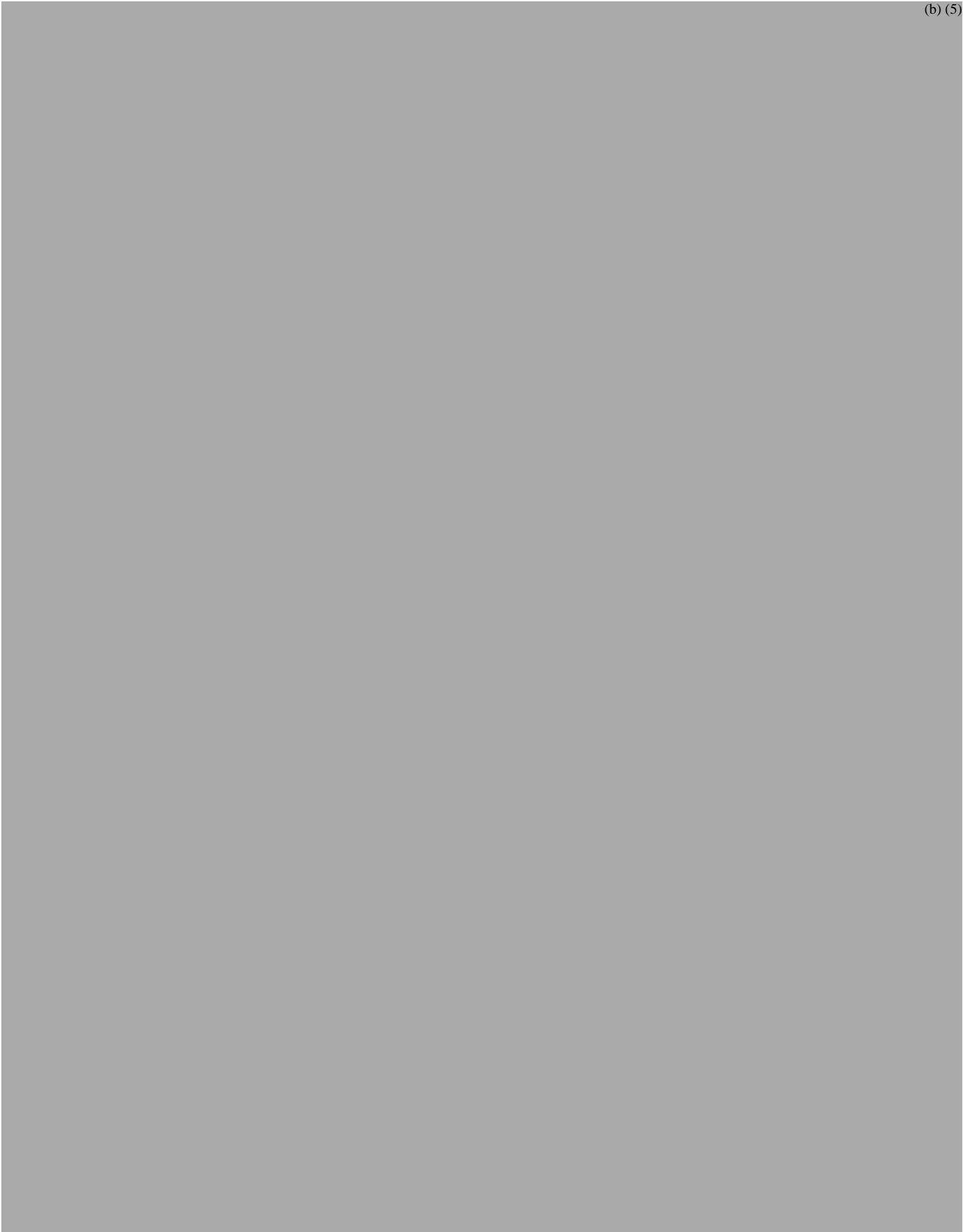


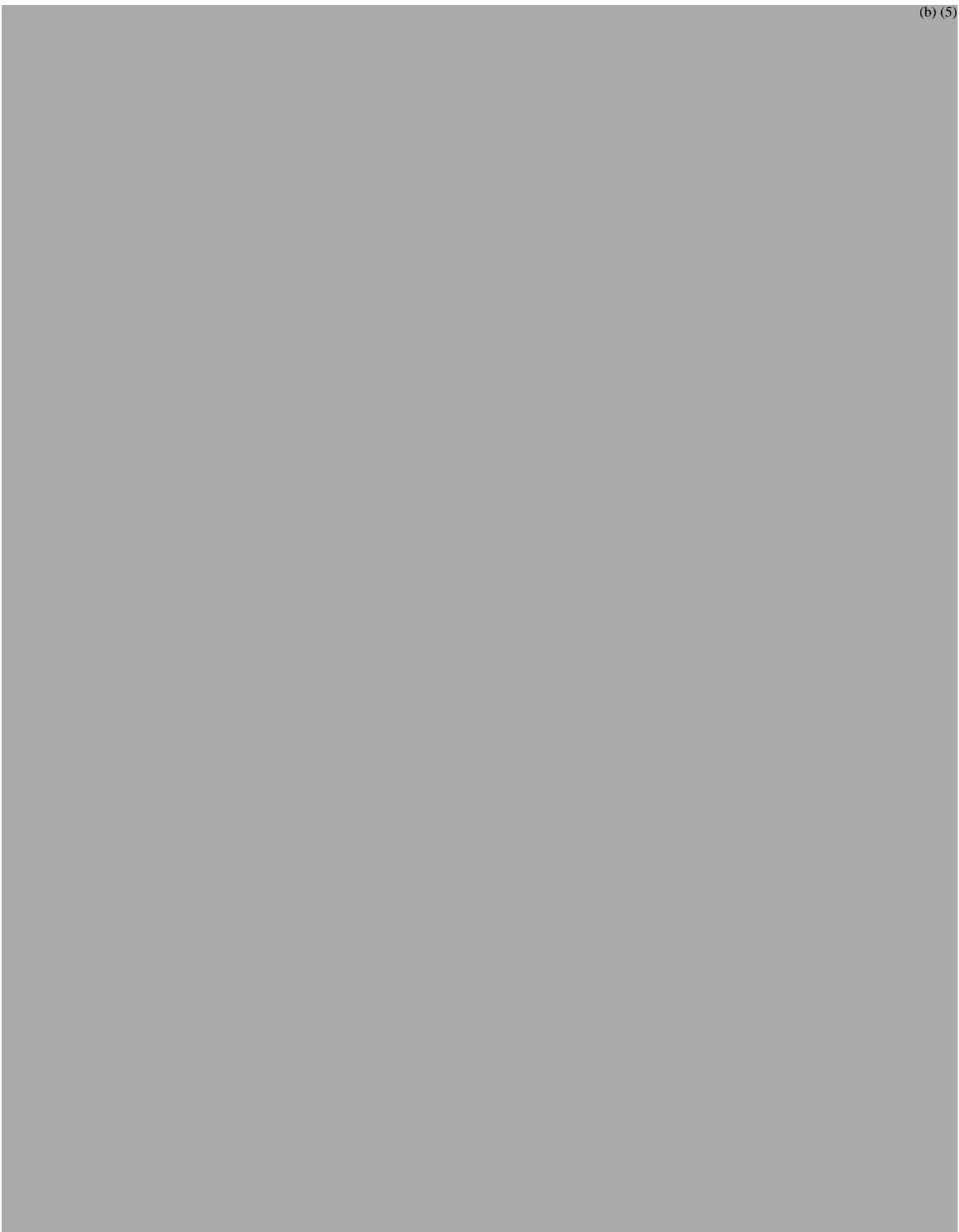
Chronic Diseases and Organ Systems













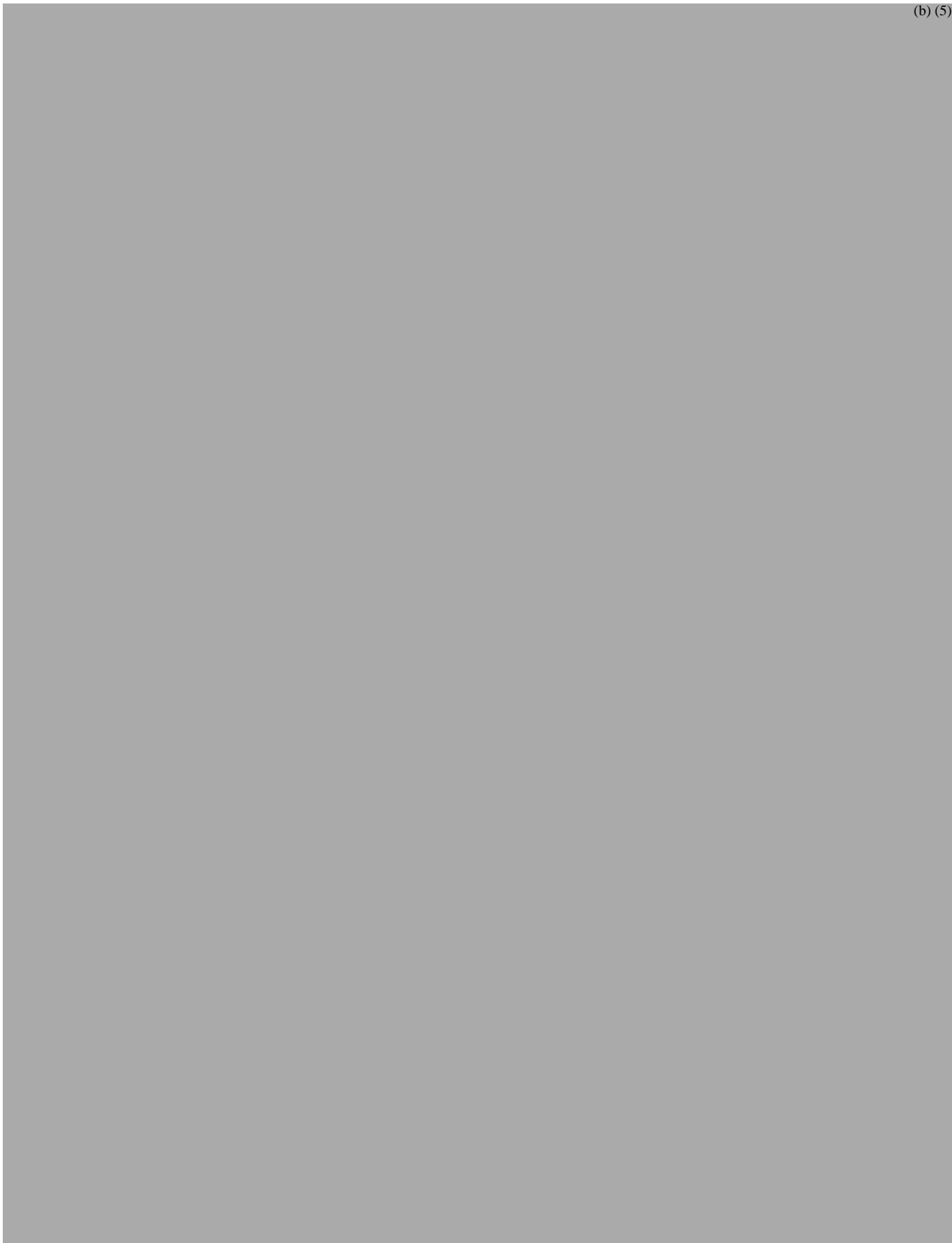




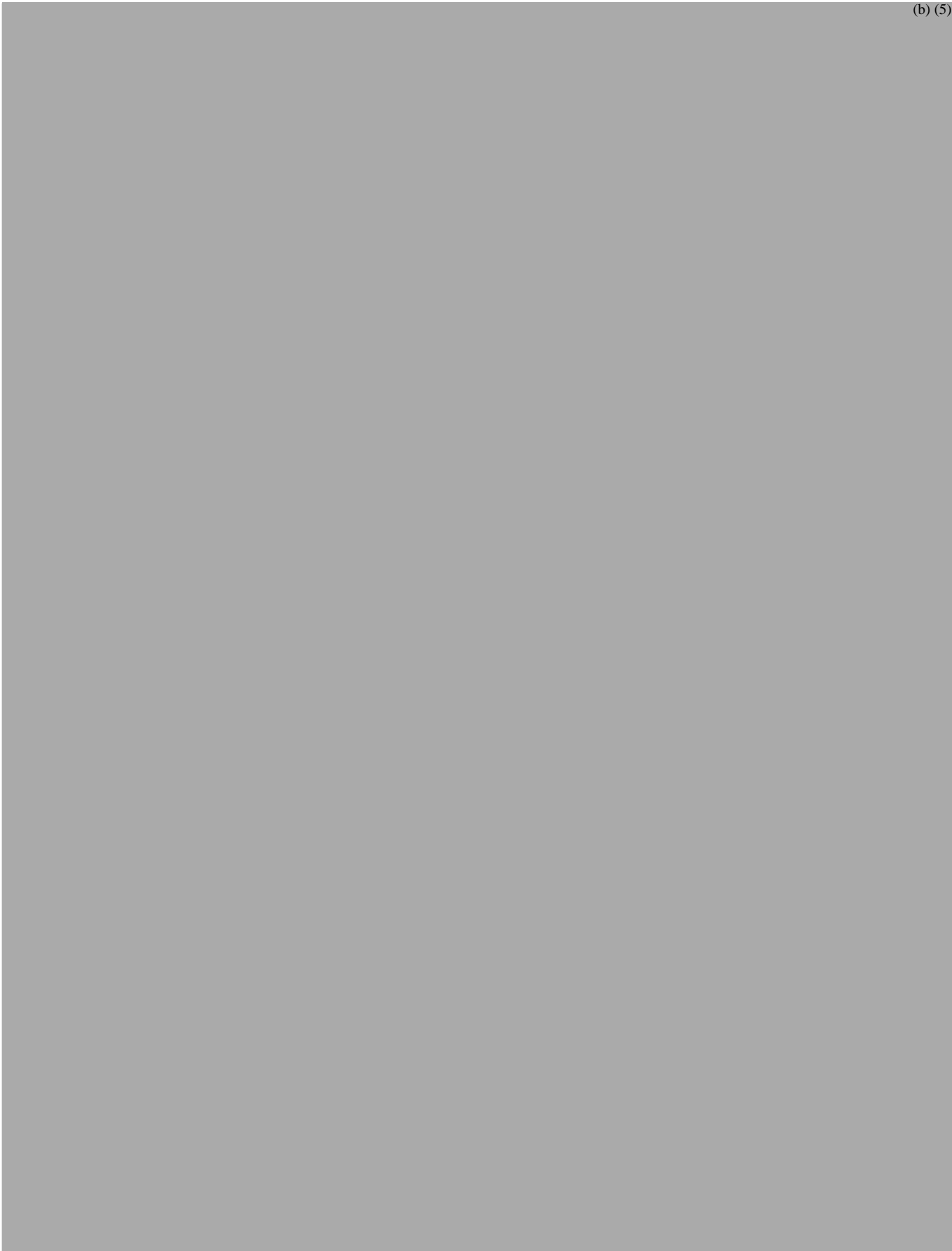


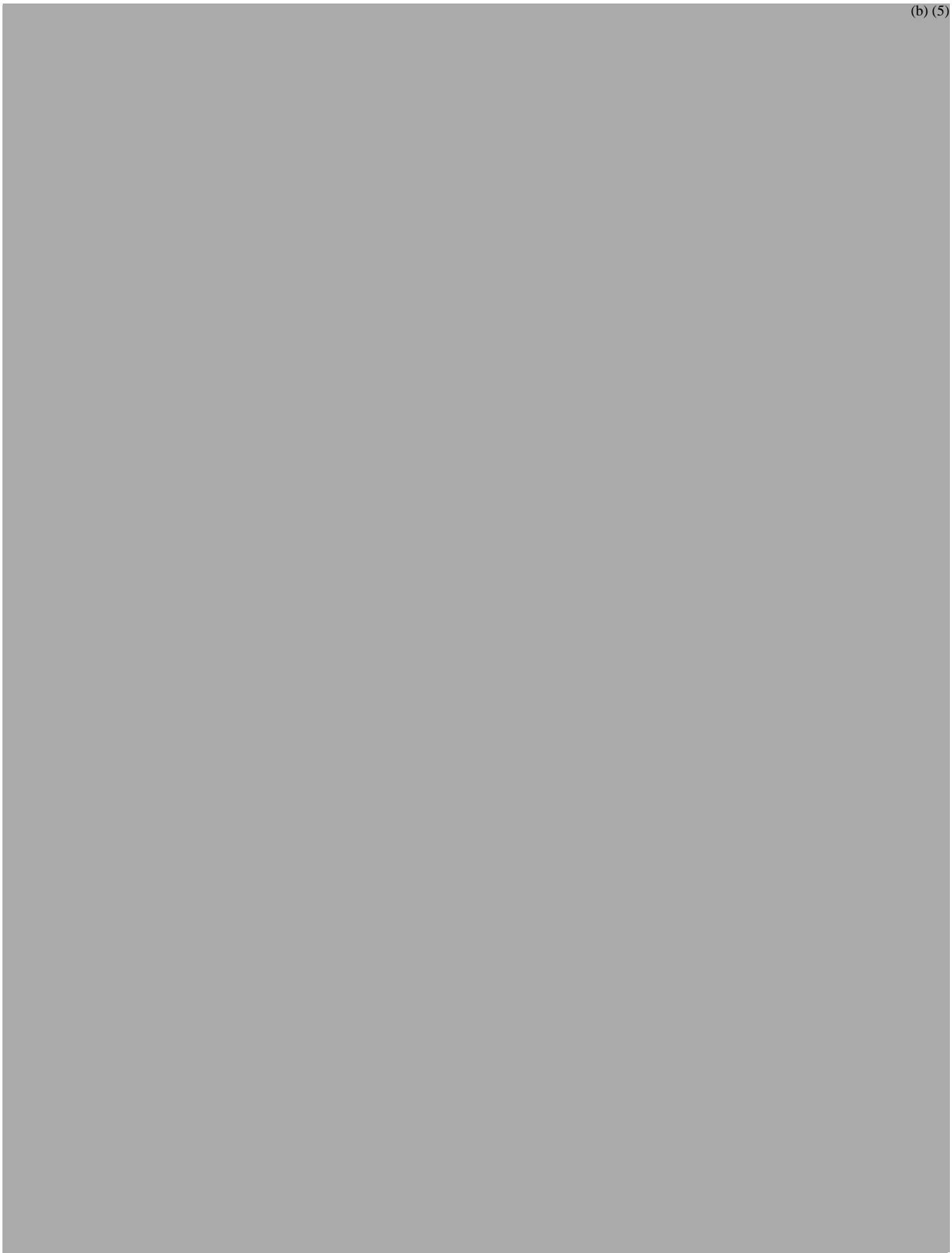


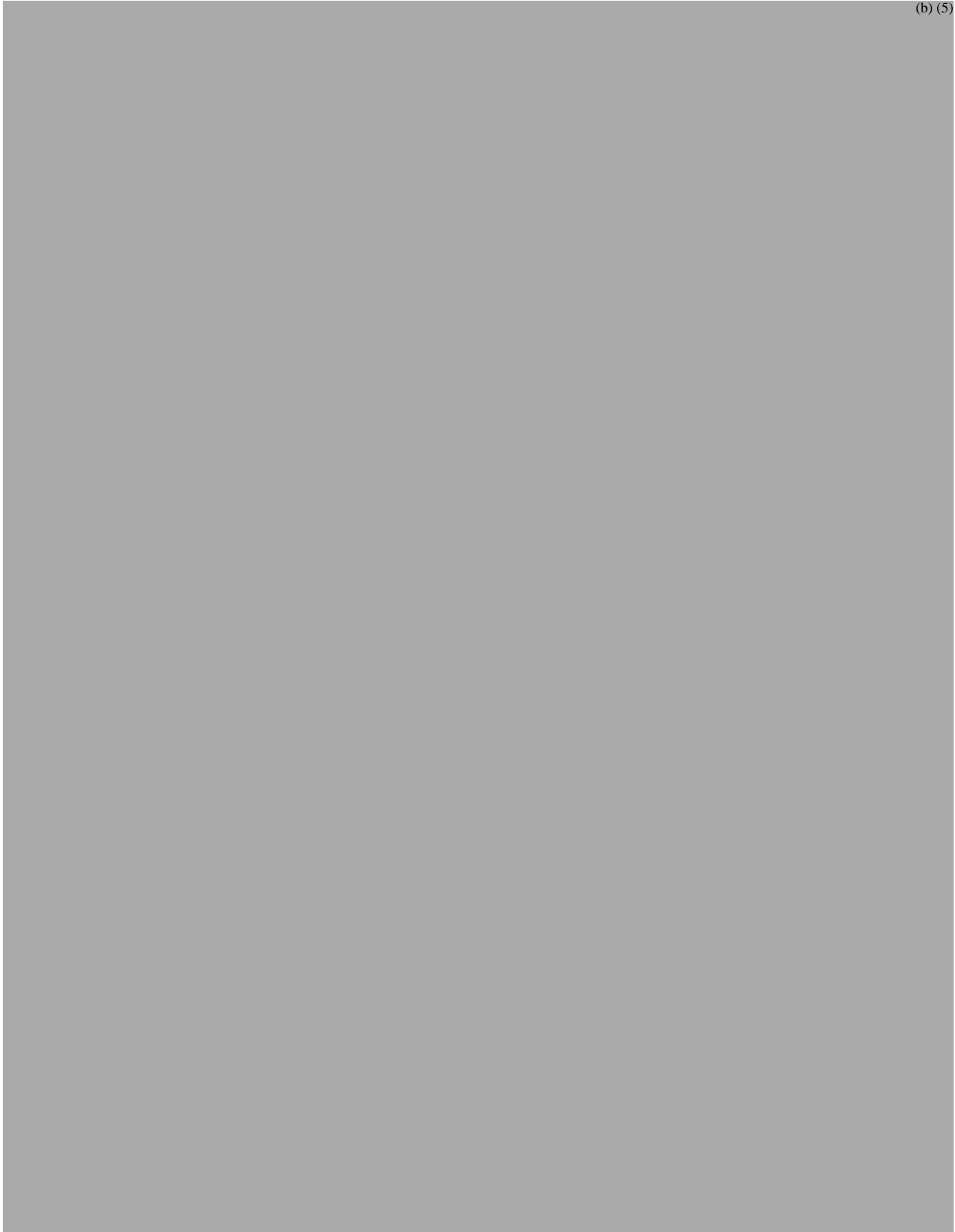


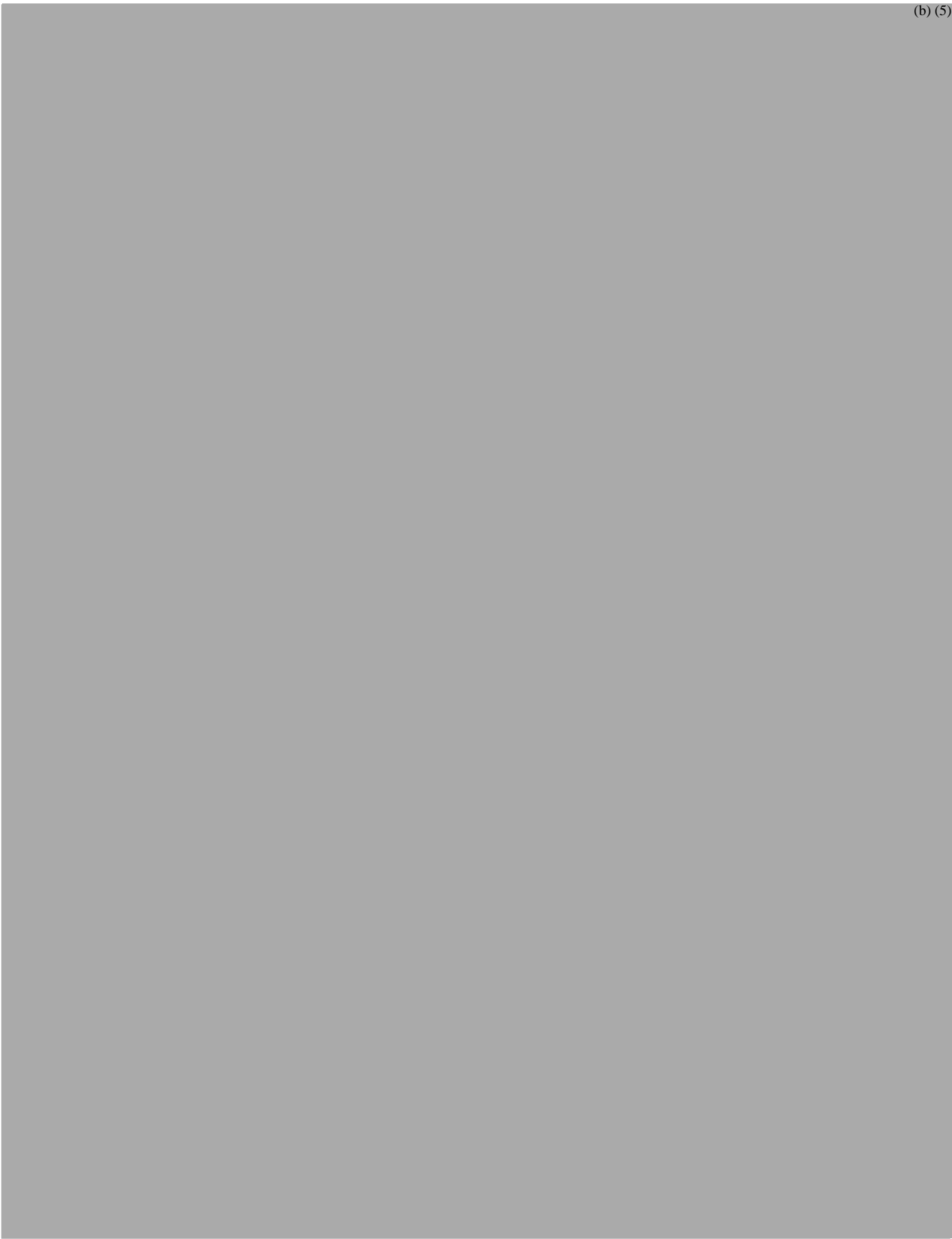


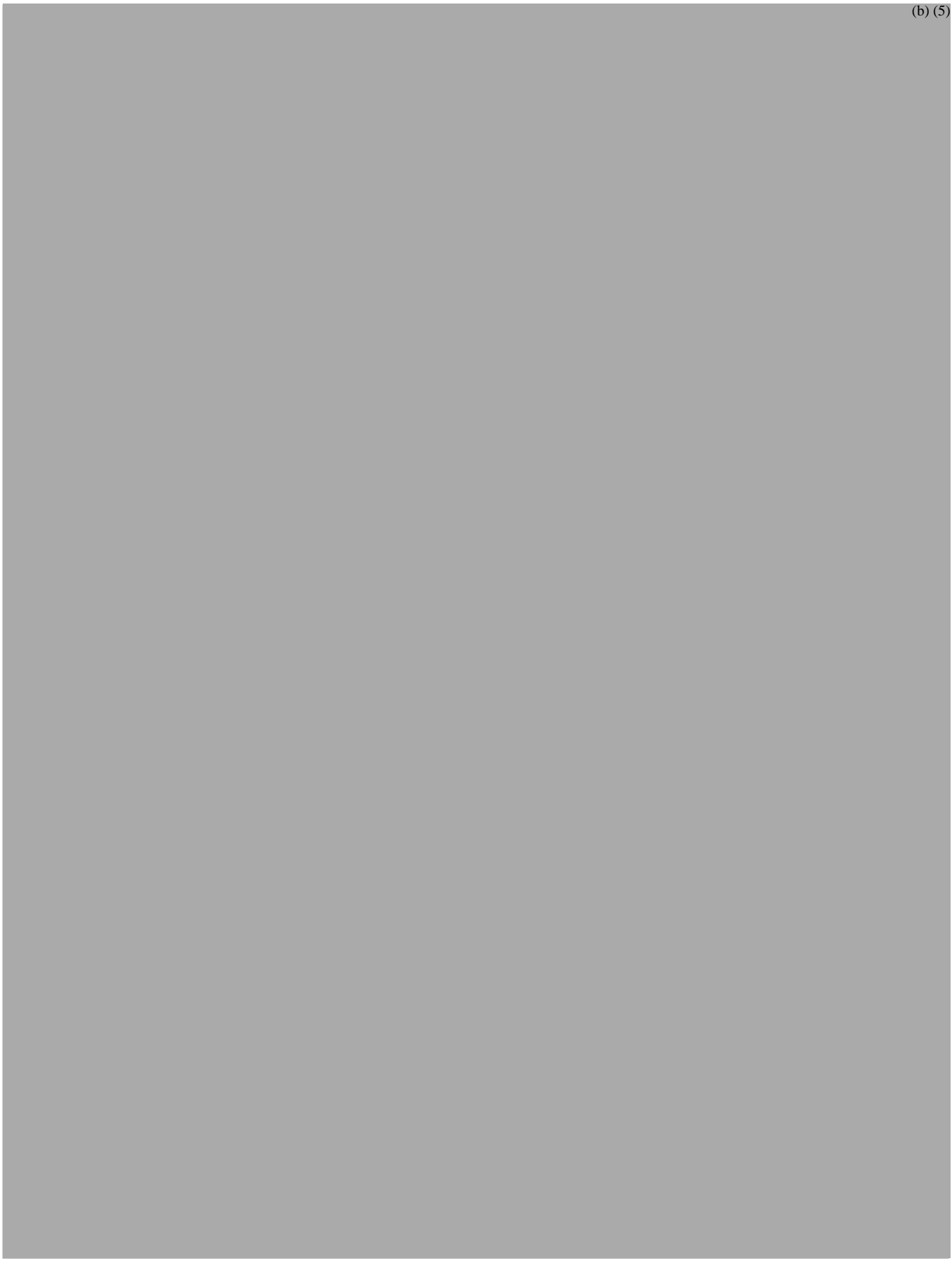




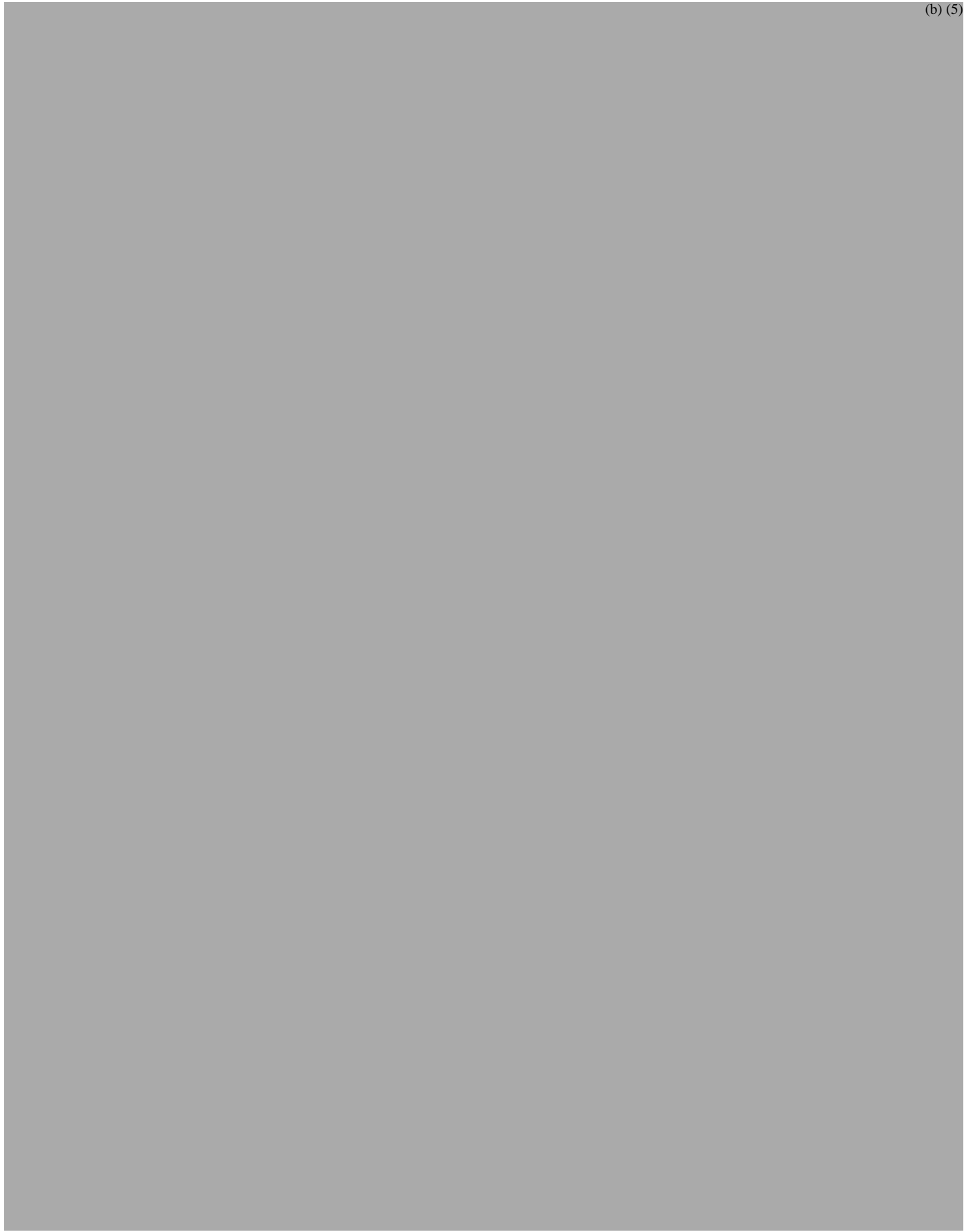
















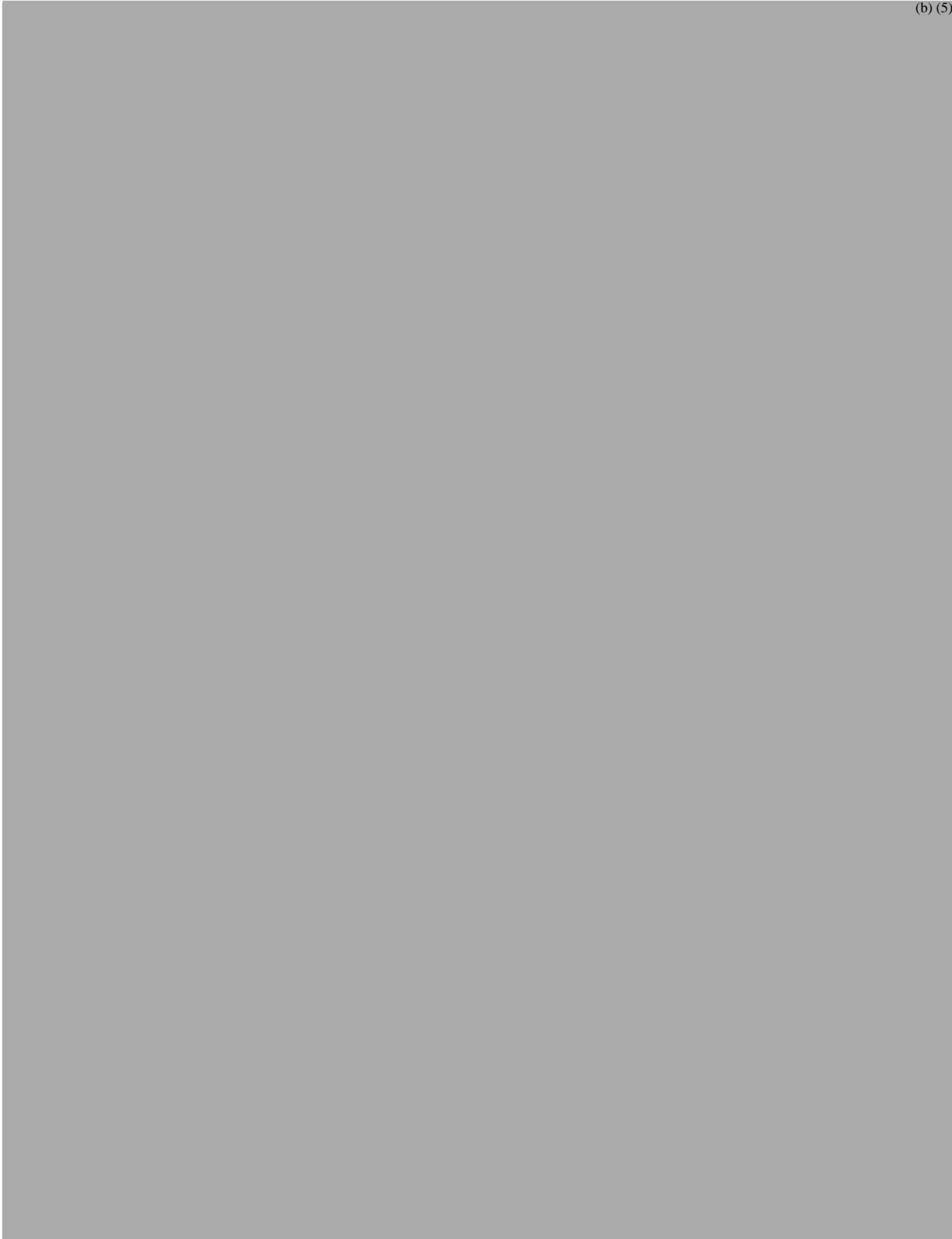


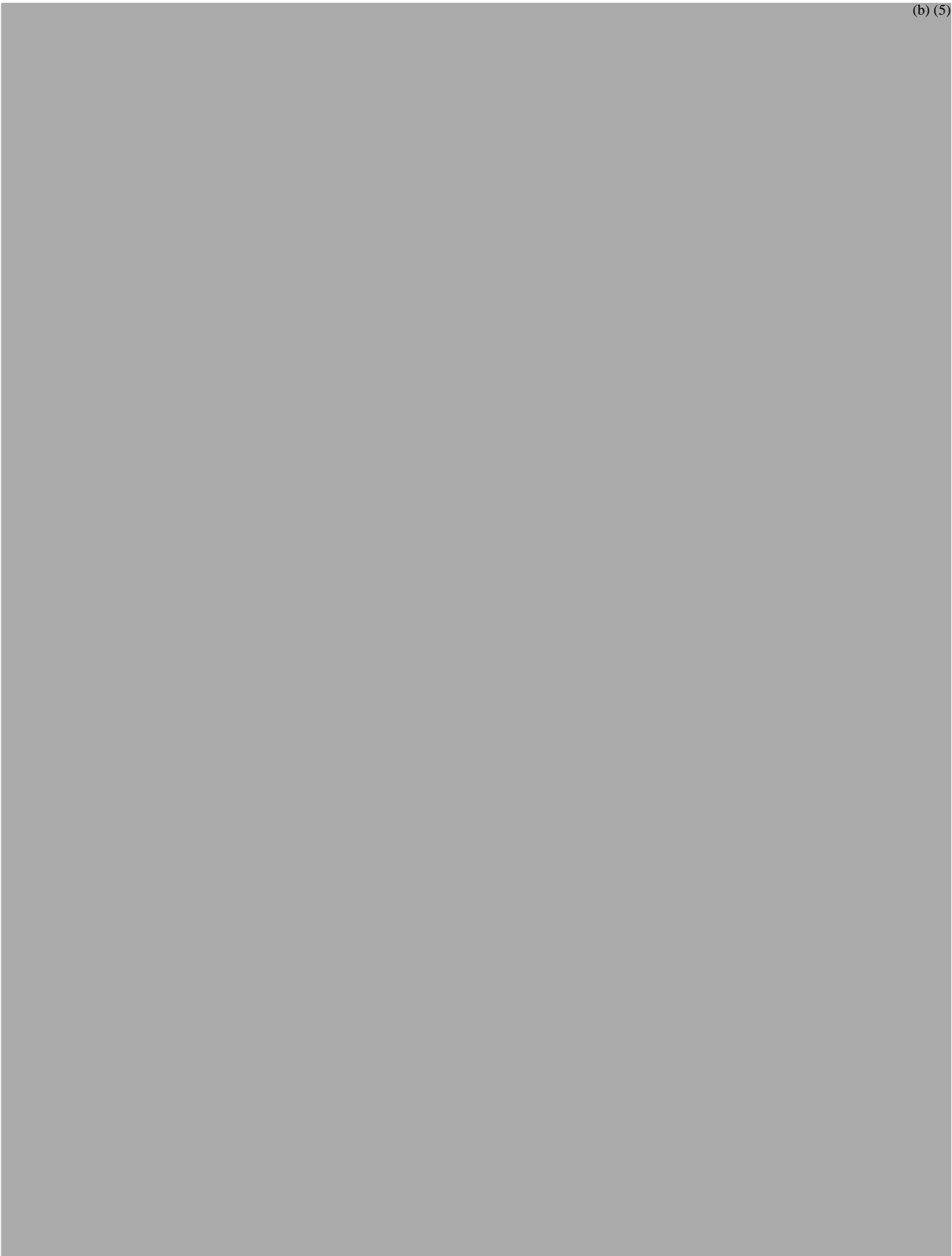


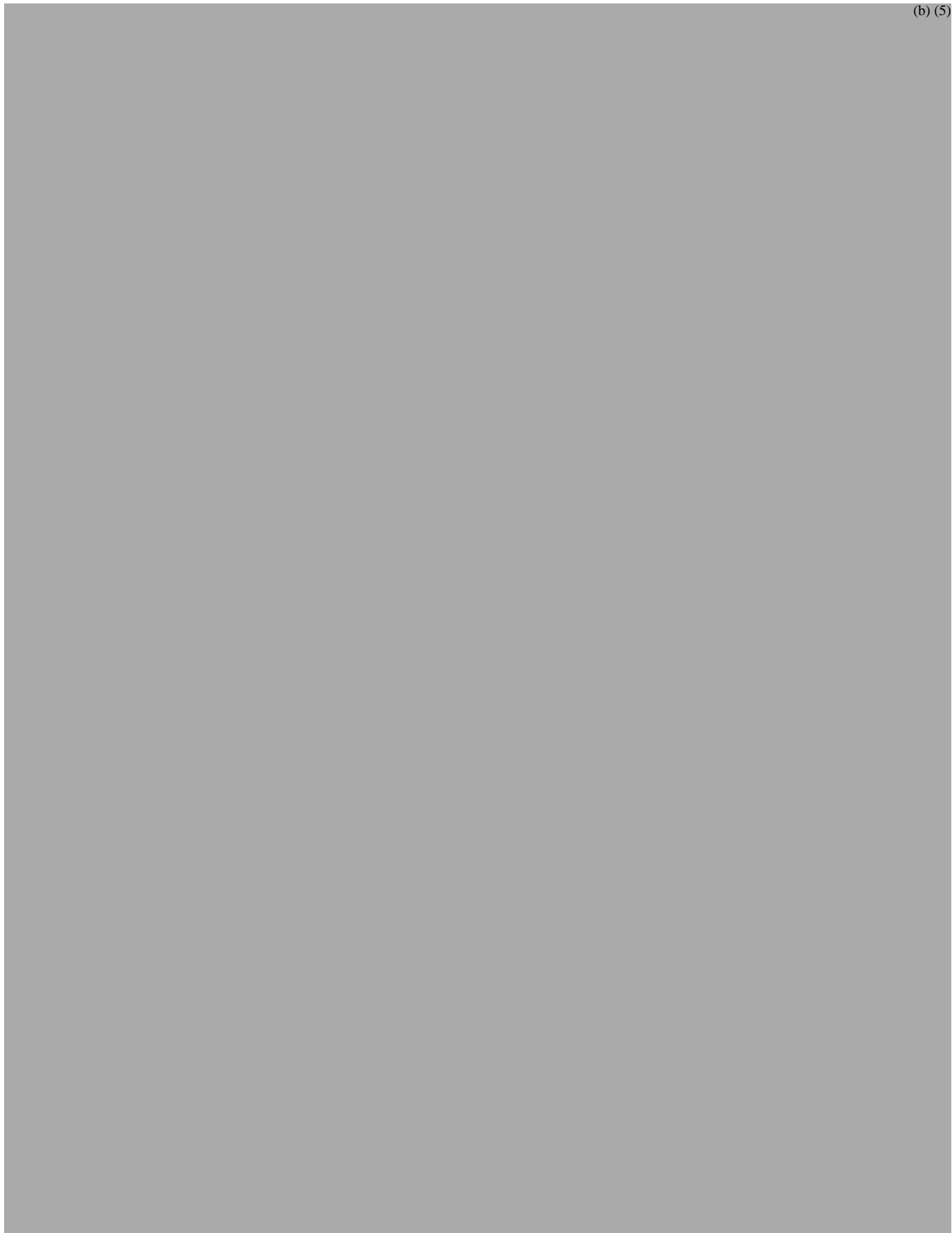




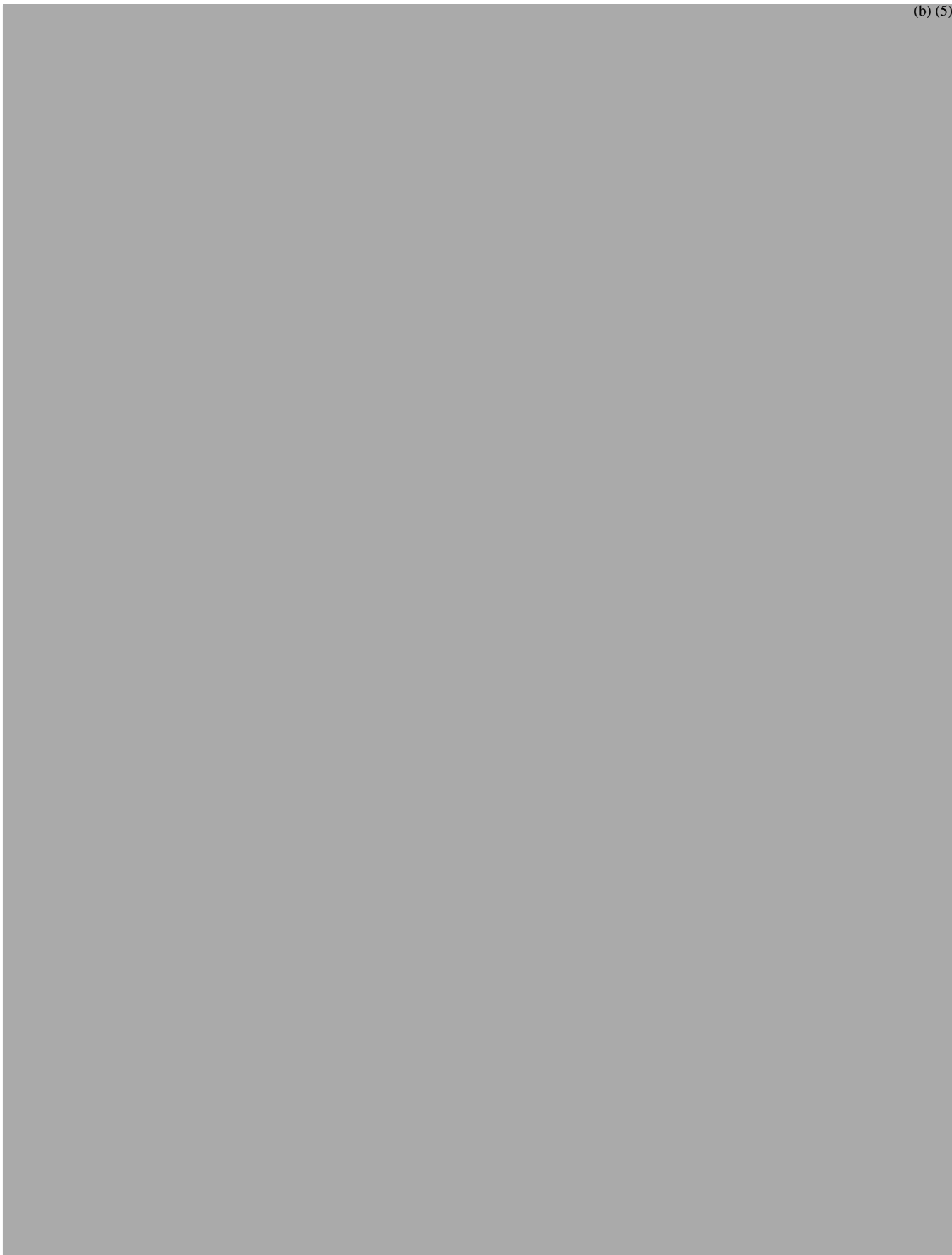


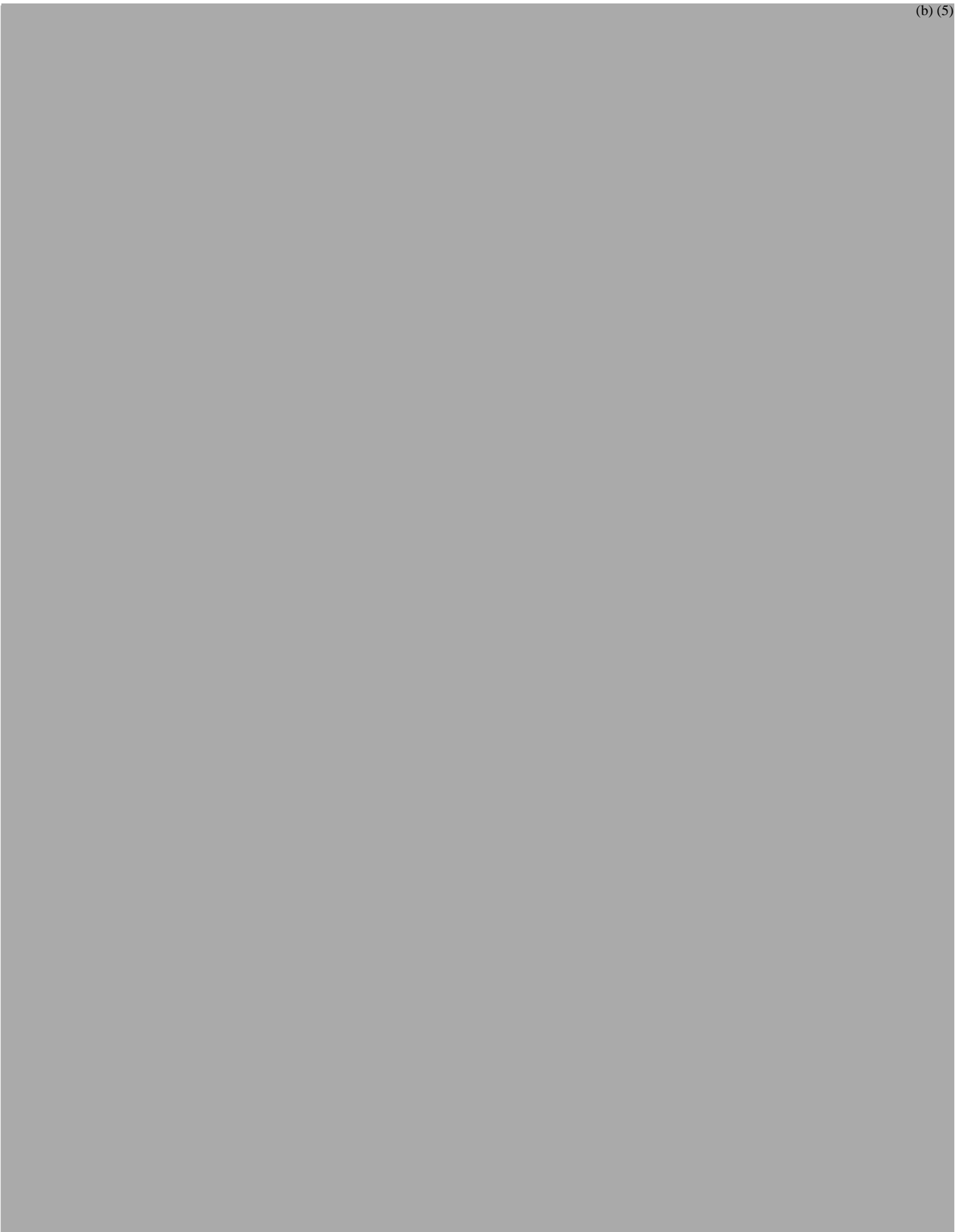




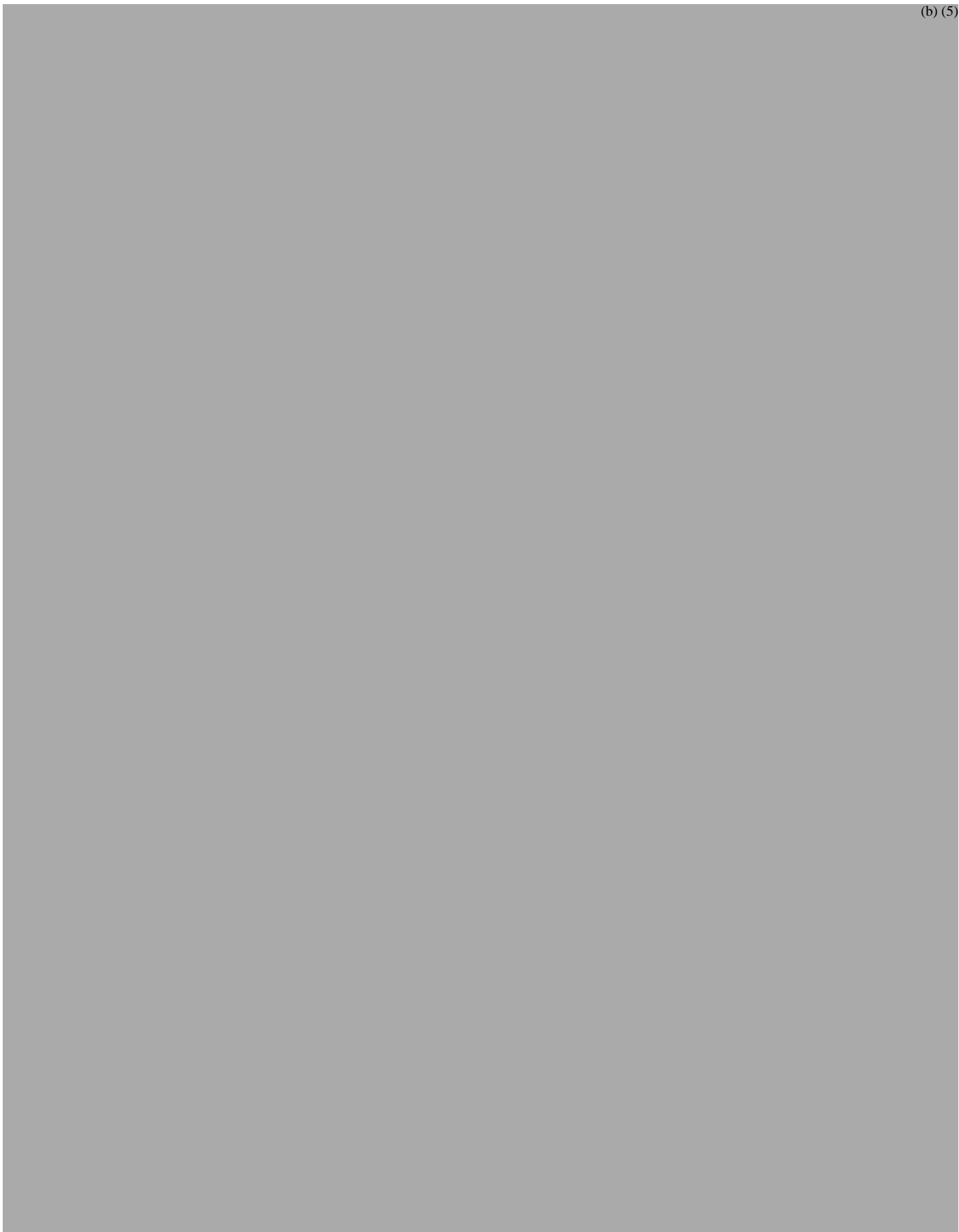


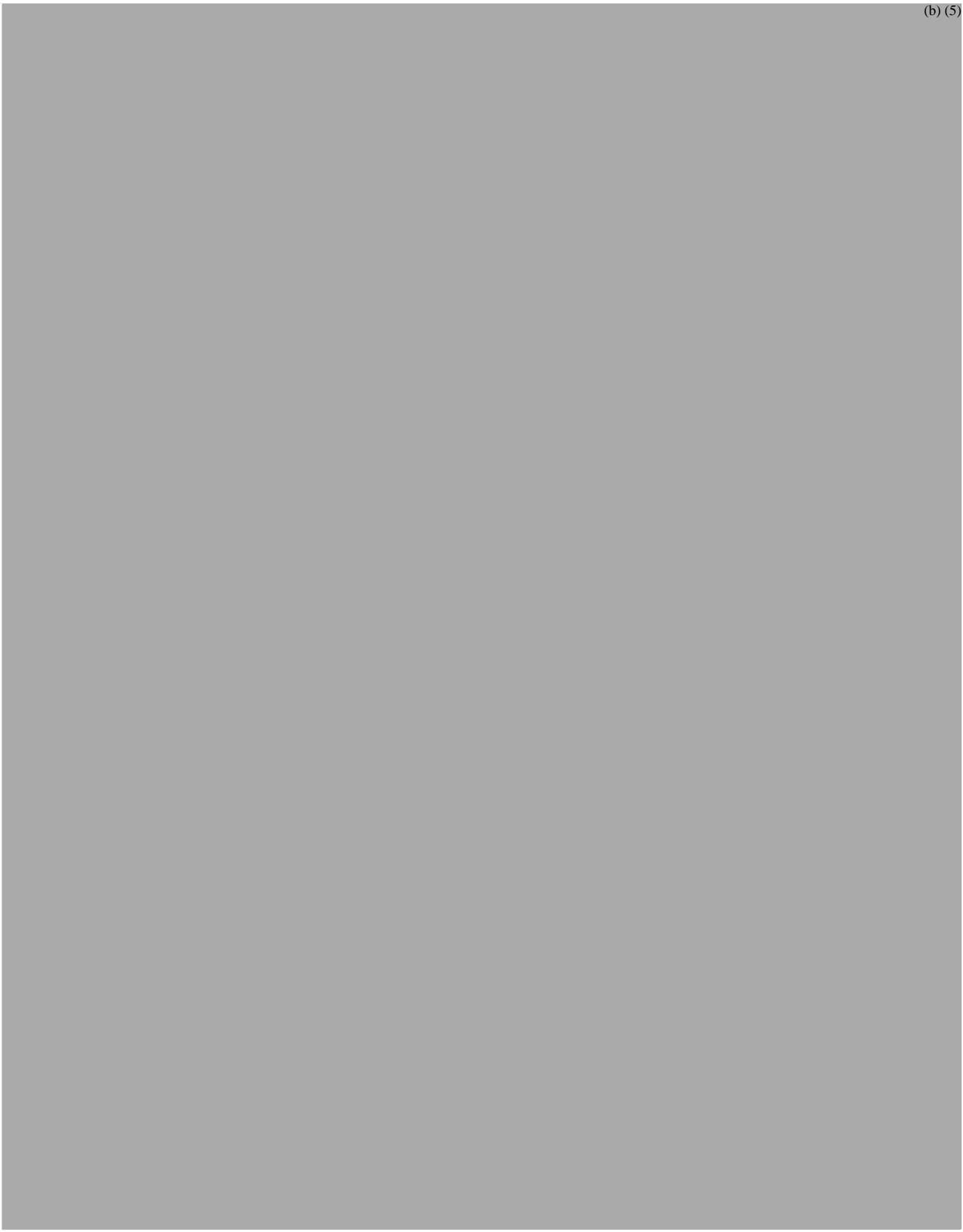


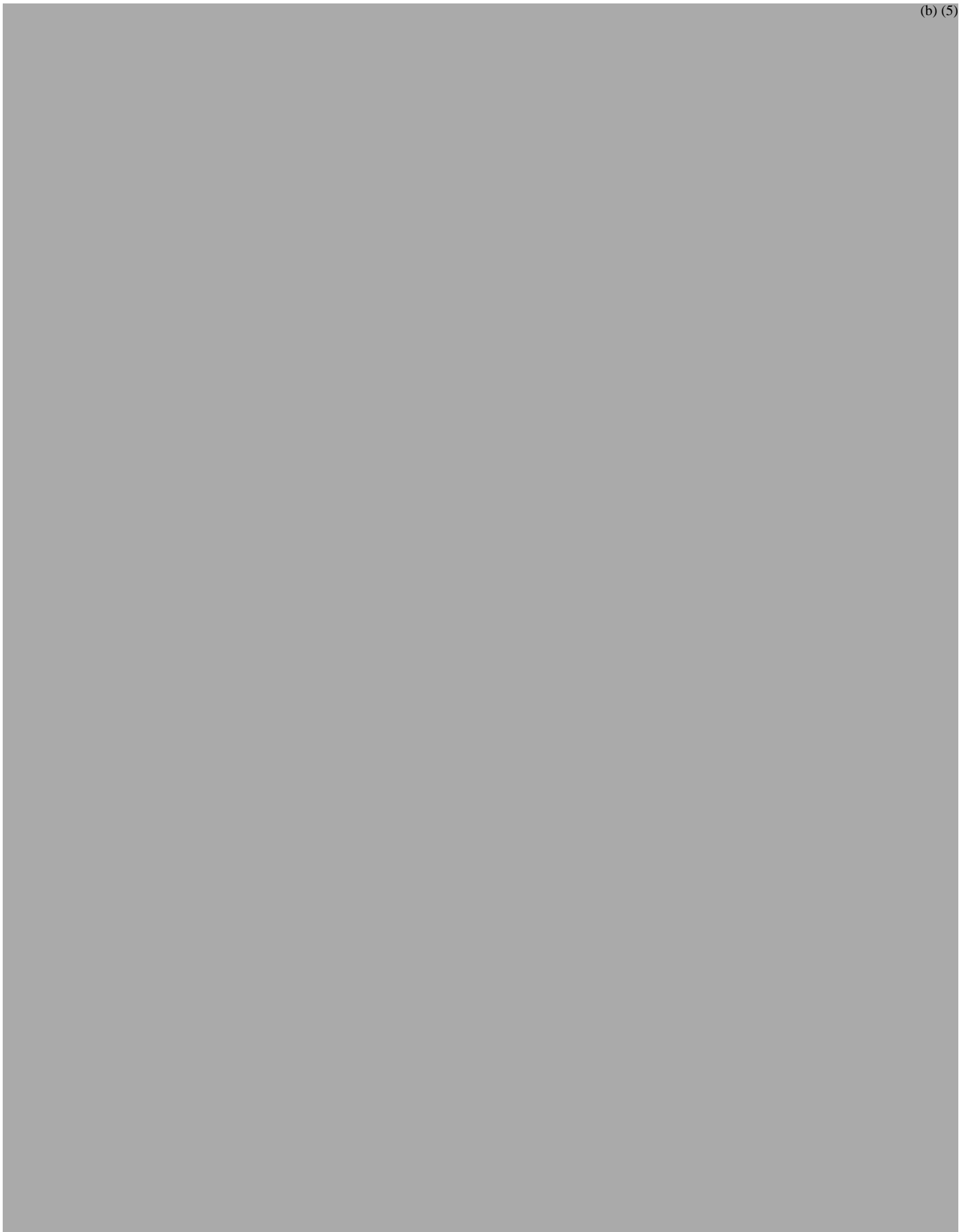


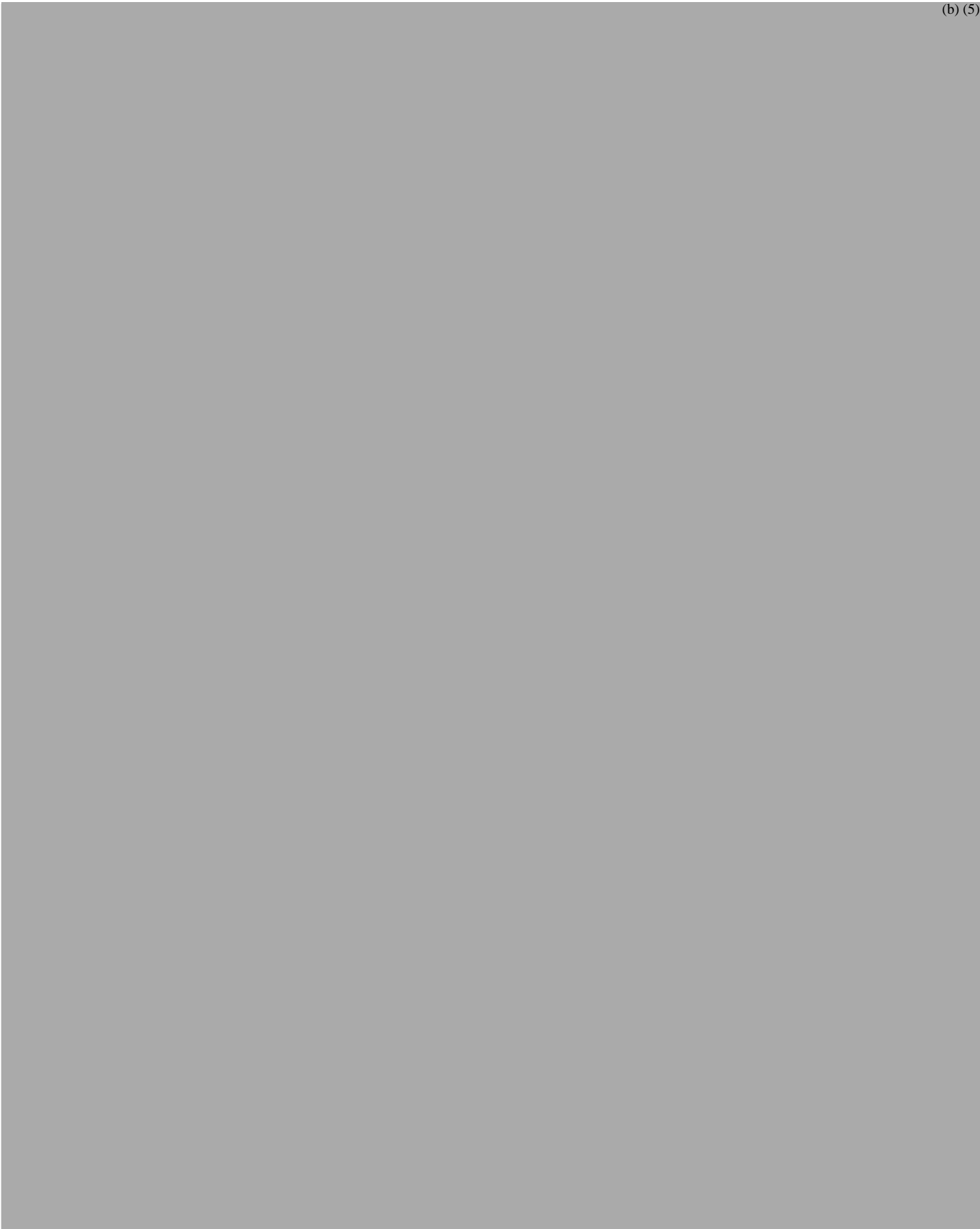


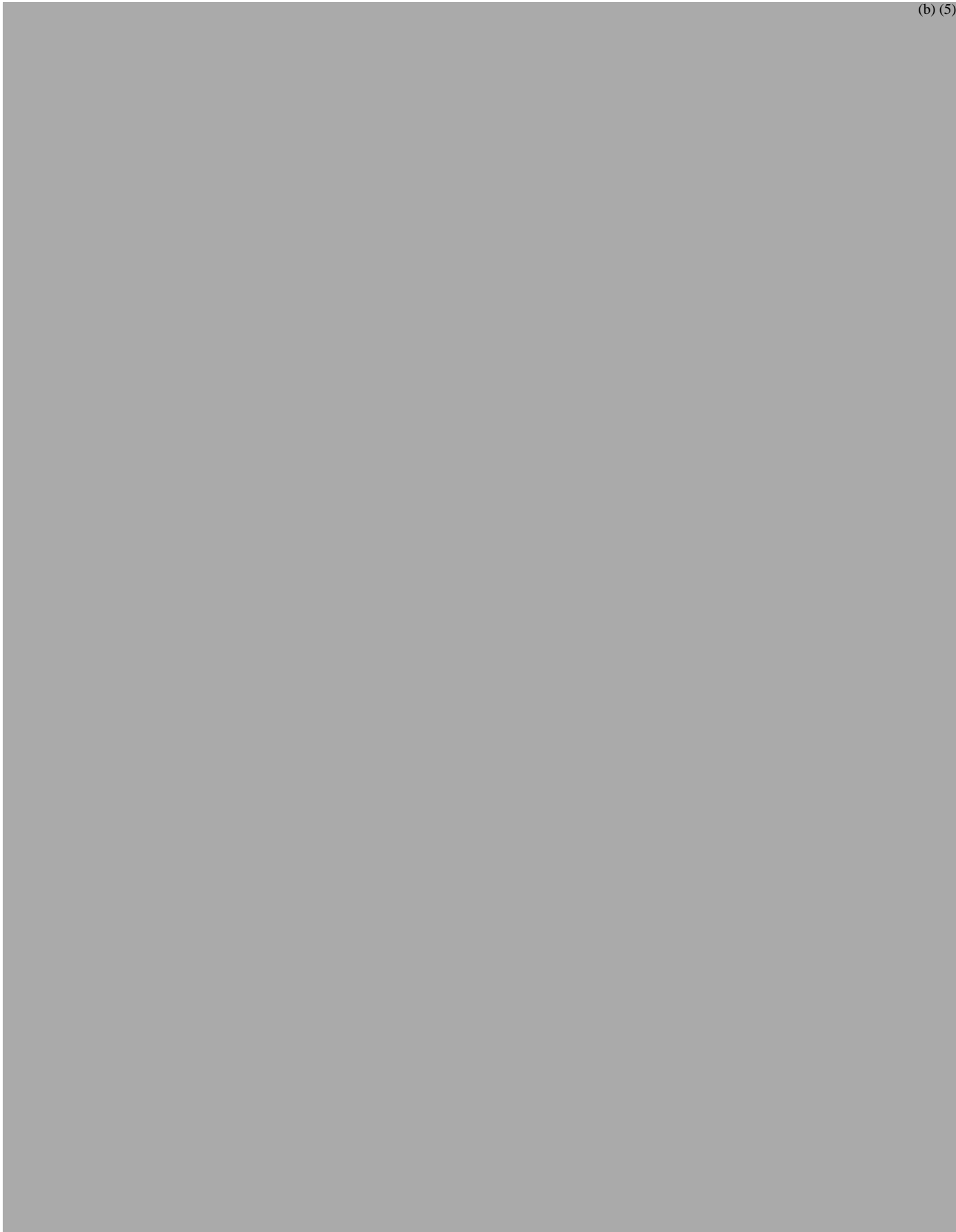


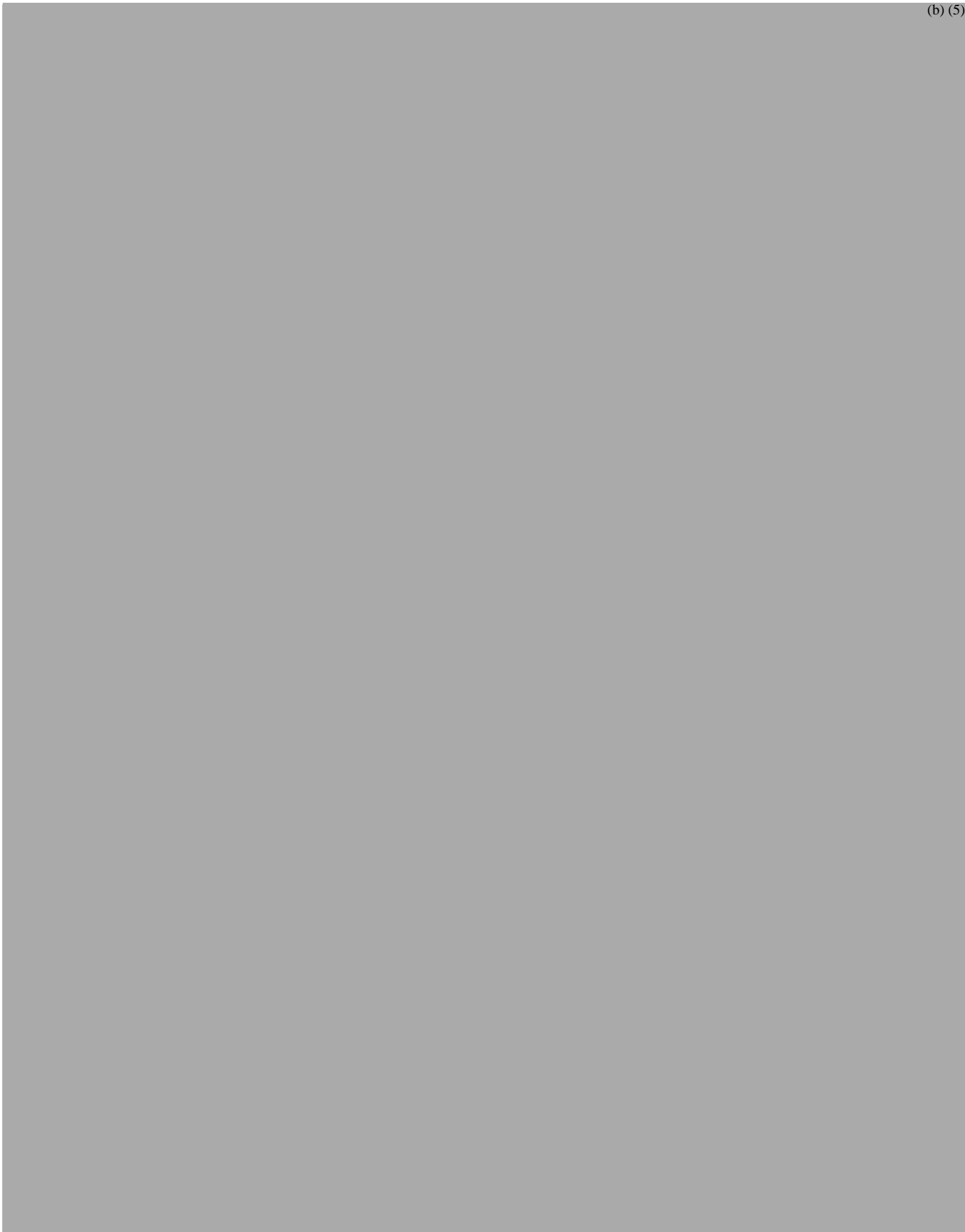


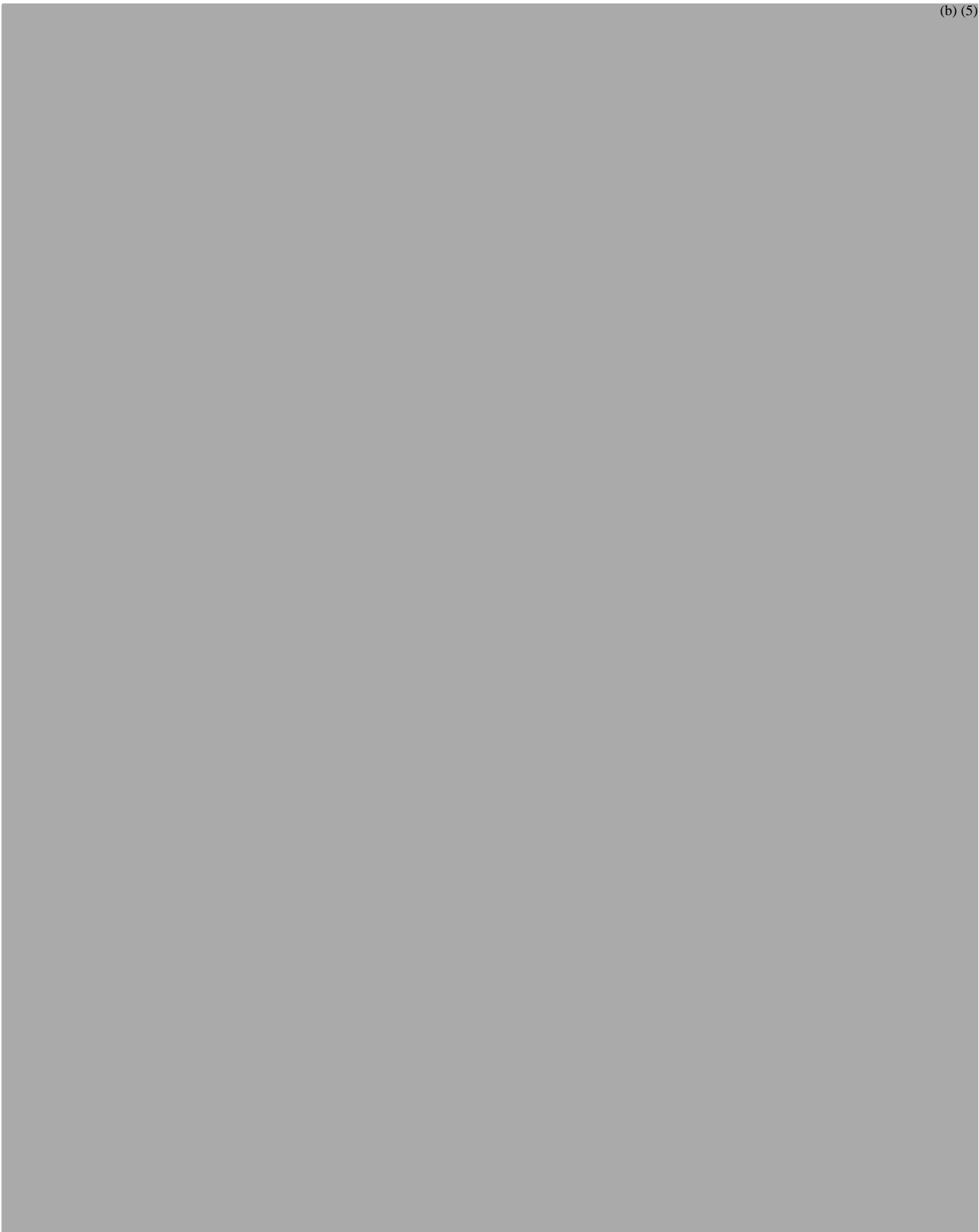












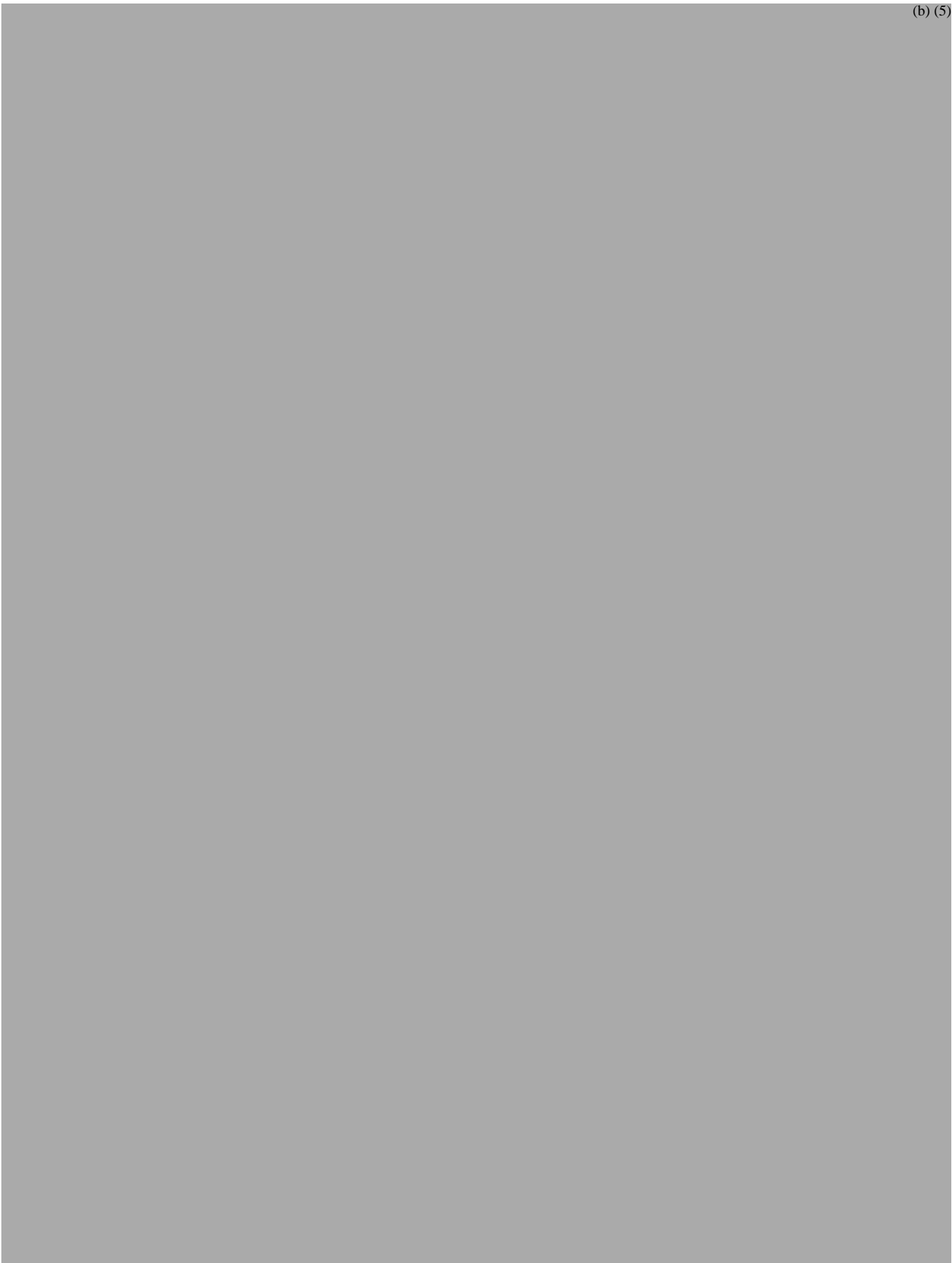








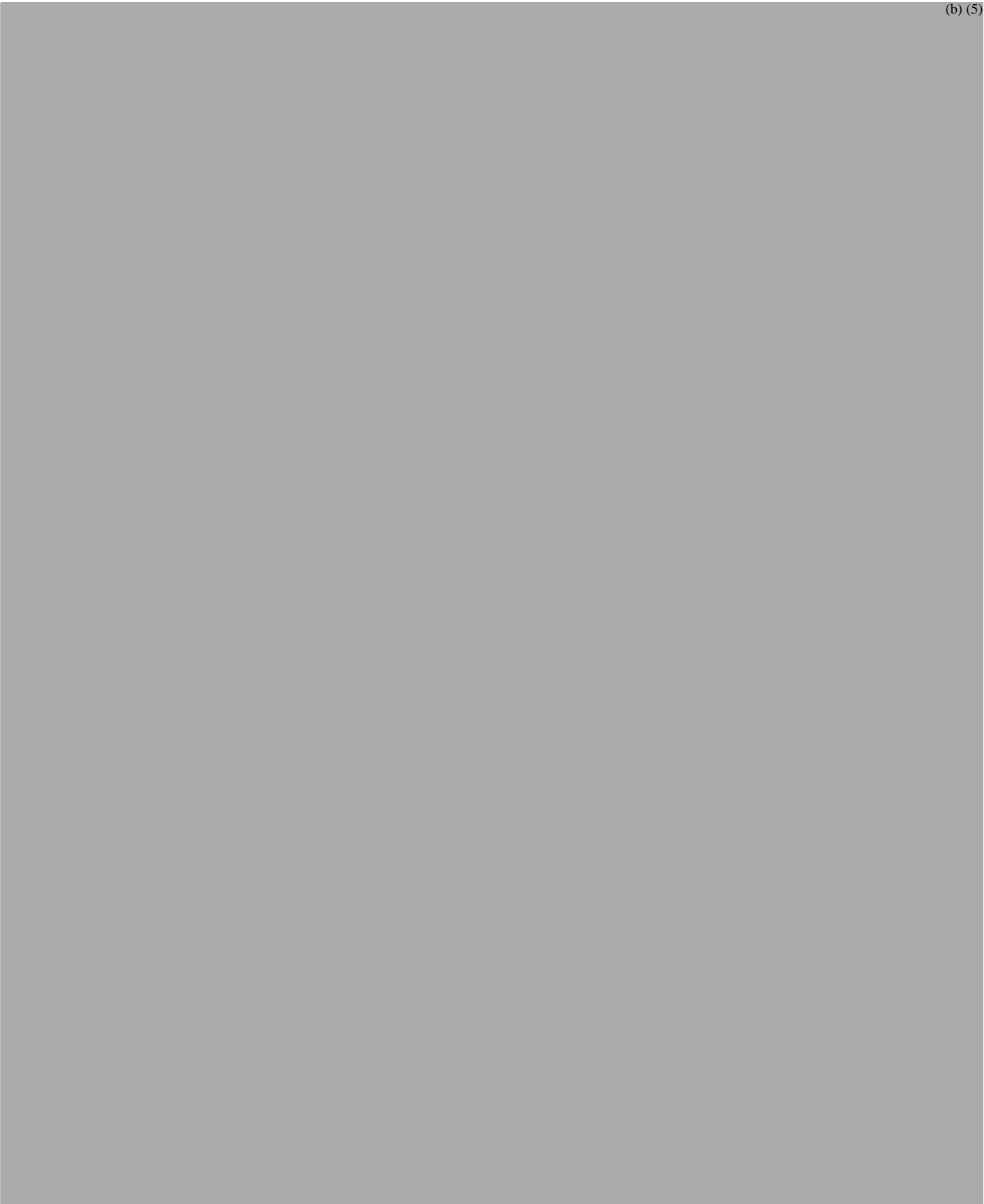








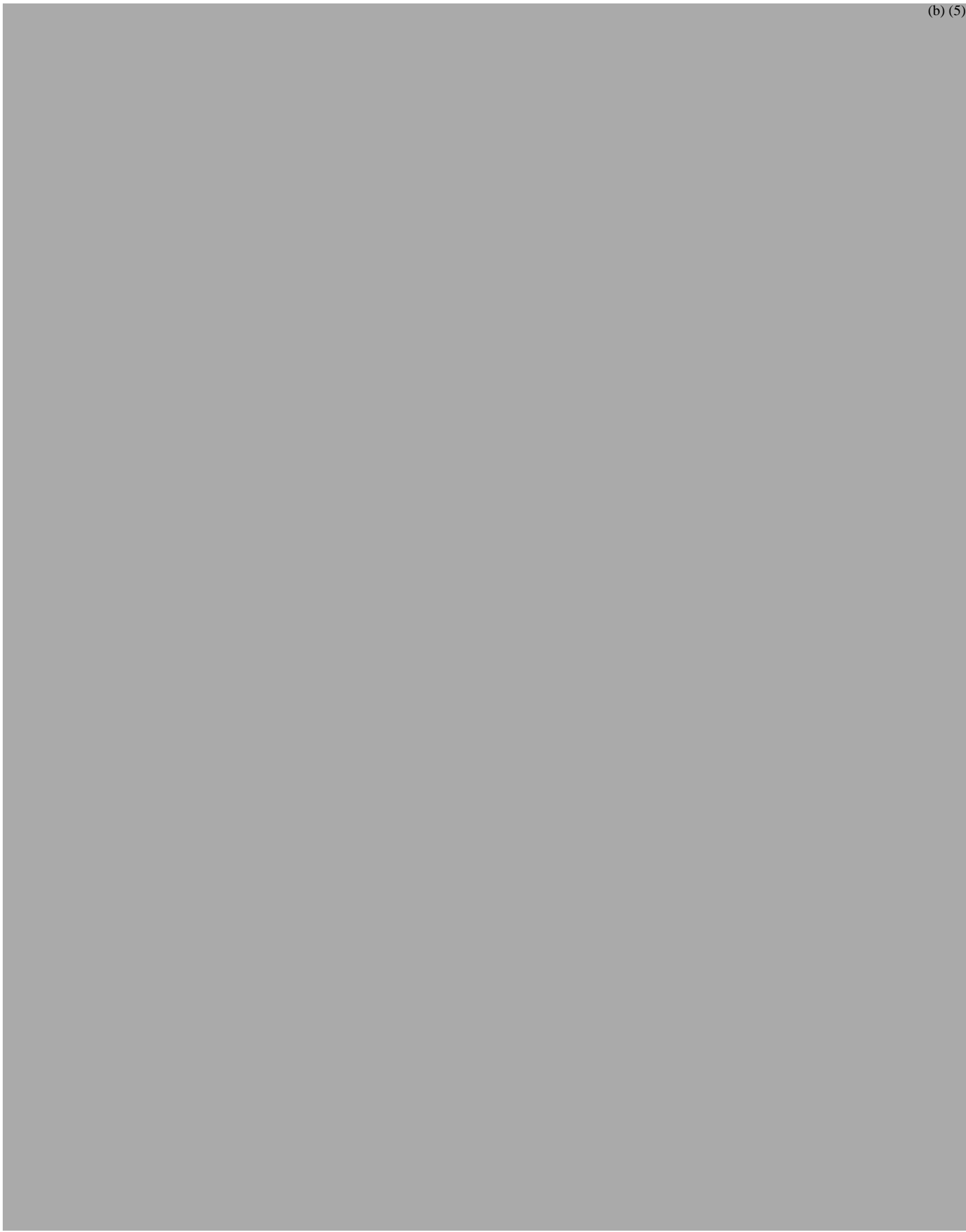


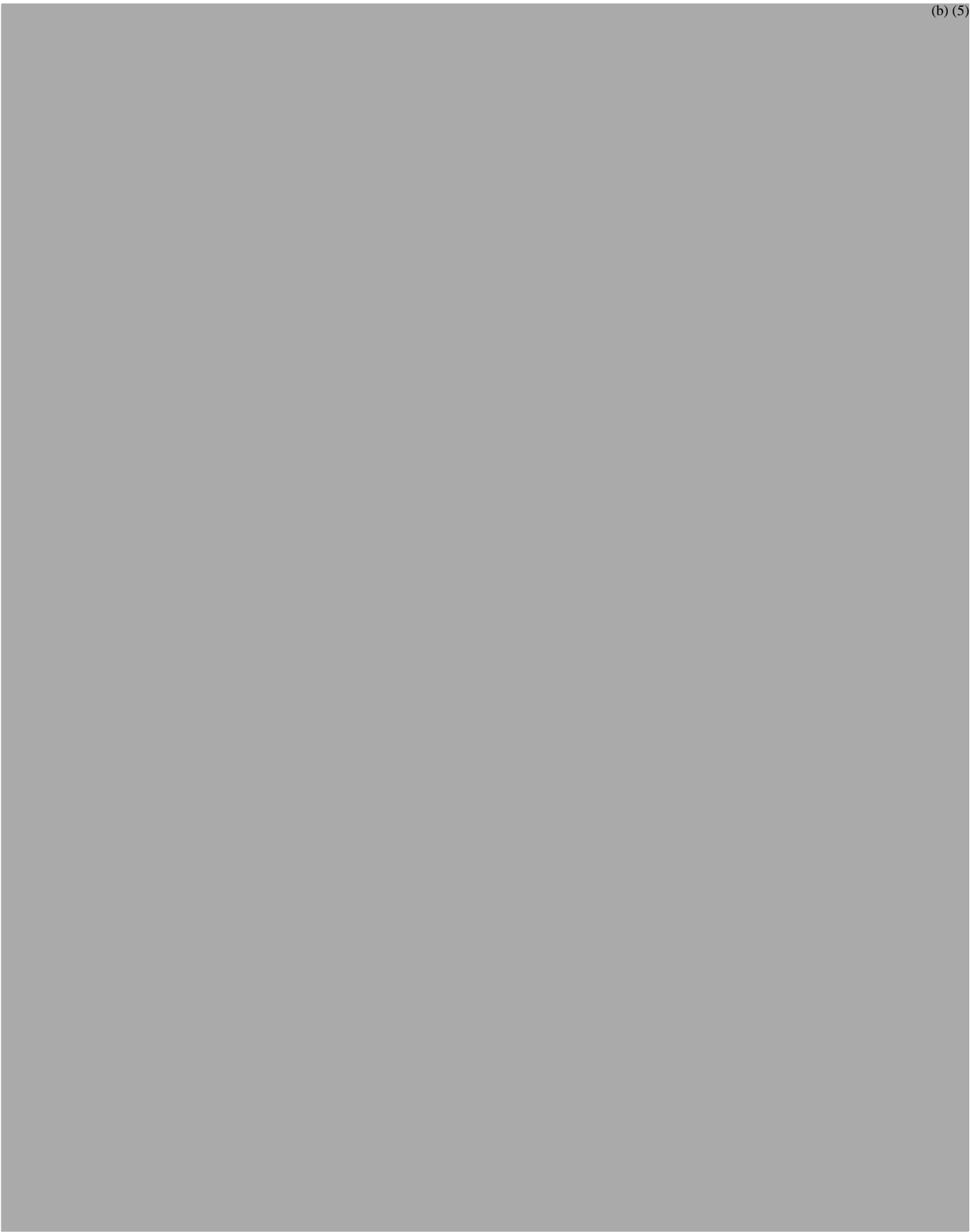








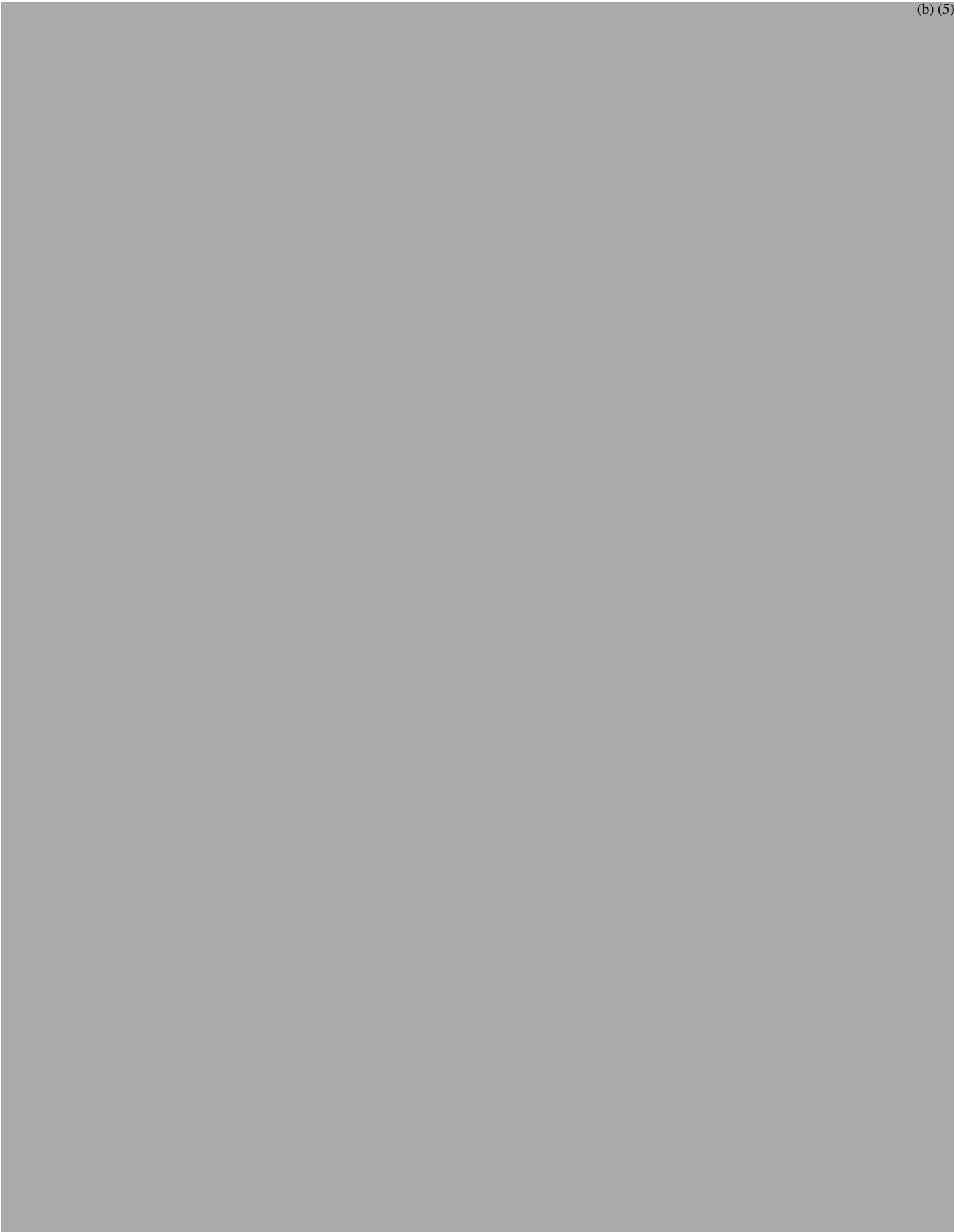


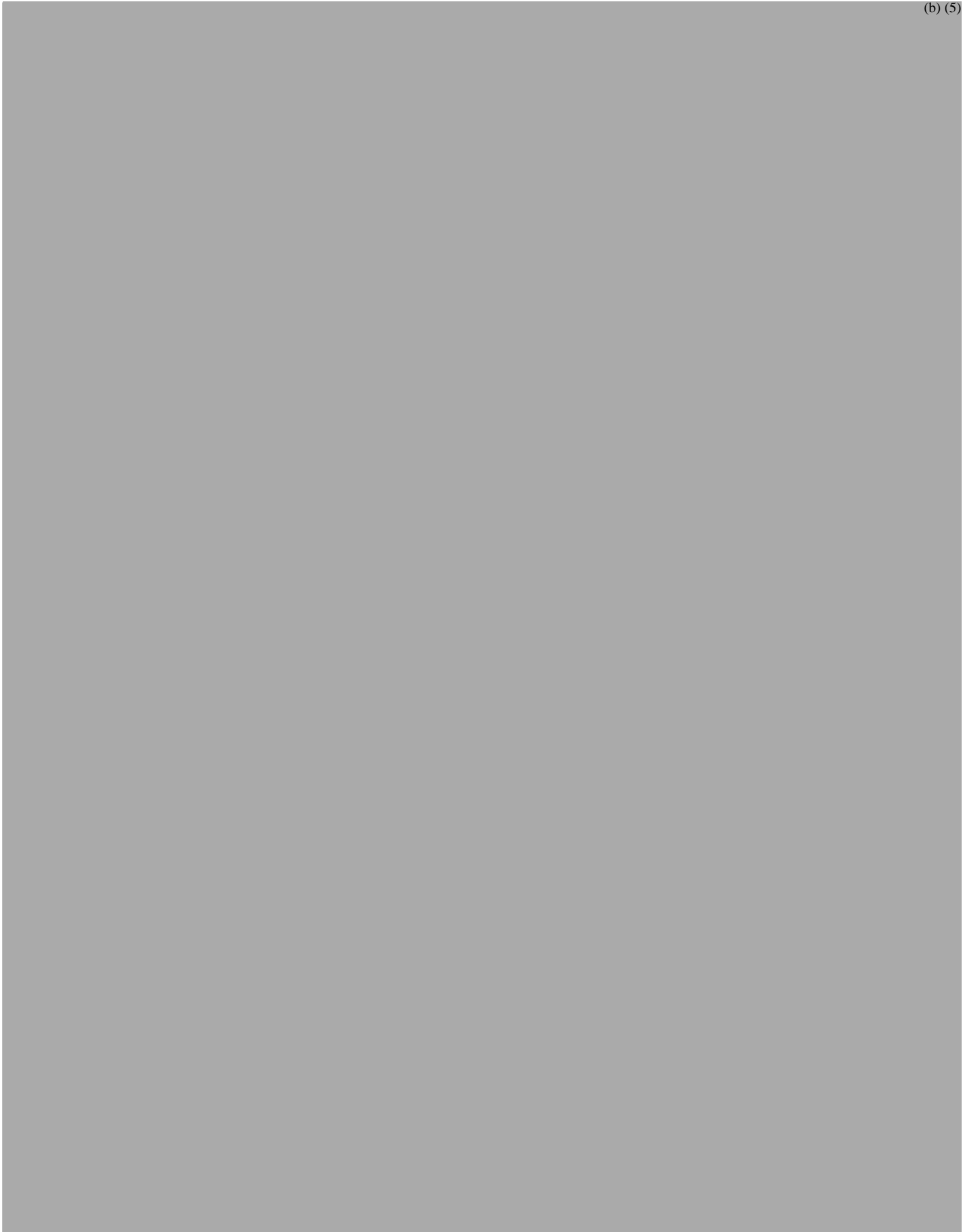


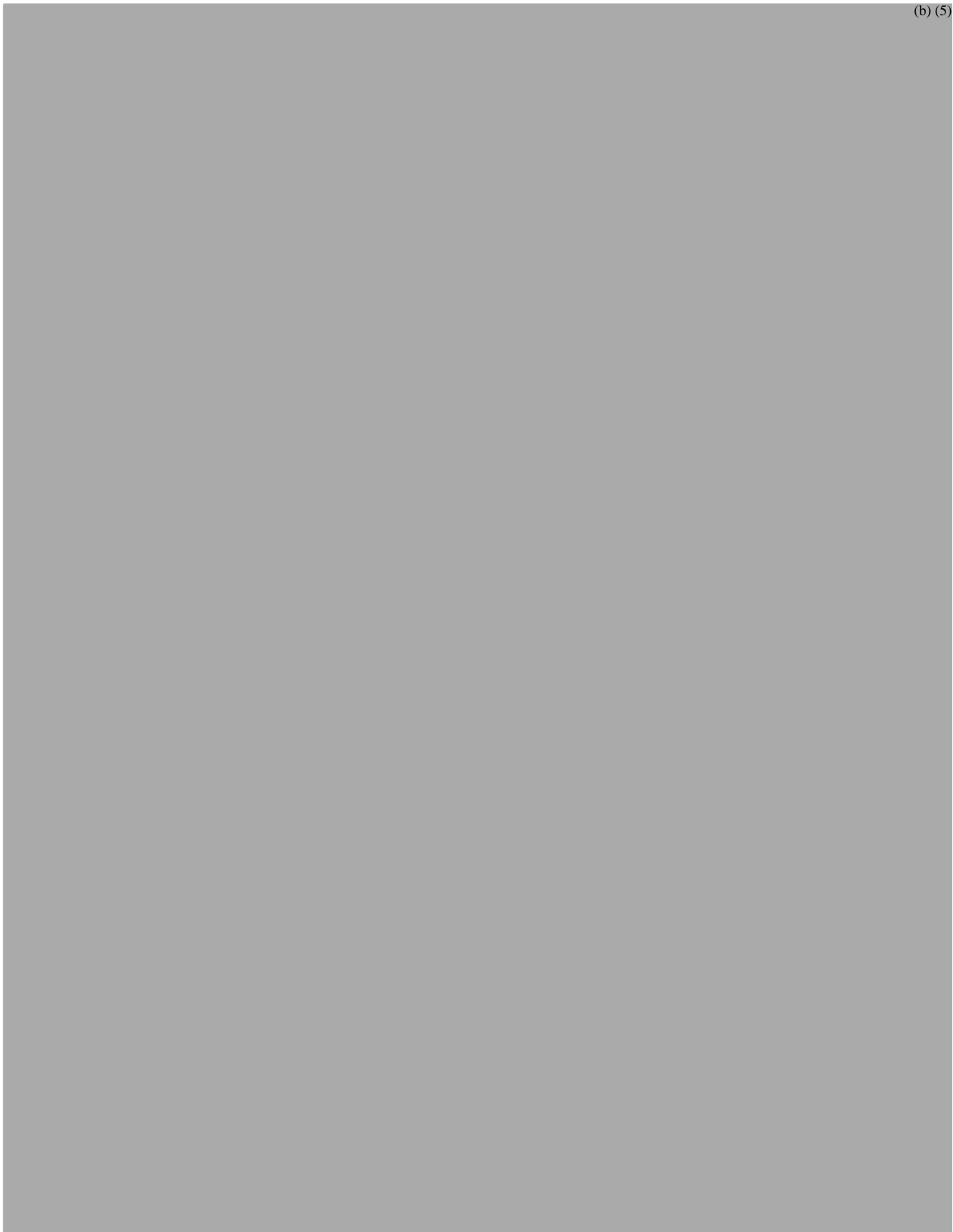


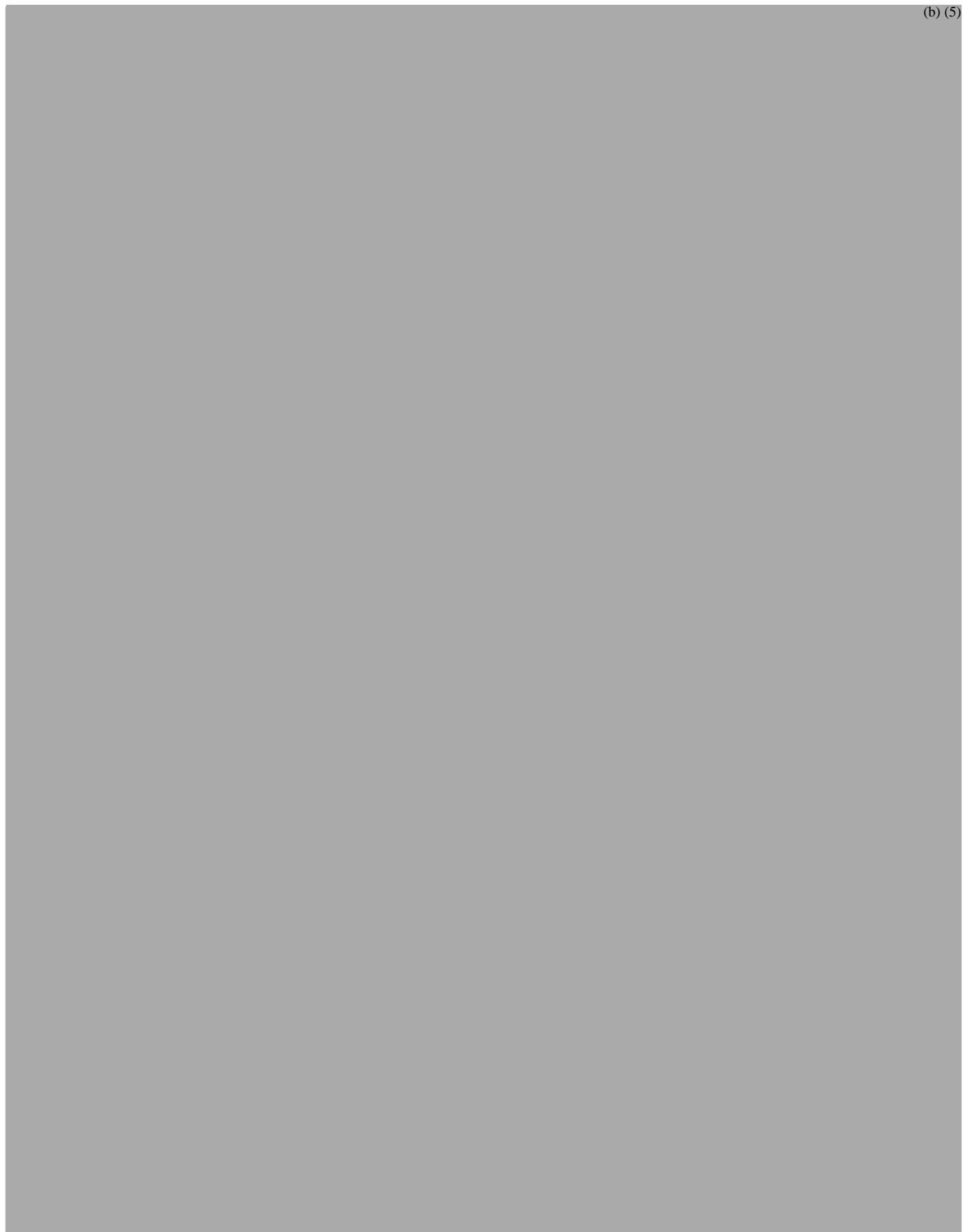






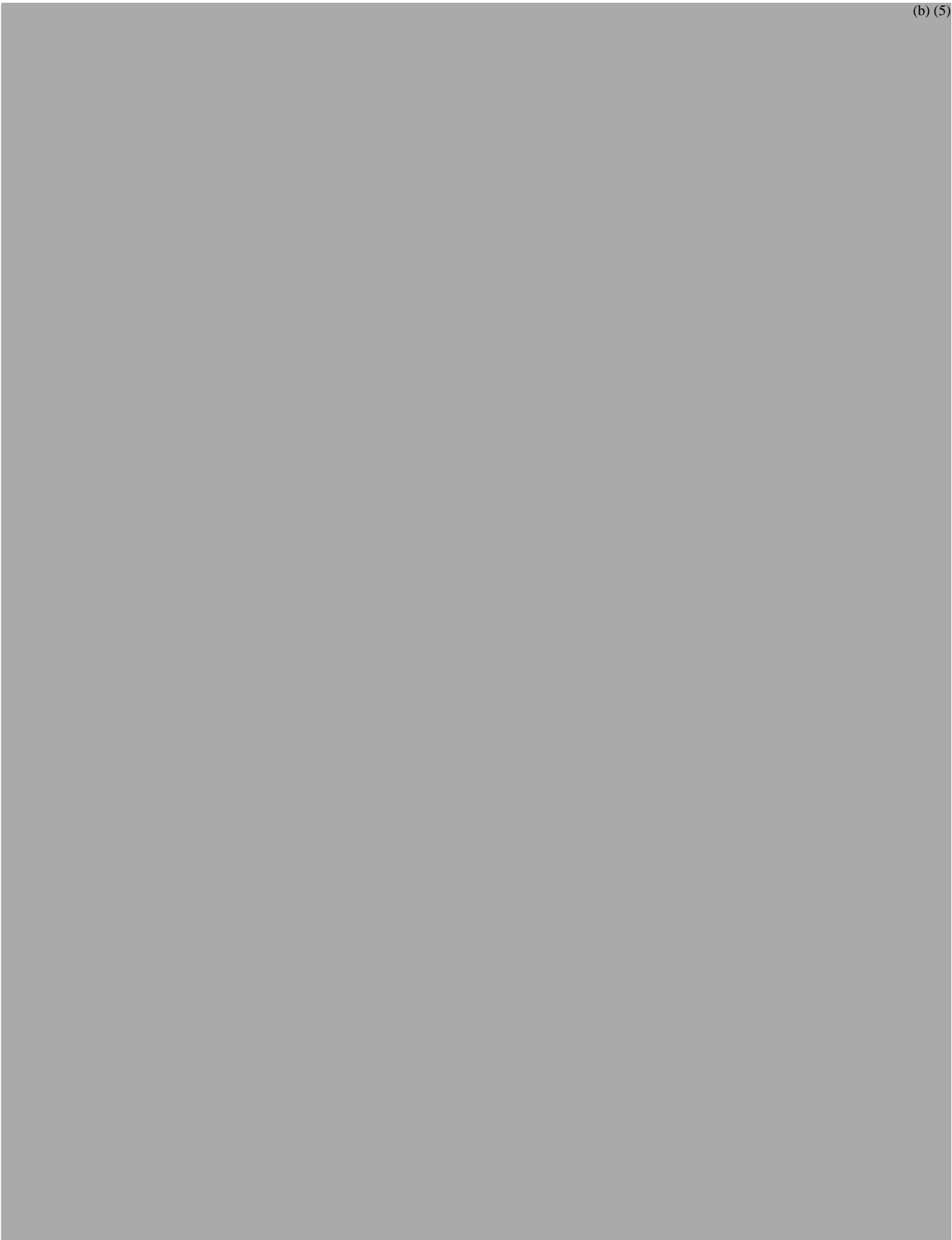


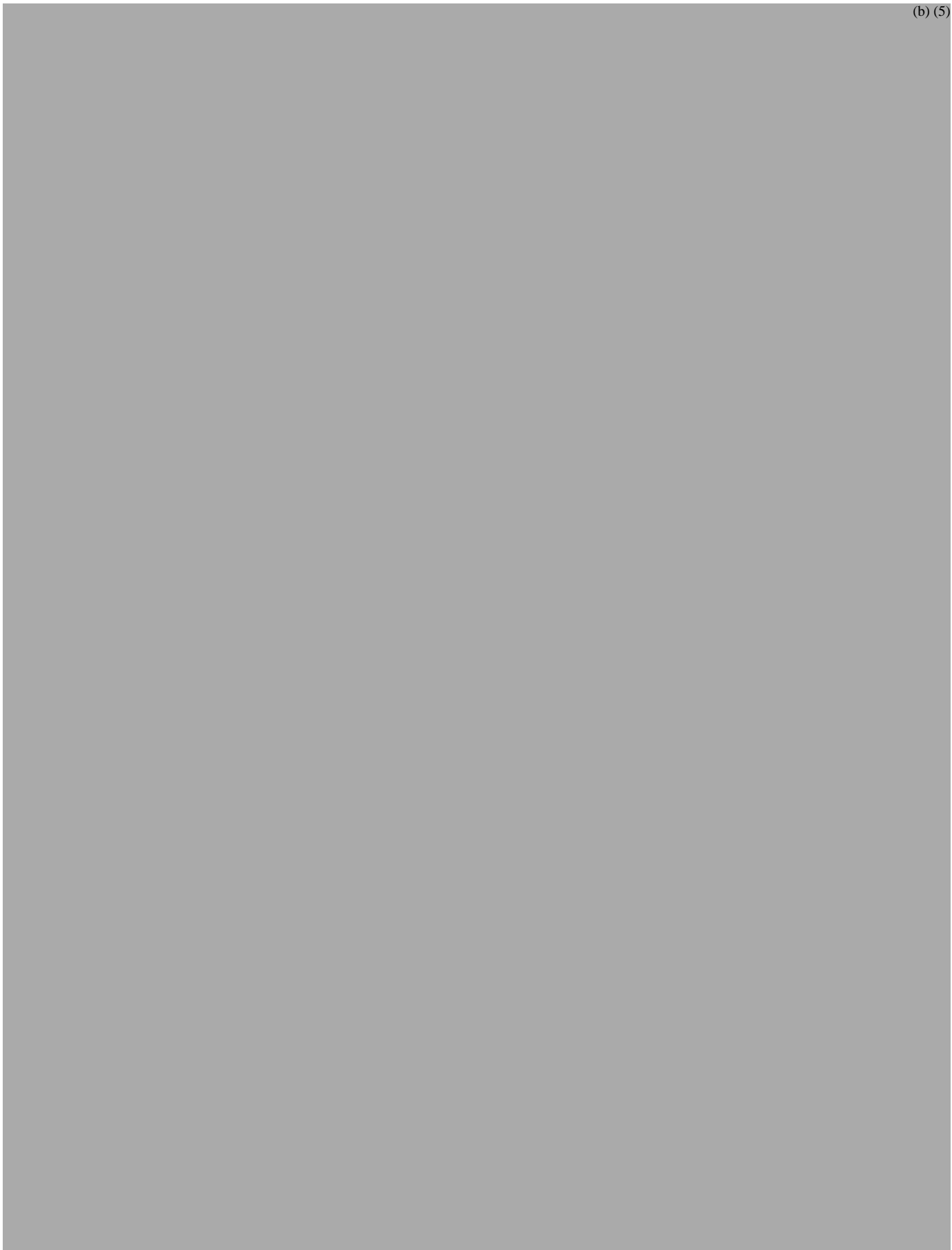


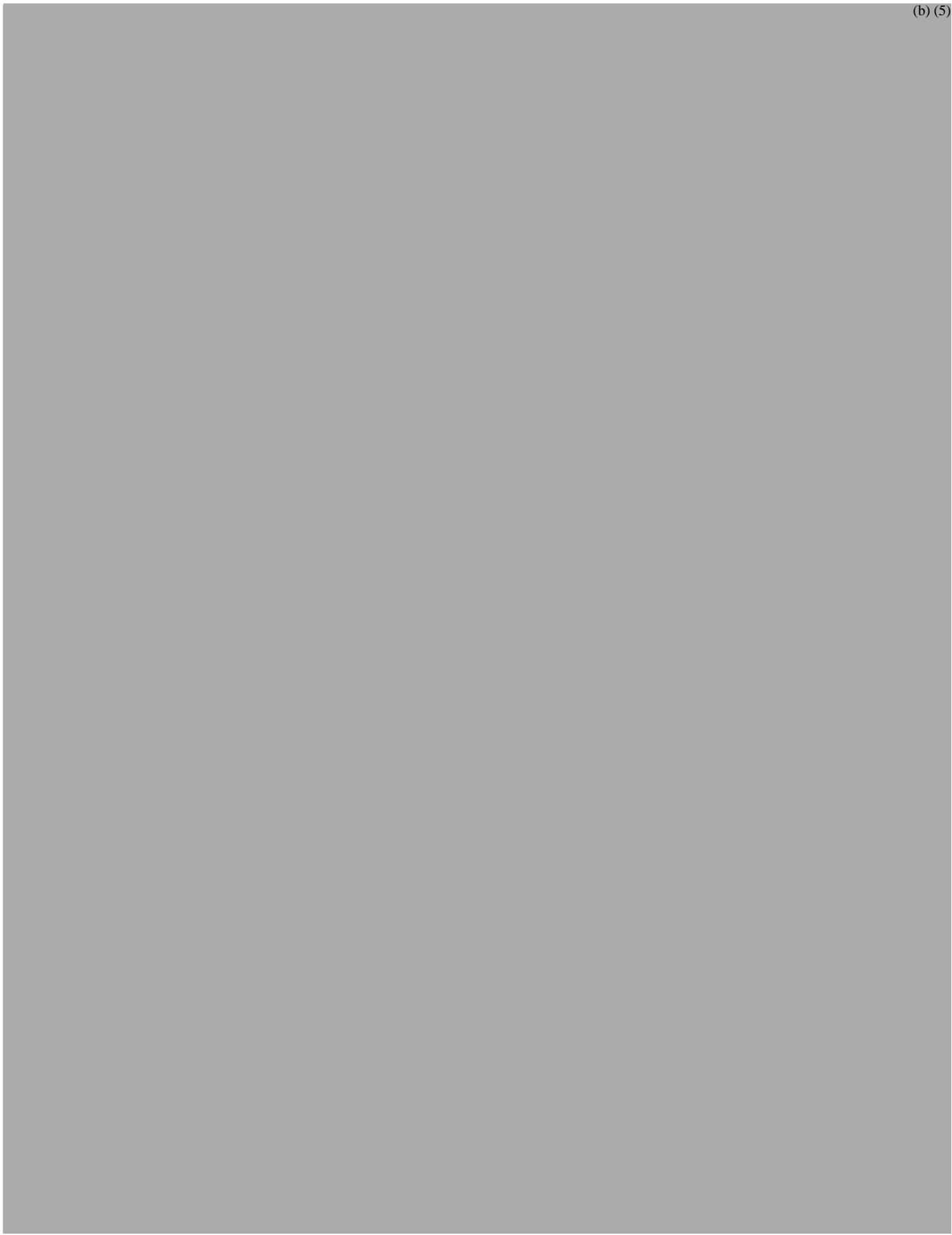






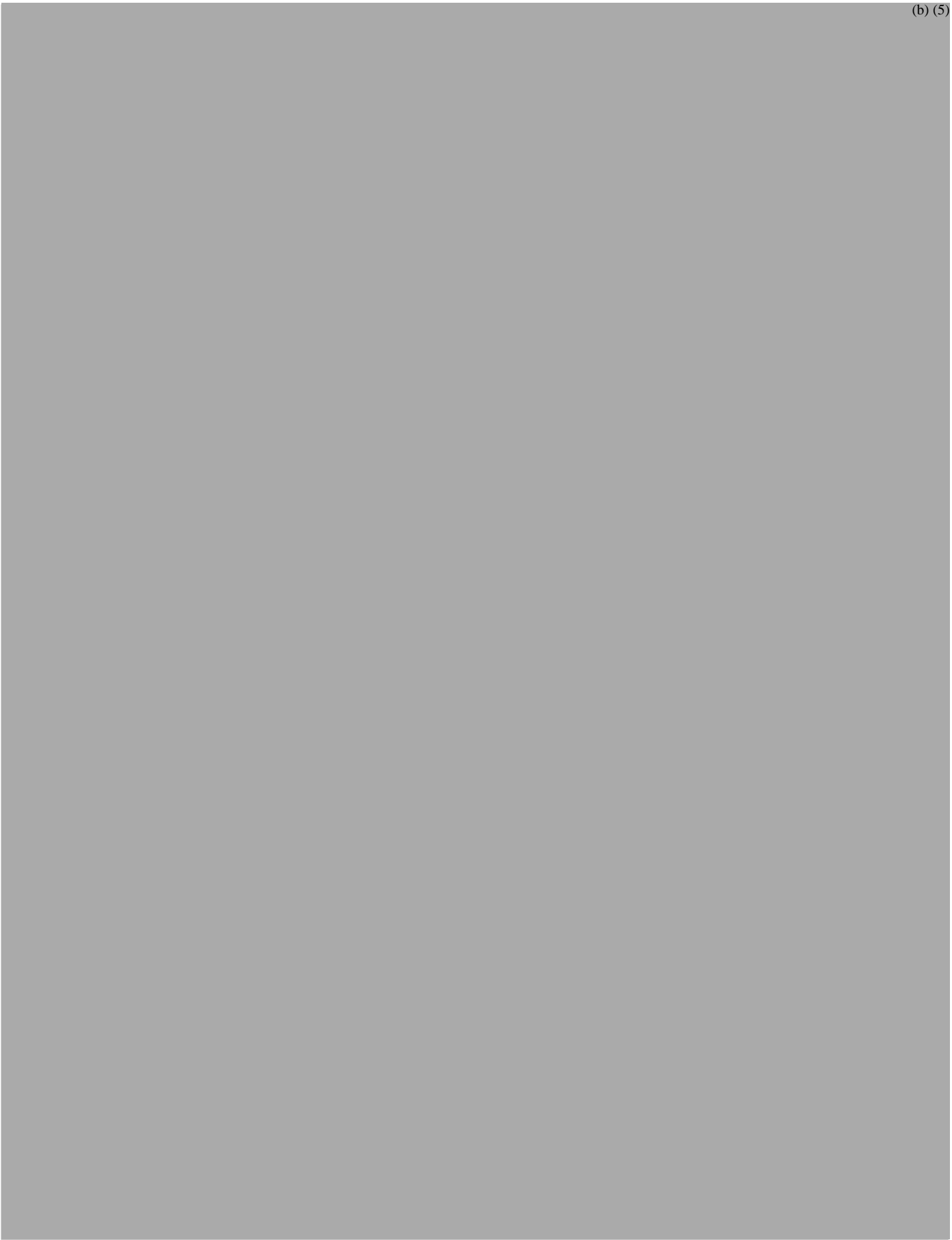






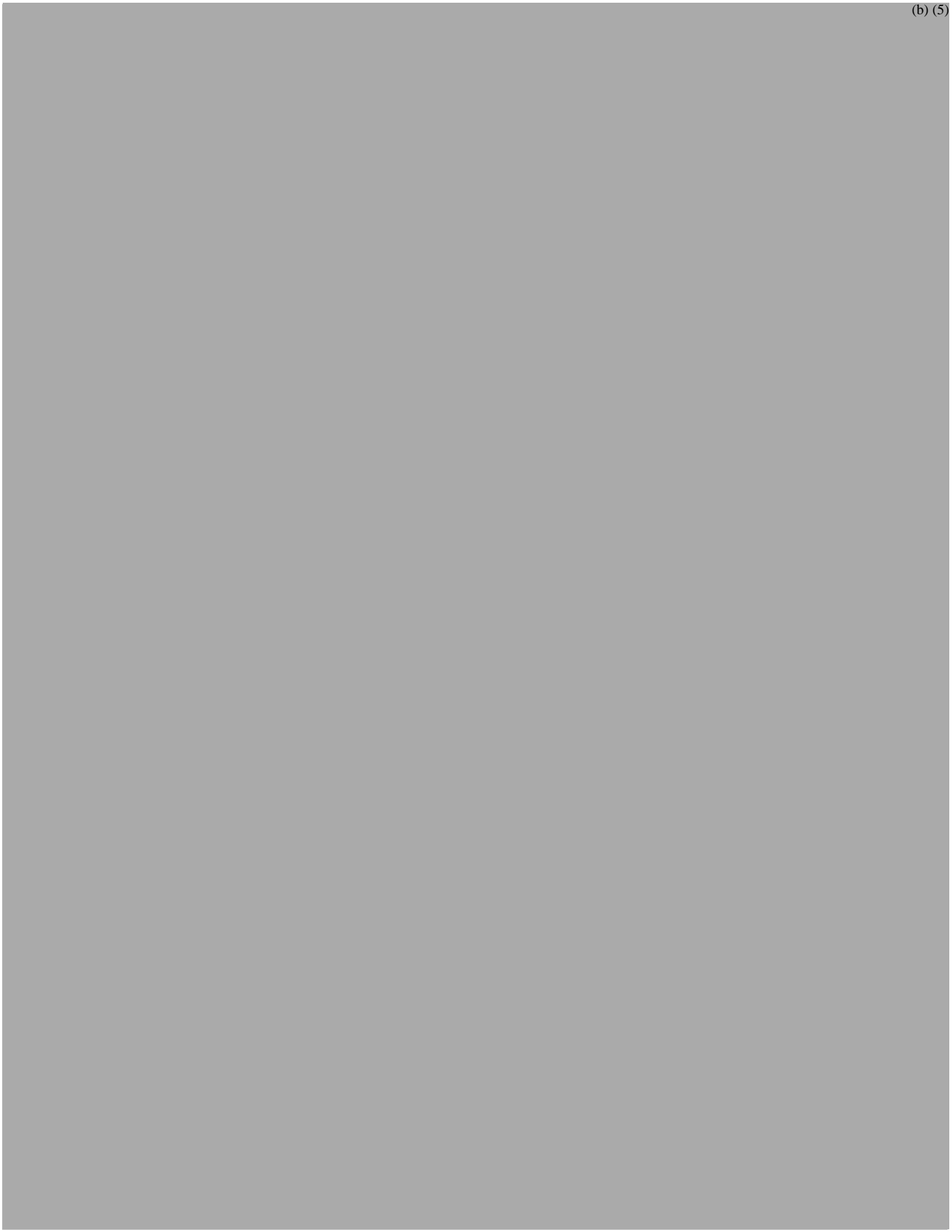




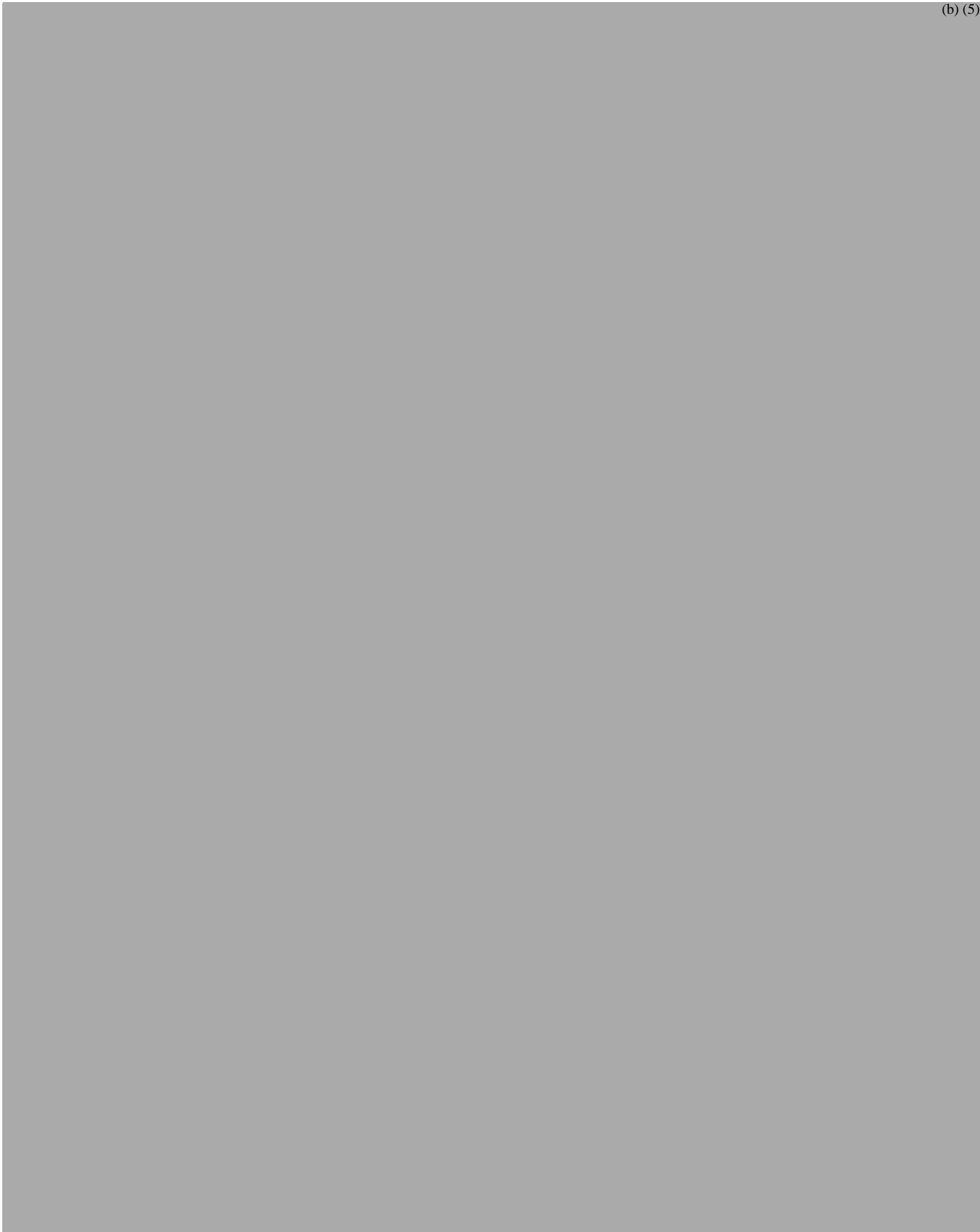


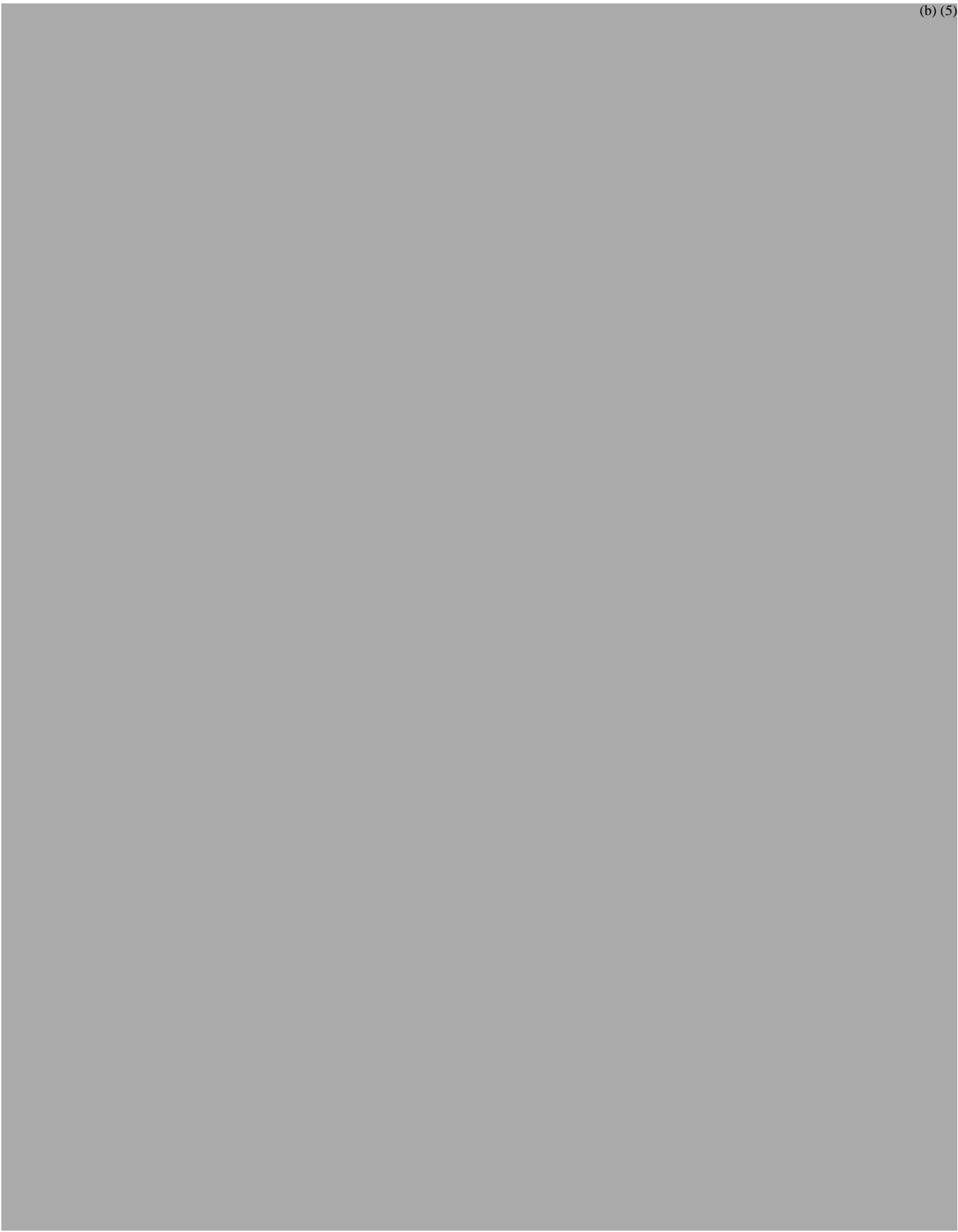


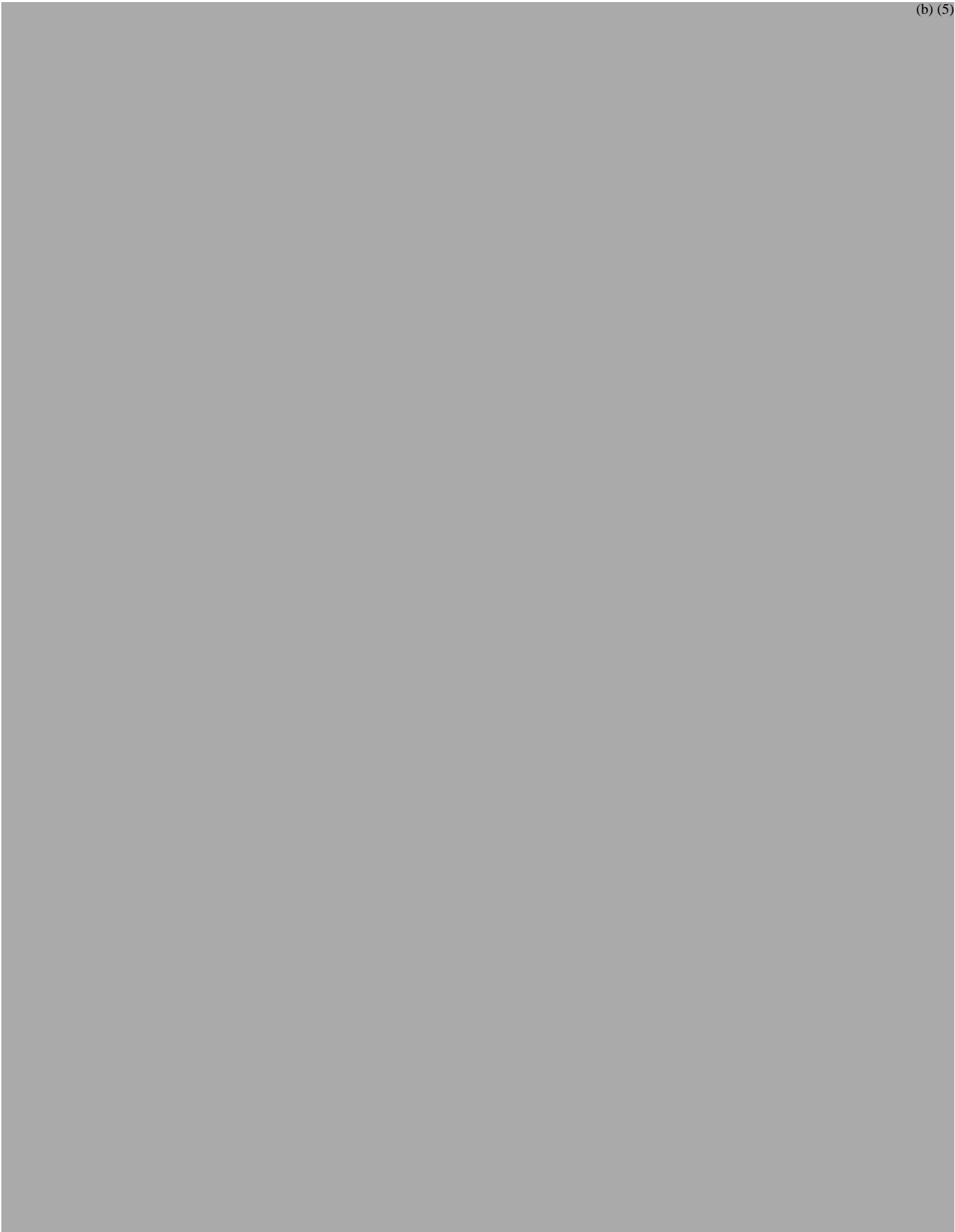


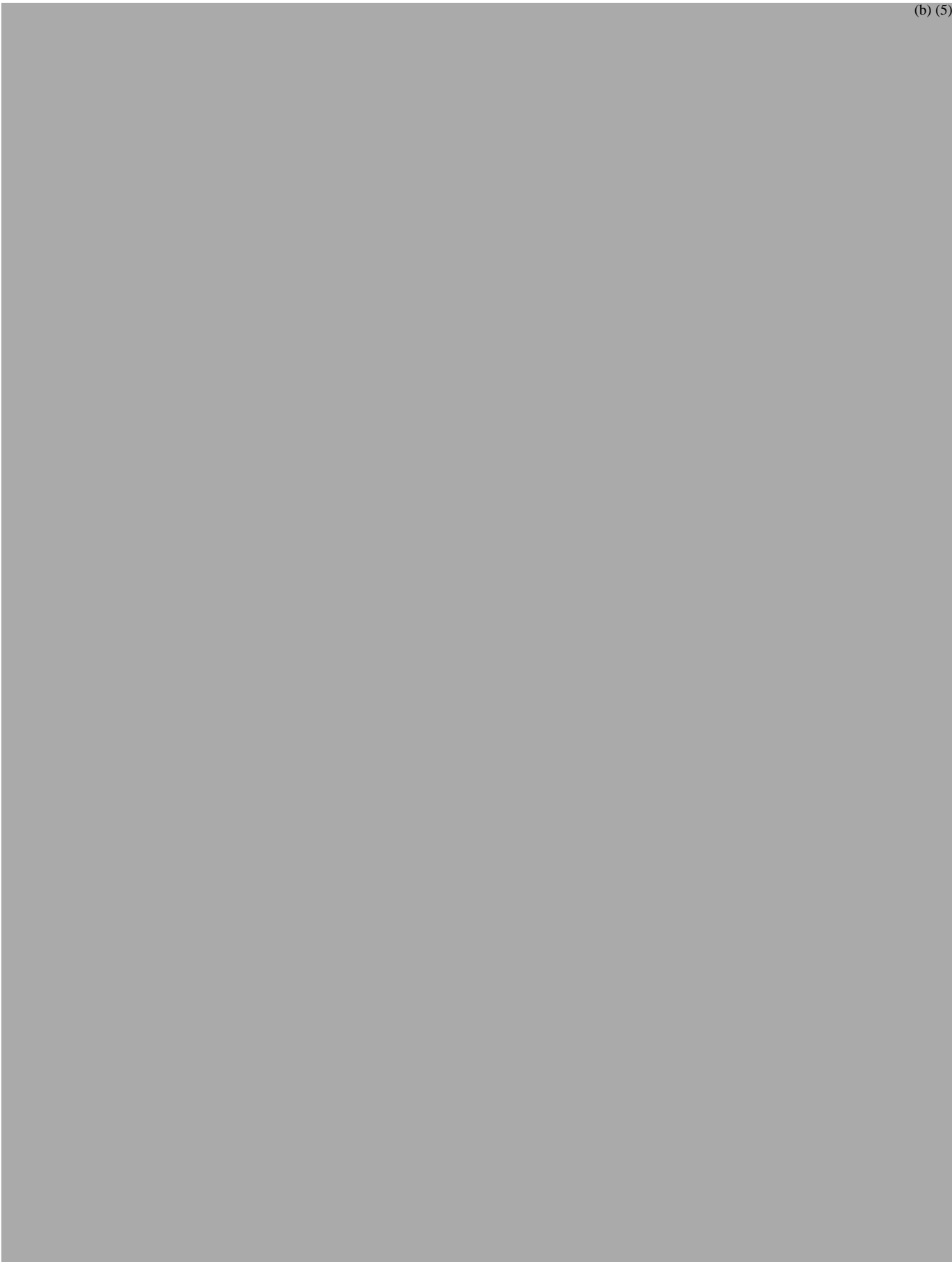




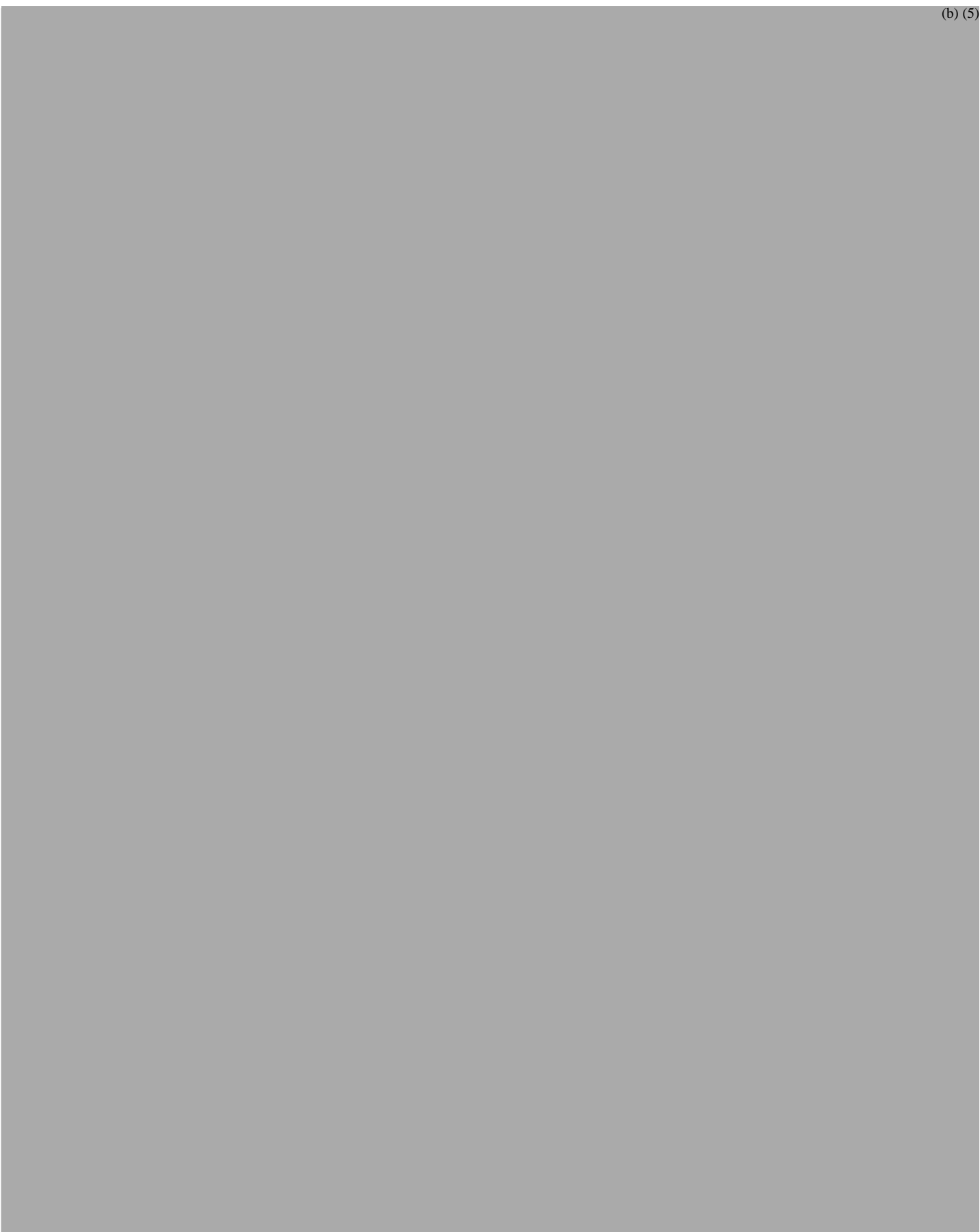


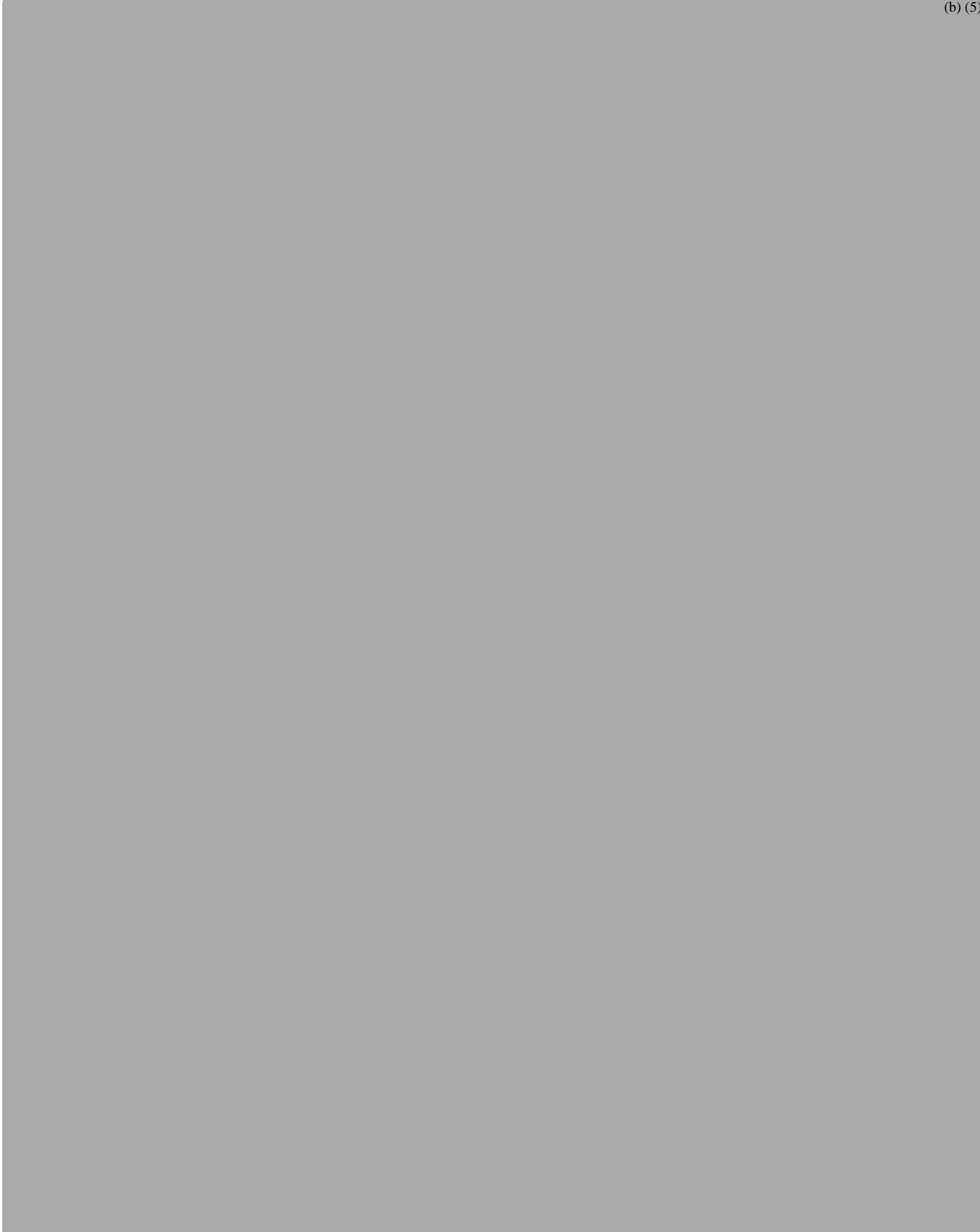






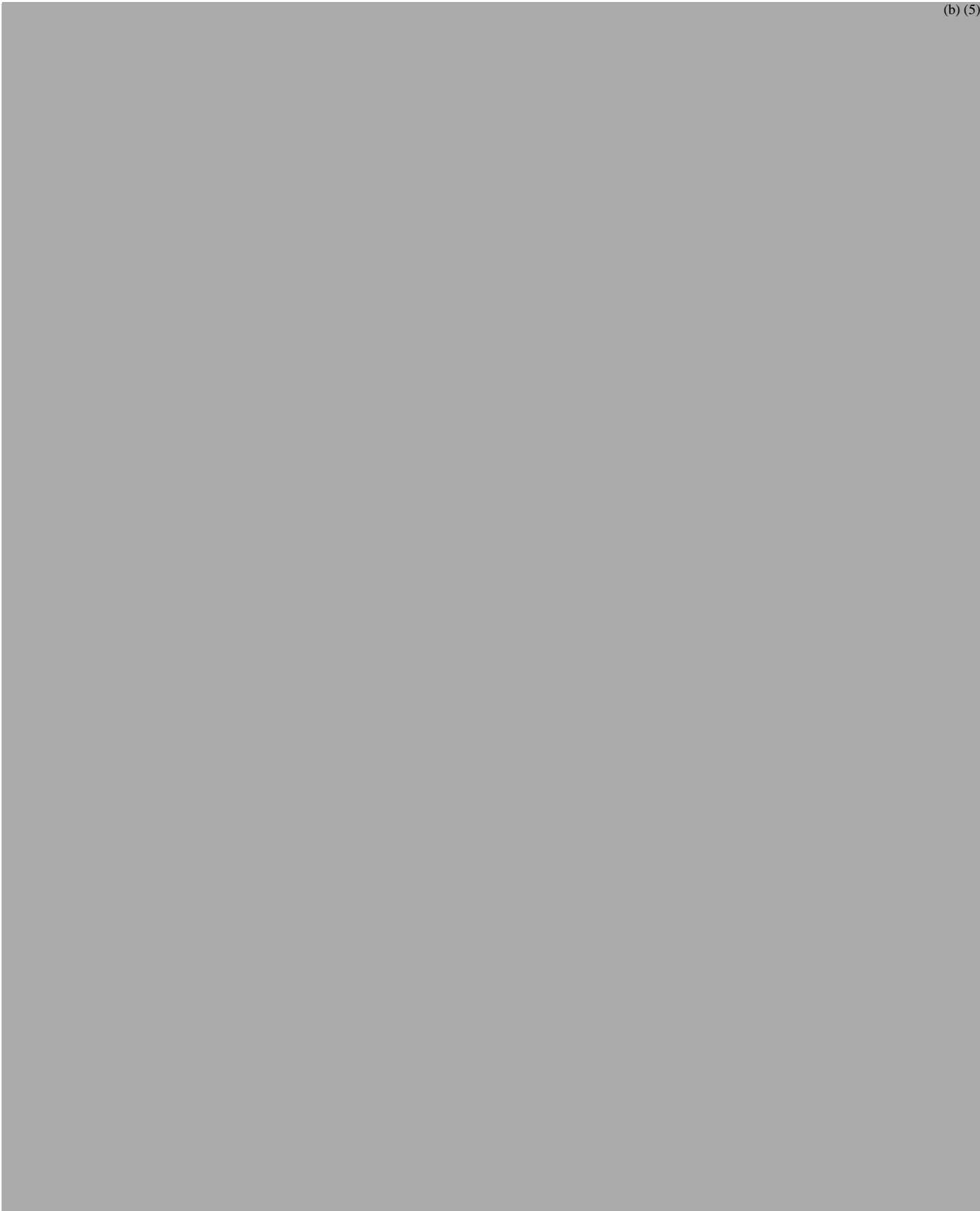


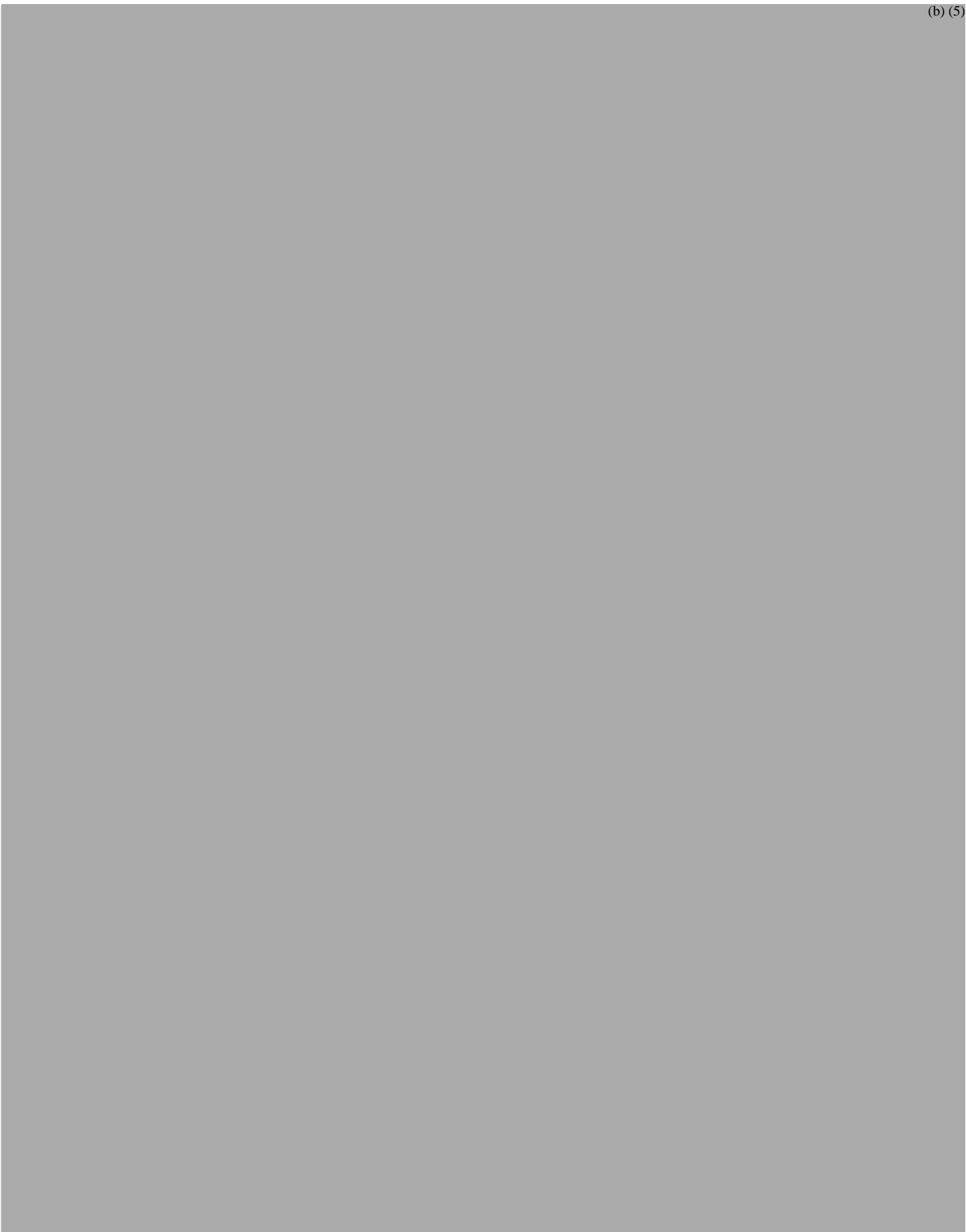


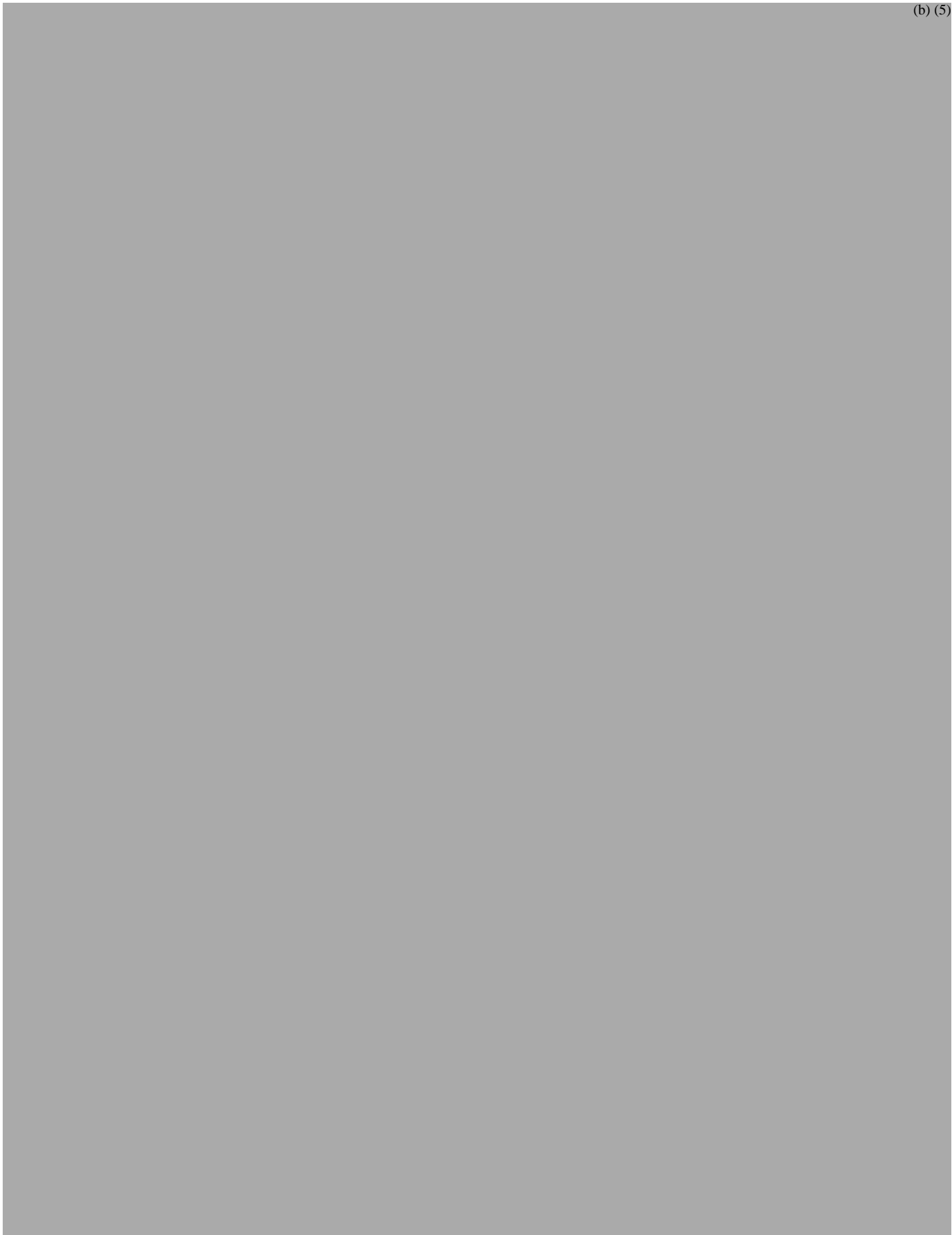


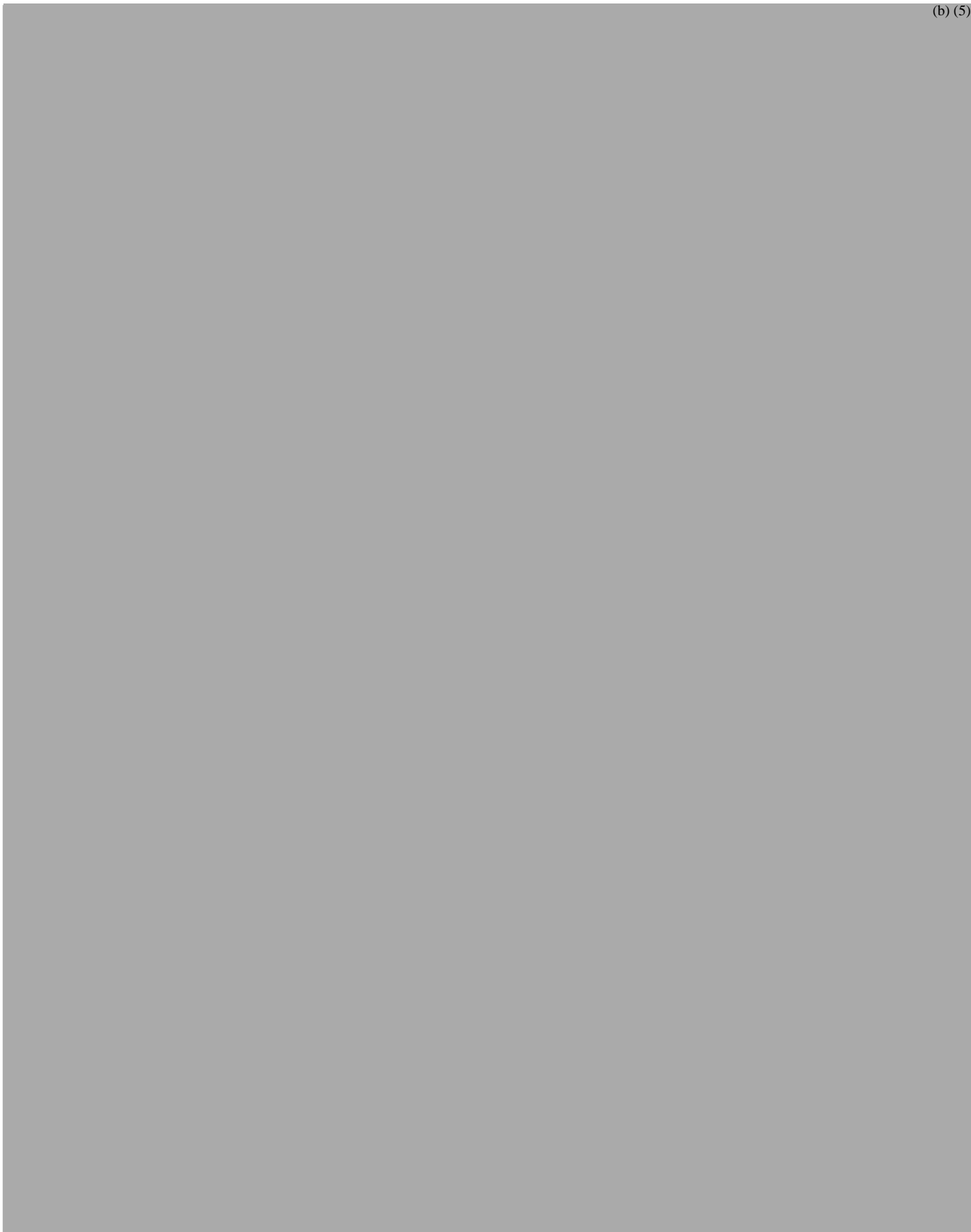










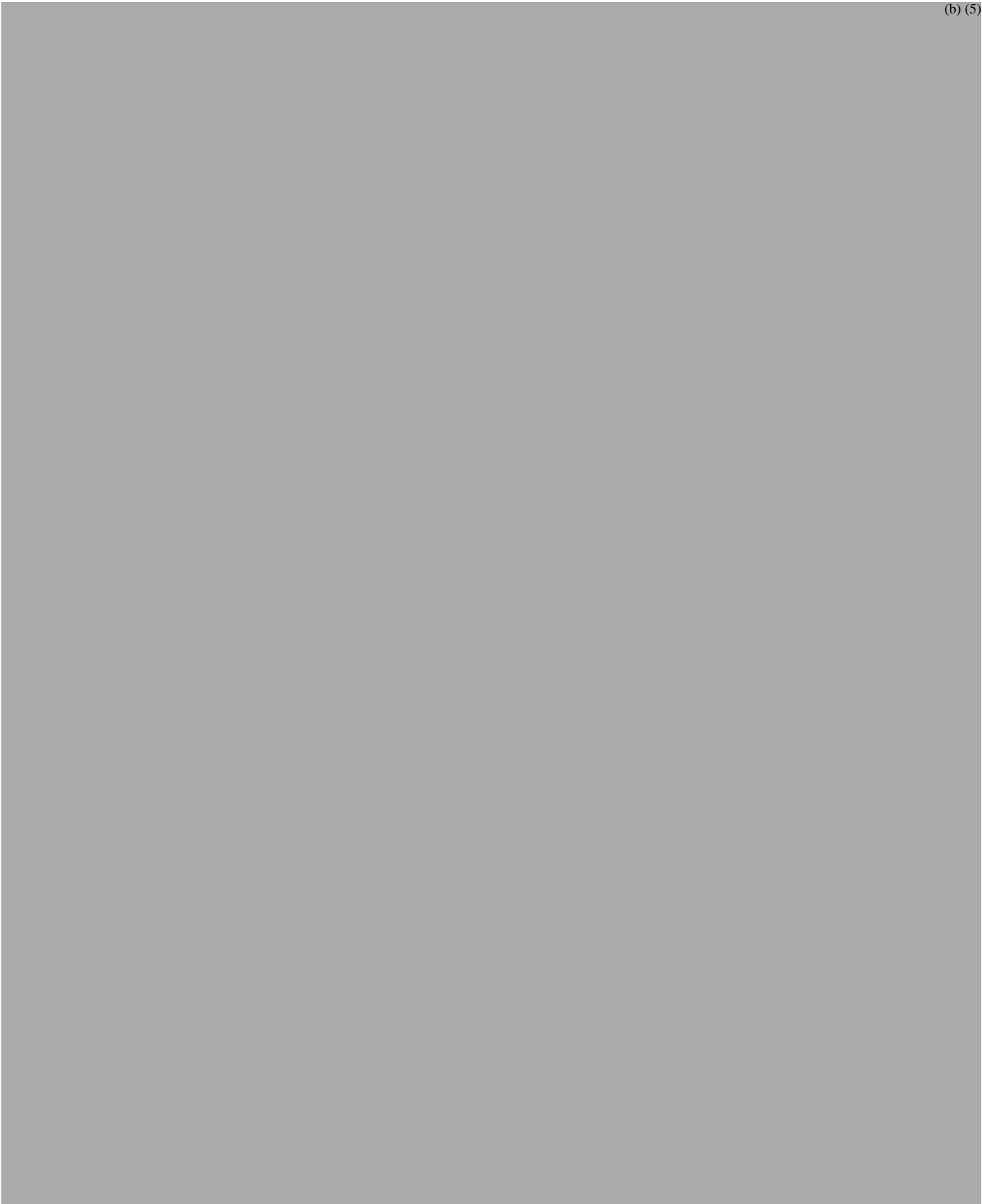


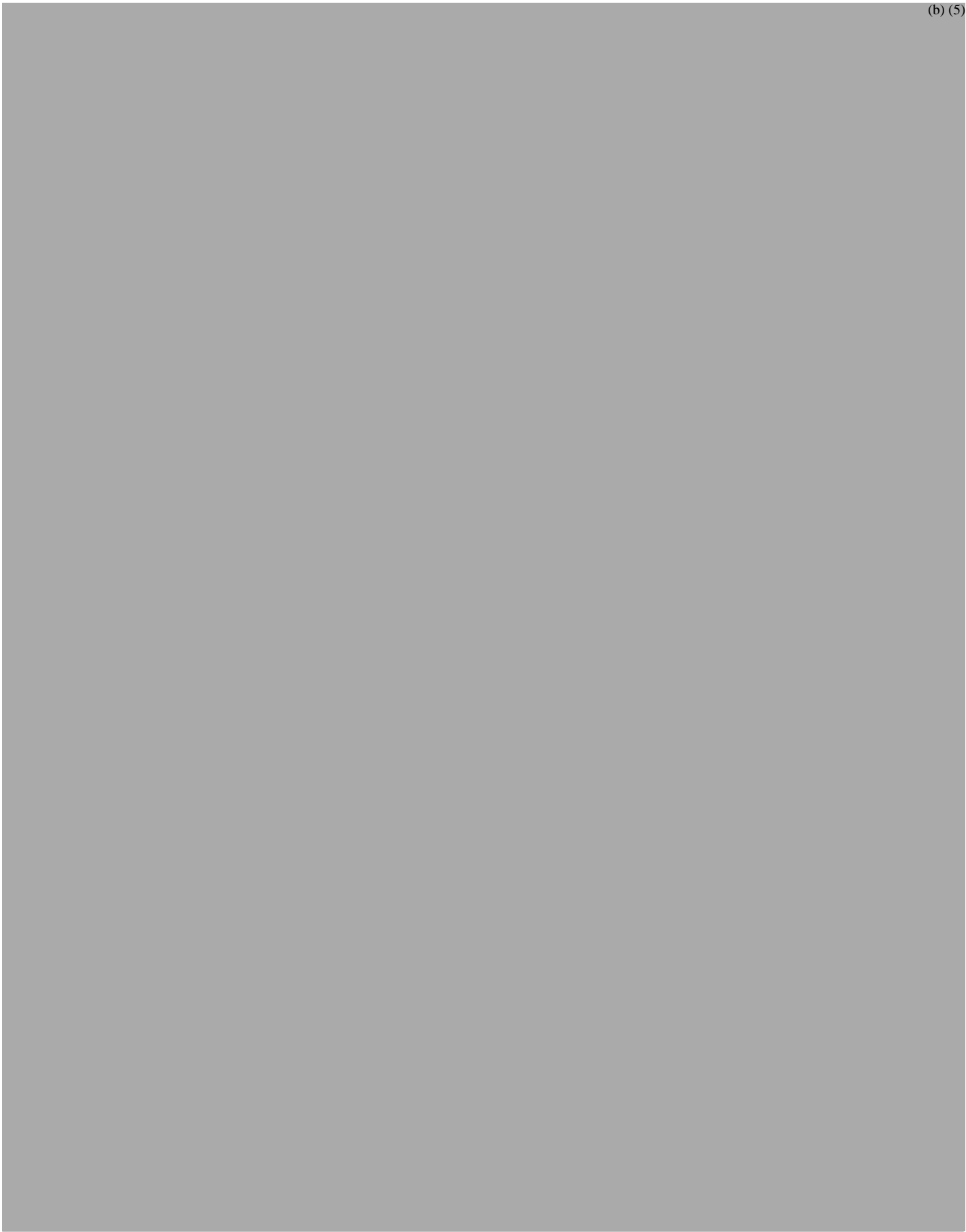




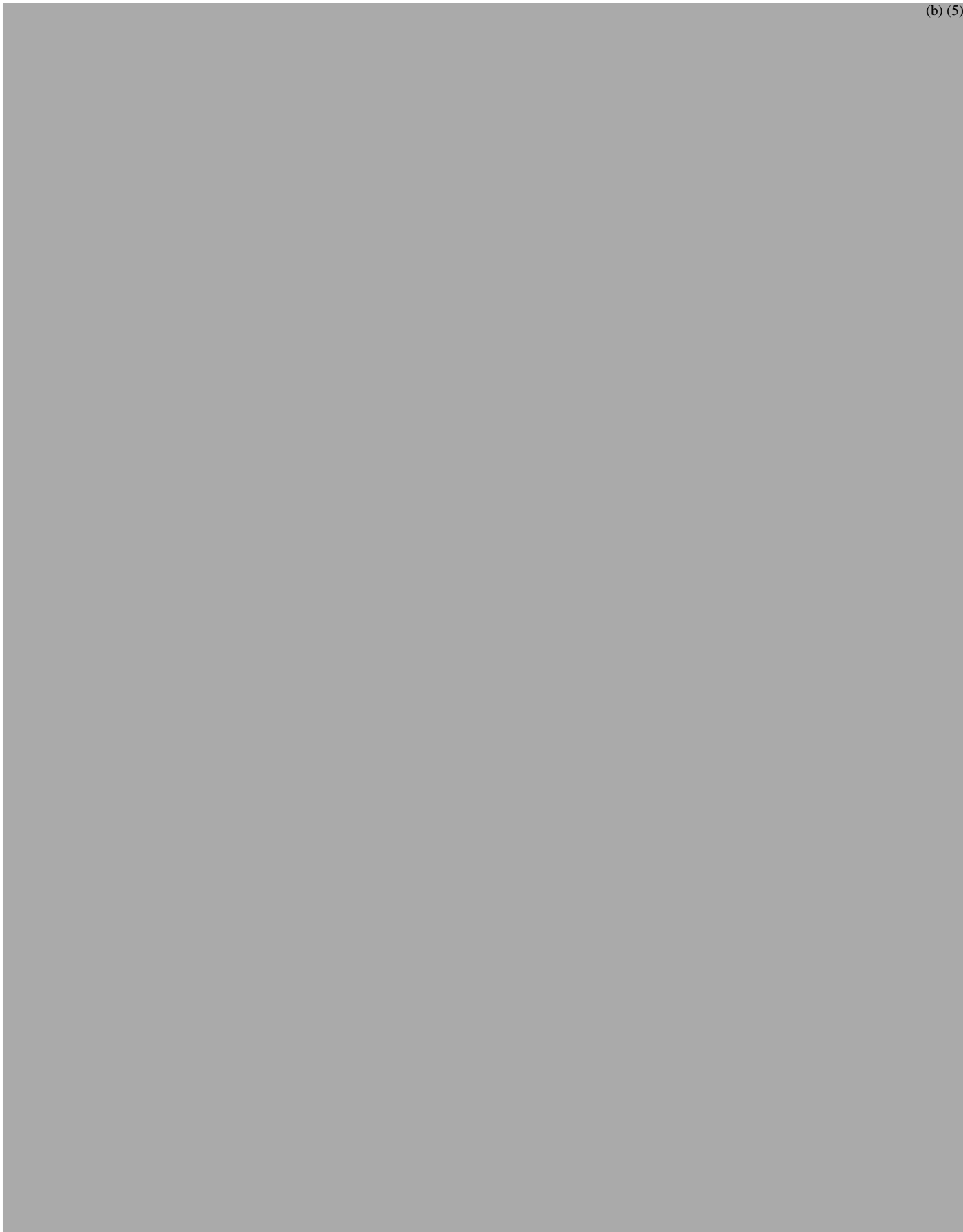


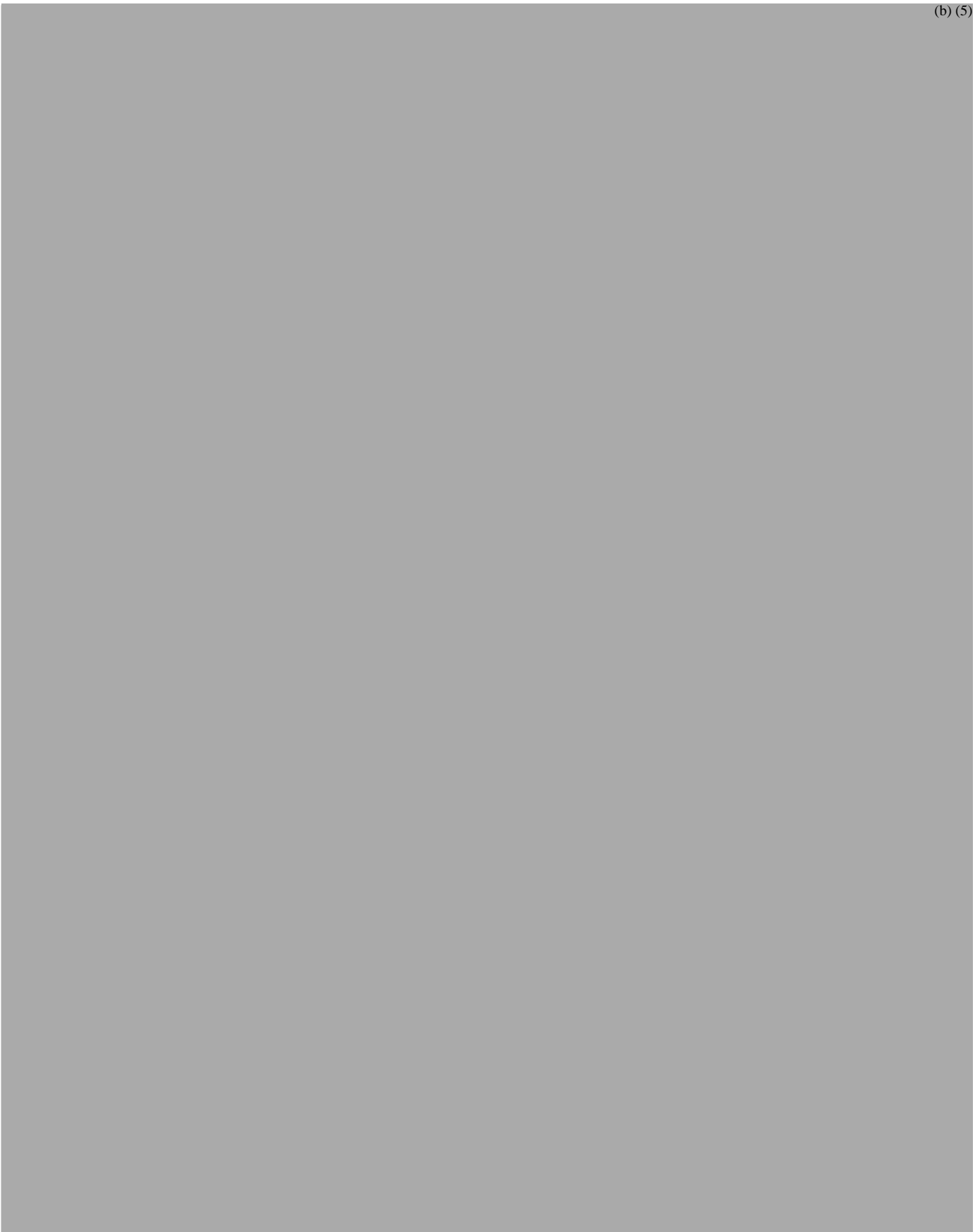




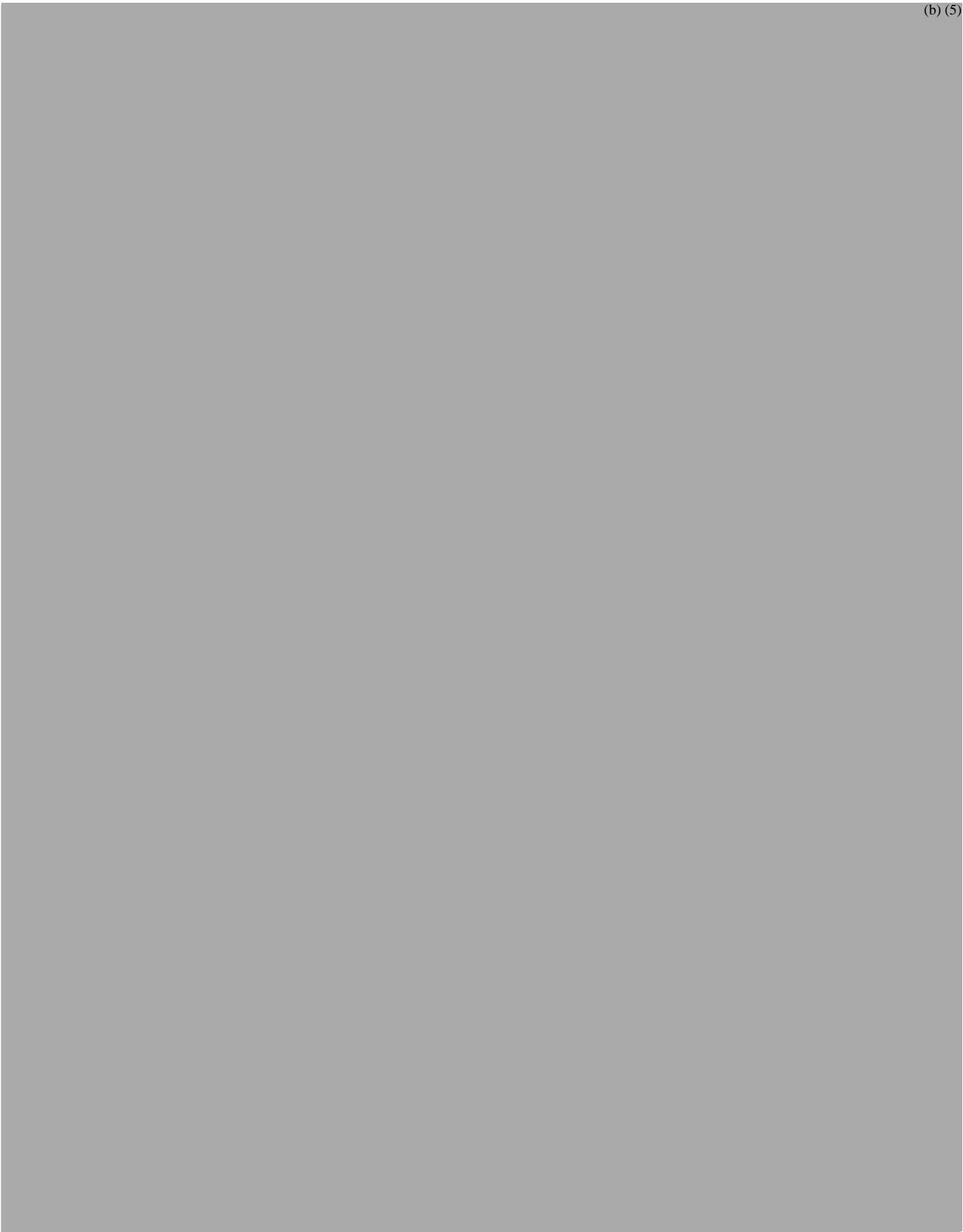


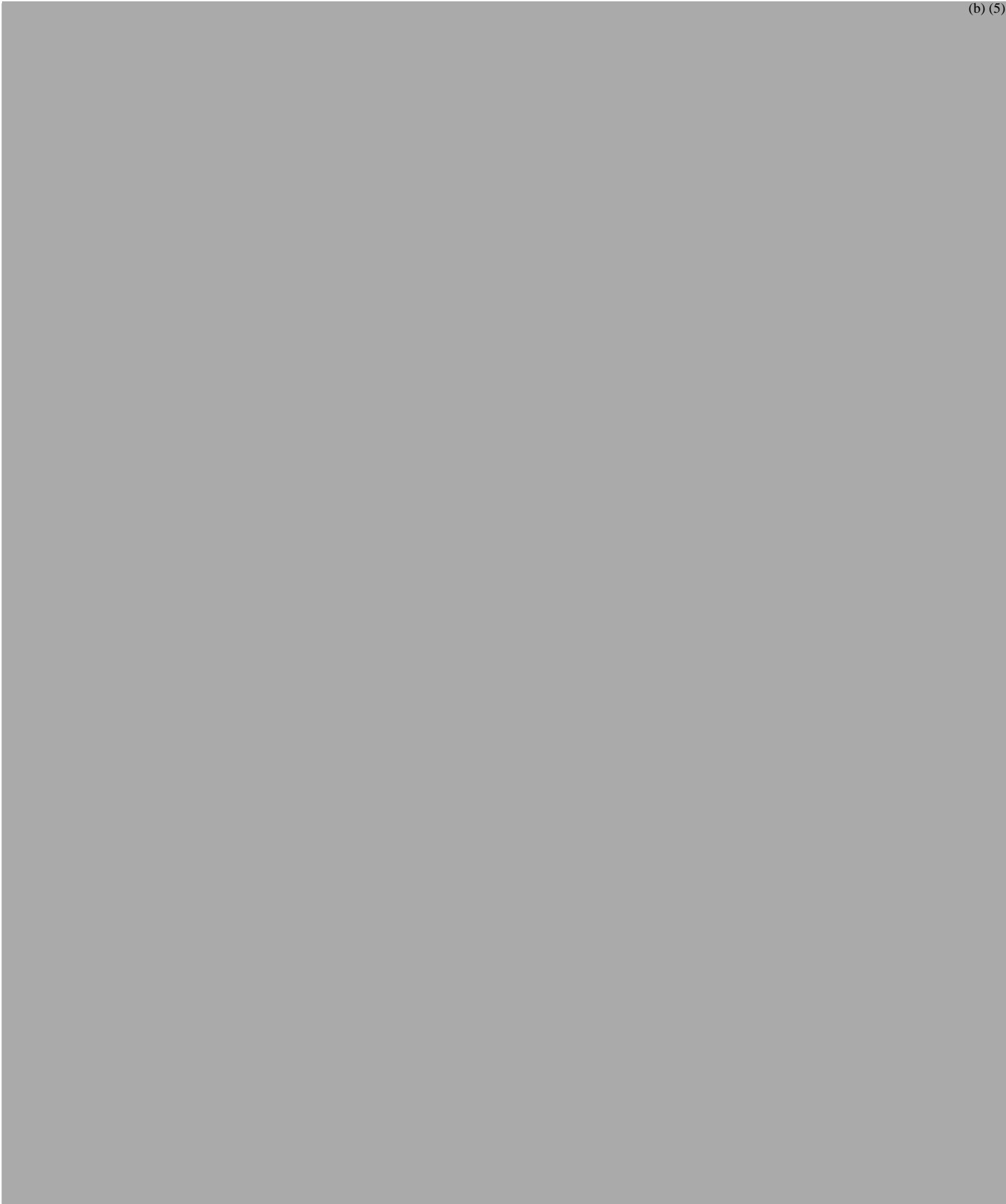


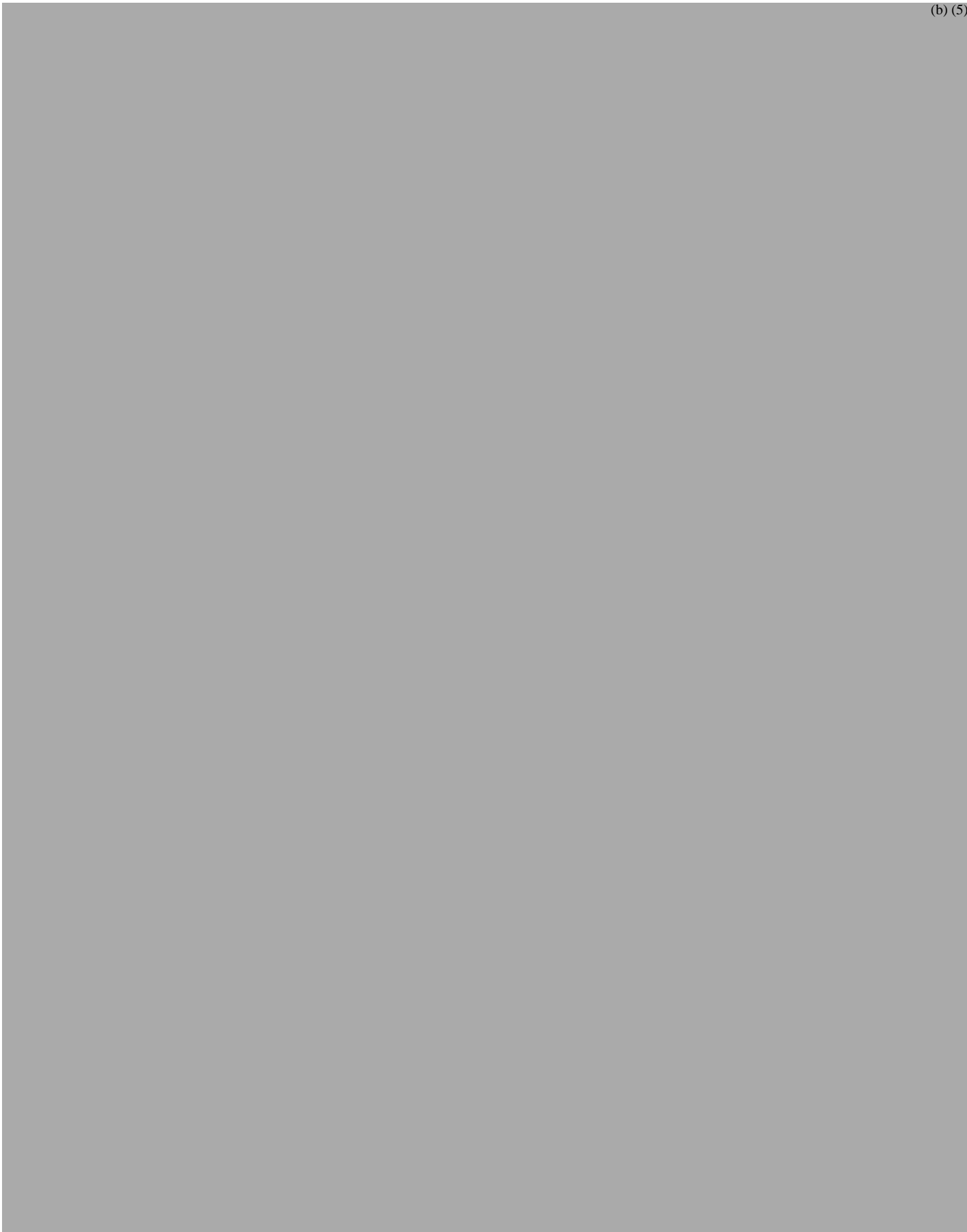




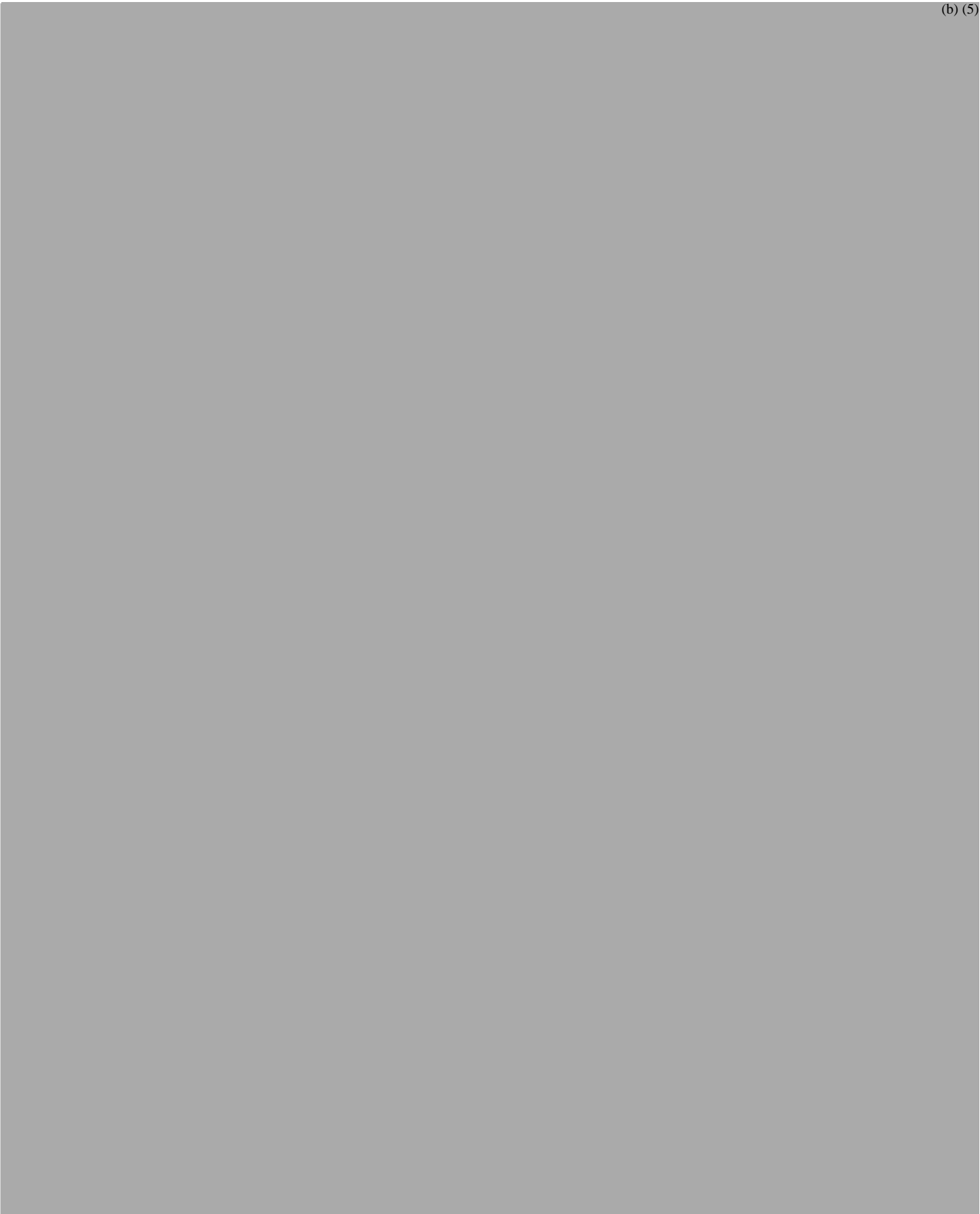






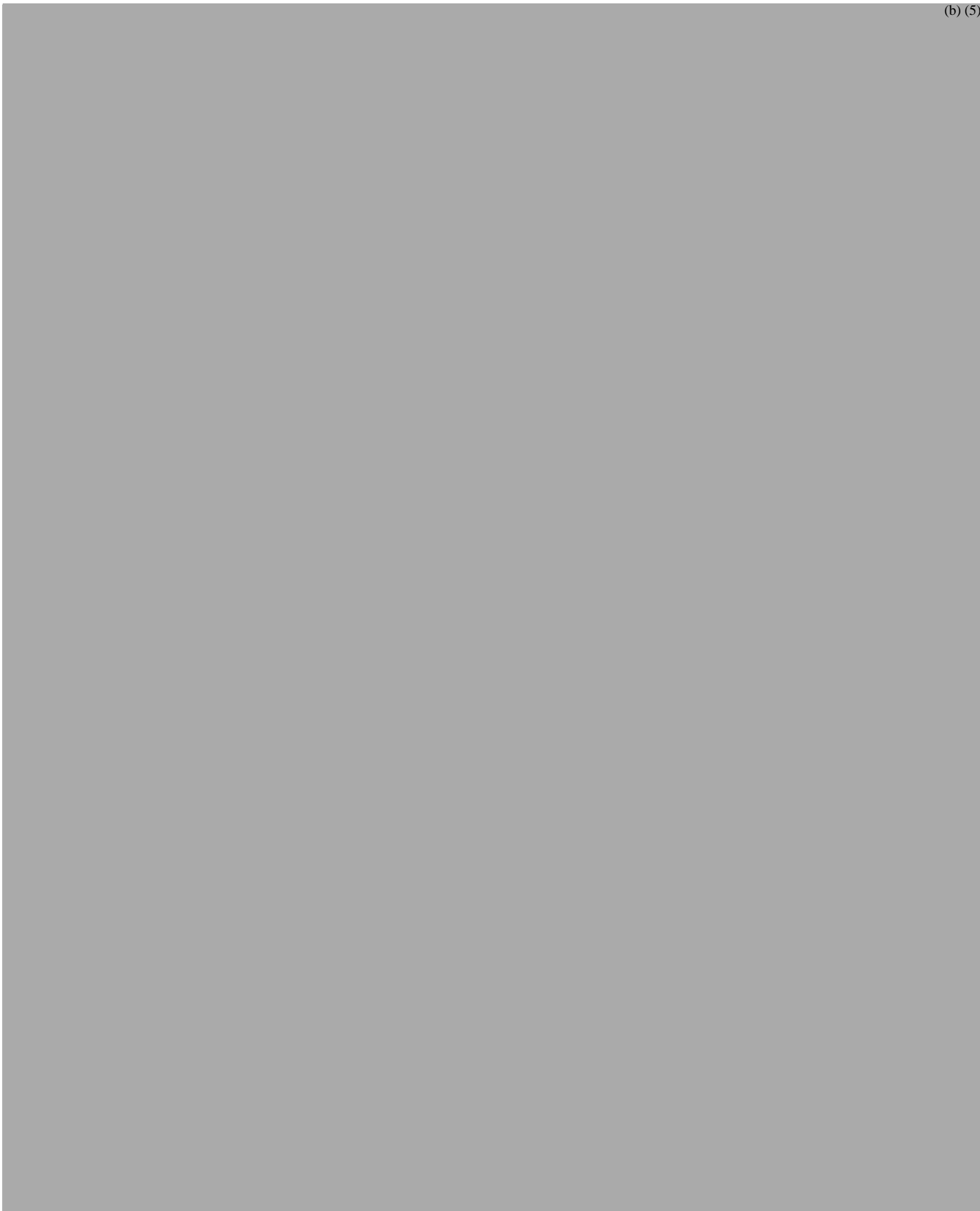




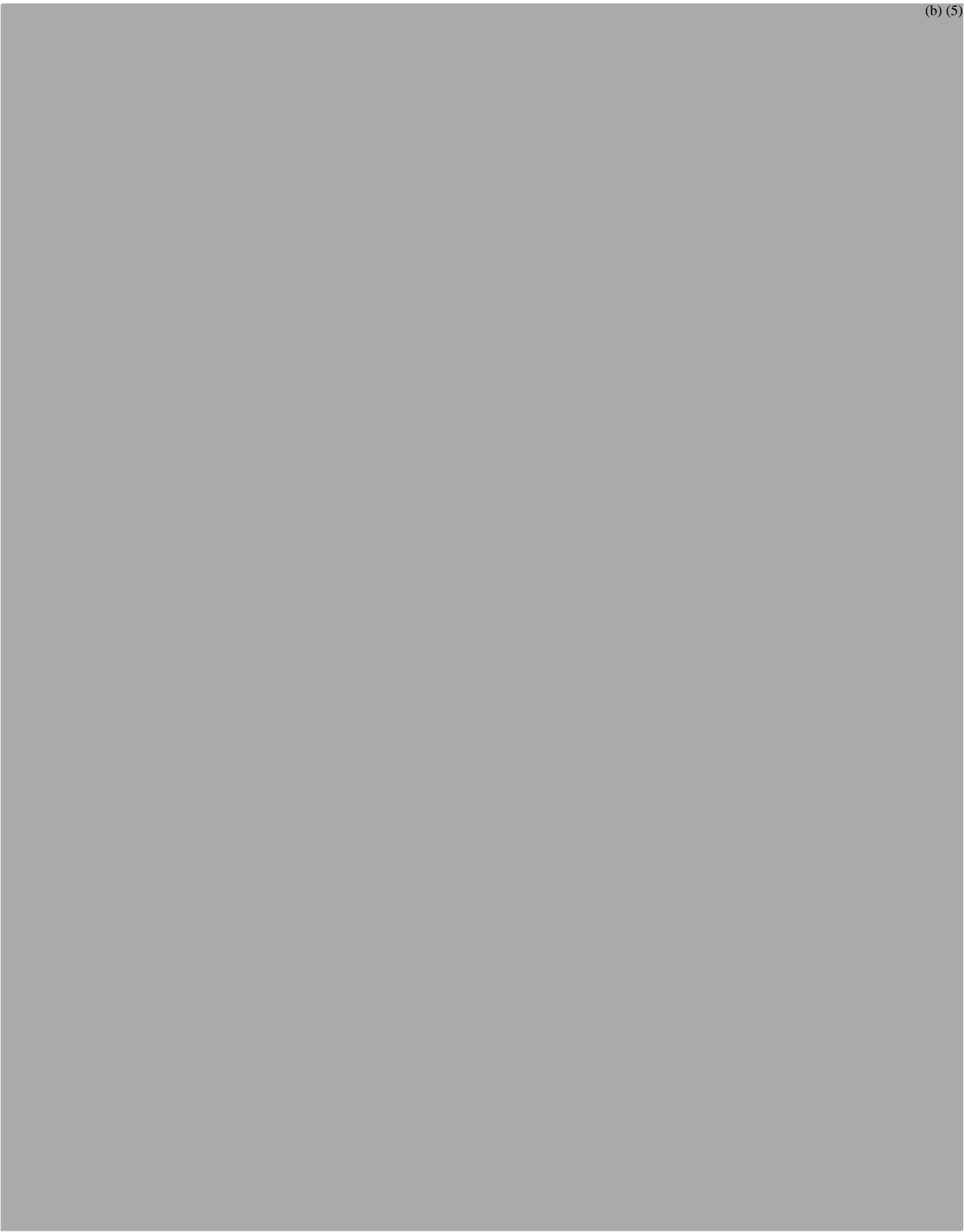












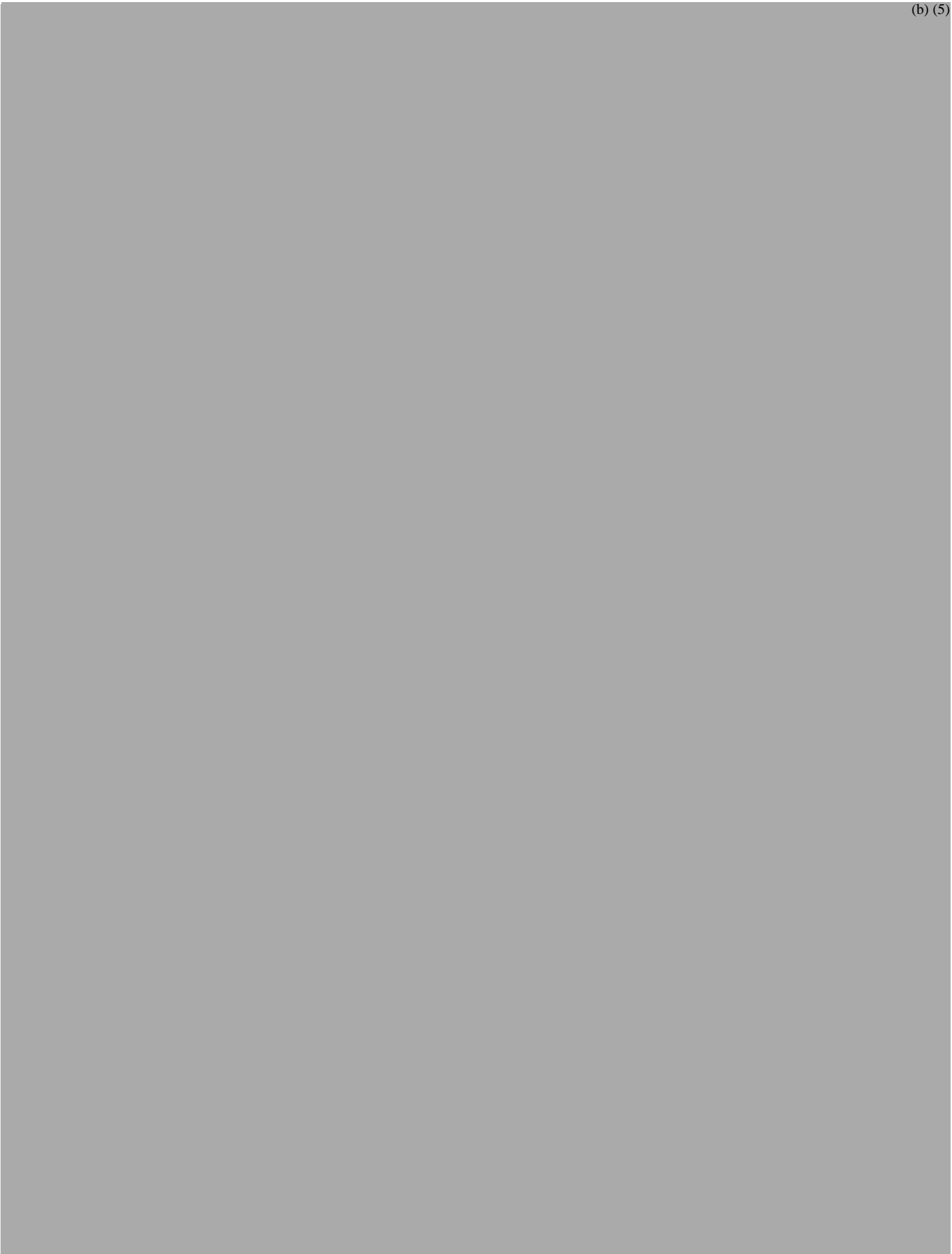


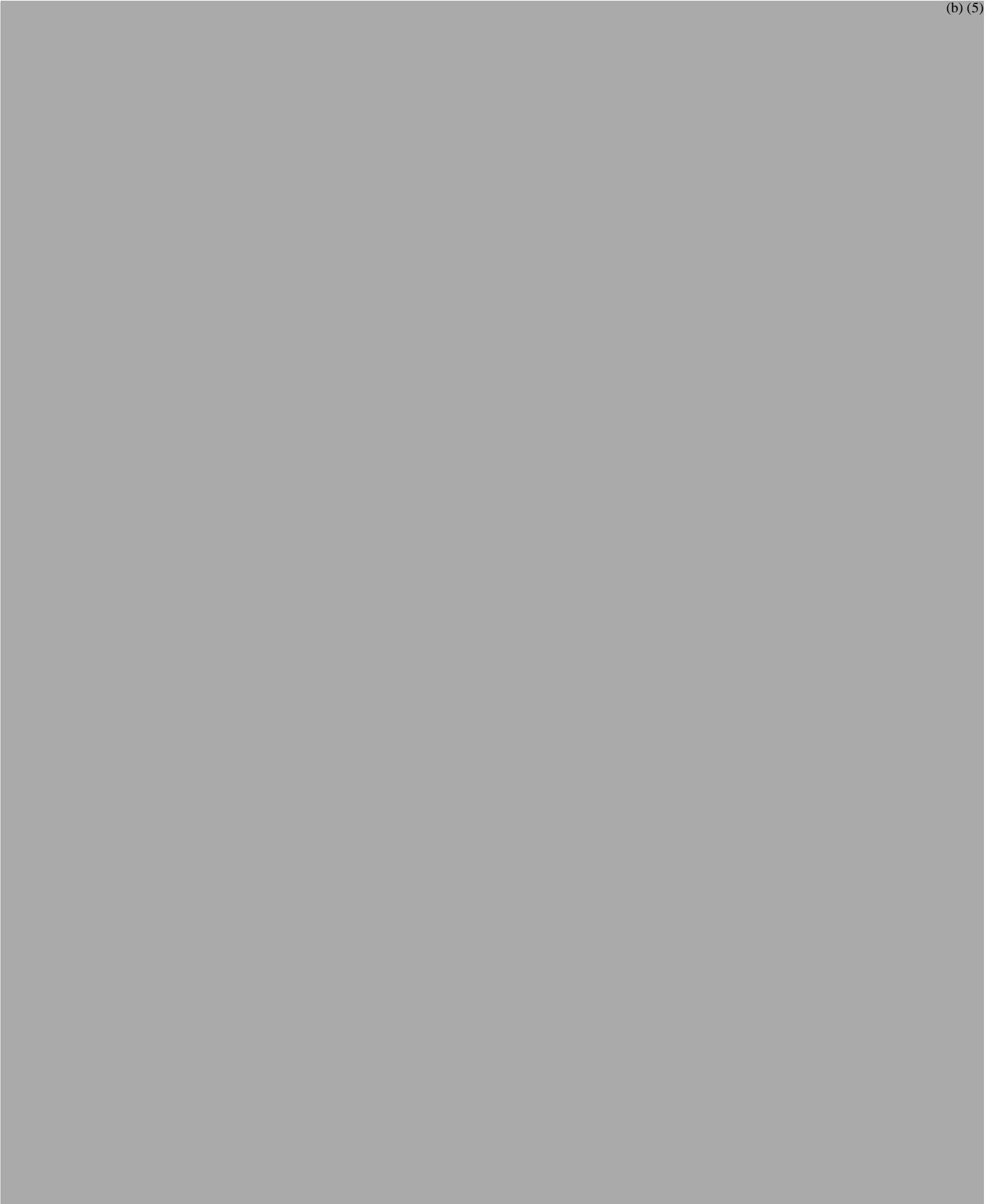


















Autoimmune Diseases









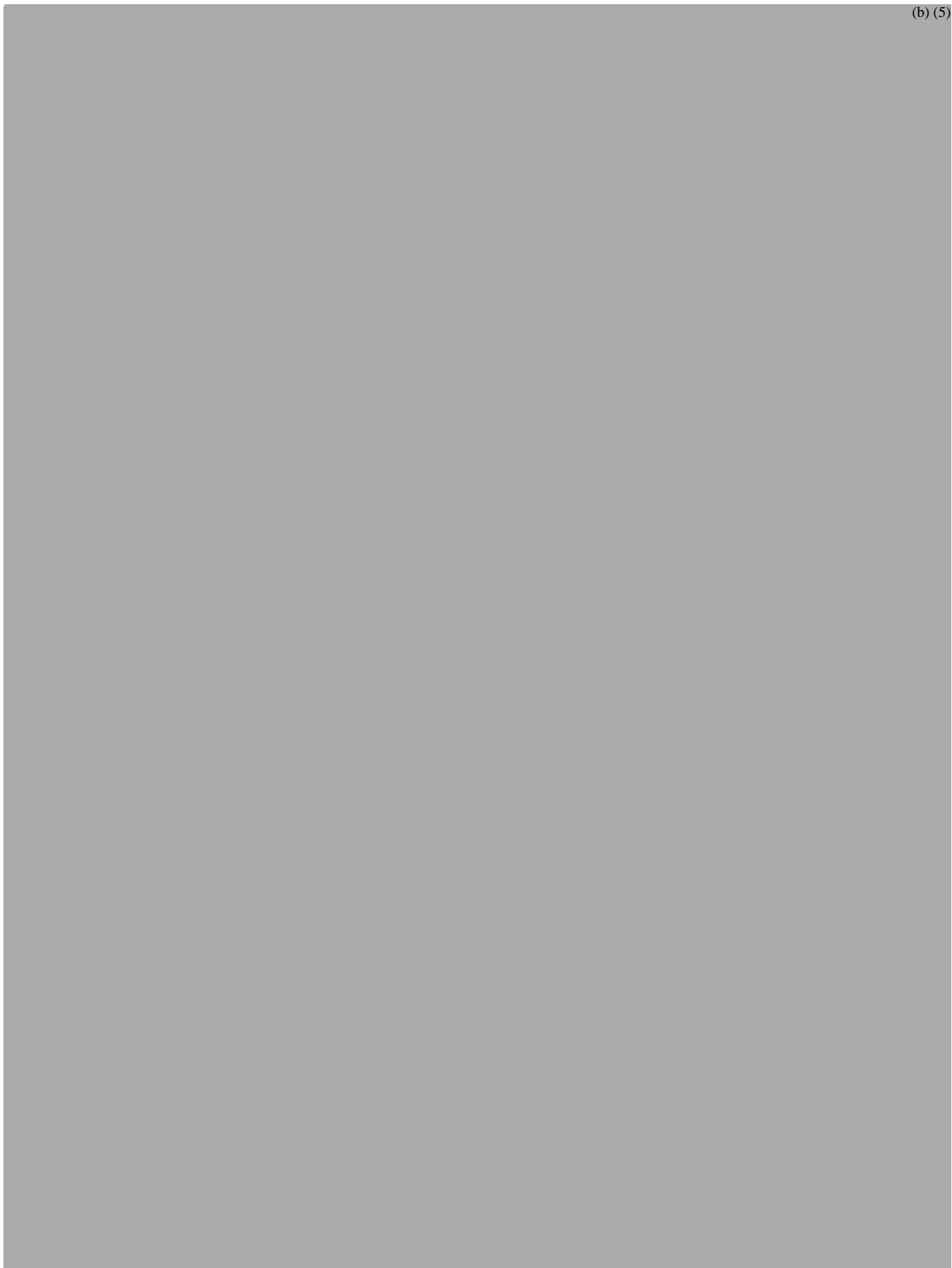


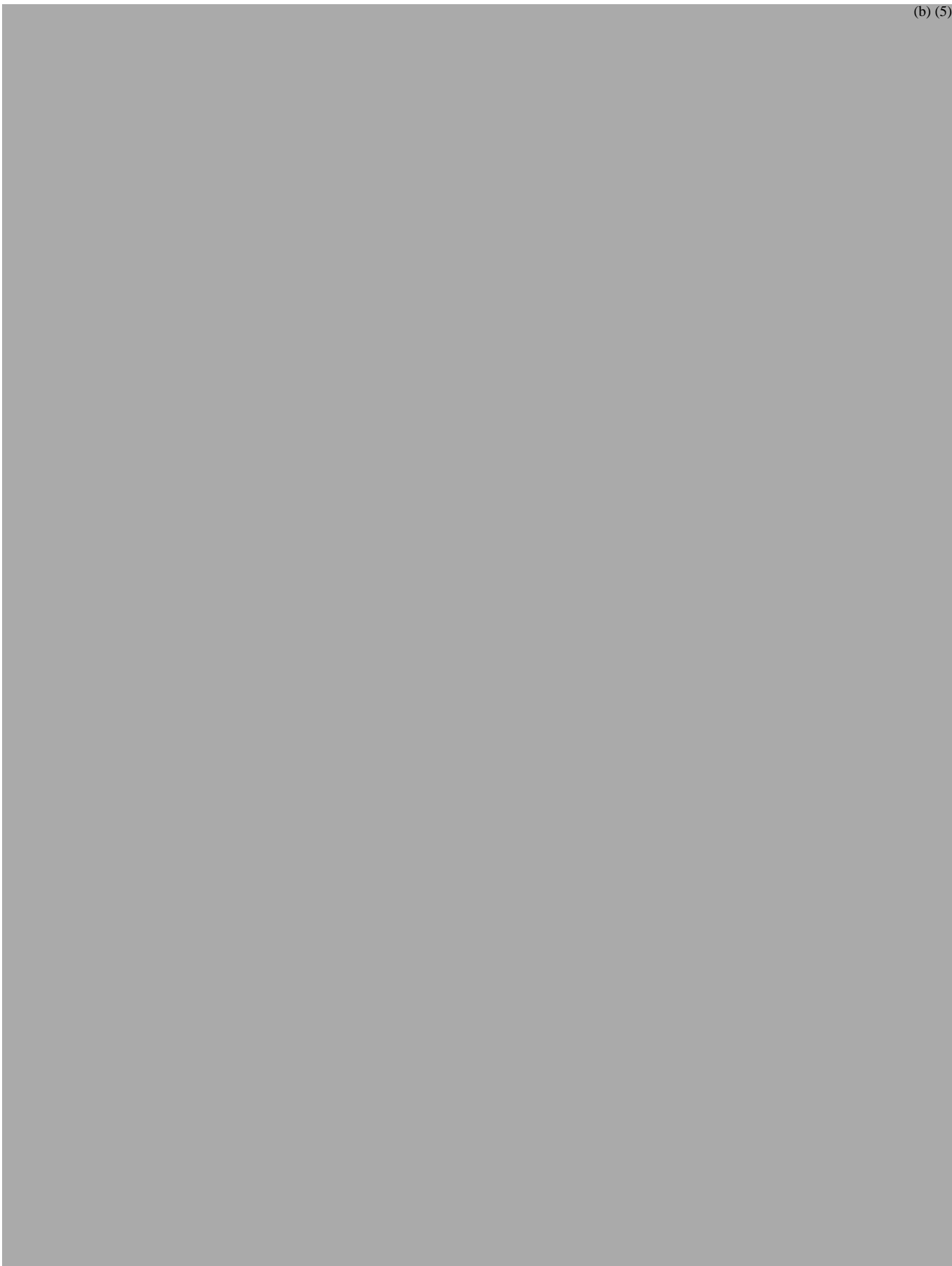


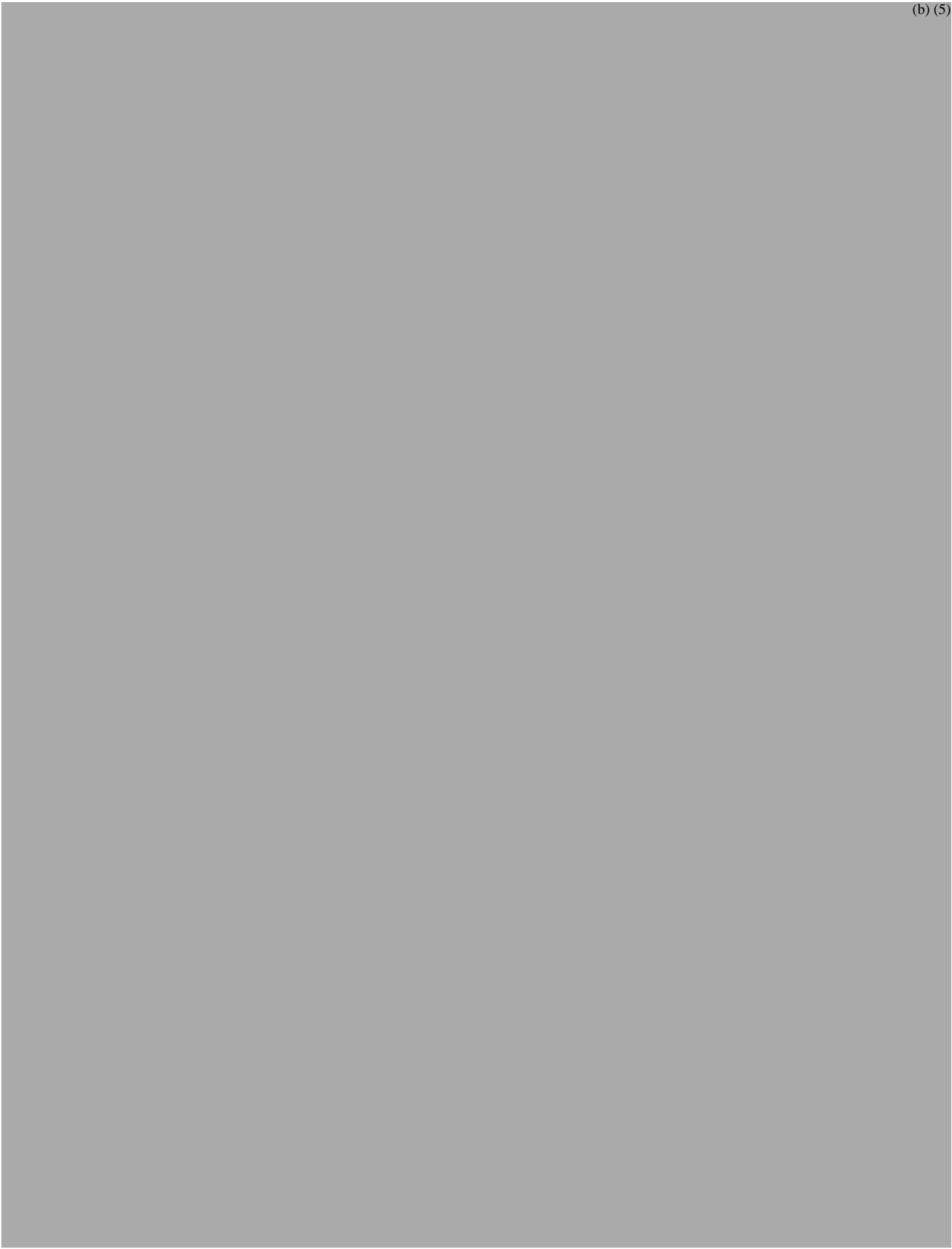


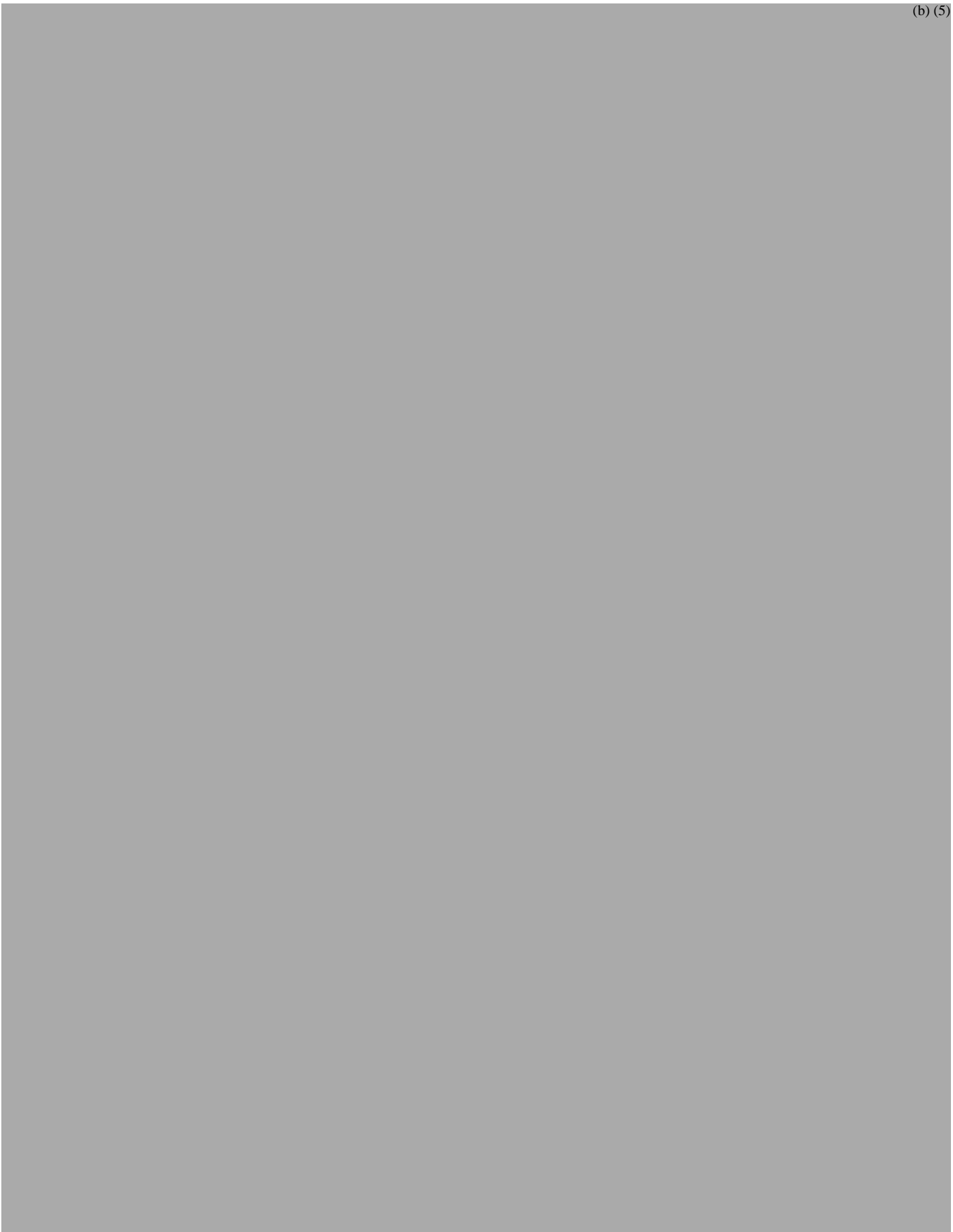
Infectious Diseases and Biodefense



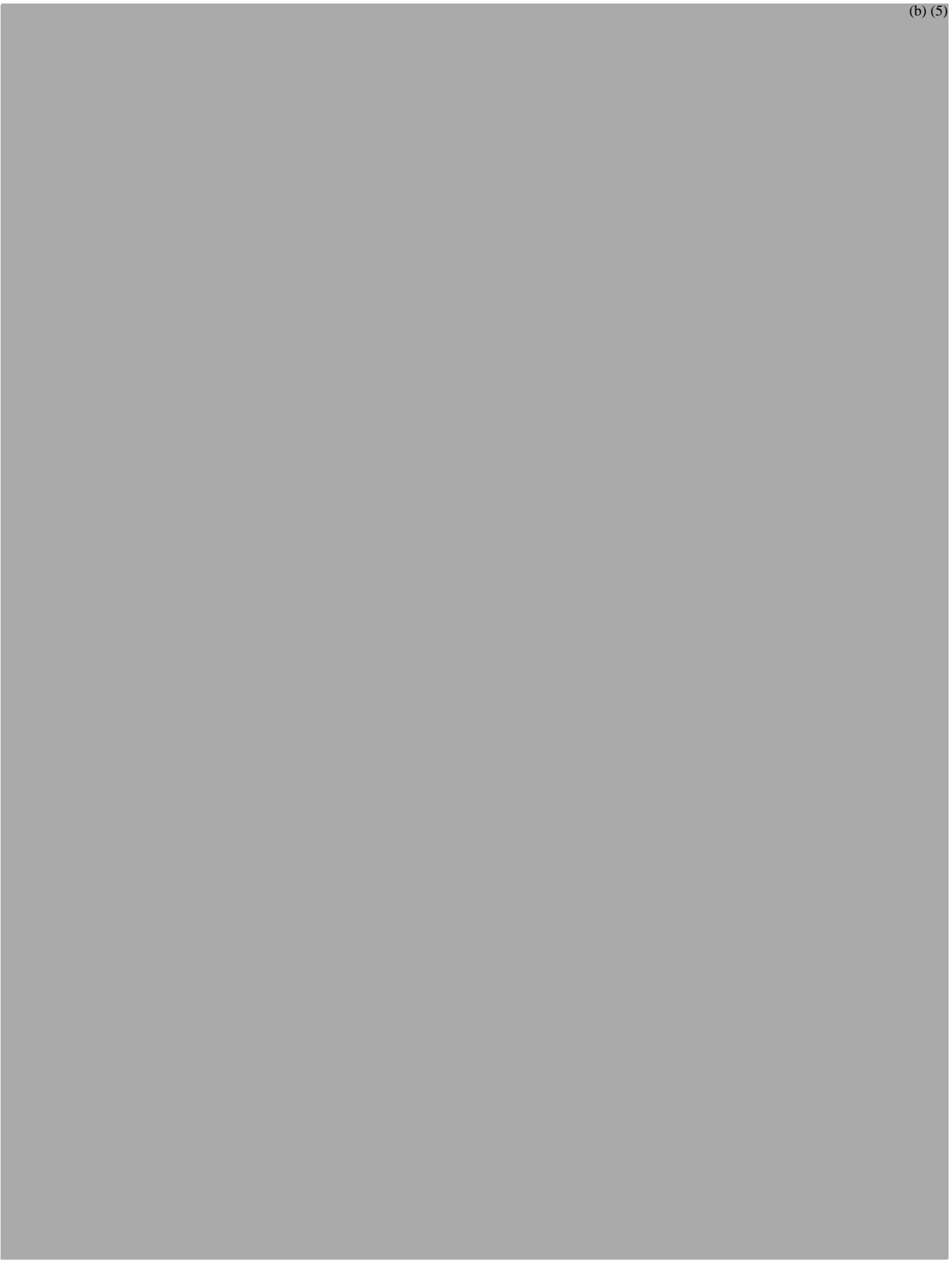




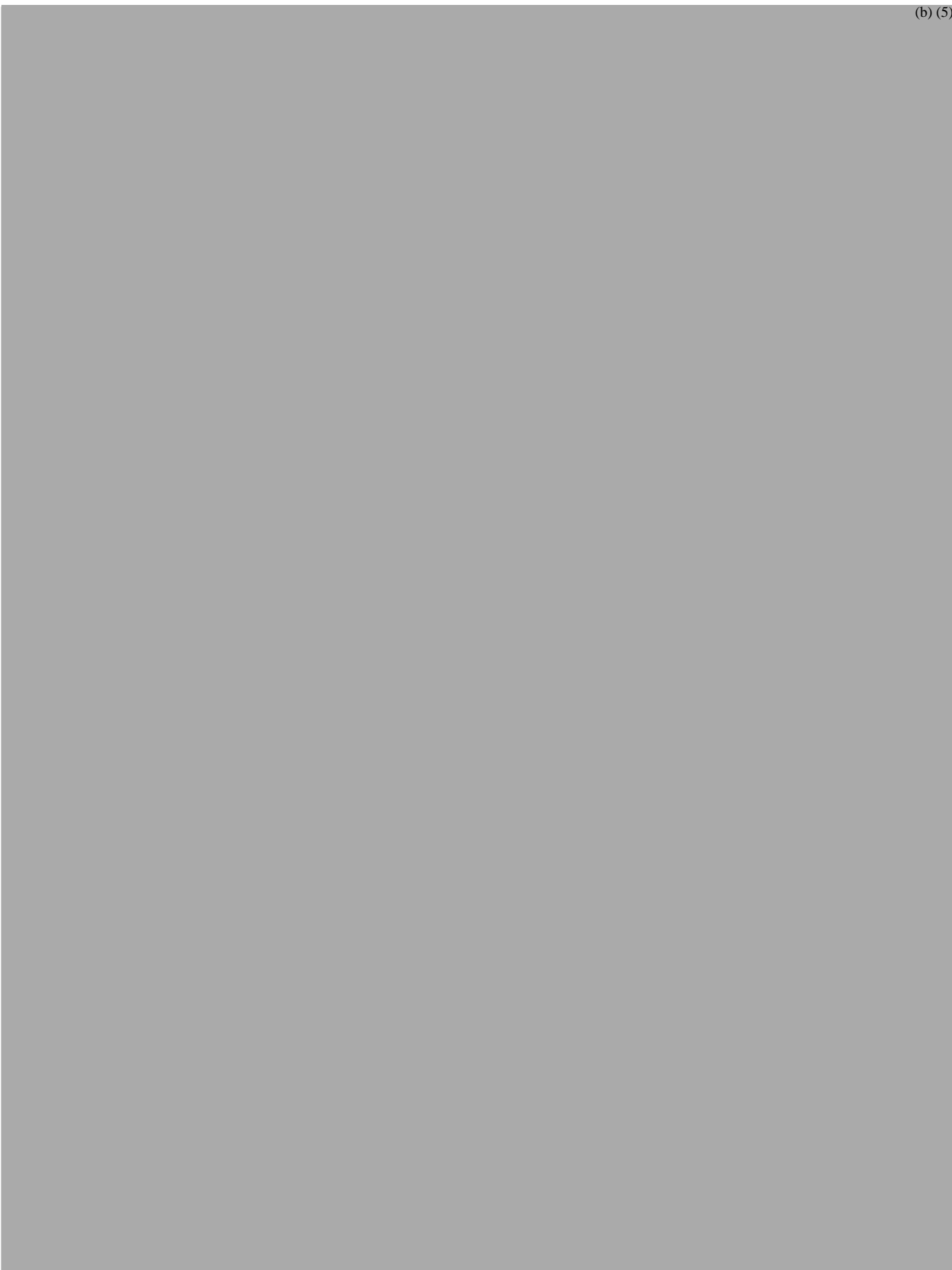


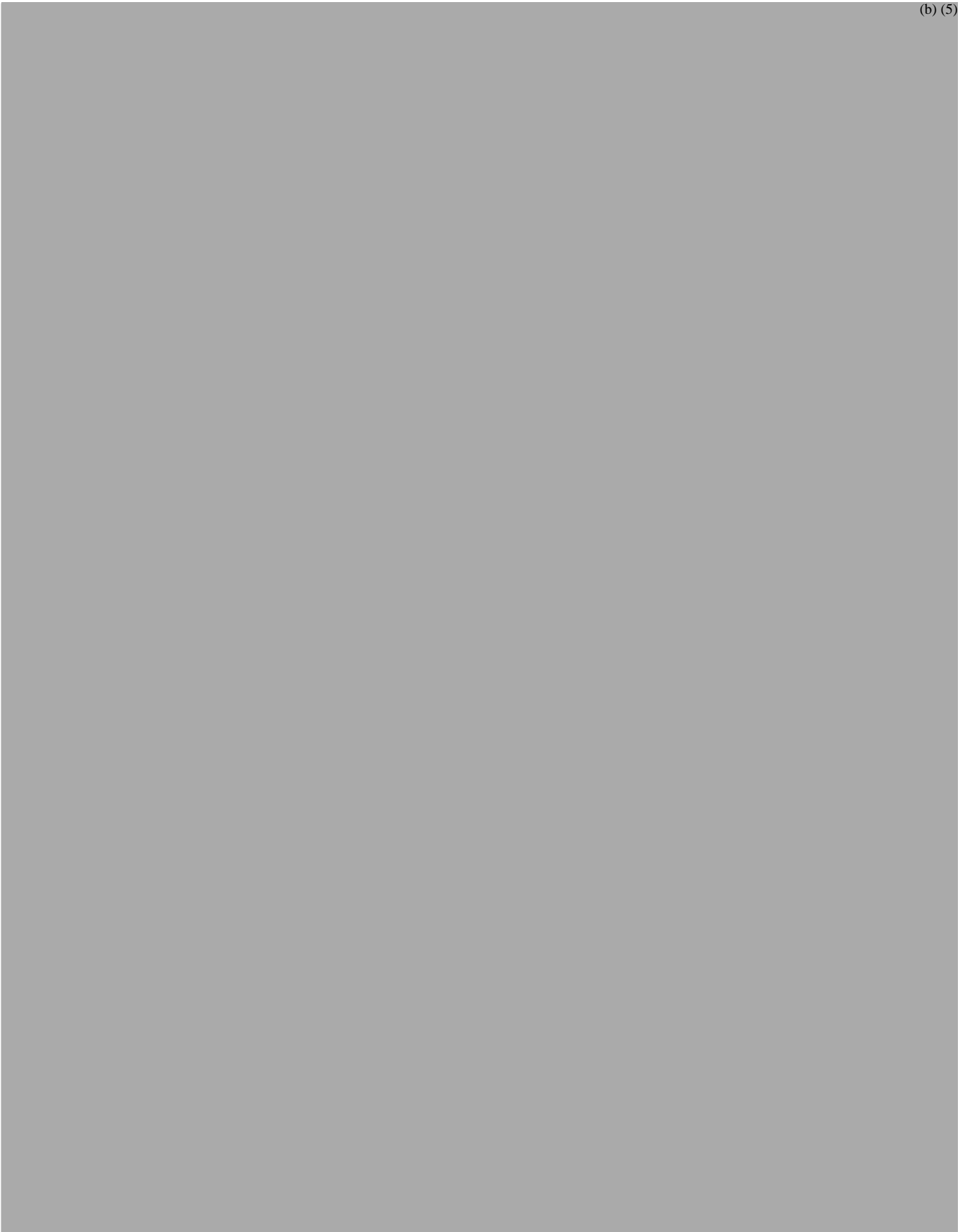






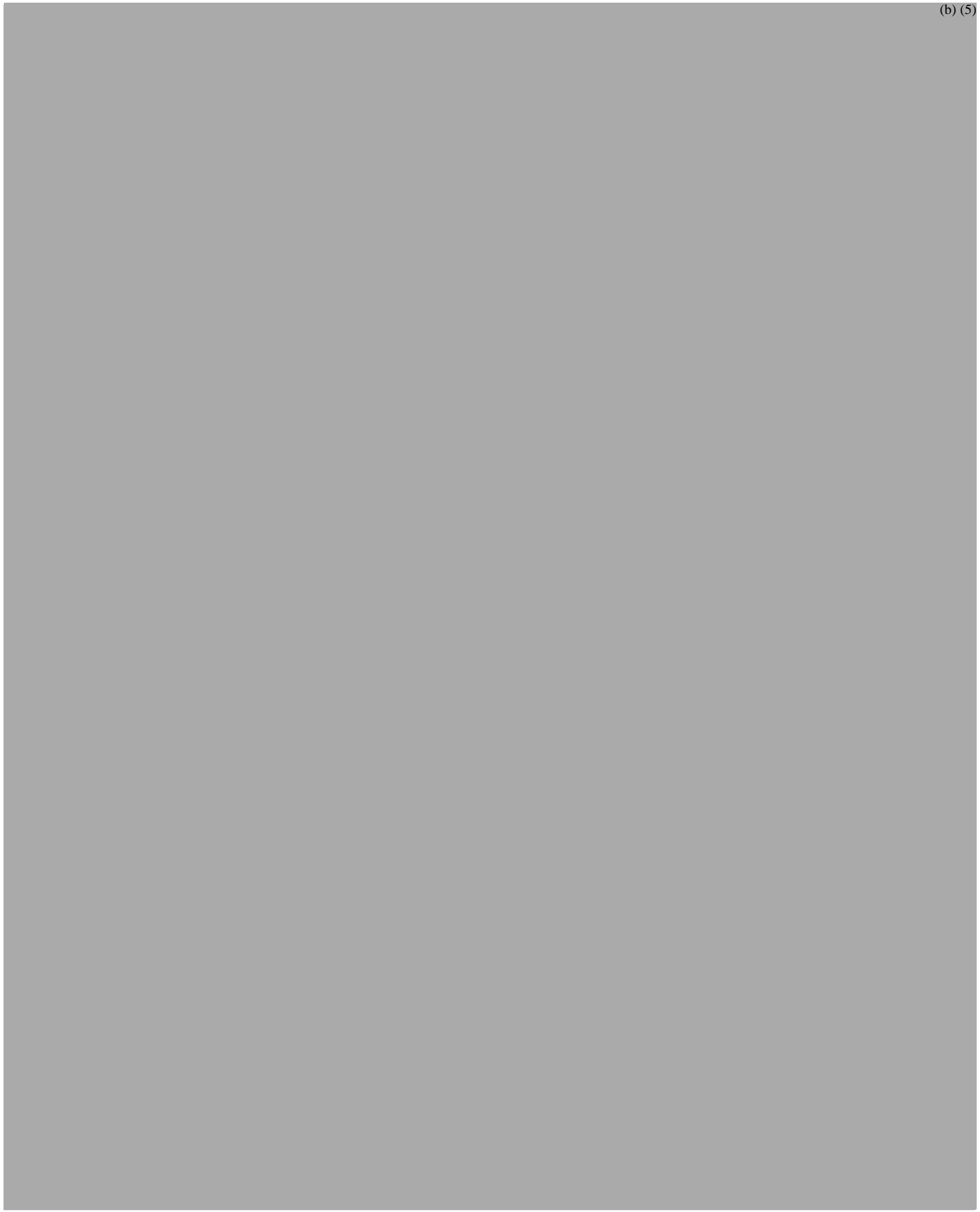


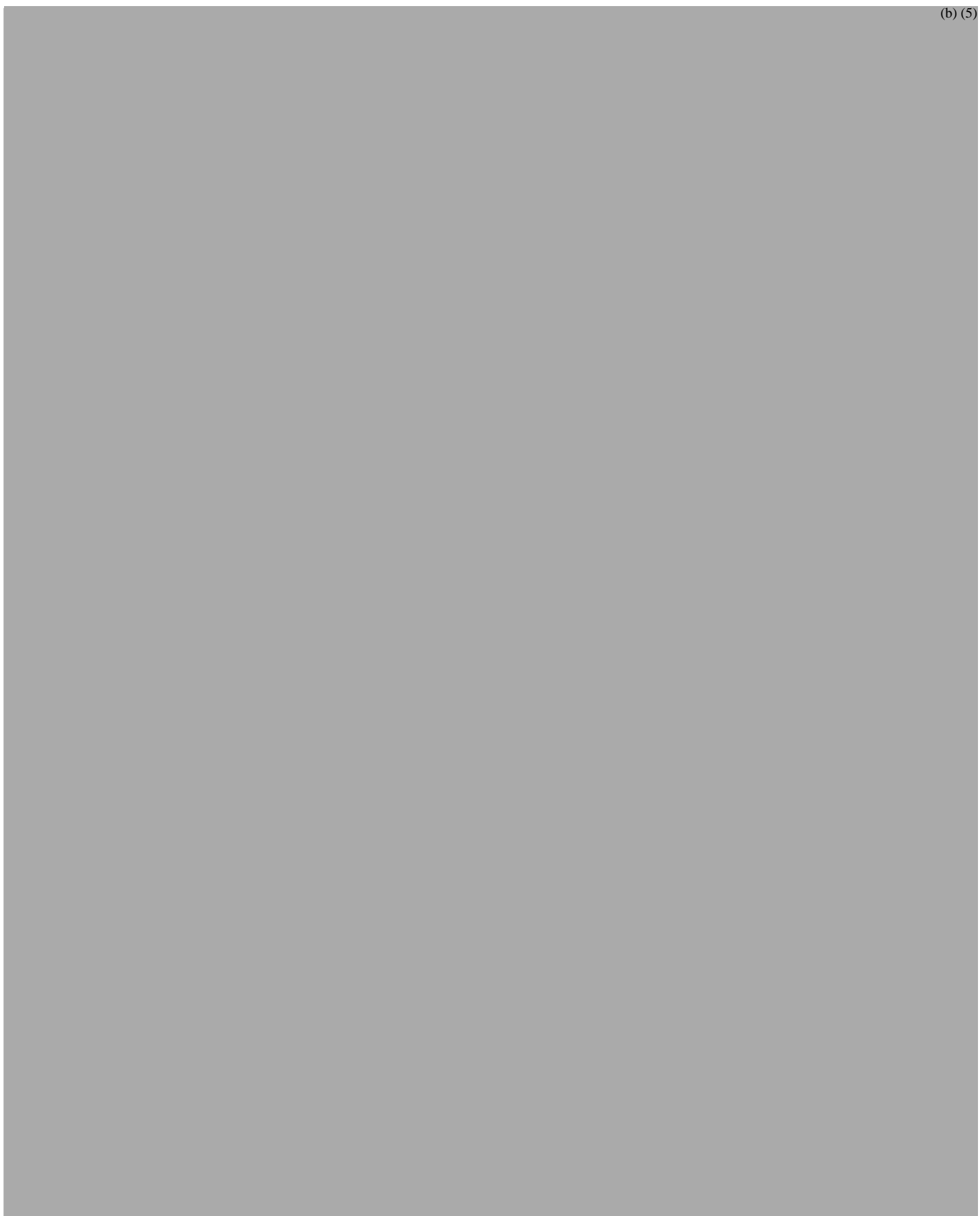


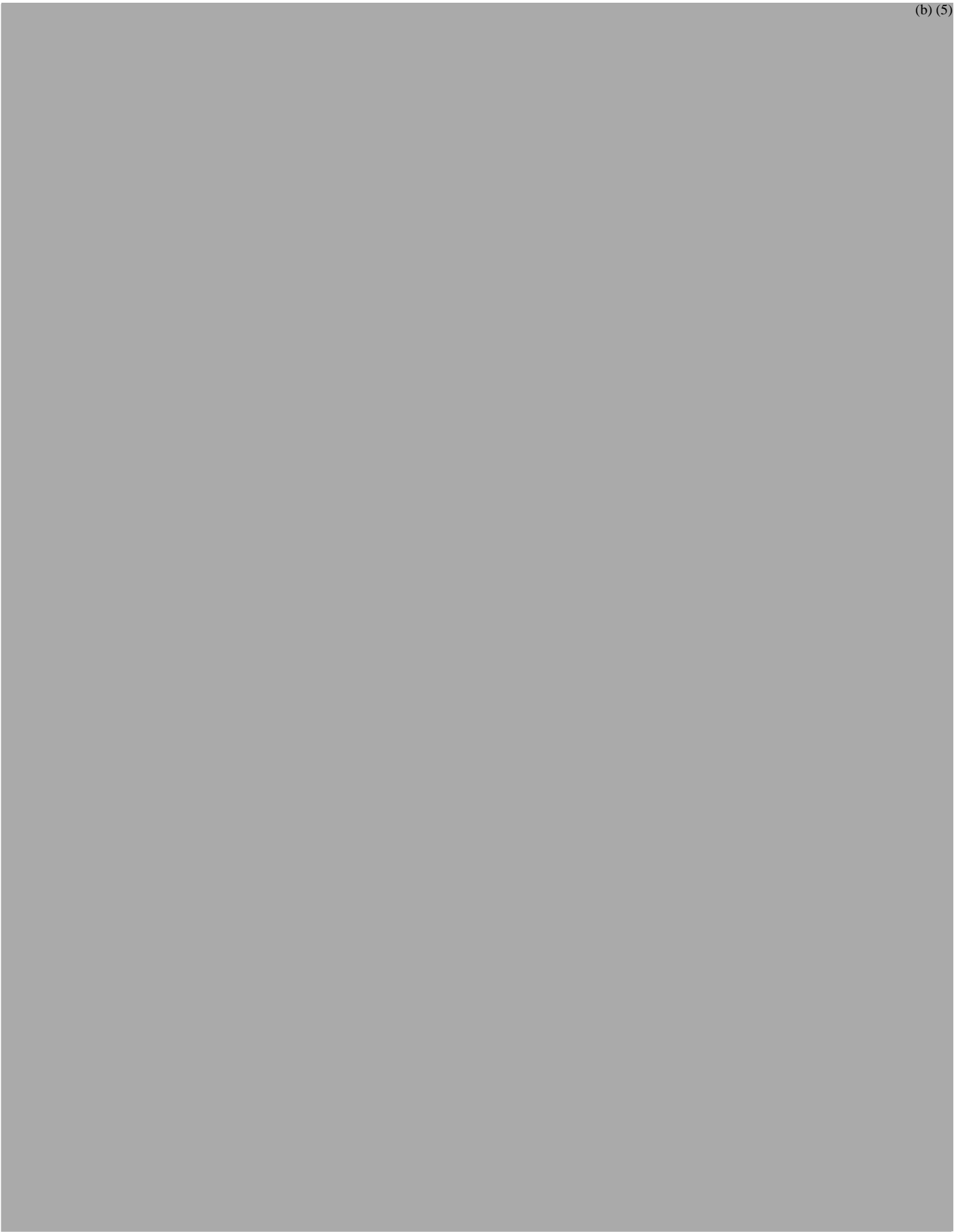


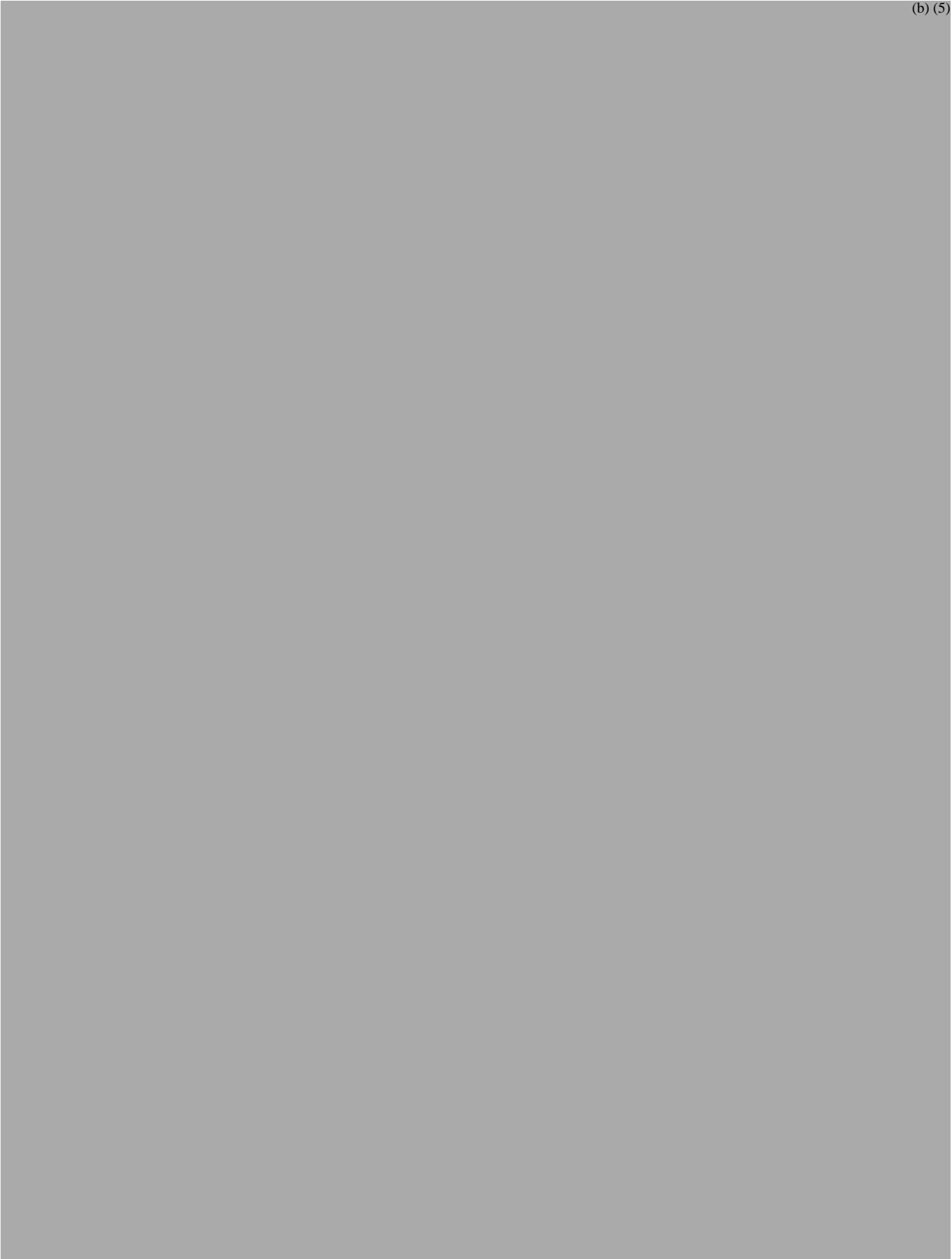


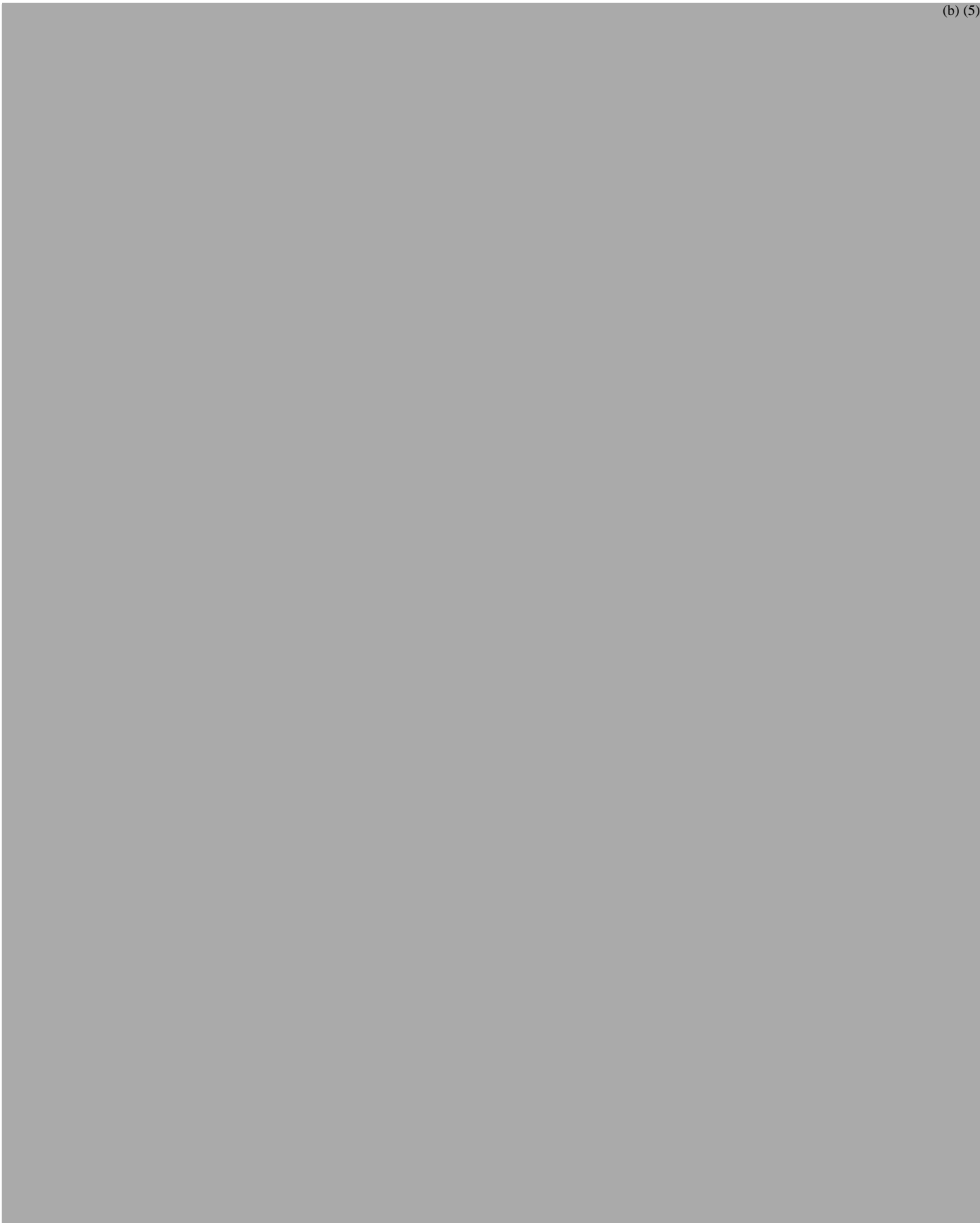






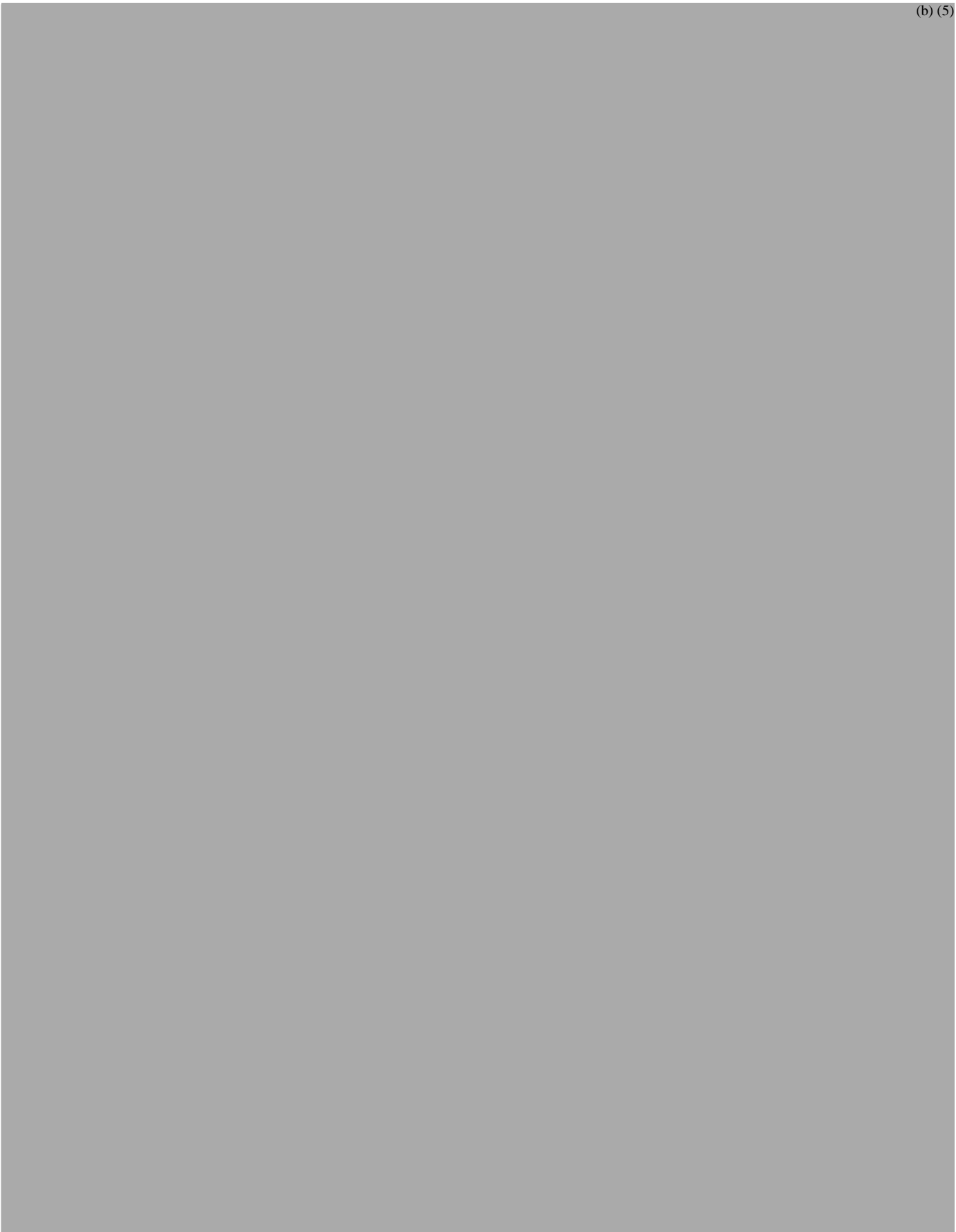


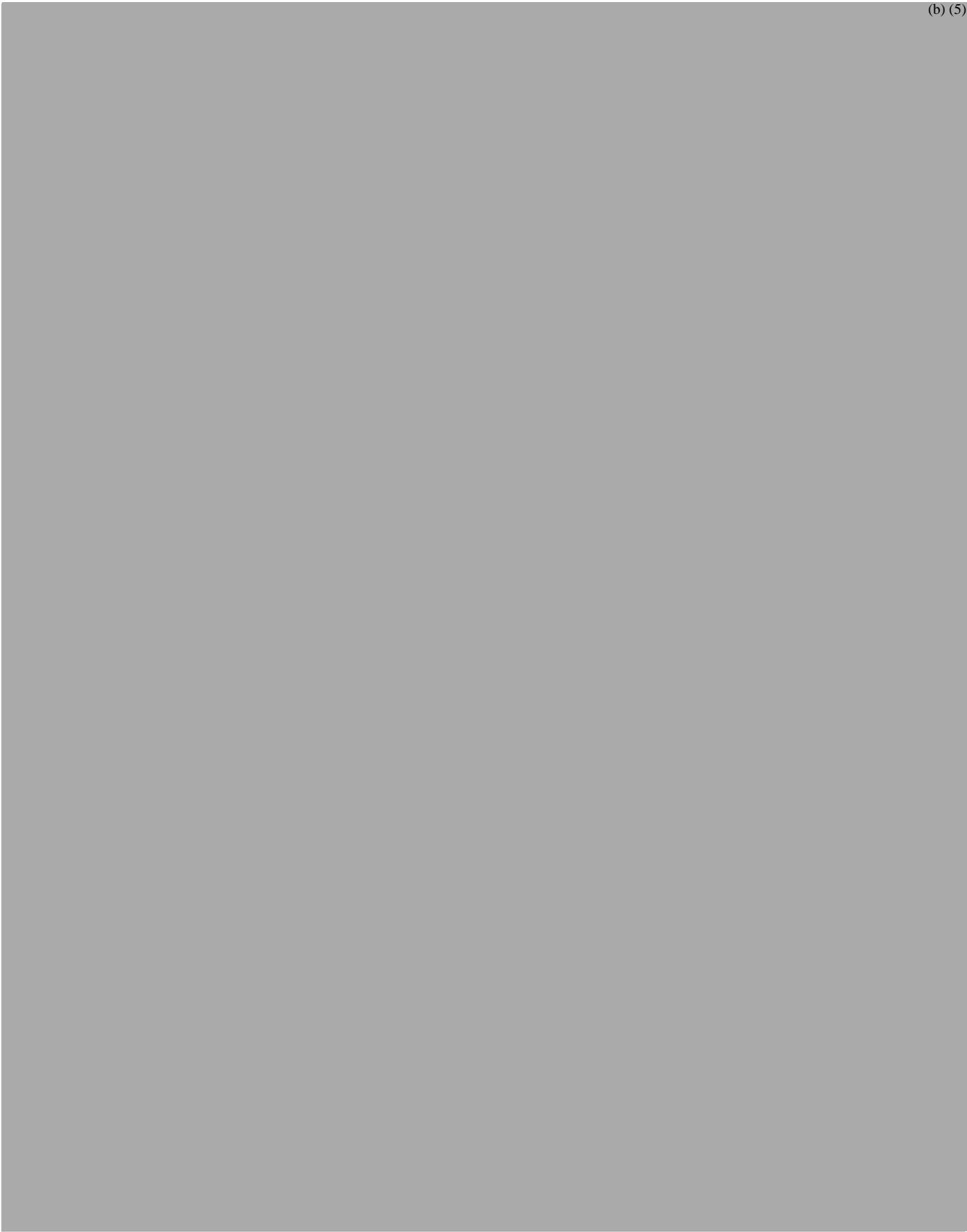






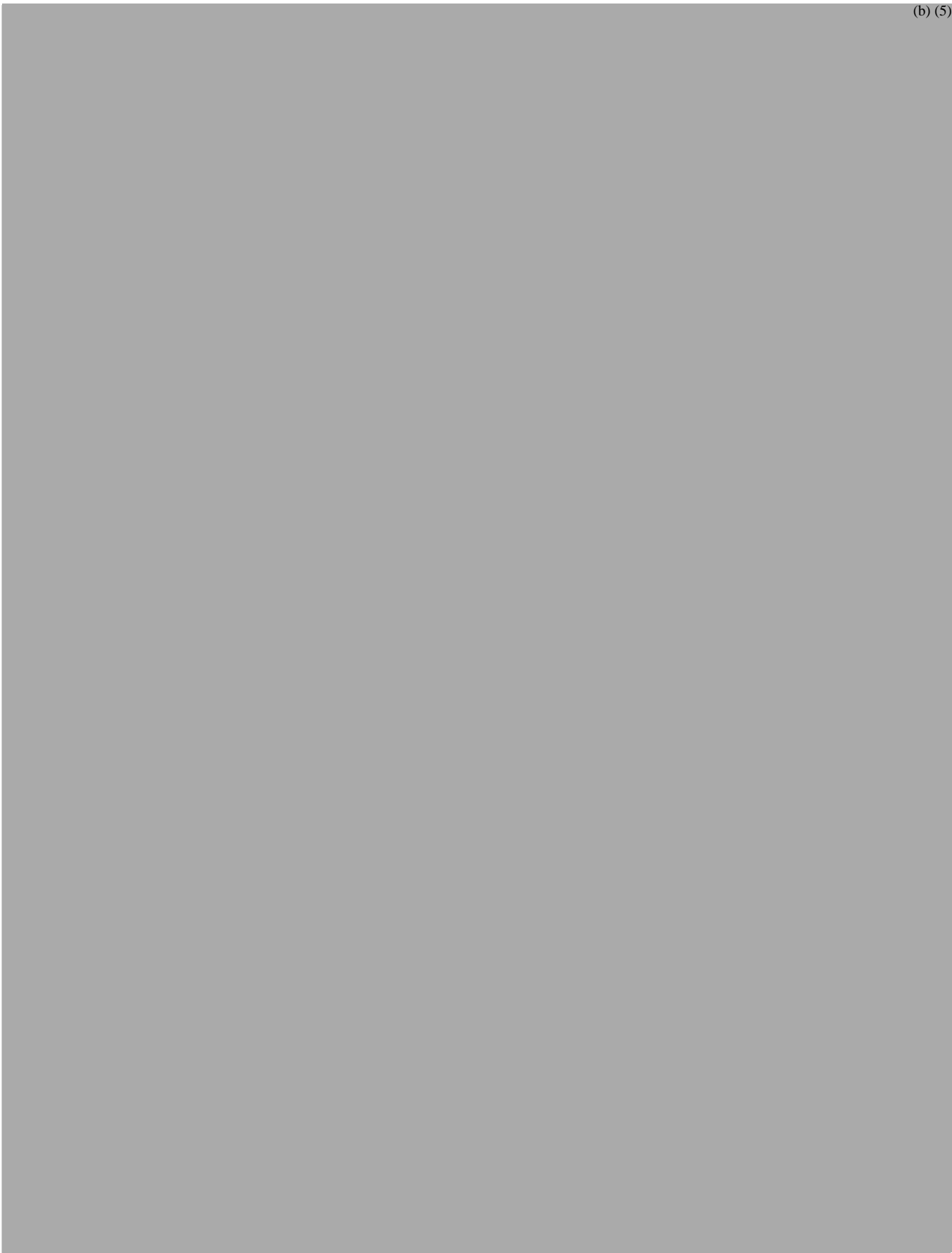


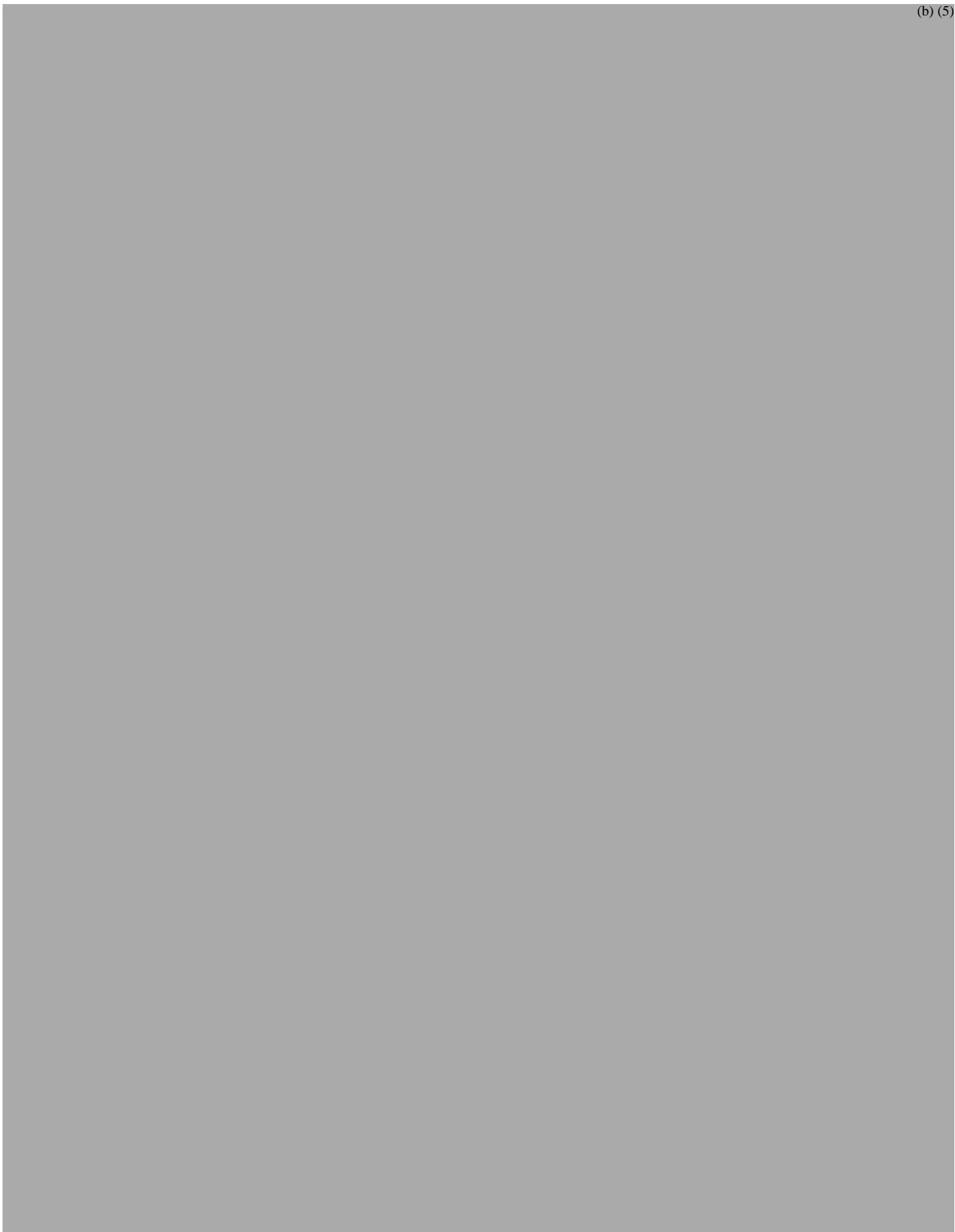


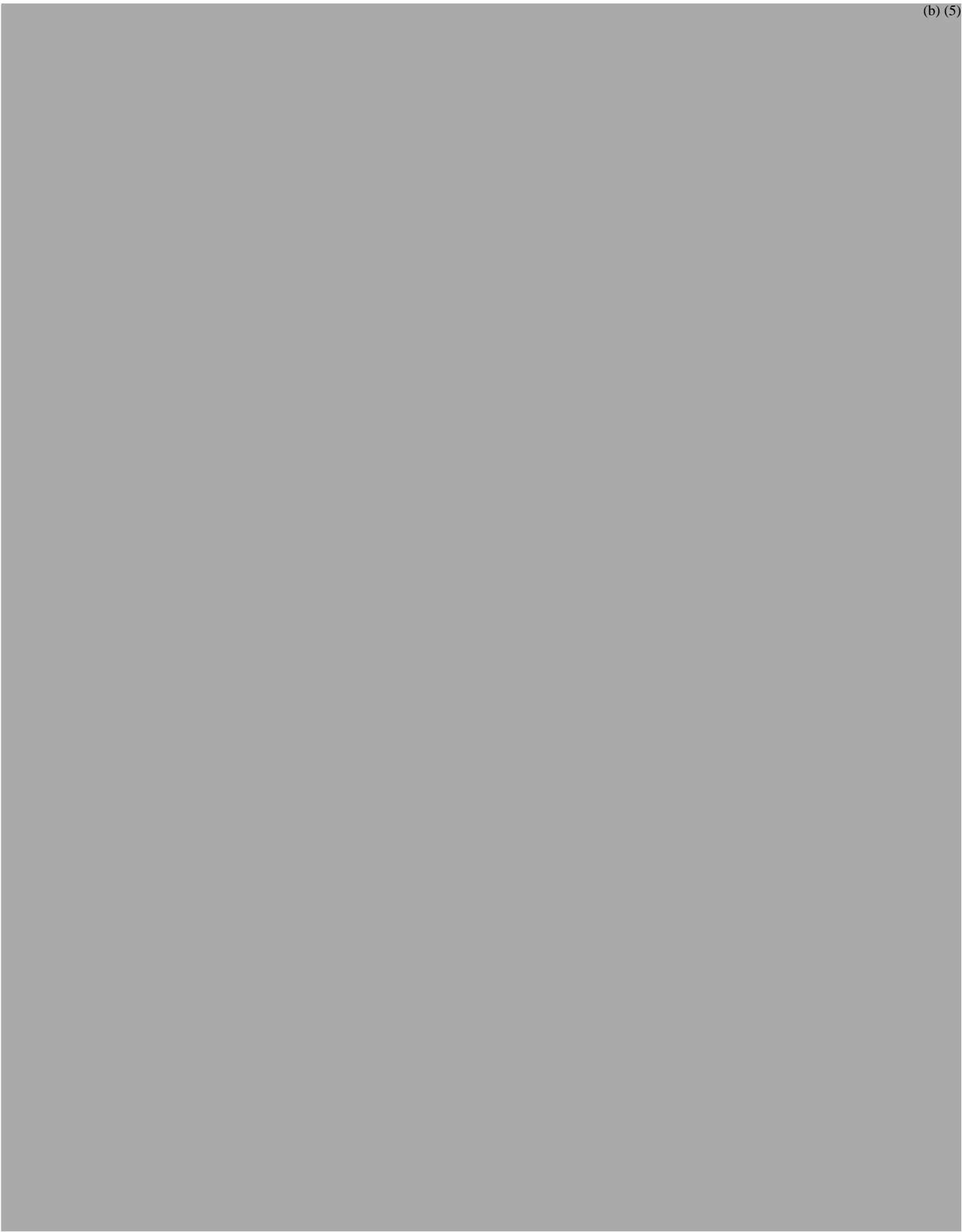


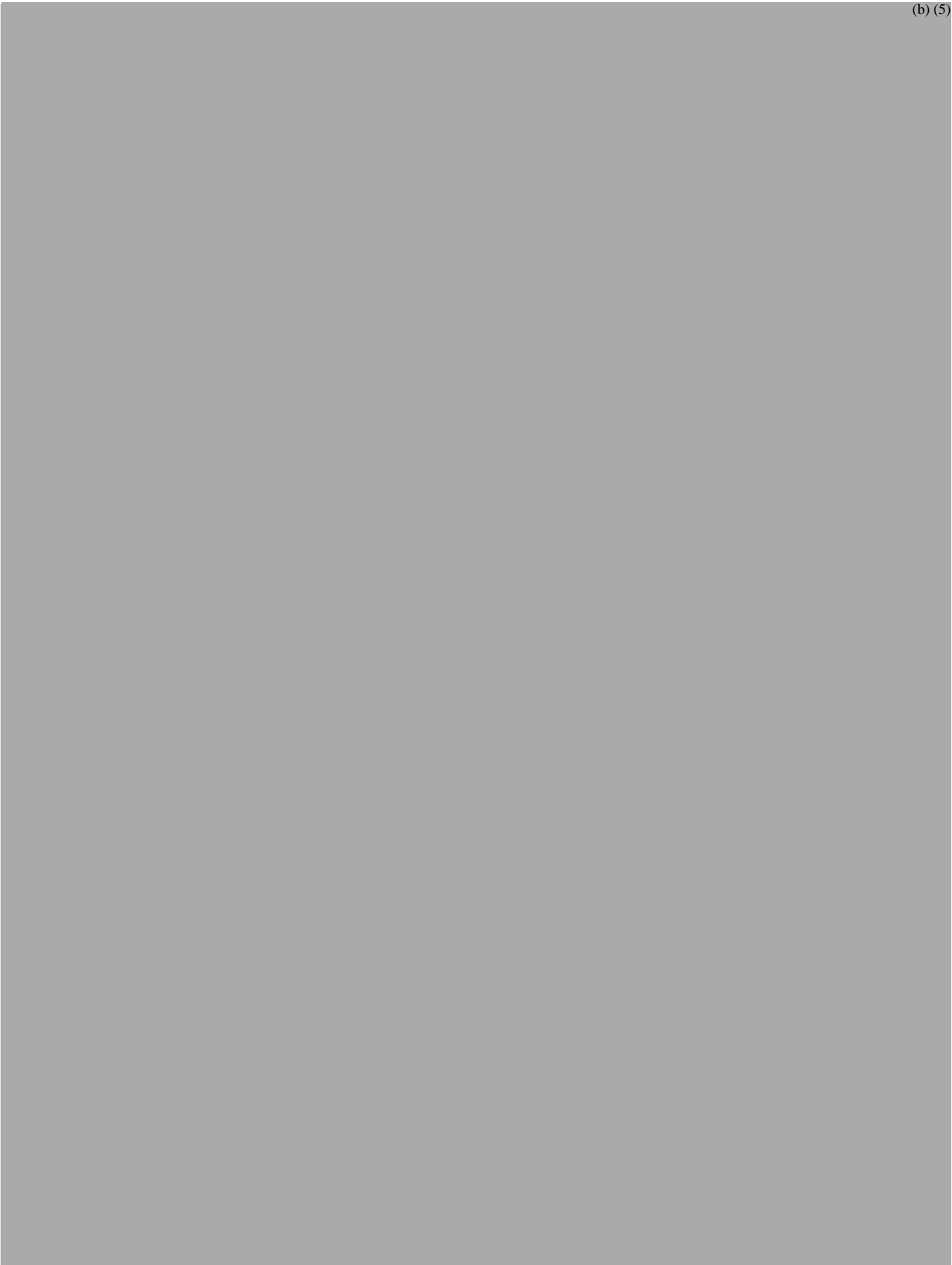


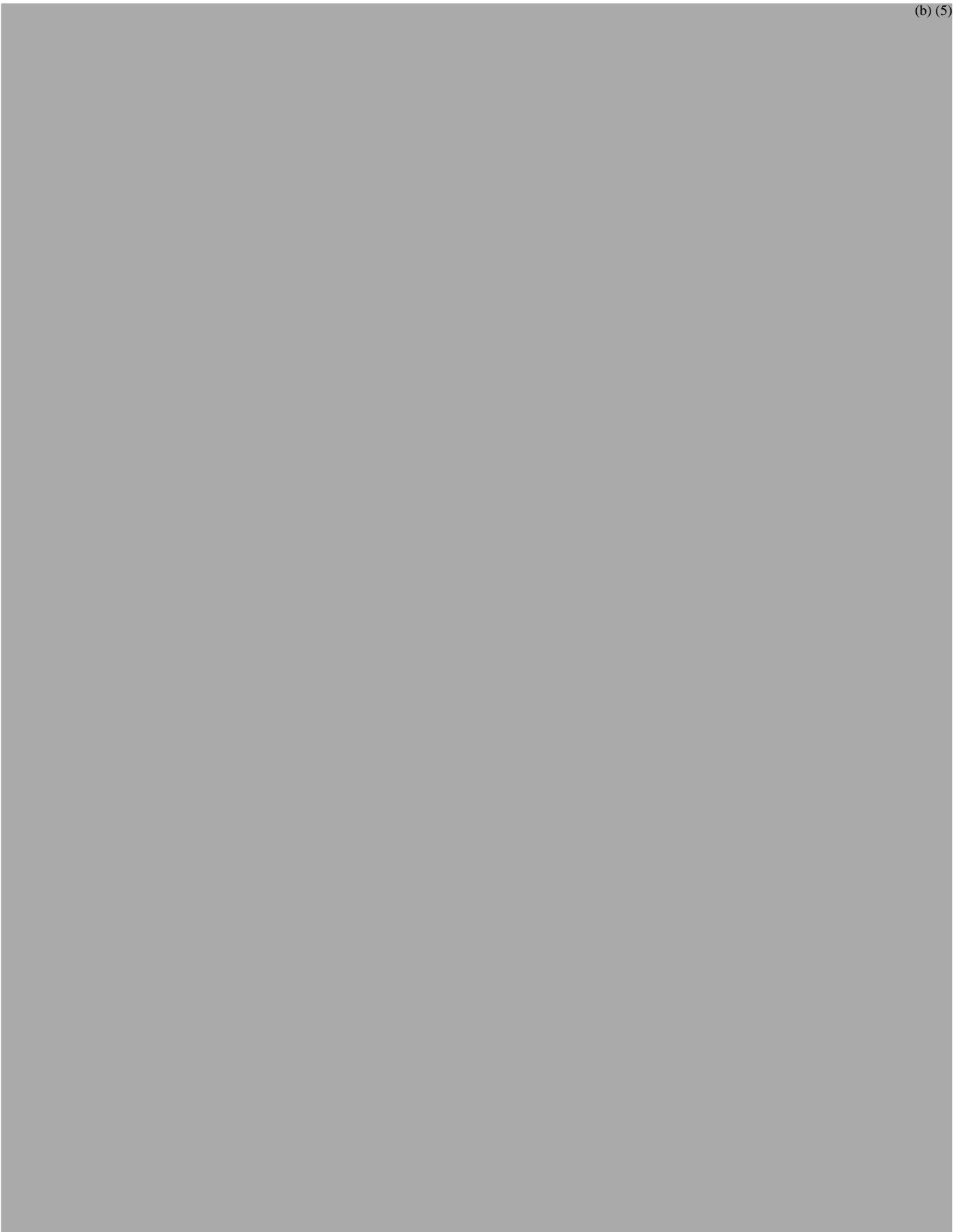


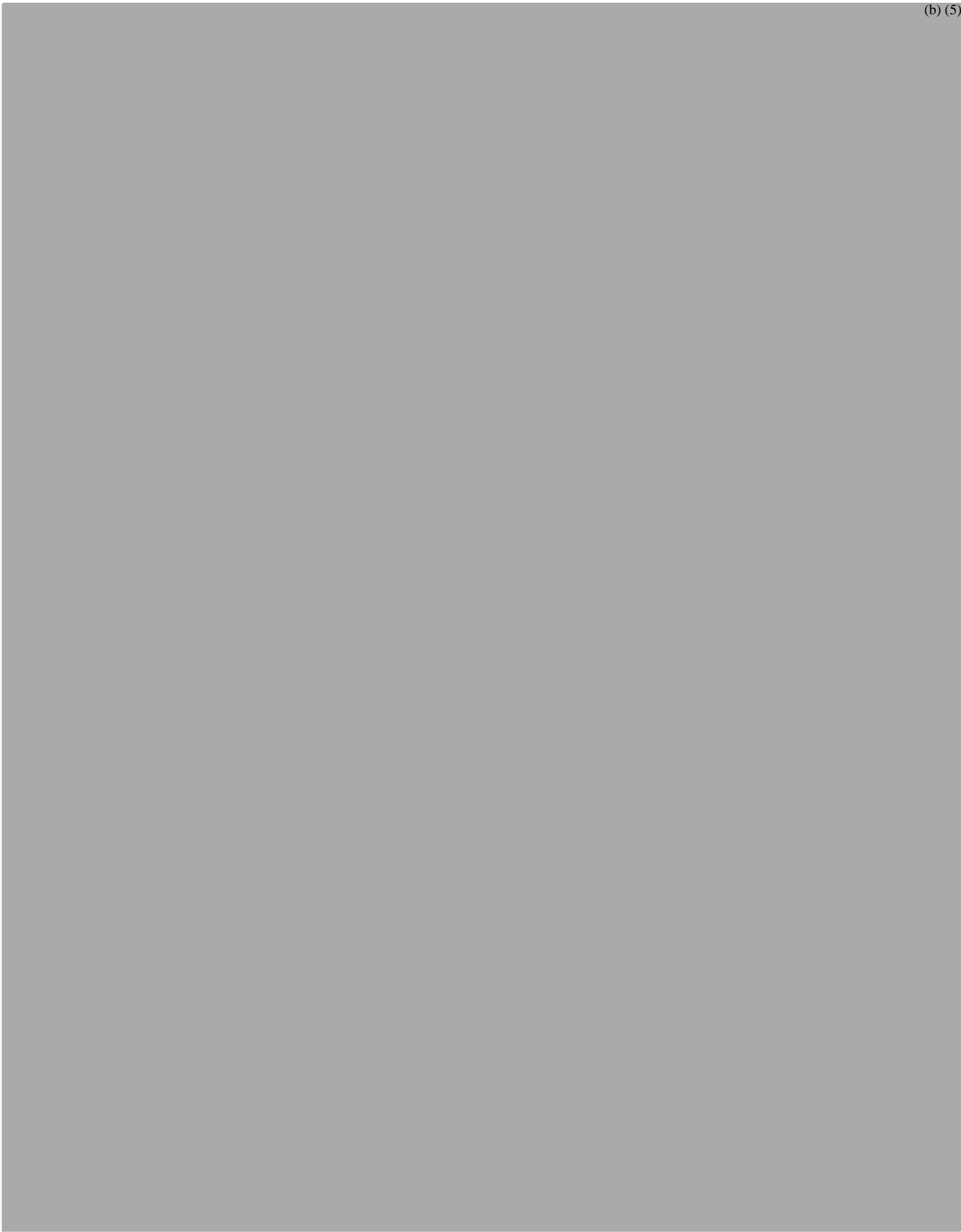






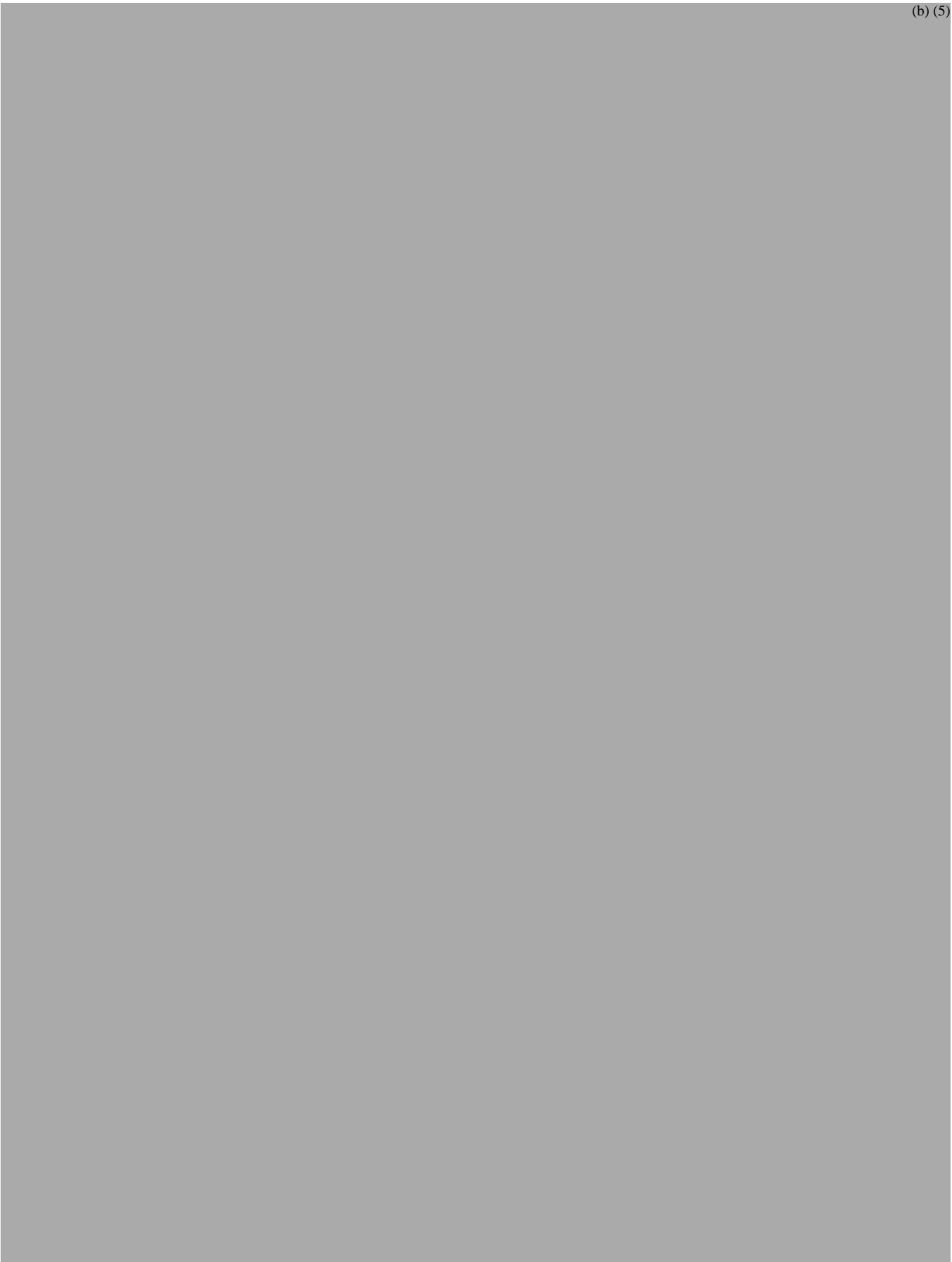


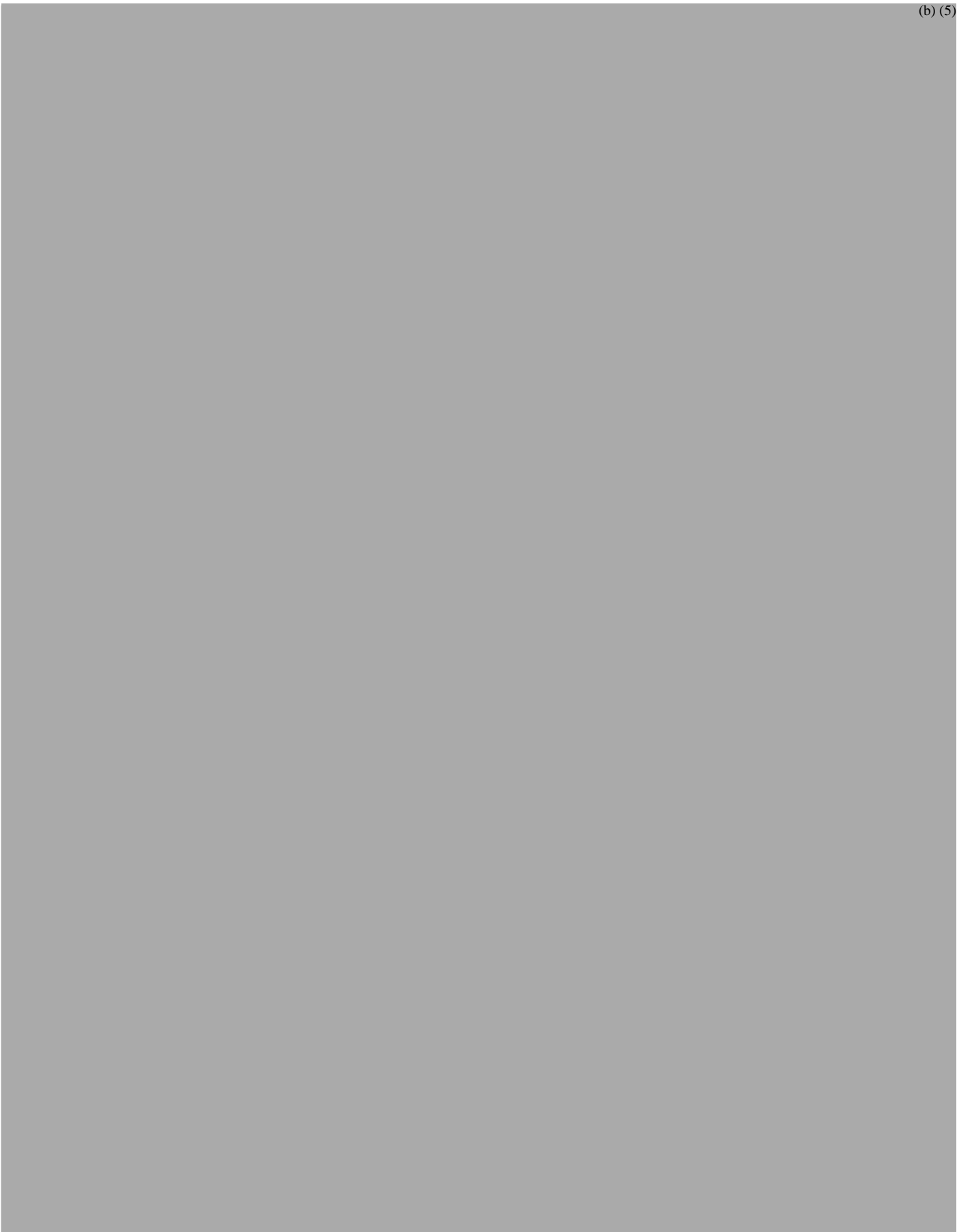








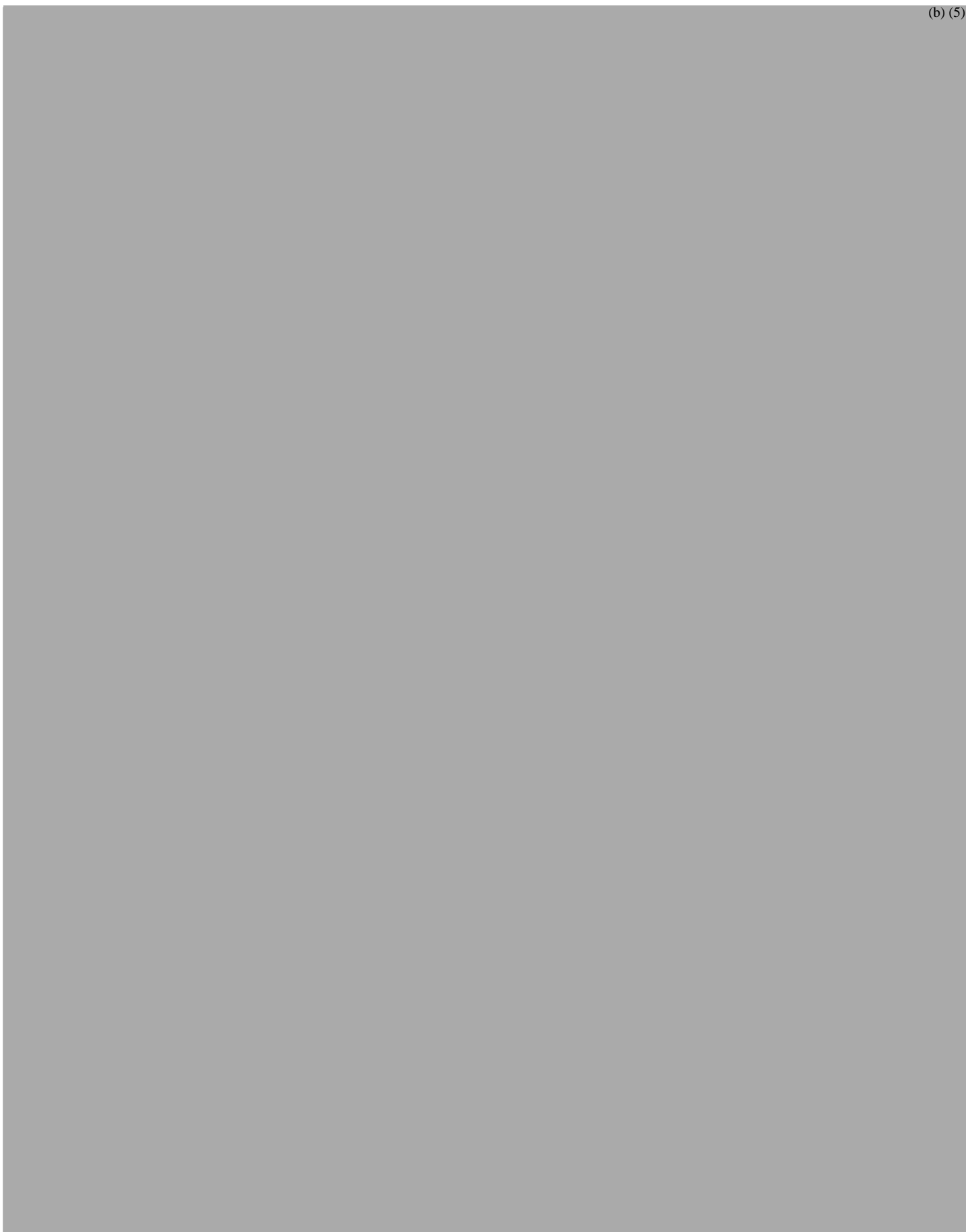


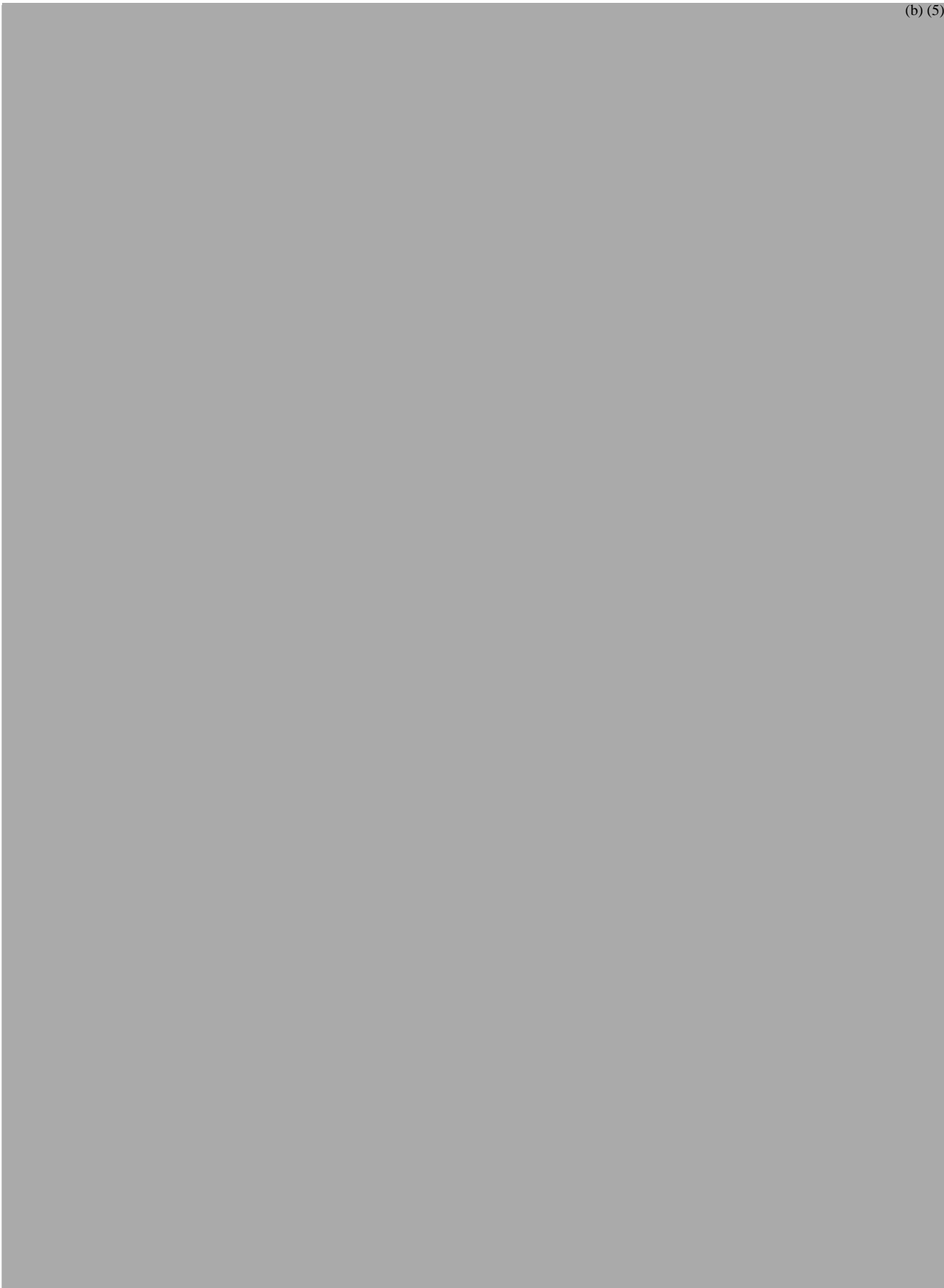




Rare and Undiagnosed Diseases

















Microbiome





