

## What is the CALERIE study?

Numerous studies have shown that chronic caloric restriction extends average life span in animals and delays age-related diseases. CALERIE is a government-funded research study to investigate the effects of two years of food restriction in normal-weight individuals in reducing the risk of disease and in slowing the aging process.

The purpose of CALERIE is to better understand the effect of prolonged caloric restriction on aging and to test how practical and safe is a 25% calorie-restricted diet in normal-weight individuals.

CALERIE is funded by the National Institute on Aging (NIA).



## Participating research centers:

**Pennington Biomedical Research Center**  
6400 Perkins Road  
Baton Rouge, LA 70808  
225-763-2596  
<http://www.pbrc.edu>

**Tufts University**  
Jean Mayer USDA Human Nutrition  
Research Center on Aging  
711 Washington Street  
Boston, MA 02111  
617-556-3125  
<http://hnrc.tufts.edu>

**Washington University School of Medicine**  
Campus Box 8113  
4566 Scott Avenue  
St. Louis, MO 63110  
314-747-3182  
<http://www.wustl.edu>

# calerie

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**Comprehensive Assessment of Long-Term  
Effects of Reducing Intake of Energy**

<http://calerie.dcri.duke.edu>

**Protocol V. 1.3**

## Who can participate?

To participate in CALERIE you must:

- Be relatively healthy
- Be between age 20–50 (inclusive) for men and age 20–47 (inclusive) for women
- Have a body mass index (BMI) of 22–27.9 (lean to slightly overweight)
- Be free of diabetes, cancer, heart and liver disease, and AIDS
- Have not experienced a recent and substantial weight loss
- Use an acceptable form of contraception (barrier method, oral contraception, intrauterine device, or similar form), and be willing to continue using such a method while enrolled in the study.

The above list does not include all eligibility requirements. You will be evaluated at the screening and baseline visits to determine if you meet all study requirements.

## Why would I participate?

A clinical research study is a scientific investigation in which volunteers can help doctors and other researchers find ways to treat disease and improve people's health. Participating in a clinical research study, like CALERIE, gives you a chance to play an active part in your own health and help others too.

If you are assigned to the caloric-restricted group you will be provided nutrition advice at no charge and you may lose weight. Weight loss may promote successful aging and has other benefits such as loss of body fat, decreased risk of diabetes, lower blood pressure and cholesterol, and improvements in cardiovascular health.

You may not receive direct benefit from participating in this study but will have the chance to contribute to medical research about the aging process.

## What will happen if I decide to participate in the CALERIE study?

Before any study procedures are started, the study staff will review and discuss all the information described in the consent form. You will have the opportunity to ask all the questions you have about the study. You will be given a copy of the consent form so you can refer to it throughout the study.

If you agree to participate in CALERIE, you will complete both the screening and baseline phases before you are enrolled in the study.

The screening phase consists of 3 separate visits where study staff will assess your eligibility to participate. At the final screening visit, the study staff will let you know if you are eligible to participate and will ask you if you would like to continue to the baseline phase.

The baseline phase will occur over a 40-day period and will consist of 5 clinic visits and 2-day/2-night residential stay. Once you have completed this phase and remain eligible and interested in the study, you will be randomized (assigned a study group) to either the calorie restricted or the regular-eating habits group.

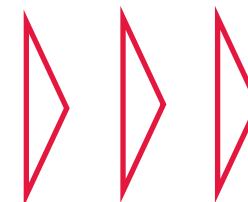
Randomization will be done by chance, similar to a flip of a coin or rolling dice in a board game. Depending on what group you have been assigned to, you will be asked to return to your study location for follow-up procedures at 1, 3, 6, 9, 12, 18, and 24 months. These visits will involve clinic as well as overnight residential stays.

## How will my safety be protected?

The same legal and ethical requirements that govern any medical practice also apply to clinical research. Clinical research studies are closely controlled and have built-in safeguards to protect participants. Researchers are required by law to follow specific procedures.

Your health and safety is of paramount concern to the investigators and institutions participating in CALERIE. The research team led by your study physician will check your health and progress regularly throughout the study. You will have frequent blood work taken and undergo other tests to monitor your health. If you feel you are having problems while enrolled in the study, you will have prompt access to a study staff member.

The CALERIE study has been approved by an Institutional Review Board (IRB). As with all research studies, an IRB must review and approve a study before participants can enroll. In addition, the CALERIE study has had a detailed review by the Data Safety and Monitoring Board (DSMB) to ensure protocol safety. The DSMB will periodically review participants' data throughout the study to make sure safety parameters are maintained.



**This brochure is designed to help you understand the CALERIE study. It is not intended to take the place of the study consent form. The consent form will outline and explain all study procedures that will take place at the screening, baseline, and follow-up visits. Please read and refer to your consent form throughout the study.**