

RESOLUTION No. 563, DATED NOVEMBER 10th, 2017

The Plenary of the National Health Council, at its 299th Meeting, held on November 9th and 10th, 2017, in Brasília, in the exercise of the attributions conferred upon it by Law No. 8,080, of September 19th, 1990; by Law No. 8,142 of December 28th, 1990; by Complementary Law No. 141/2012; by Decree No. 5,839, of July 11th, 2006, complying with the provisions of the Constitution of the Federative Republic of Brazil of 1988, of the corresponding Brazilian legislation; and

Considering Ordinance No. 199 of the Ministry of Health, dated January 30th, 2014, which establishes the National Policy for Comprehensive Care for Persons with Rare Diseases, hereby approves the Guidelines of Comprehensive Care for Persons with Rare Diseases within the Unified Health System (*Sistema Único de Saúde - SUS*) and establishes financial cost incentives;

Considering the need to define guidelines and actions in the scope of researches involving people with ultra-rare diseases in Brazil;

Considering the particularities of the population affected by ultra-rare diseases, which have a low incidence in the overall population, and the need to standardize and ensure the provision of post-study treatment to research subjects for an established time; and

Considering that the experimental product can cure, delay disease progression and mitigate the effects of the ultra-rare disease, especially in children, and that this has been a claim of patients with ultra-rare diseases.

Hereby resolves:

Art. 1 This Resolution regulates the right of the research subject to post-study access in clinical research protocols intended for patients diagnosed with ultra-rare diseases.

Art. 2 For the purposes of this Resolution, ultra-rare disease is considered to be a chronic, debilitating or life-threatening disease, with incidence lower than or equal to 1 (one) case for every 50,000 (fifty thousand) inhabitants.

Sole paragraph. The Ministry of Health shall adopt the international incidence indicators as a temporary reference and, where duly justified public health reasons so require, may determine the revision of this criterion, considering the need to build reliable national data on ultra-rare diseases in Brazil.

Art. 3 In research on ultra-rare diseases, the sponsor shall be responsible and ensure free access to all research subjects to the best prophylactic, diagnostic and therapeutic methods that have proven to be effective at the end of the study, for a period of five years after obtaining registration in the National Health Surveillance Agency (Anvisa).

Paragraph 1 In the case of medications, the term of 5 (five) years will start from the price definition in Brazilian Real in the Regulatory Board for Medications Commercialization (CMED).

Paragraph 2 The same prerogatives are ensured to research subjects contained in the caput of this article during the interval between the end of the study and the beginning of the term of five (5) years.

Paragraph 3 Access shall also be ensured between the end of the individual participation and the end of the study, in which case this guarantee may be given by means of an extension study, according to a duly justified analysis by the attending physician of the subject.

Art. 4 At the end of the study, the study sponsor guarantees to research subjects not included in this Resolution free and indefinite access to the best prophylactic, diagnostic and therapeutic methods that have proven to be effective.

RONALD FERREIRA DOS SANTOS
Board Chairman

I hereby approve CNS Resolution No. 563 of November 10th, 2017, pursuant to the Decree of Delegation of Competence, dated November 12th, 1991.

RICARDO BARROS
Minister