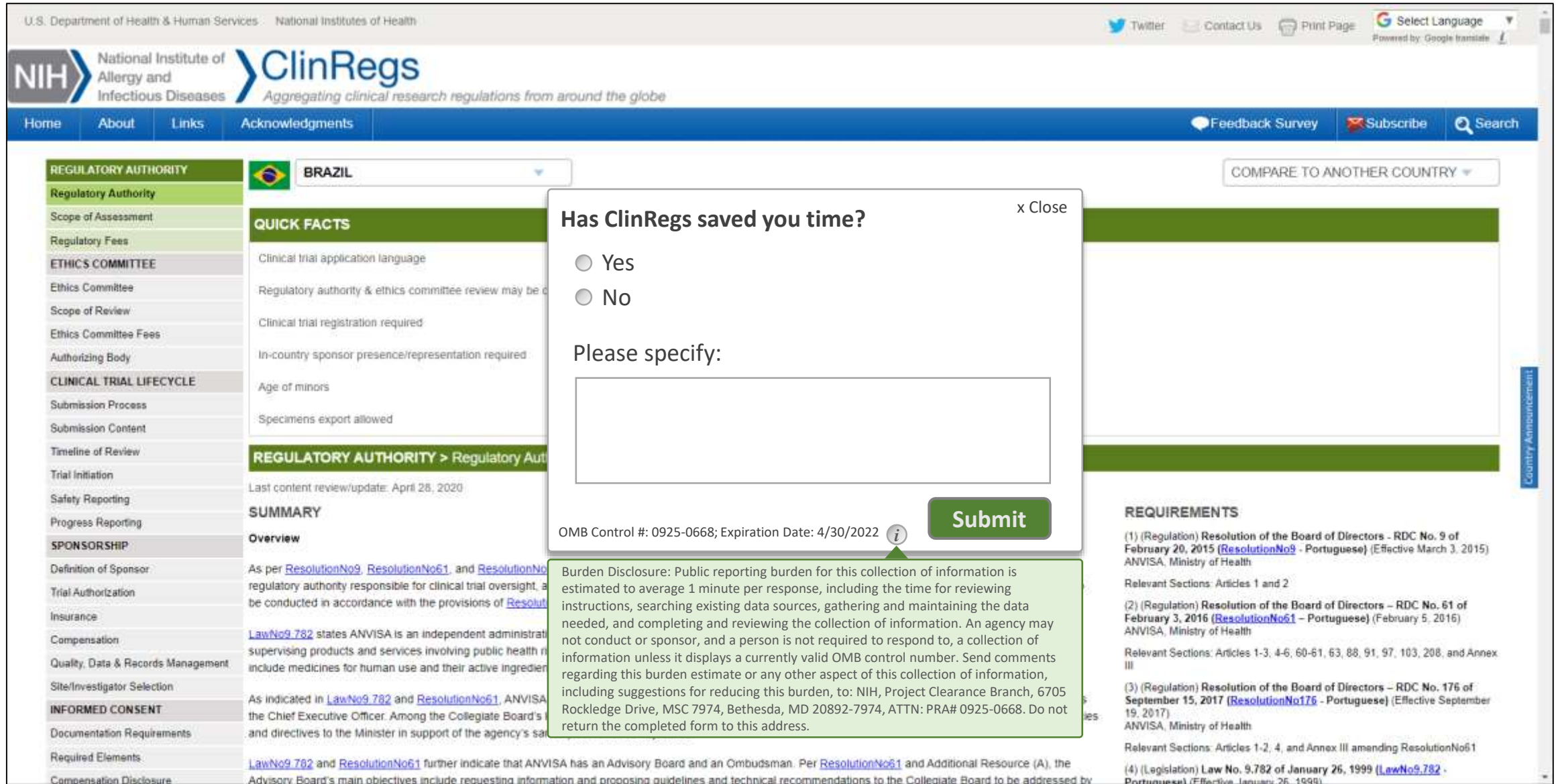


Pop-Up Question 1.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website interface. At the top, there are navigation links for Home, About, Links, and Acknowledgments, along with utility links for Feedback Survey, Subscribe, and Search. The main content area is for Brazil, with a sidebar on the left listing various regulatory and ethical categories. A pop-up survey titled "Has ClinRegs saved you time?" is overlaid on the page, featuring radio buttons for "Yes" and "No", a text input field for "Please specify:", and a "Submit" button. Below the survey, a green box contains a "Burden Disclosure" text. The background website content includes a "QUICK FACTS" section, a "REGULATORY AUTHORITY" dropdown menu, and a "REQUIREMENTS" section with several regulatory references.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY BRAZIL

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

COMPARISON TO ANOTHER COUNTRY

Country Announcement


Has ClinRegs saved you time? x Close

Yes

No

Please specify:

Submit

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be conducted

Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health and safety, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by the Chief Executive Officer. Among the Collegiate Board's main objectives are to issue resolutions and directives to the Minister in support of the agency's activities.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Board.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

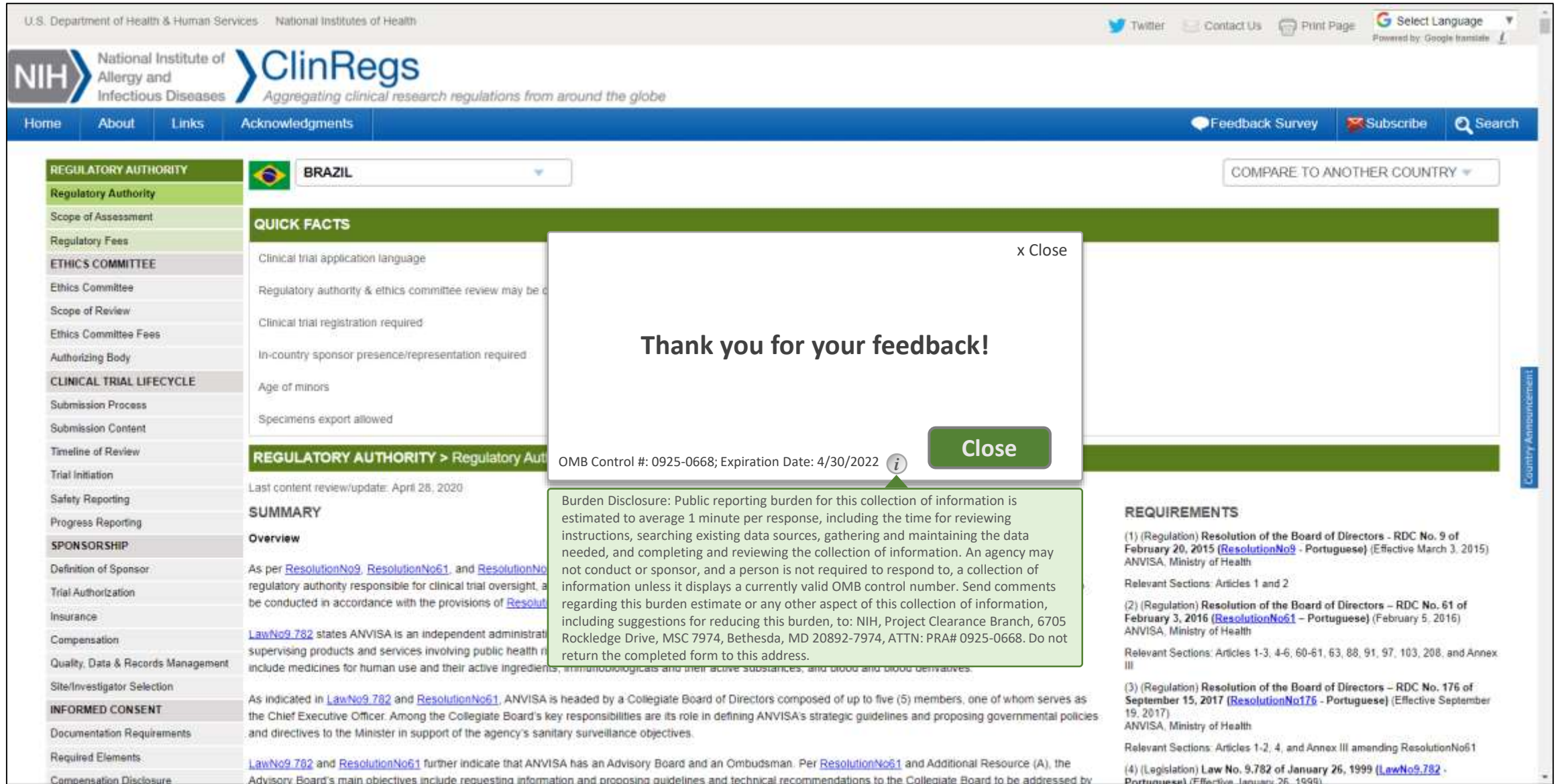
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 1.

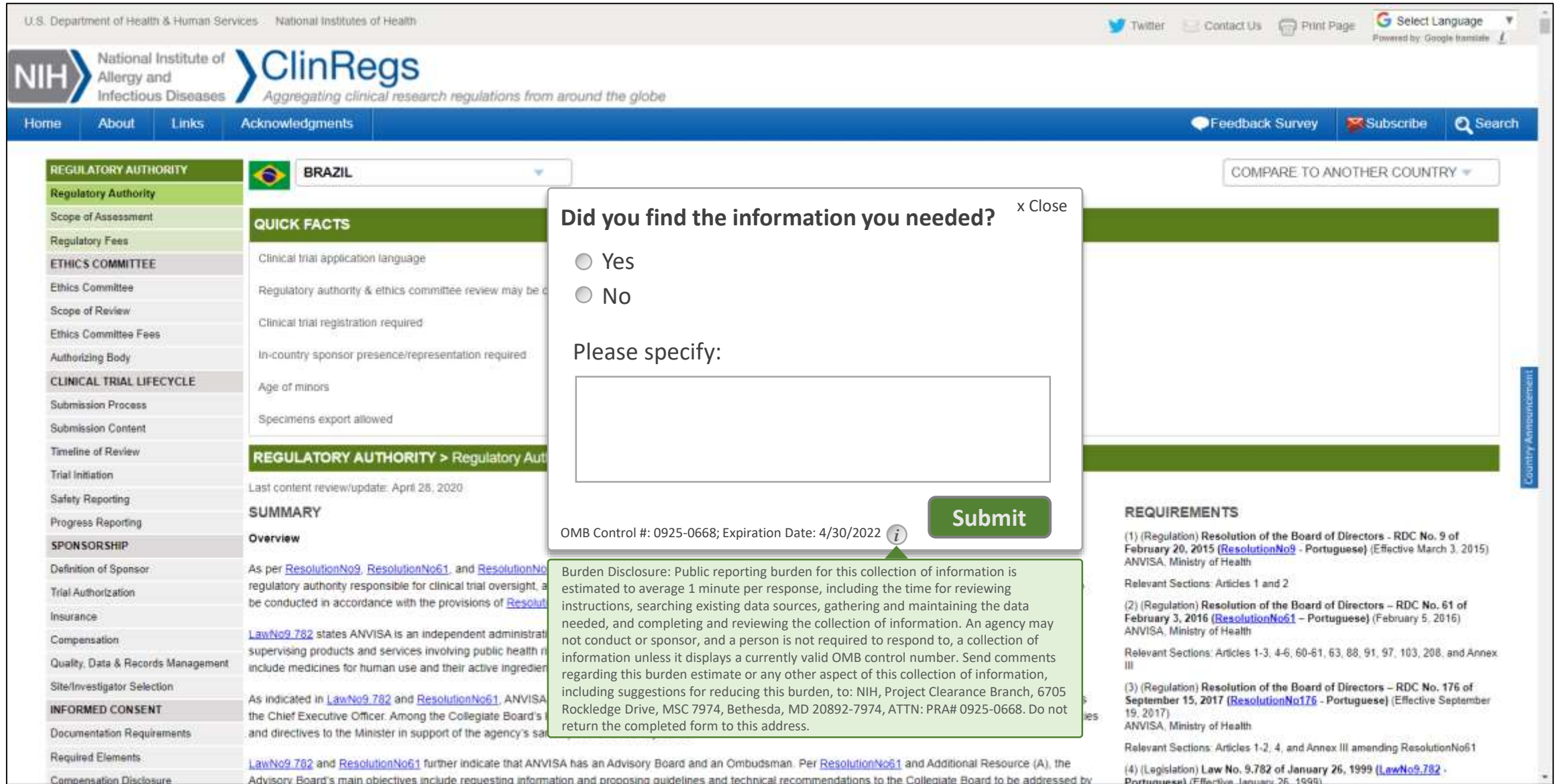
Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website interface. At the top, there are navigation links for Home, About, Links, and Acknowledgments, along with utility links for Feedback Survey, Subscribe, and Search. The main content area is divided into sections for REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP. A dropdown menu for REGULATORY AUTHORITY is set to BRAZIL. A central pop-up window displays "Thank you for your feedback!" with a "Close" button. Below the pop-up, a green box highlights the Burden Disclosure text, which is also linked to an information icon. The Burden Disclosure text states: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address." The OMB Control # is 0925-0668 and the Expiration Date is 4/30/2022. The page also includes a "REQUIREMENTS" section with several regulatory references.

Pop-Up Question 2.

Burden disclosure displayed when user clicks on or hovers over 




U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL


COMPARE TO ANOTHER COUNTRY

Did you find the information you needed? x Close

Yes
 No

Please specify:

Submit

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REGULATORY AUTHORITY > Regulatory Authority

QUICK FACTS

- Clinical trial application language
- Regulatory authority & ethics committee review may be required
- Clinical trial registration required
- In-country sponsor presence/representation required
- Age of minors
- Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health and safety, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by the Chief Executive Officer. Among the Collegiate Board's main objectives are to issue resolutions and directives to the Minister in support of the agency's activities.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Board.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

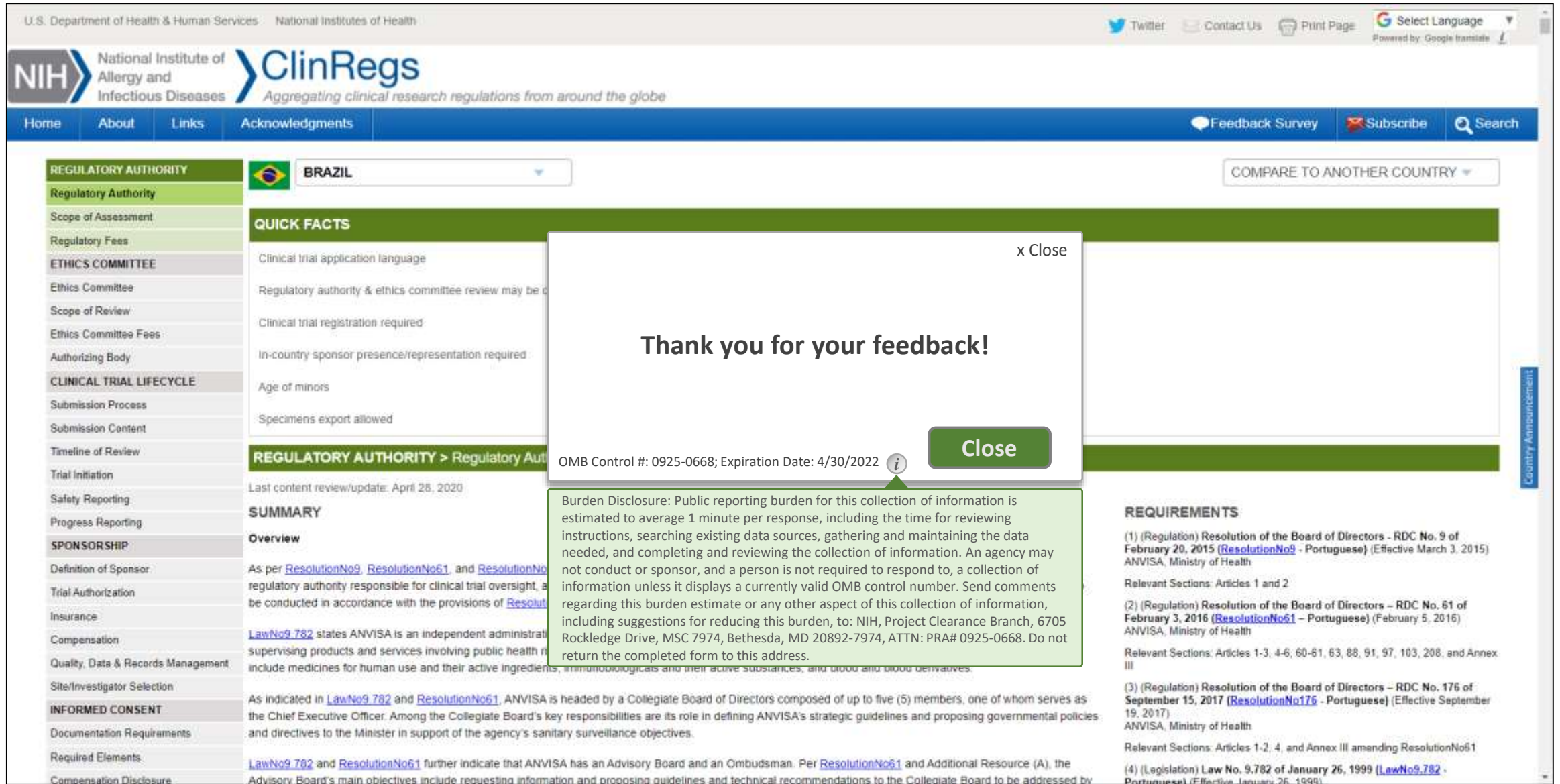
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 2.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface. At the top, there is a navigation bar with links for Home, About, Links, and Acknowledgments. A search bar and a 'Feedback Survey' button are also present. The main content area is divided into sections: REGULATORY AUTHORITY (with a dropdown menu set to BRAZIL), QUICK FACTS, REGULATORY AUTHORITY > Regulatory Authority, and SPONSORSHIP. A feedback pop-up is overlaid on the page, displaying 'Thank you for your feedback!' and a 'Close' button. Below the pop-up, a green box highlights the Burden Disclosure text, which is preceded by an information icon. The Burden Disclosure text states: 'Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.'

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate


NIH National Institute of Allergy and Infectious Diseases
Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Close

Close

Country Announcement

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health


Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

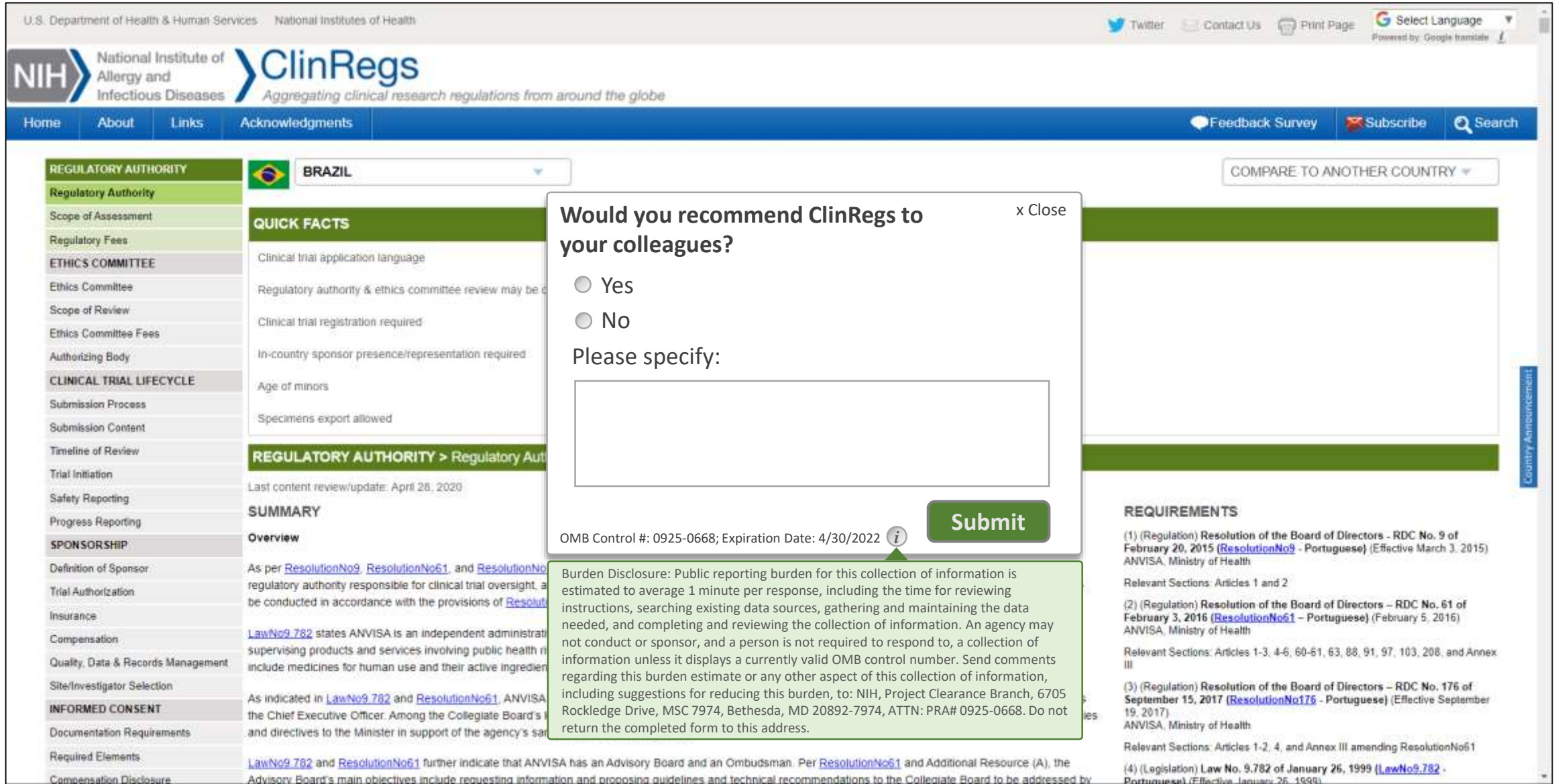
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 3.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website interface. At the top, there are navigation links for Home, About, Links, and Acknowledgments, along with utility links for Feedback Survey, Subscribe, and Search. The main content area is for Brazil, with a sidebar on the left listing various regulatory and ethical categories. A pop-up survey is centered on the screen, asking for recommendations and providing a text box for comments. Below the survey, a green box contains a burden disclosure text. The background content includes a 'QUICK FACTS' section, a 'REGULATORY AUTHORITY' section, and a 'REQUIREMENTS' section with several regulatory references.

REGULATORY AUTHORITY BRAZIL

QUICK FACTS

- Clinical trial application language
- Regulatory authority & ethics committee review may be required
- Clinical trial registration required
- In-country sponsor presence/representation required
- Age of minors
- Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo176](#), regulatory authority responsible for clinical trial oversight, and to be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo176](#). [LawNo9.782](#) states ANVISA is an independent administrative body supervising products and services involving public health and safety, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is the Chief Executive Officer. Among the Collegiate Board's responsibilities and directives to the Minister in support of the agency's safety and efficacy.

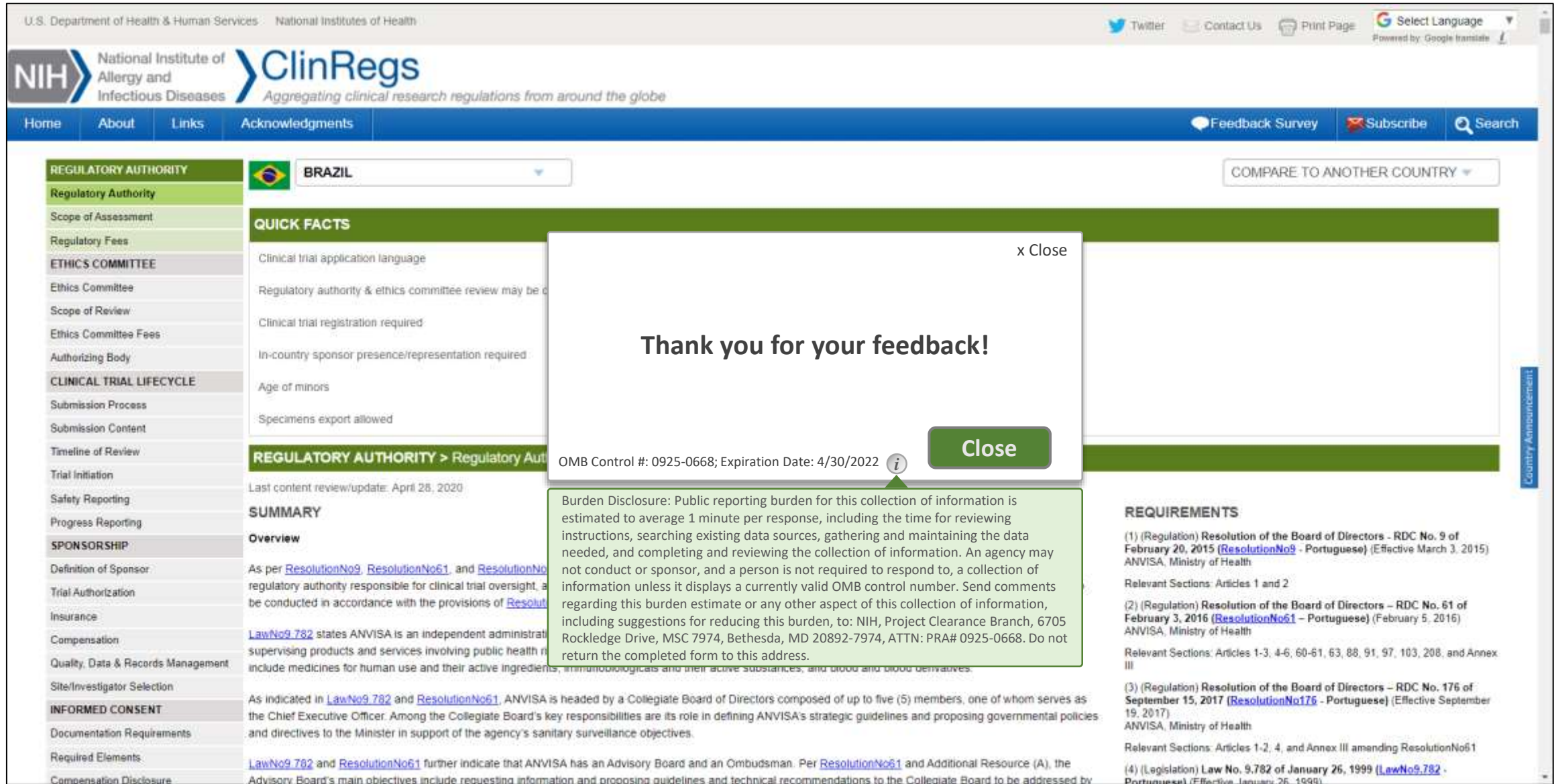
[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Board.

REQUIREMENTS

- (1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health
Relevant Sections: Articles 1 and 2
- (2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health
Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III
- (3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61
- (4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 3.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and SUMMARY sections. A feedback pop-up is overlaid on the page, and a tooltip displays the Burden Disclosure text.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate


NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Thank you for your feedback!

x Close

Close

BURDEN DISCLOSURE

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9 - Portuguese](#)) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61 - Portuguese](#)) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

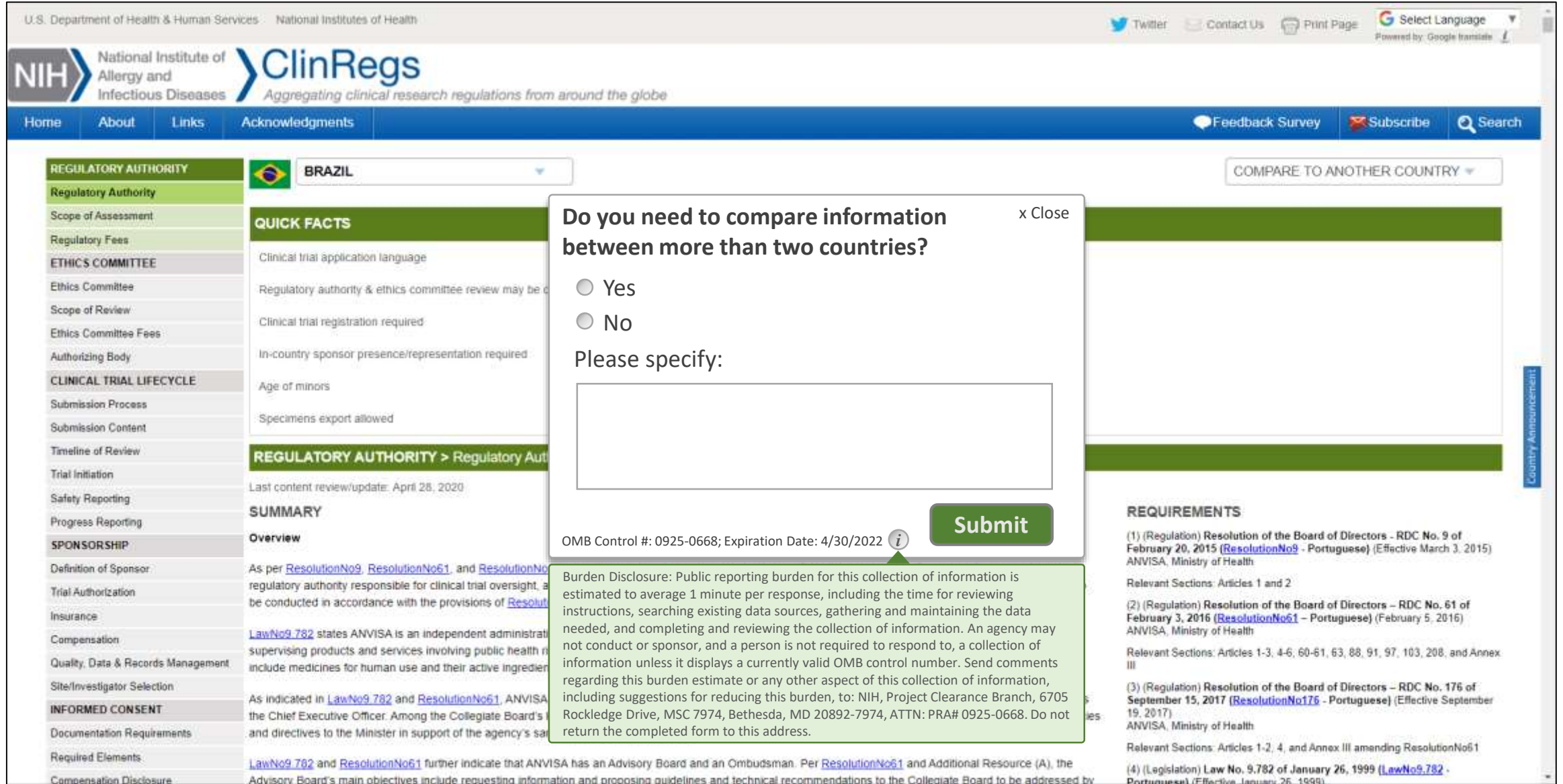
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176 - Portuguese](#)) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782 - Portuguese](#)) (Effective January 26, 1999)

Pop-Up Question 4.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website interface. At the top, there is a navigation bar with links for Home, About, Links, and Acknowledgments. The main content area is divided into a left sidebar with a table of contents and a main content area. The table of contents includes sections like REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP. The main content area is currently displaying the 'REGULATORY AUTHORITY' section for Brazil. A pop-up window is overlaid on the page, asking the user: 'Do you need to compare information between more than two countries?'. The pop-up has two radio button options: 'Yes' and 'No'. Below the options is a text input field labeled 'Please specify:'. A green 'Submit' button is located at the bottom right of the pop-up. A small info icon is visible next to the OMB Control number: '0925-0668; Expiration Date: 4/30/2022'. A green box highlights the Burden Disclosure text at the bottom of the pop-up.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY BRAZIL COMPARE TO ANOTHER COUNTRY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be conducted in Portuguese

Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health and safety, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by the Chief Executive Officer. Among the Collegiate Board's main objectives are to issue resolutions and directives to the Minister in support of the agency's activities.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Board.


Do you need to compare information between more than two countries? x Close

Yes

No

Please specify:

Submit

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

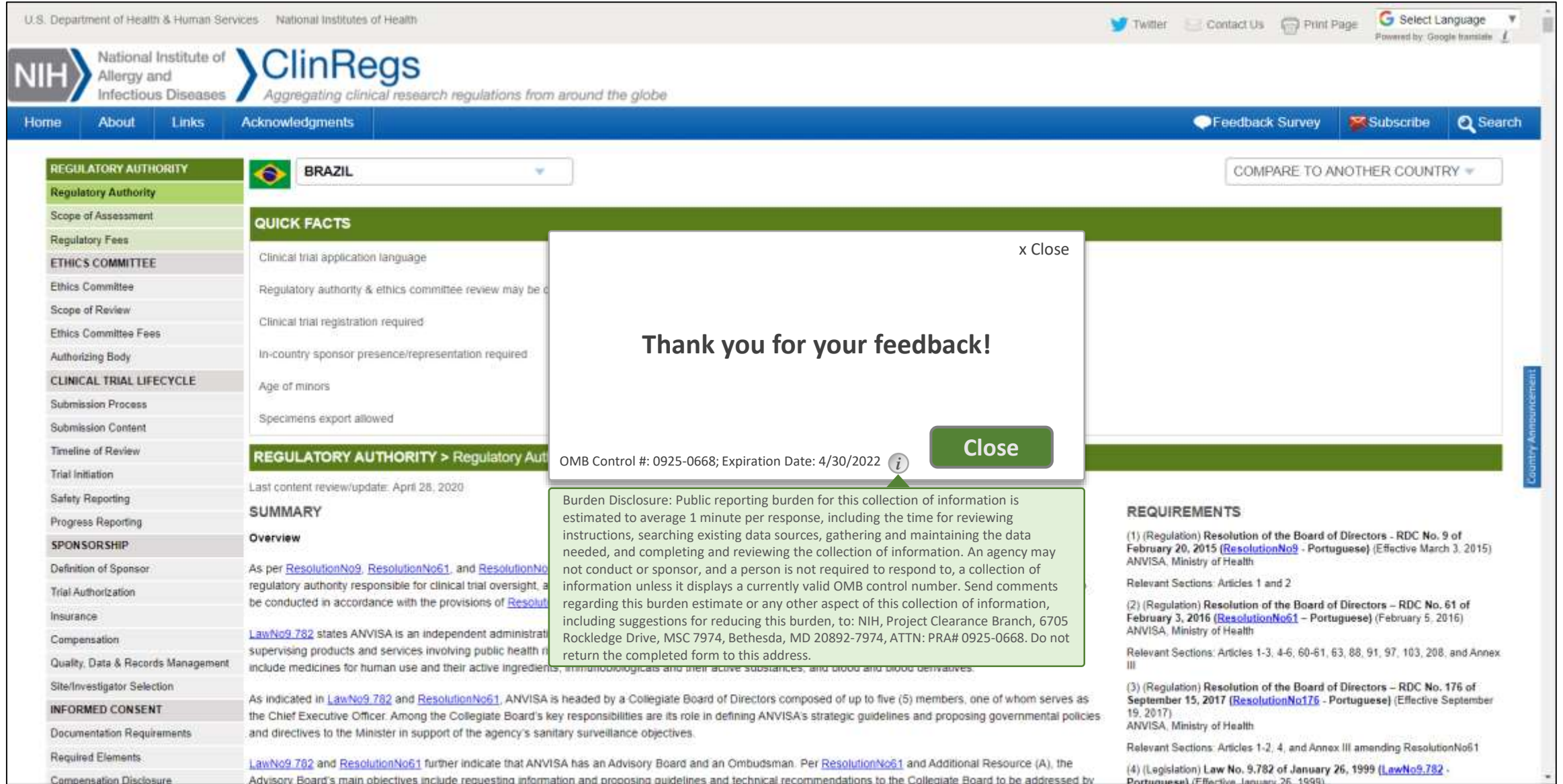
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 4.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and a SUMMARY section. A feedback pop-up is overlaid on the page, and a green box highlights the Burden Disclosure text.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be conducted


Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo61](#) and [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health risk, including medicines for human use and their active ingredients, immunobiologicals and their active substances, and blood and blood derivatives.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by a Collegiate Board of Directors composed of up to five (5) members, one of whom serves as the Chief Executive Officer. Among the Collegiate Board's key responsibilities are its role in defining ANVISA's strategic guidelines and proposing governmental policies and directives to the Minister in support of the agency's sanitary surveillance objectives.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

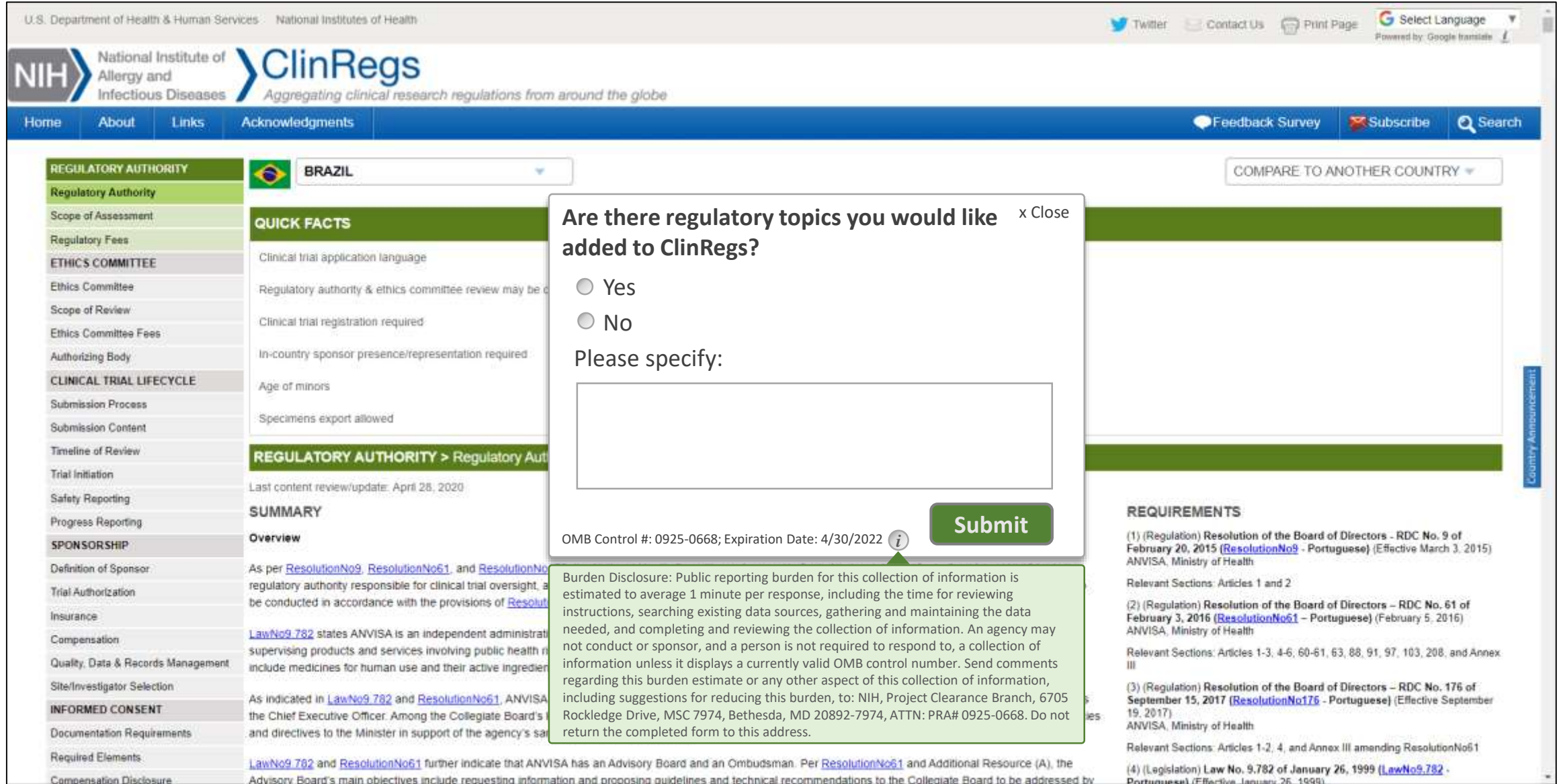
Thank you for your feedback!

x Close

Close

Pop-Up Question 5.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP, and a main content area with QUICK FACTS and REGULATORY AUTHORITY details. A pop-up survey is overlaid on the page, asking if there are regulatory topics to be added to ClinRegs, with 'Yes' and 'No' radio buttons, a 'Please specify:' text box, and a 'Submit' button. Below the pop-up, a green box contains the Burden Disclosure text.

REGULATORY AUTHORITY BRAZIL

QUICK FACTS

- Clinical trial application language
- Regulatory authority & ethics committee review may be required
- Clinical trial registration required
- In-country sponsor presence/representation required
- Age of minors
- Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#).

[LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health risk, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by the Chief Executive Officer. Among the Collegiate Board's main objectives are to issue resolutions and directives to the Minister in support of the agency's activities.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Board.

REQUIREMENTS

- (1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health
Relevant Sections: Articles 1 and 2
- (2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health
Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III
- (3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61
- (4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)


Pop-up Question: Are there regulatory topics you would like added to ClinRegs?

Yes

No

Please specify:

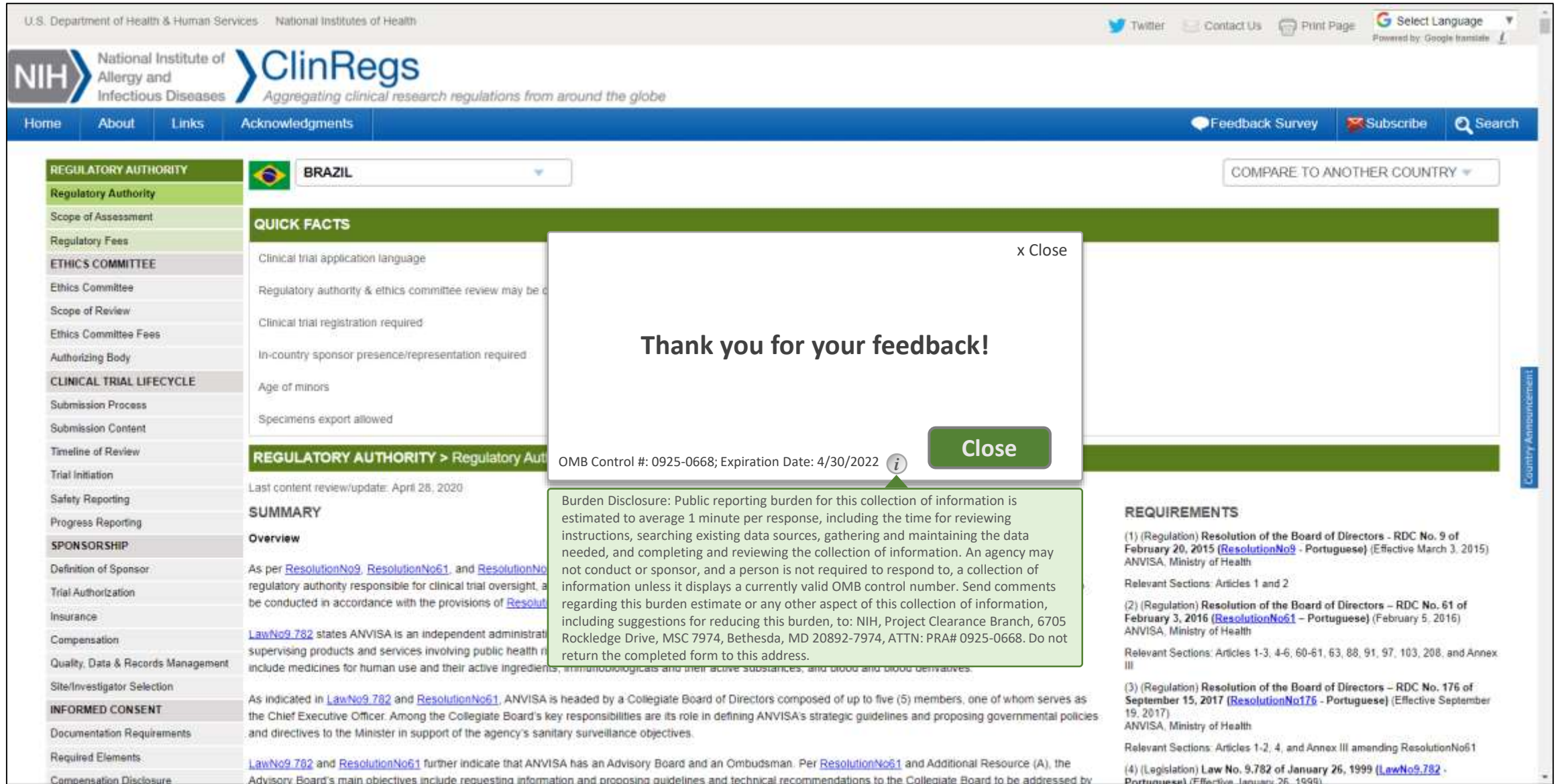
Submit

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

Pop-Up Question 5.

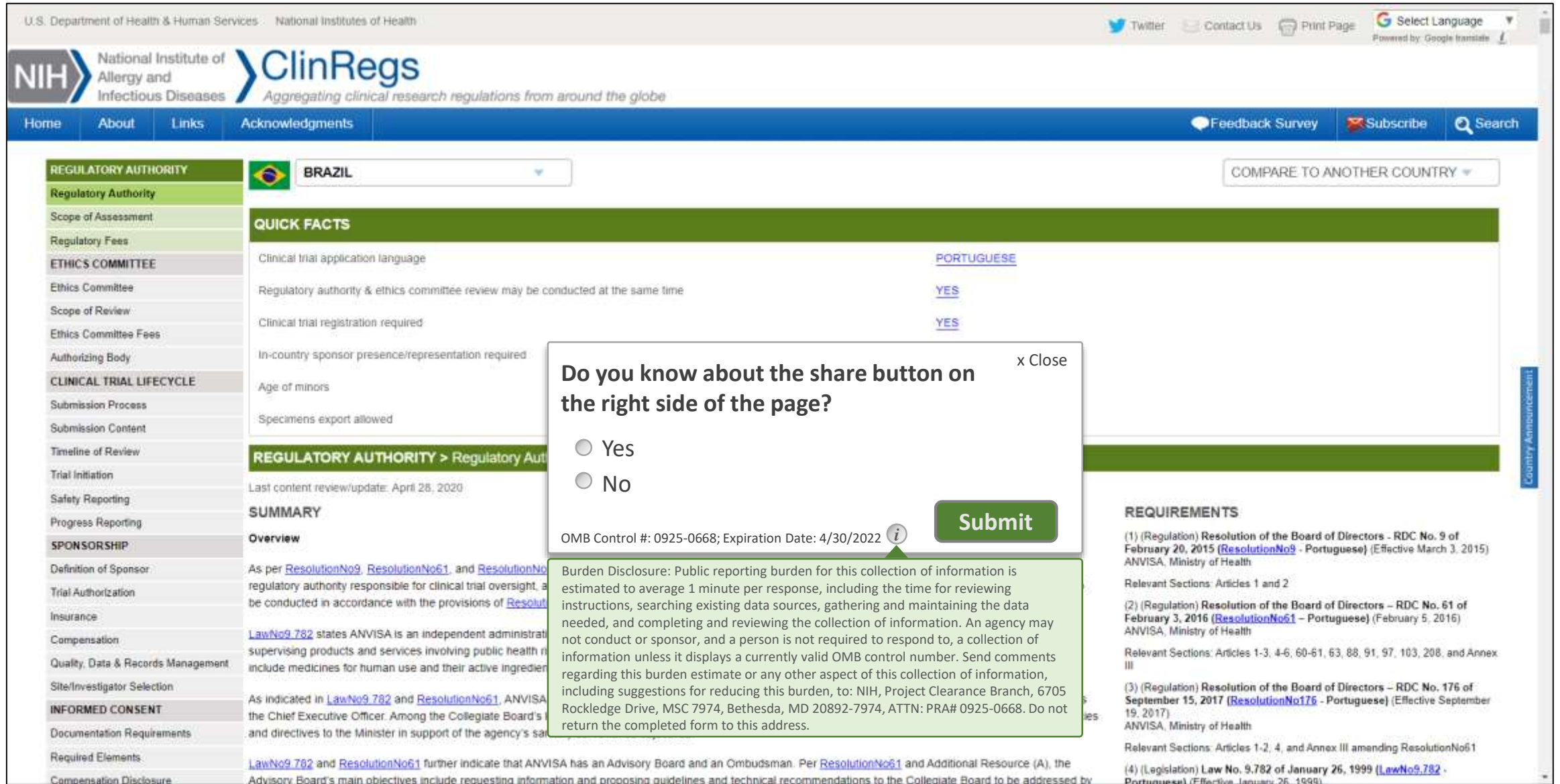
Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website interface. At the top, there is a navigation bar with links for Home, About, Links, and Acknowledgments. The main content area is divided into sections: REGULATORY AUTHORITY (with a dropdown menu set to BRAZIL), QUICK FACTS, REGULATORY AUTHORITY > Regulatory Authority, SUMMARY, and REQUIREMENTS. A feedback pop-up window is overlaid on the page, displaying "Thank you for your feedback!" and a "Close" button. Below the pop-up, a green box highlights the Burden Disclosure text, which states: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address." The OMB Control # is 0925-0668 and the Expiration Date is 4/30/2022. The website also features a "Feedback Survey" button and a "Search" bar.

Pop-Up Question 6.

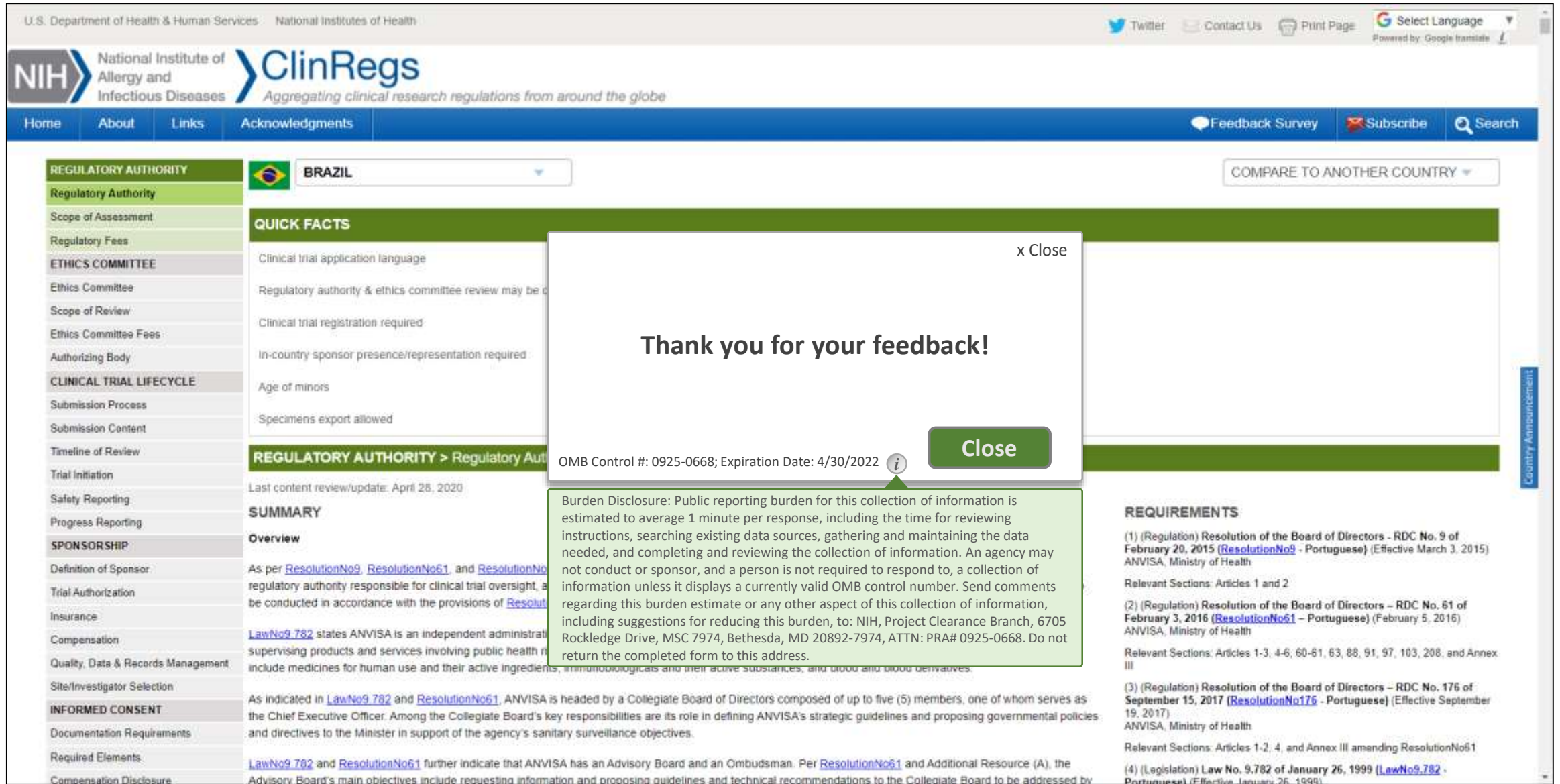
Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and REGULATORY AUTHORITY > Regulatory Authority. A pop-up question asks, "Do you know about the share button on the right side of the page?" with "Yes" and "No" radio buttons and a "Submit" button. A green box highlights a burden disclosure: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address."

Pop-Up Question 6.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and a SUMMARY section. A feedback pop-up is centered on the page, and a green box highlights the Burden Disclosure text in the SUMMARY section.

REGULATORY AUTHORITY BRAZIL

QUICK FACTS

- Clinical trial application language
- Regulatory authority & ethics committee review may be required
- Clinical trial registration required
- In-country sponsor presence/representation required
- Age of minors
- Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Close

Thank you for your feedback!

Close

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health that include medicines for human use and their active ingredients, immunobiologicals and their active substances, and blood and blood derivatives.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by a Collegiate Board of Directors composed of up to five (5) members, one of whom serves as the Chief Executive Officer. Among the Collegiate Board's key responsibilities are its role in defining ANVISA's strategic guidelines and proposing governmental policies and directives to the Minister in support of the agency's sanitary surveillance objectives.

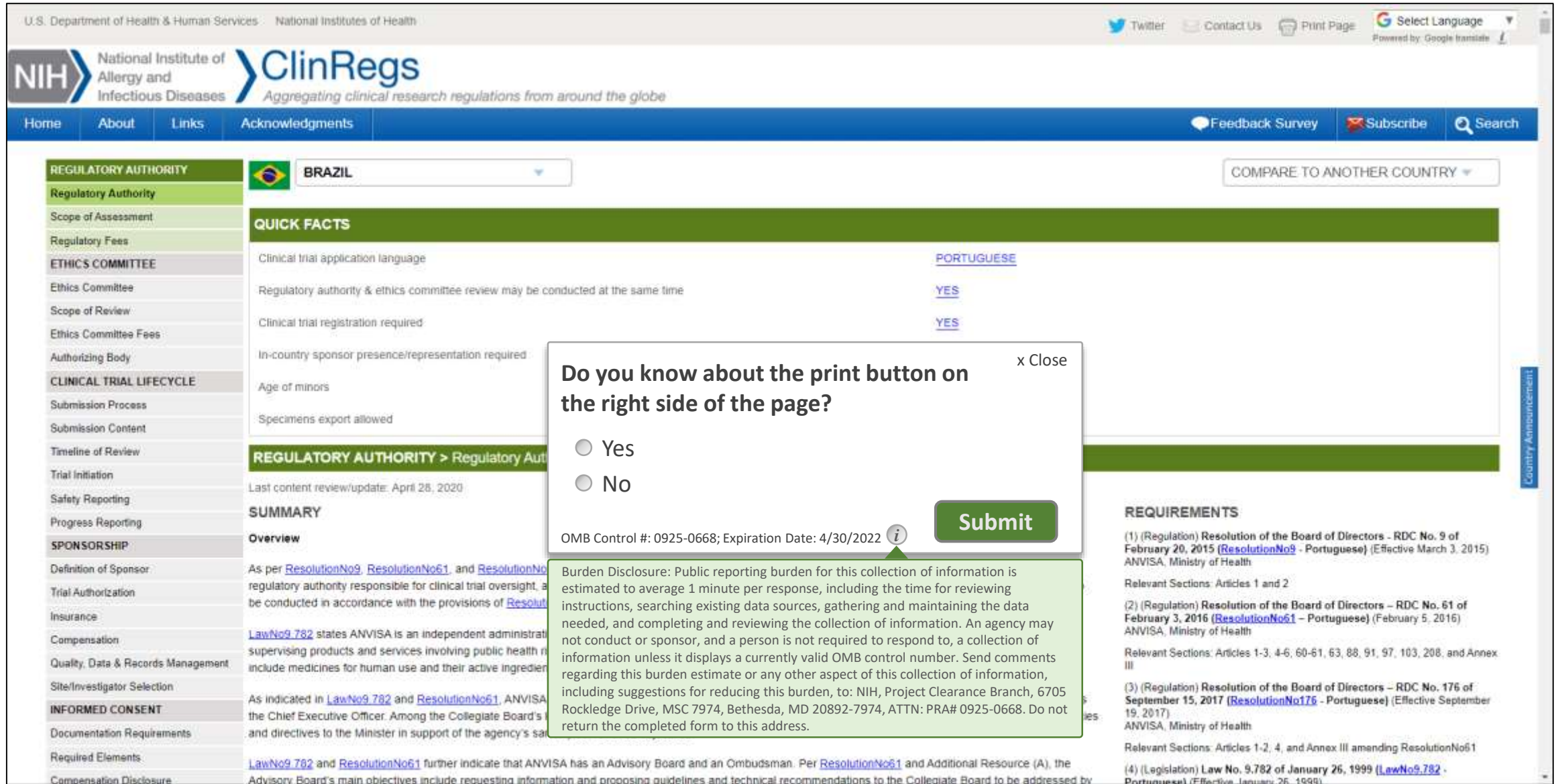
[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by

REQUIREMENTS

- (1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health
Relevant Sections: Articles 1 and 2
- (2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health
Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III
- (3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61
- (4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 7.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and REGULATORY AUTHORITY details. A pop-up question is overlaid on the page, asking about a print button. The burden disclosure text is also visible in a green box.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language [PORTUGUESE](#)

Regulatory authority & ethics committee review may be conducted at the same time [YES](#)

Clinical trial registration required [YES](#)

In-country sponsor presence/representation required

Age of minors


Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

Do you know about the print button on the right side of the page? x Close

Yes

No

Submit

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9 - Portuguese](#)) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61 - Portuguese](#)) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176 - Portuguese](#)) (Effective September 19, 2017) ANVISA, Ministry of Health

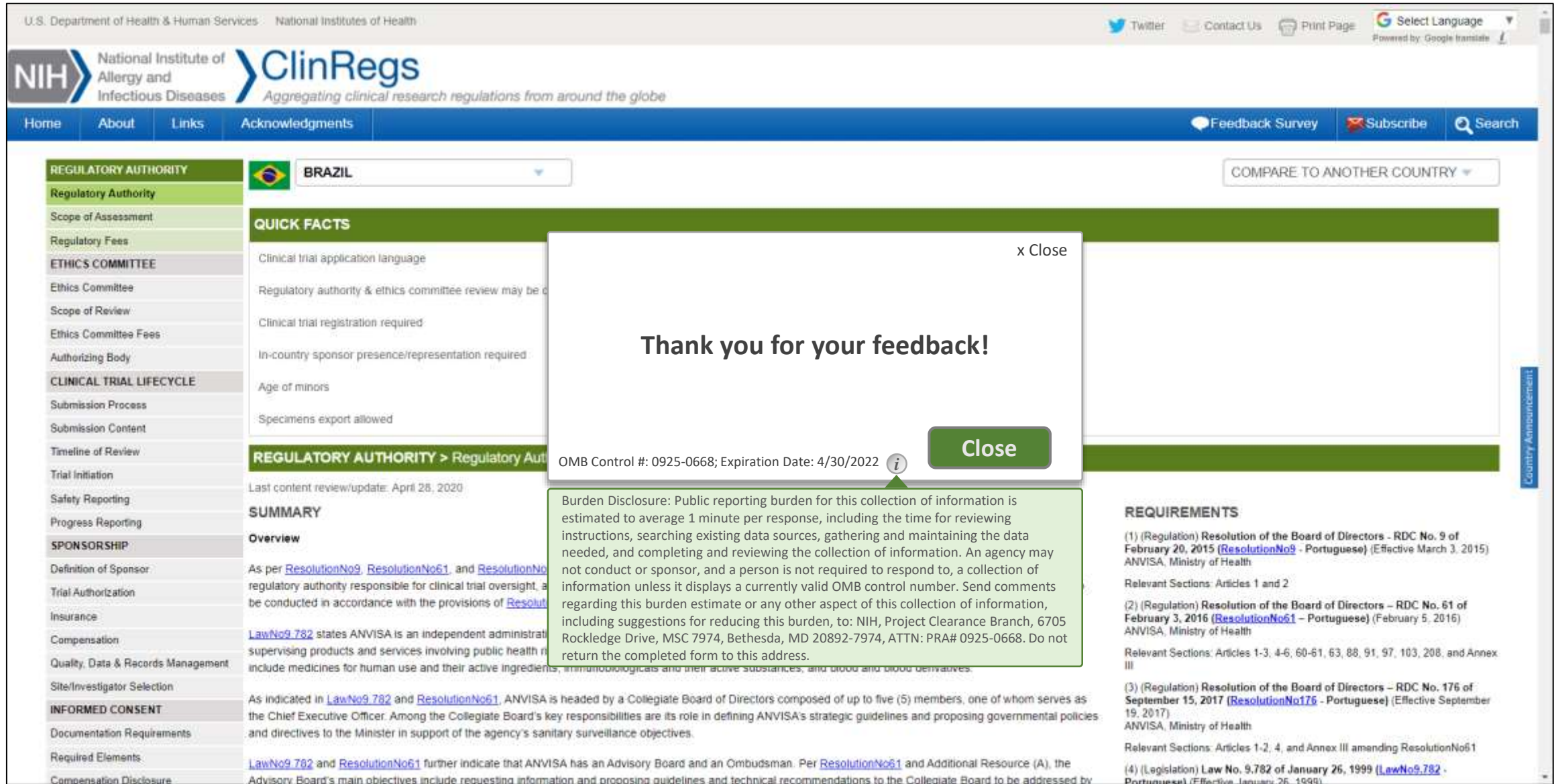
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782 - Portuguese](#)) (Effective January 26, 1999)

Country Announcement

Pop-Up Question 7.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface. At the top, there are navigation links for Home, About, Links, and Acknowledgments, along with utility links for Feedback Survey, Subscribe, and Search. The main content area is for the Regulatory Authority section, currently set to BRAZIL. A sidebar on the left lists various categories like Regulatory Authority, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP. A central pop-up window displays "Thank you for your feedback!" with a "Close" button. Below the pop-up, a green box highlights the Burden Disclosure text, which is also linked to an information icon. The bottom right of the page lists "REQUIREMENTS" with several regulatory references.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be conducted in Portuguese


Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo9](#) and [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health that include medicines for human use and their active ingredients, immunobiologicals and their active substances, and blood and blood derivatives.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by a Collegiate Board of Directors composed of up to five (5) members, one of whom serves as the Chief Executive Officer. Among the Collegiate Board's key responsibilities are its role in defining ANVISA's strategic guidelines and proposing governmental policies and directives to the Minister in support of the agency's sanitary surveillance objectives.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by

x Close

Thank you for your feedback!

Close

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

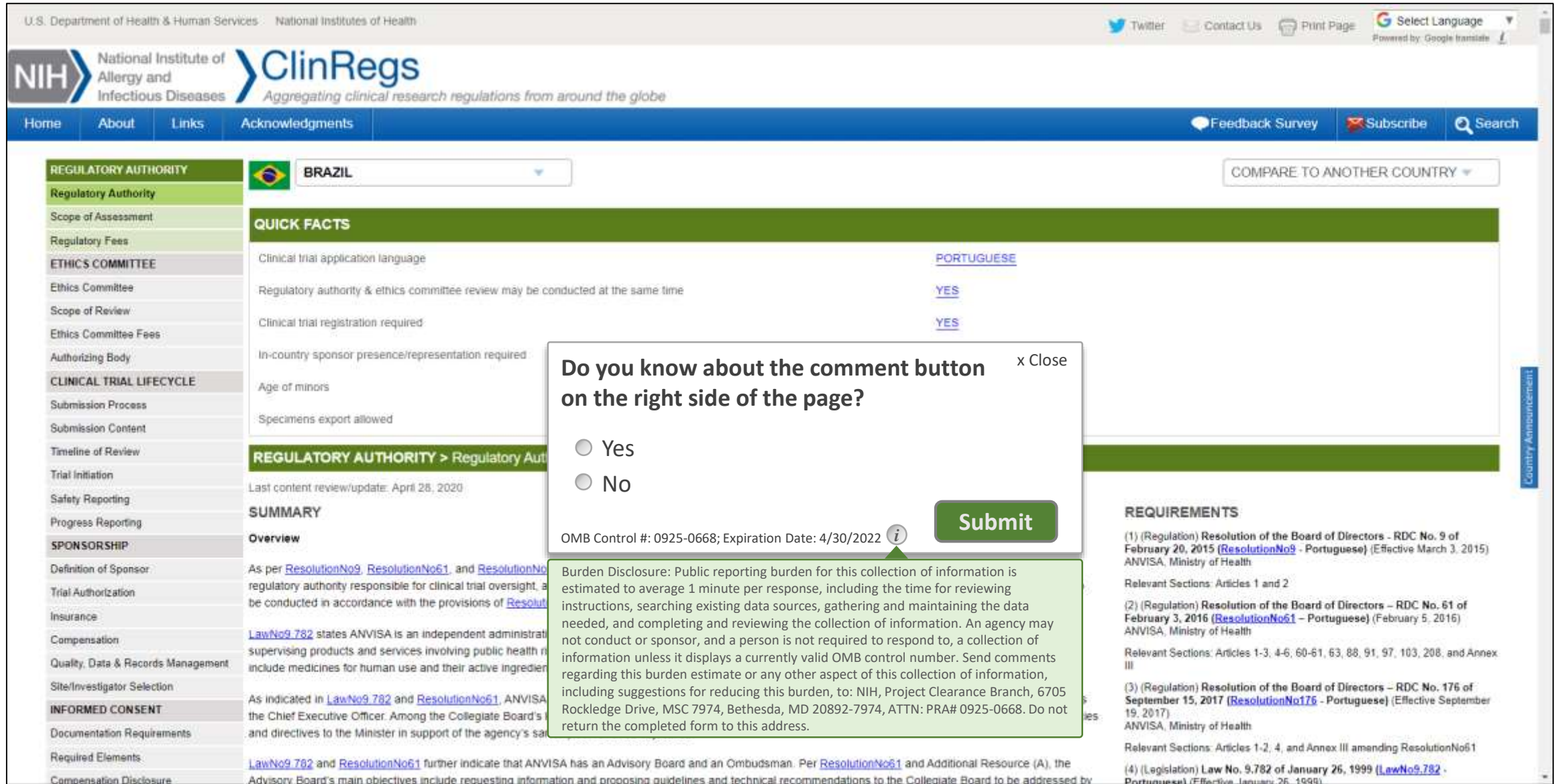
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Country Announcement

Pop-Up Question 8.

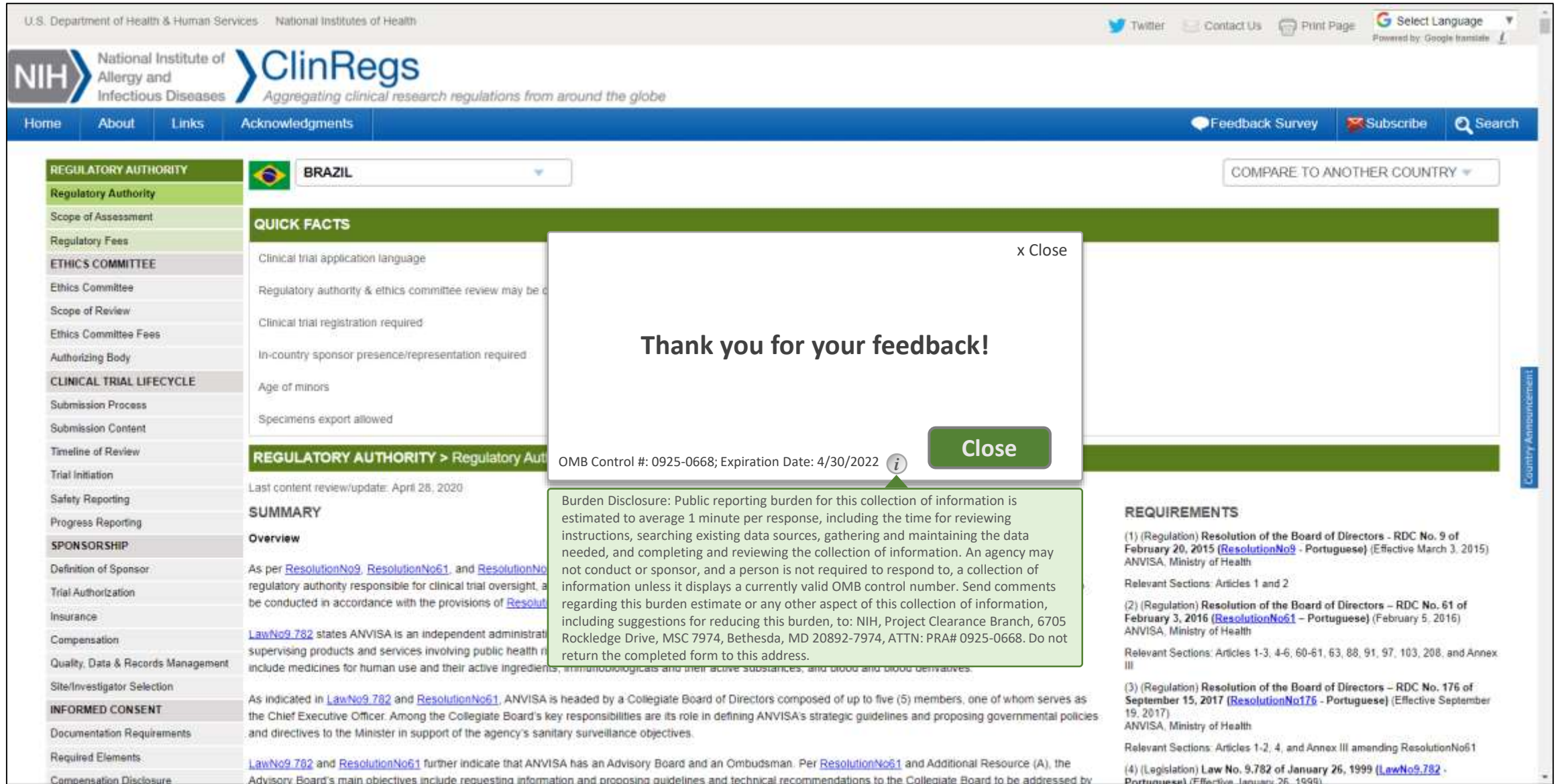
Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and a SUMMARY section. A pop-up question asks, "Do you know about the comment button on the right side of the page?" with "Yes" and "No" radio buttons and a "Submit" button. A green box highlights a burden disclosure text: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address." The OMB Control # 0925-0668 and Expiration Date 4/30/2022 are also visible.

Pop-Up Question 8.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface. At the top, there is a navigation bar with links for Home, About, Links, and Acknowledgments. A search bar and a 'Feedback Survey' button are also present. The main content area is divided into sections: REGULATORY AUTHORITY (with a dropdown menu set to BRAZIL), QUICK FACTS, REGULATORY AUTHORITY > Regulatory Authority, SUMMARY, and REQUIREMENTS. A feedback pop-up is overlaid on the page, displaying 'Thank you for your feedback!' and a 'Close' button. Below the pop-up, a green box highlights the Burden Disclosure text, which is preceded by an information icon (i) and the text 'OMB Control #: 0925-0668; Expiration Date: 4/30/2022'.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate


NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Thank you for your feedback!

Close

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

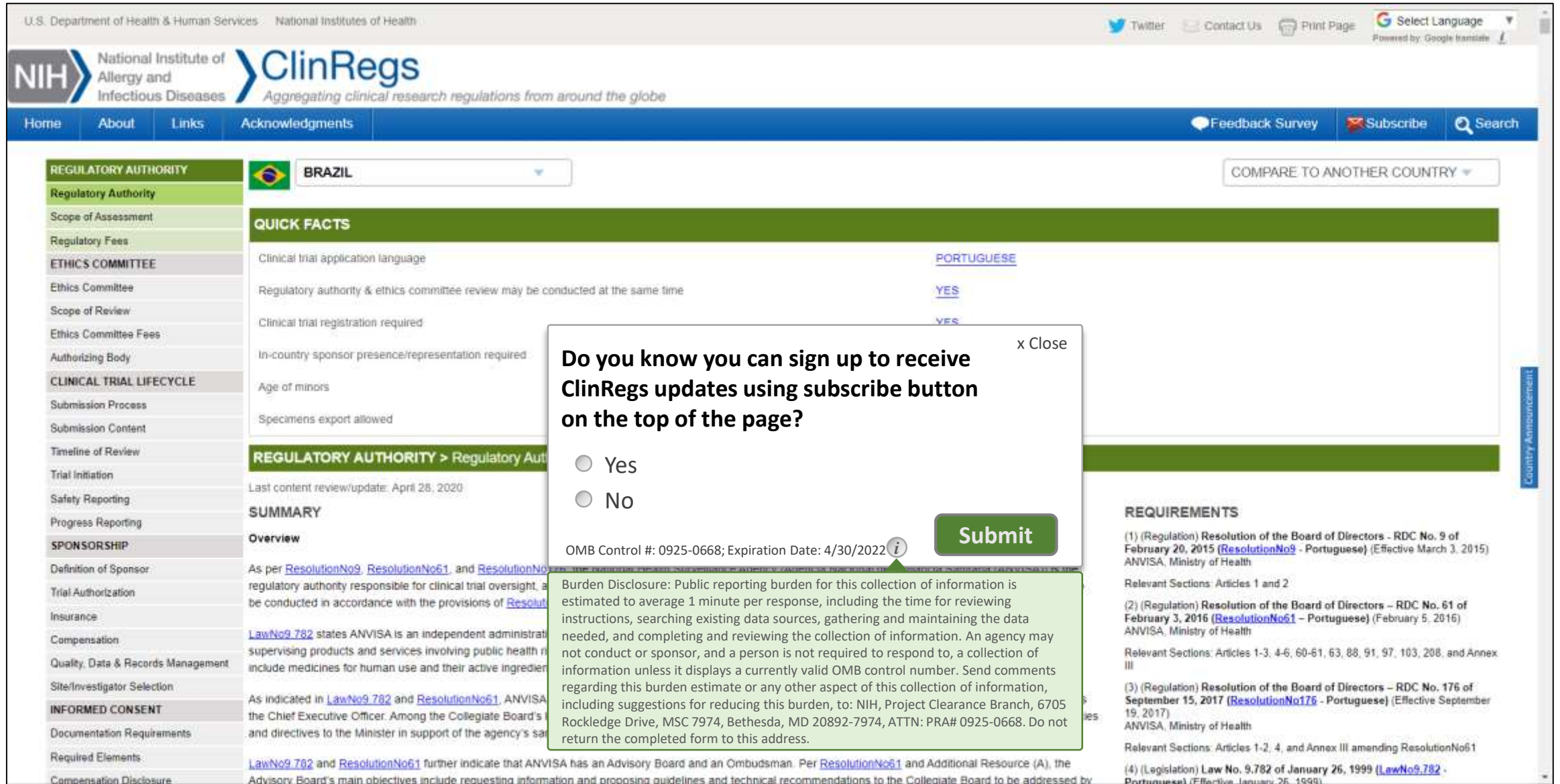
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 9.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP, and a main content area with QUICK FACTS and REGULATORY AUTHORITY details. A pop-up question asks if the user knows they can sign up for updates, with 'Yes' and 'No' radio buttons and a 'Submit' button. A green burden disclosure box is overlaid on the page, providing information about the public reporting burden for this collection of information.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY BRAZIL COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

QUICK FACTS

Clinical trial application language [PORTUGUESE](#)

Regulatory authority & ethics committee review may be conducted at the same time [YES](#)

Clinical trial registration required [YES](#)

In-country sponsor presence/representation required

Age of minors


Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9 - Portuguese](#)) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61 - Portuguese](#)) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176 - Portuguese](#)) (Effective September 19, 2017) ANVISA, Ministry of Health

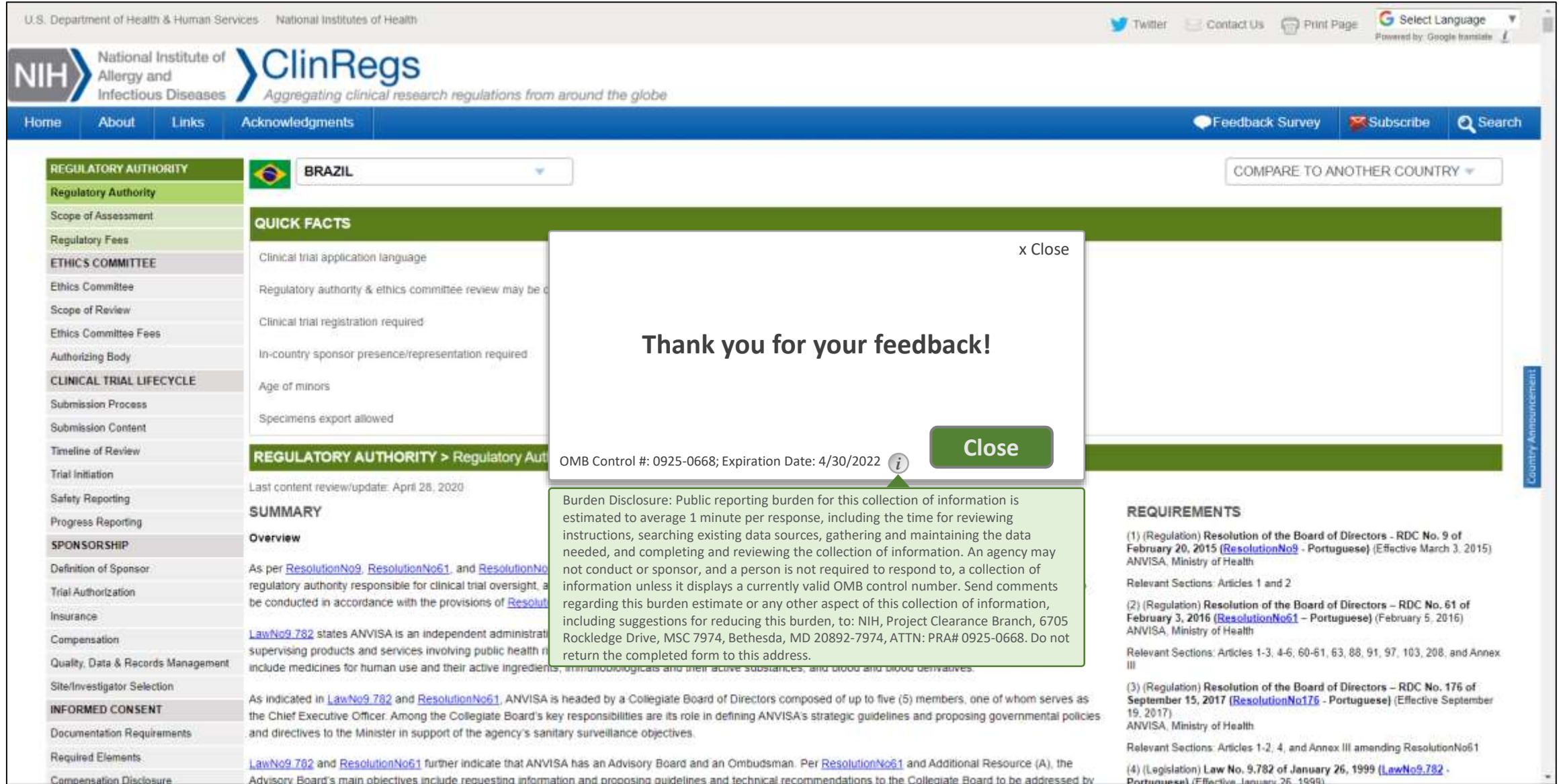
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782 - Portuguese](#)) (Effective January 26, 1999)

Country Announcement

Pop-Up Question 9.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and a SUMMARY section. A feedback pop-up is centered on the screen, and a green box highlights the Burden Disclosure text in the SUMMARY section.

REGULATORY AUTHORITY BRAZIL

QUICK FACTS

- Clinical trial application language
- Regulatory authority & ethics committee review may be required
- Clinical trial registration required
- In-country sponsor presence/representation required
- Age of minors
- Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Close

Thank you for your feedback!

Close

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, a clinical trial may be conducted in accordance with the provisions of [ResolutionNo61](#). [LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health that include medicines for human use and their active ingredients, immunobiologicals and their active substances, and blood and blood derivatives.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by a Collegiate Board of Directors composed of up to five (5) members, one of whom serves as the Chief Executive Officer. Among the Collegiate Board's key responsibilities are its role in defining ANVISA's strategic guidelines and proposing governmental policies and directives to the Minister in support of the agency's sanitary surveillance objectives.

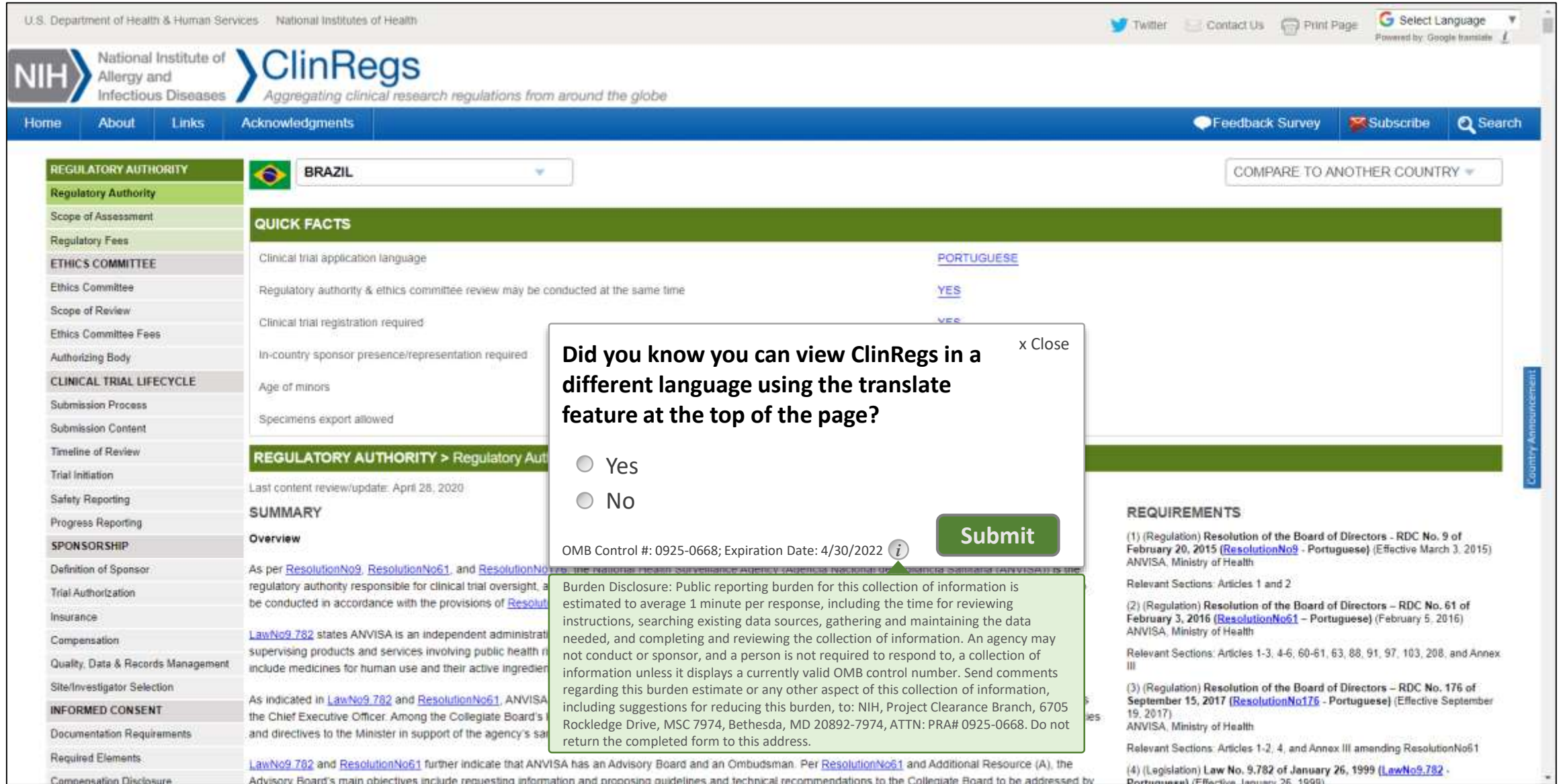
[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by

REQUIREMENTS

- (1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health
Relevant Sections: Articles 1 and 2
- (2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health
Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III
- (3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61
- (4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 10.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and REGULATORY AUTHORITY details. A pop-up question is overlaid on the page, and a burden disclosure is visible at the bottom of the main content area.

REGULATORY AUTHORITY BRAZIL

QUICK FACTS

- Clinical trial application language: [PORTUGUESE](#)
- Regulatory authority & ethics committee review may be conducted at the same time: [YES](#)
- Clinical trial registration required: [YES](#)
- In-country sponsor presence/representation required: [YES](#)
- Age of minors: [YES](#)
- Specimens export allowed: [YES](#)

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020

SUMMARY

Overview

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

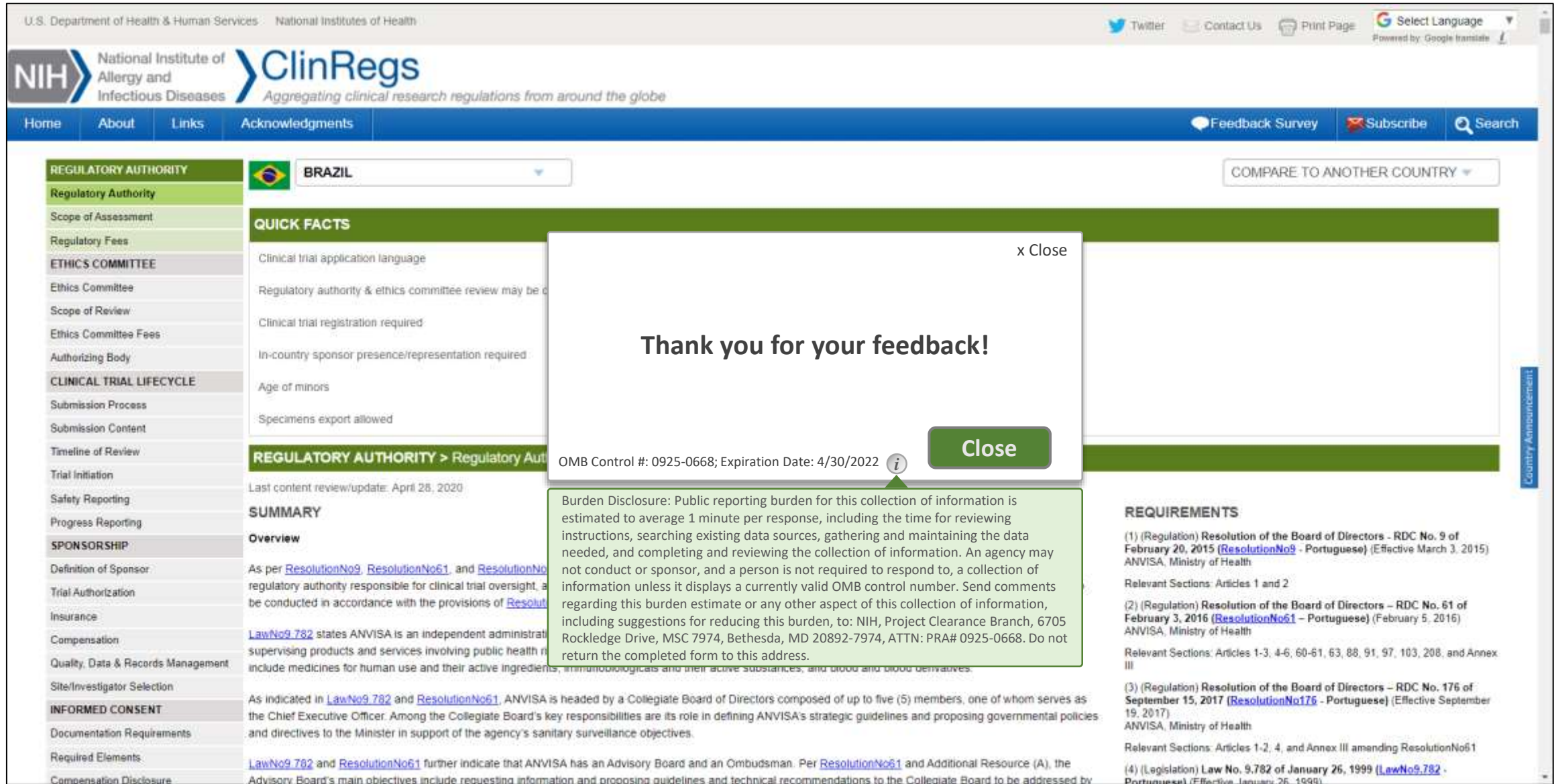
Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

- (1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health
Relevant Sections: Articles 1 and 2
- (2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health
Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III
- (3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health
Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61
- (4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 10.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and a SUMMARY section. A feedback pop-up is overlaid on the page, and a tooltip displays the Burden Disclosure text.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate


NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Thank you for your feedback!

x Close

Close

BURDEN DISCLOSURE: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9 - Portuguese](#)) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61 - Portuguese](#)) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

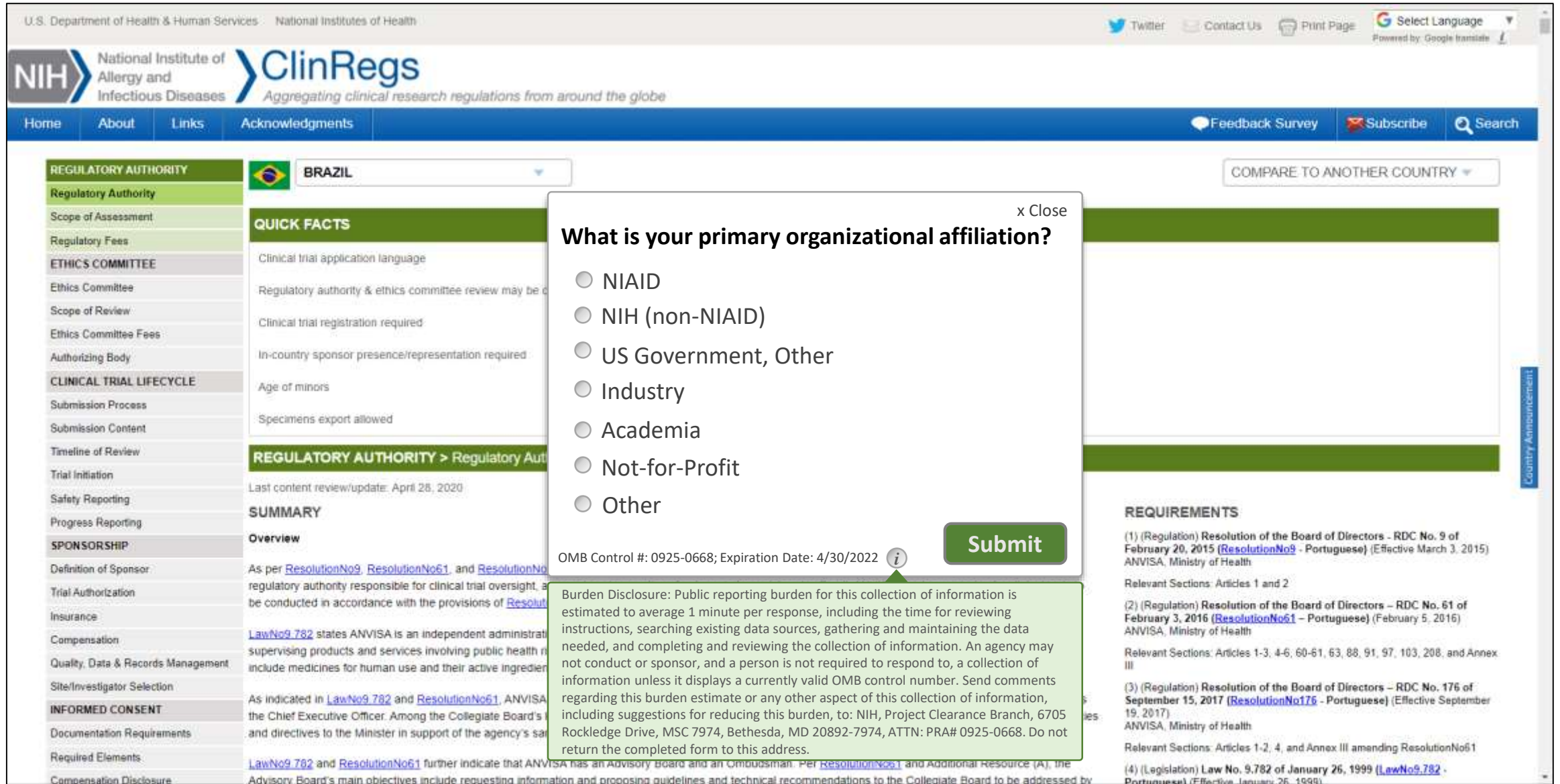
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176 - Portuguese](#)) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782 - Portuguese](#)) (Effective January 26, 1999)

Pop-Up Question 11.

Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with various regulatory categories, and a main content area. A pop-up form titled "What is your primary organizational affiliation?" is overlaid on the page, featuring a list of radio button options and a "Submit" button. Below the pop-up, a green box contains a "Burden Disclosure" text. The website header includes the NIH logo, "National Institute of Allergy and Infectious Diseases", and "ClinRegs Aggregating clinical research regulations from around the globe". The top right corner has links for Twitter, Contact Us, Print Page, and Select Language. The sidebar lists categories such as REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP. The main content area shows "QUICK FACTS" and "REGULATORY AUTHORITY > Regulatory Authority".

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY BRAZIL COMPARE TO ANOTHER COUNTRY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be conducted

Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Authority

Last content review/update: April 28, 2020


SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#), regulatory authority responsible for clinical trial oversight, and may be conducted in accordance with the provisions of [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo61](#).

[LawNo9.782](#) states ANVISA is an independent administrative agency supervising products and services involving public health and safety, including medicines for human use and their active ingredients.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by the Chief Executive Officer. Among the Collegiate Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by the Collegiate Board.

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

What is your primary organizational affiliation? x Close

- NIAID
- NIH (non-NIAID)
- US Government, Other
- Industry
- Academia
- Not-for-Profit
- Other

Submit

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

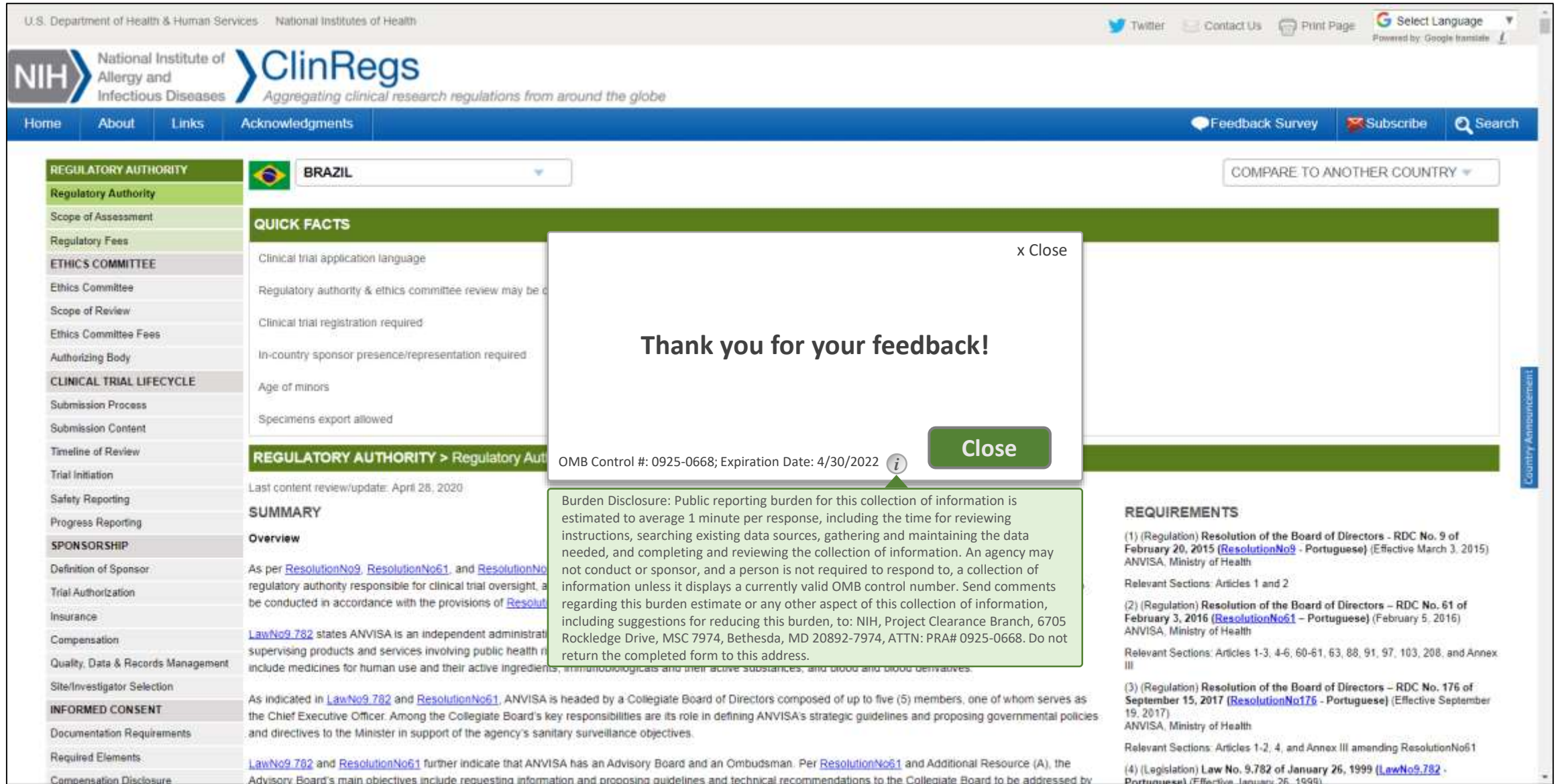
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Pop-Up Question 11.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, and SPONSORSHIP, and a main content area with QUICK FACTS and SUMMARY sections. A feedback pop-up is centered on the screen, and a tooltip is visible over an information icon in the OMB Control # field.

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate


NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL

COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY > Regulatory Authority

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Thank you for your feedback! x Close

Close

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9 - Portuguese](#)) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61 - Portuguese](#)) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

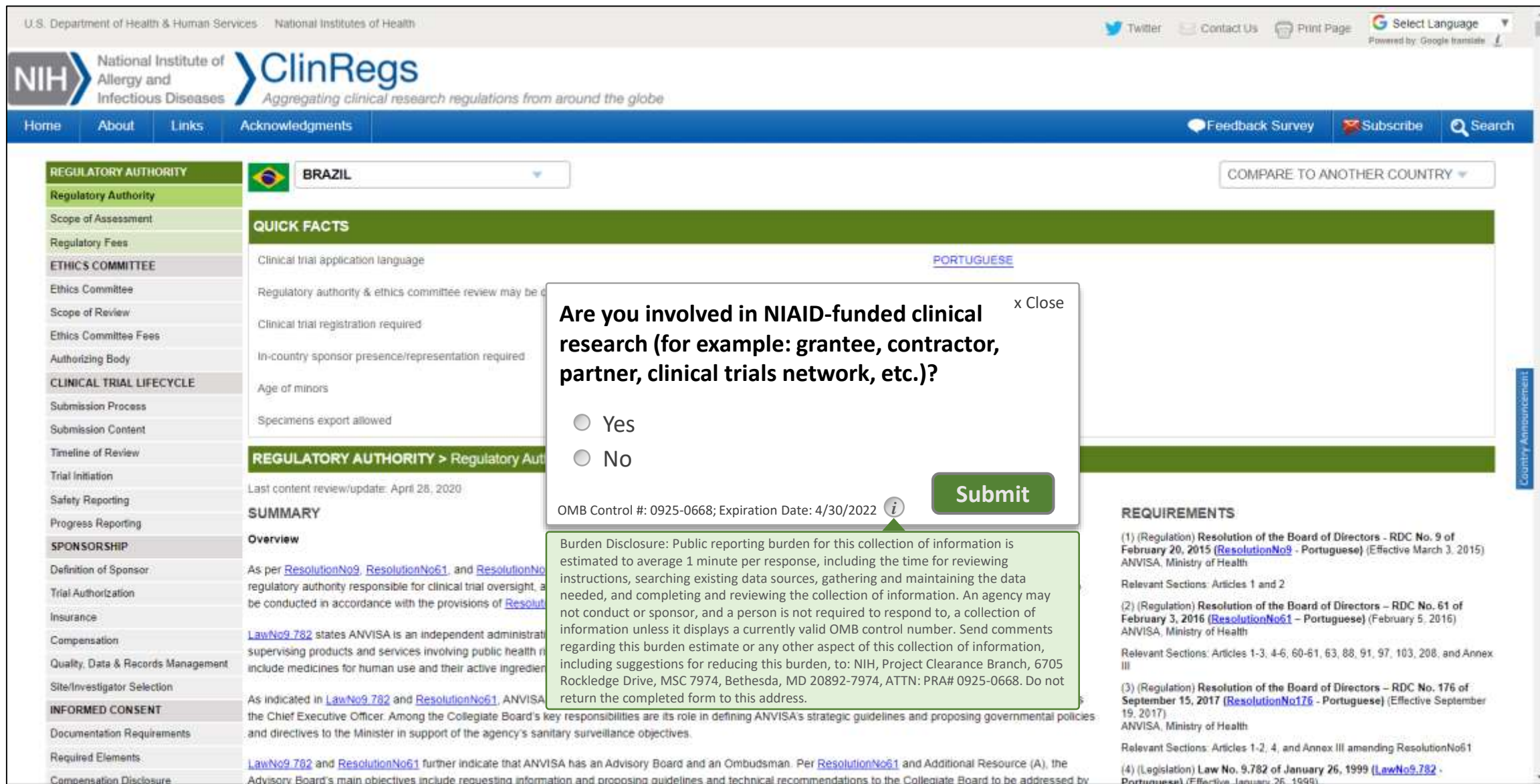
(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176 - Portuguese](#)) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782 - Portuguese](#)) (Effective January 26, 1999)


Pop-Up Question 12.

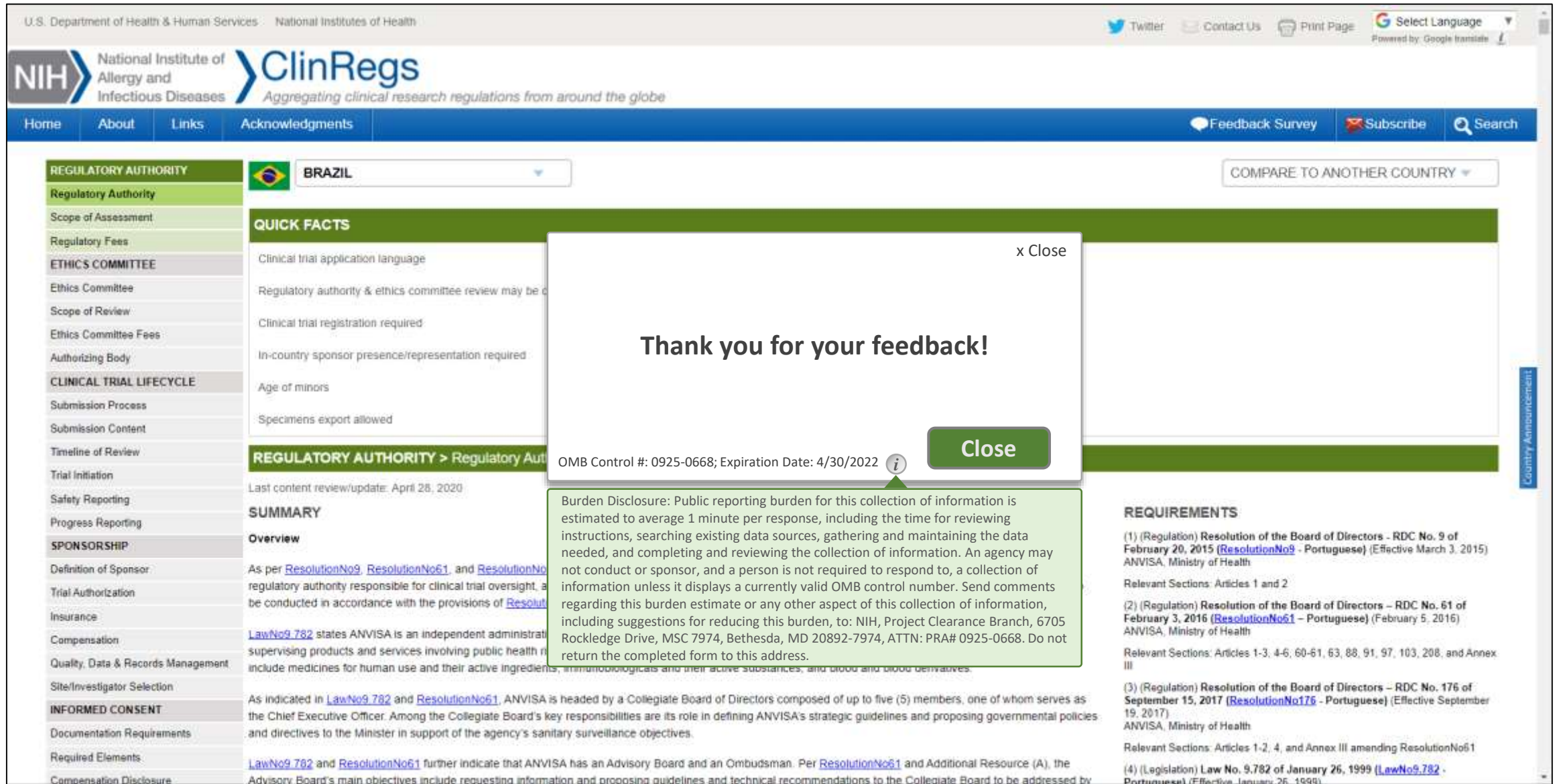
Burden disclosure displayed when user clicks on or hovers over 



The screenshot shows the NIH ClinRegs website for Brazil. The page includes a navigation menu, a sidebar with categories like REGULATORY AUTHORITY, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, SPONSORSHIP, and INFORMED CONSENT, and a main content area with QUICK FACTS and REGULATORY AUTHORITY details. A pop-up survey asks: "Are you involved in NIAID-funded clinical research (for example: grantee, contractor, partner, clinical trials network, etc.)?" with radio buttons for "Yes" and "No", and a "Submit" button. A burden disclosure box is also visible, stating: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address."

Pop-Up Question 12.

Burden disclosure displayed when user clicks on or hovers over 




The screenshot shows the NIH ClinRegs website interface. At the top, there are navigation links for Home, About, Links, and Acknowledgments, along with utility links for Feedback Survey, Subscribe, and Search. The main content area is for the Regulatory Authority section, currently set to BRAZIL. A sidebar on the left lists various categories like Regulatory Authority, ETHICS COMMITTEE, CLINICAL TRIAL LIFECYCLE, and SPONSORSHIP. A central pop-up window displays "Thank you for your feedback!" with a "Close" button. Below the pop-up, a green box highlights the Burden Disclosure text, which is also linked to by an info icon in the OMB Control # field. The OMB Control # is 0925-0668, with an expiration date of 4/30/2022. The Burden Disclosure text states: "Burden Disclosure: Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address."

U.S. Department of Health & Human Services · National Institutes of Health

Twitter Contact Us Print Page Select Language
Powered by Google Translate

NIH National Institute of Allergy and Infectious Diseases
ClinRegs Aggregating clinical research regulations from around the globe

Home About Links Acknowledgments Feedback Survey Subscribe Search

REGULATORY AUTHORITY  BRAZIL COMPARE TO ANOTHER COUNTRY

REGULATORY AUTHORITY

Regulatory Authority

Scope of Assessment

Regulatory Fees

ETHICS COMMITTEE

Ethics Committee

Scope of Review

Ethics Committee Fees

Authorizing Body

CLINICAL TRIAL LIFECYCLE

Submission Process

Submission Content

Timeline of Review

Trial Initiation

Safety Reporting

Progress Reporting

SPONSORSHIP

Definition of Sponsor

Trial Authorization

Insurance

Compensation

Quality, Data & Records Management

Site/Investigator Selection

INFORMED CONSENT

Documentation Requirements

Required Elements

Compensation Disclosure

QUICK FACTS

Clinical trial application language

Regulatory authority & ethics committee review may be c


Clinical trial registration required

In-country sponsor presence/representation required

Age of minors

Specimens export allowed

REGULATORY AUTHORITY > Regulatory Aut

OMB Control #: 0925-0668; Expiration Date: 4/30/2022 

Last content review/update: April 28, 2020

SUMMARY

Overview

As per [ResolutionNo9](#), [ResolutionNo61](#), and [ResolutionNo](#) regulatory authority responsible for clinical trial oversight, a be conducted in accordance with the provisions of [Resolut](#)

[LawNo9.782](#) states ANVISA is an independent administrat supervising products and services involving public health n include medicines for human use and their active ingredients, immunobiologicals and their active substances, and blood and blood derivatives.

As indicated in [LawNo9.782](#) and [ResolutionNo61](#), ANVISA is headed by a Collegiate Board of Directors composed of up to five (5) members, one of whom serves as the Chief Executive Officer. Among the Collegiate Board's key responsibilities are its role in defining ANVISA's strategic guidelines and proposing governmental policies and directives to the Minister in support of the agency's sanitary surveillance objectives.

[LawNo9.782](#) and [ResolutionNo61](#) further indicate that ANVISA has an Advisory Board and an Ombudsman. Per [ResolutionNo61](#) and Additional Resource (A), the Advisory Board's main objectives include requesting information and proposing guidelines and technical recommendations to the Collegiate Board to be addressed by

x Close

Thank you for your feedback!

Close

REQUIREMENTS

(1) (Regulation) Resolution of the Board of Directors - RDC No. 9 of February 20, 2015 ([ResolutionNo9](#) - Portuguese) (Effective March 3, 2015) ANVISA, Ministry of Health

Relevant Sections: Articles 1 and 2

(2) (Regulation) Resolution of the Board of Directors - RDC No. 61 of February 3, 2016 ([ResolutionNo61](#) - Portuguese) (February 5, 2016) ANVISA, Ministry of Health

Relevant Sections: Articles 1-3, 4-6, 60-61, 63, 88, 91, 97, 103, 208, and Annex III

(3) (Regulation) Resolution of the Board of Directors - RDC No. 176 of September 15, 2017 ([ResolutionNo176](#) - Portuguese) (Effective September 19, 2017) ANVISA, Ministry of Health

Relevant Sections: Articles 1-2, 4, and Annex III amending ResolutionNo61

(4) (Legislation) Law No. 9.782 of January 26, 1999 ([LawNo9.782](#) - Portuguese) (Effective January 26, 1999)

Country Announcement