



State of California—Health and Human Services Agency  
Department of Health Care Services



EDMUND G. BROWN JR.  
Governor

February 22, 2012

TO: ALL COUNTY WELFARE DIRECTORS Letter No.: 12-07  
ALL COUNTY WELFARE ADMINISTRATIVE OFFICERS  
ALL COUNTY MEDI-CAL PROGRAM SPECIALISTS/LIAISONS  
ALL COUNTY HEALTH EXECUTIVES  
ALL COUNTY MENTAL HEALTH DIRECTORS  
ALL COUNTY MEDS LIAISONS

SUBJECT: CLINICAL TRIALS ACT OF 2009

The purpose of this All County Welfare Director's Letter is to clarify how to treat compensation received for participation in a clinical trial involving research and testing of treatments for rare diseases or conditions.

Public Law 111-255, signed October 5, 2010, provides for an income and resource exclusion that applies to the first \$2,000 per year of compensation received for participating in clinical trials that research treatment of a rare disease or condition as defined in section 5(b)(2) of the Orphan Drug Act. The exclusion applies to individuals as well as spouses. This exclusion is effective April 3, 2011, and will expire on October 5, 2015.

The trial must meet three criteria in order for the exclusion to apply:

- The trial must be reviewed and approved by an Institutional Review Board (IRB).
- The trial must protect the rights and welfare of human subjects participating in scientific research.
- The trial must be conducted in accordance with the requirements of part 46 of Title 45, of the Code of Federal Regulations.

## 1. Verification the payments meet the criteria.

The informed consent form is primary evidence and provides most of the information needed to determine whether the income exclusion applies. If the participant is currently involved in a clinical trial, he or she must submit the informed consent form as evidence. The informed consent form must be requested from the clinical trial participant. If the participant does not have the informed consent form, instruct him or her to obtain a copy from the clinical trial administrator.

Some clinical trial participants may submit an official letter from the administrator of the clinical trial, if it provides all the relevant information of the informed consent in a summarized format. You can use this letter in lieu of the informed consent form.

### a) The Informed consent form is available

Health and Human Services regulations dictate that IRBs must approve all informed consents; therefore, you can accept an informed consent form as proof that an IRB reviewed and approved the clinical trial.

To determine if the clinical trial meets the other exclusion requirements, review the informed consent form and follow the instructions in this table:

IF:	THEN:
The clinical trial does <u>not</u> involve research and testing of treatments.	The income exclusion does not apply.
The clinical trial involves research and testing of treatments.	Proceed to verify whether the clinical trial targets a rare disease or condition. Some commonly known rare diseases are amyotrophic lateral sclerosis (Lou Gehrig's disease), Crohn's disease, cystic fibrosis, cystinosis, Duchenne muscular dystrophy, Huntington's disease, and Tourette syndrome. If the condition listed in the summary is not part of this list, and the documentation provided does not indicate the condition is a rare disease or condition, verify whether the Office of Rare Diseases Research's rare disease database lists the condition named in the informed consent form as a rare disease or condition. Verify the Office of Rare Disease Research's database at: <a href="http://rarediseases.info.nih.gov/">http://rarediseases.info.nih.gov/</a>

IF:	THEN:
The clinical trial does <u>not</u> target a rare disease or condition.	The income exclusion does not apply.
The clinical trial targets a rare disease or condition.	The income exclusion applies. Proceed to document the clinical trial information.

**b) The Informed consent form is unavailable**

If the informed consent form is unavailable as evidence, request any of the following information from the clinical trial participant:

- name and location of the clinical trial,
- name of disease or condition, or
- name, phone, and address of the clinical trial administrator.

[Clinicaltrials.gov](http://Clinicaltrials.gov) is a registry and [results database](#) of federally and privately supported clinical trials conducted in the United States and around the world & provides information about a trial's purpose, who may participate, locations, and phone numbers for more details. Use the information provided to locate the clinical trial.

If the clinical trial appears in the website, assume it is IRB approved. All clinical trials in the United States, involving human subjects, must meet federal regulations by having an IRB review and approve the research. To determine if the clinical trial meets the other two exclusion requirements, look for the following details in the clinical trial information:

- type of clinical trial, which is usually listed under the primary purpose, the title, or stated in the purpose summary; and
- name of the condition.

Follow the instructions in this table:

IF:	THEN:
The clinical trial does <u>not</u> involve research and testing of treatments.	The income exclusion does not apply.
The clinical trial involves research and testing of treatments.	<p>Proceed to verify whether the clinical targets a rare disease or condition.</p> <p>Some commonly known rare diseases are amyotrophic lateral sclerosis (Lou Gehrig's disease), Crohn's disease, cystic fibrosis, cystinosis, Duchenne muscular dystrophy, Huntington's disease, and Tourette syndrome.</p> <p>If the condition listed in the summary is not part of this list, and the documentation provided does not state the condition is a rare disease or condition, verify whether the Office of Rare Disease Research's rare disease database lists the condition named in the informed consent form as a rare disease or condition. Verify the Office of Rare Diseases Research's database at: <a href="http://rarediseases.info.nih.gov/">http://rarediseases.info.nih.gov/</a>.</p>
The disease or condition is <u>not</u> rare.	The income exclusion does not apply.
The disease or condition is rare.	<p>The income exclusion applies.</p> <p>Proceed to document the clinical trial information.</p>

Due to the delay in implementing this change, the county shall rescind any discontinuance or denial due to excess property as a result of not disregarding this payment and shall reevaluate eligibility and share-of-cost (SOC) as appropriate and issue corrected notices of action whenever:

- A case is known to the county to have been denied or discontinued in error or assessed an incorrect SOC.
- A case is brought to the county's attention.
- A case is processed at reapplication, a change in circumstances or annual redetermination.
- When reopening a case that was closed since April 3, 2011.

If you have any questions, please contact Harold Higgins at (916) 327-0412 or by e-mail at [harold.higgins@dhcs.ca.gov](mailto:harold.higgins@dhcs.ca.gov).

Original signed by

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