

**The English version of this Decree was prepared in order to help comprehension by non-Italian mother tongue users, but it is NOT an official document. Please, refer to the Italian version for the only official document.**

RESOLUTION 23<sup>rd</sup> December 2008.

Self-certification of the minimum requirements of the Contract Research Organisation (CRO) within the field of clinical trials of medicines according to article 7, sub-article 5 and 6, and of article 8 of the ministerial decree 31 March 2008.

#### The Director General

Having regard to article 8 and 9 of the legislative decree 30 July 1999, n. 300;

Having regard to article 48 of the decree with the force of law 30 September 2003, n. 269, converted into law 24 November 2003, n. 326 afterwards called institutive law, which has established the Italian Medicines Agency, hereinafter called AIFA;

Having regard to the decree of the Minister of the Health in agreement with the Ministers of the Public Administration and of Economy and Finance of 20 September 2004 n. 245, which according to the sub-article 13 of the above mentioned article 48, has established the rules of the organisation and the functioning of AIFA;

Having regard to the Regulations of the organisation, administration and arrangement of personnel of the Italian Medicines Agency issued in the Official Gazette n. 149 of 29 June 2005;

Having regard to the legislative decree 30 March 2001, n. 165 and following modifications and integrations;

Having regard to the decree of the Minister of Labour and Social Affairs of 16 July 2008, registered by the Central Budget Office in the Simple Visa Register, sheet n. 803 on 18 July 2008, according to which Professor Guido Rasi has been appointed as Director General of the Italian Medicines Agency;

Having regard to the Ministerial Decree of 15 July 1997 concerning "Adoption of the European Union guidelines implementation of good clinical practice in the conduct of clinical trials of medicinal products for human use", published in the ordinary supplement of the Official Gazette n. 191 of 18 August 1997;

Having regard to Legislative Decree n. 211 of 24 June 2003 published in the ordinary supplement of the Official Gazette n. 184 of 9 August, 2003, concerning the "Transposition of 2001/20/EC Directive relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use";

Having regard, in particular, to article 20, sub-article 3 of the aforementioned Legislative Decree n. 211 of 24 June 2003, which foresees that with a Decree by the Ministry of Health the minimum requirements are established that private organizations must satisfy when they are delegated by sponsors to perform any or all of the trial-related functions in compliance with good clinical practice, without prejudice to the sponsor's responsibility for the correlated research, and considering that said organizations are considered Contract Research Organizations (CRO) pursuant to section 1.20 of Attachment 1 of the aforementioned Ministerial Decree 15 July 1997;

Having regard to ministerial decree 31 March 2008 concerning "Definition of the minimum requirements which Contract Research Organizations (CRO) shall satisfy in order to work within clinical trials on medicinal products" published in the ordinary supplement of the Official Journal n. 279 of 29 November, 2008;

Having regard to article 7, sub-article 5 of the aforementioned ministerial decree 31 March 2008 which establishes that before the entrance into force of this decree the CROs must notify the satisfaction of the above mentioned minimum requirements by self certification edited according to the resolution of the General Director of AIFA to be transmitted to the GCP inspectorate and to the Clinical Trials Office of the Italian Medicines Agency (AIFA).

Having regard to article 7, sub-article 6 of the aforementioned ministerial decree 31

March 2008, which establishes that when a new CRO begins its activity after the entrance into force of this decree, the notification referred to in sub-article 5 must be made at least 30 days before the beginning of the activity;

Having regard to article 7, sub-article 4, of the aforementioned ministerial decree 31 March 2008 which establishes that all the individual professionals or technical workers who, within their independent professional or consulting activities, after having stipulated contracts with the sponsor of the trials or with a CRO, perform single functions referred to in this Decree, must satisfy the same requirements foreseen by this Decree in order to perform said functions and must operate within the quality system of such structures;

Having regard to article 8, sub-article 1 of the same ministerial decree 31 March 2008, which establishes that the CROs with head office outside Italy who intend to perform their activities in Italy must be provided with a legal representative in one of the Members States of the European Union and must satisfy the requirements equivalent at least to those ones established in this decree;

Regarded necessary, in accordance with the aforementioned articles of the ministerial decree 31 March 2008, to define the forms for the self-certification of the minimum requirements of the Contract Research Organizations (CRO) for clinical trials with medicines, to be published in the website of AIFA and in the Official Gazette of the Italian Republic;

Hereby resolves:

#### Article 1.

1. The self certification of the requirements of the Contract Research Organizations (CRO), with headquarters in Italy referred to in article 7, sub-articles 5 and 6, of ministerial decree 31 March 2008 referred to in the premise, must be edited in compliance with the attachment 1 to this Resolution, of which it is an integral part.

2. The self certification of the requirements of the Contract Research Organizations with headquarters outside Italy, with a legal representation in one of the Member States of the European Union and which intend to carry out activities within the Italian territory, according to article 8 of the ministerial decree 31 March 2008 referred to in the premise, must be edited in compliance with Attachment 2 of this Resolution, of which it is an integral part.

3. The self certifications referred to in the previous sub-articles 1 and 2 must be notified via e-mail to the internet address specified in the attachments to this Resolution and, in any case, via ordinary mail, to the GCP Inspectorate of the Italian Medicines Agency (AIFA) at the address reported in the same attachments.

4. This Resolution will being published in the Internet website of AIFA – ([www.agenziafarmaco.it](http://www.agenziafarmaco.it)) and in the Official Gazette of the Italian Republic.

Rome, 23 December 2008

The Director General: Rasi

**ATTACHMENT 1** to the Resolution of the Director General of the Italian Medicines Agency (AIFA) (article 1, sub-article 1) concerning the self certification of the minimum requirements of the Contract Research Organisations (CROs) for clinical trials with medicines according to article 7, sub-articles 5 and 6, and to article 8 of the ministerial decree 31 March 2008.

**FORM FOR SELF CERTIFICATION IN COMPLIANCE WITH ARTICLE 7, SUB-ARTICLES 5 AND 6, OF MINISTERIAL DEECREE 31<sup>ST</sup> MARCH 2008** “Definition of the minimum requirements for contract research organizations (CRO) within clinical trials with medicines. (Official Gazette n.279 of 28-11-2008) (for CRO WITH BRANCH OFFICE IN ITALY).

To be sent:

- via internet at the address: [http://oss-sper-clin.agenziafarmaco.it/nuovi\\_utenti.htm](http://oss-sper-clin.agenziafarmaco.it/nuovi_utenti.htm) and it will be forwarded to the GCP Inspectorate automatically;
- via mail to GCP Inspection Office AIFA with a recorded-delivery letter with advice of receipt (*Agenzia Italiana del Farmaco - Ispettorato GCP - Via della Sierra Nevada, 60 - 00144 Roma*).

This form must be transmitted:

- within **26<sup>th</sup> February 2009** by the CROs satisfying the requirements in order to continue to work;
- at least **30 days** before the beginning of the activities for the new CROs.

I, the undersigned .....

born at ..... on .....

resident in ..... province (.....) at  
 (address) ..... with  
 the current qualification of ..... as  
 legal representative of the CRO (full name of organisation).....

.....

with legal branch office in Italy at the address (write it full): .....

.....

which according to its own founding deed (S.p.A., s.r.l., Foundation, scientific association etc.) takes on the legal status of (please specify): .....

- working as a CRO from
- intends to work as a CRO from

aware of the sanctions provided for in the penal code and in special laws on the matter according to article 76 in the Decree of the President of the Republic 28 December 2000 n. 445 and following modifications and integrations, for the hypothesis of falseness in acts and mendacious declarations

### **DO HEREBY DECLARE**

under my own responsibility that:

1. the above mentioned C.R.O. satisfies the general minimum requirements specified in article 3 (and if applicable, in article 7, sub-article 2) of the Ministerial Decree 31<sup>st</sup> March 2008

the CRO performs / intends to perform the following activities (if different with respect to point 2, please specify):

2. the above mentioned CRO satisfies the specific minimum requirements concerning the activities which it performs or intends to perform and these are listed here below:
  - Requirements for monitoring activity (art. 4 of the Ministerial Decree of 31<sup>st</sup> March 2008)
  - Requirements for the activity of auditing on clinical trials or clinical sites (article 5 of the Ministerial Decree 31<sup>st</sup> March 2008)
  - Requirements for the statistical activity and data management (article 6 and, if applicable, article 7, sub-article 3, of the Ministerial Decree 31<sup>st</sup> March 2008)

Should the CRO make use of personnel according to article 7, sub-article 4 of the Ministerial Decree 31<sup>st</sup> March 2008 I, the declarer undertake to verify that this personnel satisfies the minimum requirements specified in the same decree.

I, the undersigned aware that the above mentioned requirements may be verified by AIFA according to article 7, sub-article 7 of the Ministerial Decree 31<sup>st</sup> March 2008 within inspection activity according to article 15 of the Legislative Decree 24<sup>th</sup> June 2003, n. 211 and to Chapters V and VI of the Legislative Decree 6<sup>th</sup> November 2007, n. 200.

In the Attachment 1, signed and dated form with the full data of the branch office of the CRO in Italy including the indication of the main coordinating branch office (if applicable).

Please find here attached the photocopy (front and back) of a valid identity document issued by a public administration.

Place and date \_\_\_\_\_

The declarant

\_\_\_\_\_  
(full signature)

#### Appendixes

- ITALY – List and signed of the full data of the branch office of the CRO in Italy including the indication of the main coordinating branch office (if applicable).
- Photocopy (front and back) of a valid identity document issued by a public administration.

**APPENDIX ITALY (for CRO WITH BRANCH OFFICE IN ITALY)**

To the attachment 1 to the Resolution of the Director General of the Italian Medicines Agency (AIFA) (article 1, sub-article 1) concerning the self certification of the minimum requirements of the Contract Research Organisations (CROs)for clinical trials according to the article 7, sub articles 5 and 6 and to the article 8 of the ministerial decree 31 March 2008.

LIST DATED AND SIGNED OF THE FULL DATA OF THE BRANCH OFFICE OF THE CRO IN ITALY INCLUDING THE INDICATION OF THE MAIN COORDINATING BRANCH OFFICE (IF APPLICABLE).

**LEGAL BRANCH OFFICE**

NAME .....

FULL ADDRESS .....

TELEPHONE .....

FAX .....

E-MAIL ADDRESS .....

**MAIN COORDINATING BRANCH OFFICE**

Name .....

Full address .....

Telephone .....

Fax .....

E-mail address .....

Services provided by this CRO:

- Monitoring
- Auditing
- Statistical analysis and data analysis
- Other (specify here below)

.....  
.....  
.....  
.....

OTHER BRANCH OFFICE

Name .....

Full address .....

Telephone .....

Fax .....

E-mail .....

Services provided by this CRO:

- Monitoring
- Auditing
- Statistical analysis and data analysis
- Other (specify here below)

.....  
.....  
.....  
.....

OTHER BRANCH OFFICE

Name .....

Full address .....

Telephone .....

Fax .....

E-mail .....

Services provided by this CRO:

- Monitoring
- Auditing
- Statistical analysis and data analysis
- Other (specify here below)

.....  
.....  
.....  
.....

Place and date

\_\_\_\_\_

The declarant

\_\_\_\_\_

(full signature)

**ATTACHMENT 2 to the Resolution of the Director General of the Italian Medicines Agency (AIFA) (article 1, sub-article 1) concerning the self certification of the minimum requirements of the Contract Research Organisations (CROs) for clinical trials with medicines according to article 7, sub-articles 5 and 6, and to article 8 of the ministerial decree 31 March 2008.**

**FORM FOR SELF CERTIFICATION IN COMPLIANCE WITH ARTICLE 7, SUB-ARTICLES 5 AND 6, OF MINISTERIAL DEECREE 31<sup>ST</sup> MARCH 2008** “Definition of the minimum requirements for contract research organizations (CRO) within clinical trials with medicines. (Official Gazette n.279 of 28-11-2008) (for CRO WITH BRANCH OFFICE OUTSIDE ITALY).

To be sent:

- via internet at the address: [http://oss-sper-clin.agenziafarmaco.it/nuovi\\_utenti.htm](http://oss-sper-clin.agenziafarmaco.it/nuovi_utenti.htm) and it will be forwarded to the GCP Inspectorate automatically;
- via mail to GCP Inspection Office AIFA with a recorded-delivery letter with advice of receipt (*Agenzia Italiana del Farmaco - Ispettorato GCP - Via della Sierra Nevada, 60 - 00144 Roma*).

This form must be transmitted:

- within **26<sup>th</sup> February 2009** by the CROs satisfying the requirements in order to continue to work;
- at least **30 days** before the beginning of the activities for the new CROs.

I, the undersigned .....

born at ..... on .....

resident in ..... province (.....) at  
 (address) ..... with  
 the current qualification of ..... as  
 legal representative of the CRO (full name of organisation).....

.....  
 with legal branch office at the address (write it full): .....

.....  
 which according to its own founding deed (S.p.A., s.r.l., Foundation, scientific association

etc.) takes on the legal status of (please specify): .....

- working abroad as a CRO from
- working in Italy as a CRO from
- intends to work in Italy as a CRO from

aware of the sanctions provided for in the penal code and in special laws on the matter according to article 76 in the Decree of the President of the Republic 28 December 2000 n. 445 and following modifications and integrations, for the hypothesis of falseness in acts and mendacious declarations

**DO HEREBY DECLARE**

under my own responsibility that:

1. the above mentioned C.R.O. has legal branch in the European Union, in (city, State)

.....

2. the above mentioned C.R.O. satisfies the general minimum requirements or at least equivalent specified in article 3 (and if applicable, in article 7, sub-article 2) of the Ministerial Decree 31<sup>st</sup> March 2008

the CRO performs / intends to perform the following activities (if different with respect to point 3, please specify):

3. the above mentioned CRO satisfies the specific minimum requirements concerning the activities which it performs or intends to perform and these are listed here below:

- Requirements for monitoring activity (art. 4 of the Ministerial Decree of 31<sup>st</sup> March 2008)
- Requirements for the activity of auditing on clinical trials or clinical sites (article 5 of the Ministerial Decree 31<sup>st</sup> March 2008)
- Requirements for the statistical activity and data management (article 6 and, if applicable, article 7, sub-article 3, of the Ministerial Decree 31<sup>st</sup> March 2008)

Should the CRO make use of personnel according to article 7, sub-article 4 of the Ministerial Decree 31<sup>st</sup> March 2008 I, the declarer undertake to verify that this personnel satisfies the minimum requirements specified in the same decree.

I, the undersigned aware that the above mentioned requirements may be verified by AIFA according to article 7, sub-article 7 of the Ministerial Decree 31<sup>st</sup> March 2008 within inspection activity according to article 15 of the Legislative Decree 24<sup>th</sup> June 2003, n. 211 and to Chapters V and VI of the Legislative Decree 6<sup>th</sup> November 2007, n. 200.

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Place and date \_\_\_\_\_

The declarant

\_\_\_\_\_  
(full signature)

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