



## Clinical Trials

There is no central registry database for spinal cord injury (SCI) related clinical trials; however, there are several databases you can check to see if you might qualify for any clinical trials currently being conducted. Most of the following information can be found on the PRC's web site ([www.paralysis.org](http://www.paralysis.org)) in the Research section, under the category entitled Clinical Trials.

Before enrolling in a clinical trial, it is important to review the following information from the National Institute of Health (NIH):

### CLINICAL TRIALS

Drugs and treatments are developed from laboratory experiments. Clinical research is usually conducted in a series of trials that become progressively larger. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Once researchers test new therapies or procedures in the laboratory and get promising results, they begin planning Phase I clinical trials. New therapies are tested on people *only* after laboratory and animal studies show promising results.

A Phase I clinical trial is directly built upon basic and animal research and is primarily used to test the safety of a therapy for a particular disease or condition and to estimate possible usefulness in a few human subjects.

A Phase II clinical trial usually involves many subjects at several different centers and is used to test safety and efficacy on a broader scale, to test different dosing for medications or to perfect techniques for surgery, and to determine the best methodology for the bigger Phase III clinical trial to come.

A Phase III clinical trial often involves many centers and sometimes several hundred subjects. The trial usually has two patient groups who receive different treatments, but all other standard care is the same. The trial may compare two treatments, or, if there is only one treatment to test, patients who do not receive the test therapy receive instead a placebo (dummy drug).

Many Phase III trials are called double-blind, randomized clinical trials. Double-blind means that neither the subjects nor the doctors treating the subjects and determining the response to the therapy know which treatment a subject receives. Randomization refers to the placing of subjects

into one of the treatment groups in a way that can't be predicted by the patients or investigators. These clinical trials usually involve many investigators and take many years to complete.

Most treatments for general use come out of Phase III clinical trials. After one or more phase III trials are finished, and if the results are positive for the treatment, the investigators can petition the FDA for government approval to use the drug or procedure to treat patients. Once the FDA approves the treatment, doctors throughout the country can prescribe it.

## **PROTECTIONS FOR PEOPLE IN CLINICAL TRIALS**

The government has strict safeguards to protect people who participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected.

## **INFORMED CONSENT**

Informed consent is the process of learning the key facts about a clinical trial before you decide whether or not to participate. These facts include:

- Why the research is being done
- What the researchers want to accomplish
- What will be done during the trial and for how long
- What risks are involved in the trial
- What benefits can be expected from the trial
- What other treatments are available
- The fact that you have the right to leave the trial at any time

If you are considering joining a clinical trial, the research staff will give you informed consent documents that include the details about the study. Since joining a clinical trial is an important decision, you should ask the research team any questions you may have about the study and the consent forms before you make a decision.

Remember informed consent is more than signing a form. It is a process that continues through the study. You should feel free to ask the research team questions before, during, and after the study. Informed consent continues as long as you are in the study.

## **WHO CAN PARTICIPATE IN A CLINICAL TRIAL?**

All clinical trials have guidelines about who can get into the program. Guidelines are based on such factors as age, type of disease, medical history, and current medical condition. Before you join a clinical trial, you must qualify for the study. Some research studies seek volunteers with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Healthy volunteers participate in Phase I trials, vaccine studies, and trials on research on preventive care for children or adults.

It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

If you plan to participate, some questions you might ask about the research include:

- Why is this research being done and who is sponsoring it?
- How do the possible risks and benefits of the study compare with approved treatments for me?
- What are the possible immediate and long-term side effects?
- What other treatment options do I have?
- Will I have to pay anything to participate in the study?

Source: National Institutes of Health

## WEBSITES

### **General Information**

<http://www.ciscrp.org/patient/index.html>

#### **The Center for Information & Study on Clinical Research Participation (CISCRP)**

CISCRP provides information on clinical trials designed to help people become informed participants.

<http://www.ChristopherReeve.org>

[http://www.christopherreeve.org/site/c.ddJFKRNoFiG/b.4435101/k.99A4/Clinical\\_Trials.htm](http://www.christopherreeve.org/site/c.ddJFKRNoFiG/b.4435101/k.99A4/Clinical_Trials.htm)

#### **Christopher & Dana Reeve Foundation: Clinical Trials**

Stay in touch with the latest news and actions from the Christopher & Dana Reeve Foundation. Fill out the form for the FREE, monthly e-newsletter about the Reeve Foundation's efforts to find a cure for paralysis caused by spinal cord injury and other central nervous system disorders. (Put your email address in the box where it says "Free Newsletter Sign Up" and hit enter). You'll get news and information about the cutting-edge research the Reeve Foundation funds, Quality of Life grants, the Reeve Foundation's advocacy for increased research funding, and much more, sent directly to your e-mail account. It's free, and the Reeve Foundation will never sell or trade your personal information to another group.

[http://icord.org/wp-content/uploads/2009/07/Experimental\\_treatment\\_for\\_SCI-full.pdf](http://icord.org/wp-content/uploads/2009/07/Experimental_treatment_for_SCI-full.pdf)

**Experimental Treatments for Spinal Cord Injury: What You Should Know if You Are Considering Participation in a Clinical Trial** (International Campaign for Cures of Spinal Cord Injury Paralysis 2007)

<http://www.fda.gov/oashi/clinicaltrials/default.htm>

**Food and Drug Administration: Clinical Trials and Drug Development**

<http://www.froedtert.com/ClinicalResearch/ClinicalTrialsBasics/ClinicalTrialsBasics.htm>

## **Froedtert & Medical College of Wisconsin: Clinical Trial Basics**

[http://icord.org/wp-content/uploads/2009/07/Experimental\\_treatment\\_for\\_SCI-full.pdf](http://icord.org/wp-content/uploads/2009/07/Experimental_treatment_for_SCI-full.pdf)

**International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP): Experimental Treatments for Spinal Cord Injury: What You Should Know if You Are Considering Participation in a Clinical Trial.** February 2007.

<http://www.nlm.nih.gov/medlineplus/clinicaltrials.html>

**MedlinePlus: Clinical Trials**

<http://clinicalcenter.nih.gov/participate/faqaboutcs.shtml>

**NIH Clinical Center: FAQs About Clinical Studies**

<http://nihseniorhealth.gov/participatinginclinicaltrials/toc.html>

**NIH Senior Health: Participating in Clinical Trials**

[http://www.nia.nih.gov/HealthInformation/Publications/clinicaltrials\\_tipsheet.htm](http://www.nia.nih.gov/HealthInformation/Publications/clinicaltrials_tipsheet.htm)

**National Institute on Aging's Tip Sheet: Clinical Trials and Older People**

<http://www.nlm.nih.gov/services/ctresults.html>

**National Library of Medicine FAQ on Clinical Trial Results**

<http://www.nlm.nih.gov/services/faqctgov.html>

**National Library of Medicine FAQ on ClinicalTrials.gov Questions**

The FAQ includes information on using ClinicalTrials.gov as well as general information on clinical trials.

<http://www.webmd.com/a-to-z-guides/clinical-trial-guide-patients>

**WebMD: Clinical Trials: A Guide for Patients**

### **Databases of Clinical Trials**

<http://www.centerwatch.com>

#### **CenterWatch**

10 Winthrop Square, Fifth Floor

Boston, MA 02110

Phone: 617-948-5100, 866-219-3440 (Toll-free)

E-mail: [customerservice@centerwatch.com](mailto:customerservice@centerwatch.com)

CenterWatch's website has a wealth of information related to clinical trials and is designed to be a resource for both patients interested in participating in clinical trials and for research professionals. CenterWatch is a division of the Thomson Corporation.

<http://www.clinicalstudyresults.org>

#### **Clinical Study Results**

This database reporting the results of clinical trials can be searched by condition, company name, and/or drug name.

<http://www.ClinicalTrials.gov>

### **ClinicalTrials.gov**

ClinicalTrials.gov offers general information on clinical trials and specific information on federally and privately supported clinical trials (conducted in the United States and around the world) for a wide range of diseases and conditions. The website provides information about a trial's purpose, eligible participants, locations, and contacts. ClinicalTrials.gov also has a results database that reports summary results of registered clinical trials and observational studies.

<http://www.controlled-trials.com/mrct>

### **Current Controlled Trials: metaRegister of Controlled Trials (mRCT)**

The mRCT allows users to search for controlled trials across multiple clinical trial registries including international ones.

<http://www.searchclinicaltrials.org/>

### **Search Clinical Trials**

This database run by the Center for Information & Study on Clinical Research Participation allows people to search multiple websites for clinical trials, clinical study results and medical news.

<http://www.spinalcord.uab.edu/show.asp?durki=21777>

### **Spinal Cord Injury Information Network: Research Studies**

The Spinal Cord Injury Information Network's page on research studies provides information on studies at the University of Alabama at Birmingham's Spain Rehabilitation Center and elsewhere.

<http://www.unite2fightparalysis.org/clinicaltrials>

### **Unite 2 Fight Paralysis: Spinal Cord Injury Clinical Trials**

<http://apps.who.int/trialsearch>

### **World Health Organization: International Clinical Trials Registry**

The World Health Organization's searchable database of clinical trials registered in various countries

## **Research Centers and Programs**

<http://www.research.va.gov/programs/csp/>

### **Department of Veterans Affairs (VA): Cooperative Studies Program**

The VA Cooperative Studies Program conducts research studies, including multicenter clinical trials and epidemiological studies, in collaboration with other federal, international, university, and private industry partners.

<http://www.campaignforcure.org/iccp/>

### **International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP)**

Non-profit organizations affiliated with ICCP work to fund research into cures for paralysis caused by spinal cord injury. The website provides information on spinal cord injury research.

<http://www.spinalcordrecovery.org/>

**The International Center for Spinal Cord Injury (ICSCI) at Kennedy Krieger Institute**

801 North Broadway

Baltimore, MD 21205

Care Management Office Phone: 443-923-9222 (local referral), 888-923-9222 (Toll-free referral)

E-mail: [info.sci@spinalcordrecovery.org](mailto:info.sci@spinalcordrecovery.org)

The ICSCI focuses on restoration and rehabilitation for children and adults with chronic paralysis. Research includes activity based restorative therapies which are designed to help individuals with spinal cord injury recover sensation, function, and mobility.

<http://www.reeve.uci.edu/>

**The Reeve-Irvine Research Center**

College of Medicine, University of California, Irvine

2109 Gillespie Neuroscience Research Facility

Irvine, CA 92697-4292

E-mail: [rirc@uci.edu](mailto:rirc@uci.edu)

The Reeve-Irvine Research Center has been established to study injuries to and diseases of the spinal cord that result in paralysis or other loss of neurologic function, with the goal of finding a cure. Named for actor Christopher Reeve, the Center is part of the College of Medicine of the University of California, Irvine. The Reeve-Irvine Research Center is located in the Gillespie Neuroscience Research Facility and is led by Dr. Oswald Steward. Activities under the Center's auspices promote the coordination and cooperation of scientists around the world seeking a cure for paraplegia and quadriplegia and amelioration of diseases impacting neurological function.

<http://www.tbi-sci.org>

**Rehabilitation Research Center**

Santa Clara Valley Medical Center

751 South Bascom Avenue

San Jose, CA 95128

Phone: 408-793-6433

[tbisci@tbi-sci.org](mailto:tbisci@tbi-sci.org)

The Rehabilitation Research Center (RRC) conducts research to better understand and improve outcomes for people who have experienced traumatic brain injury and spinal cord injury.

<http://www.keck.ucsf.edu/keck>

**W.M. Keck Foundation Center for Integrative Neuroscience**

University of California, San Francisco

513 Parnassus Ave, Box 0444, Room HSE-812

San Francisco, CA 94143-0444

E-mail: [keck-info@phy.ucsf.edu](mailto:keck-info@phy.ucsf.edu)

Scientists at the Keck Center conduct research on how the nerve cells in brains work together to generate human behaviors, leading to insights on senses, limb movement, pain, learning and remembering, and speech and language.

**Definitions of Embryonic Stem Cells and Adult Stem Cells**

<http://www.nlm.nih.gov/medlineplus/ency/article/007120.htm>

### **Medline Plus Health Information**

<http://www.aaas.org/spp/sfrrl/projects/stem/index.shtml>

### **Stem Cell Research & Applications: Scientific, Ethical, and Policy Issues**

The following books are available for free loan from the PRC library. For more information, please see [www.paralysis.org](http://www.paralysis.org) and click *Borrow from Our Lending Library* under PRC Quick Links.

#### **Books**

- Anderson, Diana L. **A Guide to Patient Recruitment and Retention**. Boston: Thomson Centerwatch, 2004.
- **Assessing Quality of Life in Clinical Trials**. Edited by Peter Fayers and Ron Hays. New York: Oxford University Press, 2005. 2<sup>nd</sup> ed.
- Bachenheimer, Joan F. and Bonnie A. Brescia. **Reinventing Patient Recruitment: Revolutionary Ideas for Clinical Trial Success**. Burlington, Vt.: Gower, 2007.
- **Clinical Trials in Osteoporosis**. Derek Pearson and Colin G. Miller, editors. London: Springer, 2007. 2<sup>nd</sup> ed. Written for health care professionals
- **Clinical Trials of Drugs and Biopharmaceuticals**. Boca Raton, Fla.: CRC Taylor & Francis, 2006.
- Getz, Kenneth. **The Gift of Participation: A Guide to Making Informed Decisions About Volunteering for a Clinical Trial**. Bar Harbor, ME: Jerian Publishing, 2007.
- Getz, Kenneth and Deborah Borfritz. **Informed Consent**. Boston, MA: Center Watch, 2002.
- Giffels, J. Joseph. **Clinical Trials: What You Should Know Before Volunteering To Be A Research Subject**. New York, N.Y: Demos Vermande, 1996.
- Mulay, Marilyn. **A Step-By-Step Guide to Clinical Trials**. Sudbury, Mass.: Jones and Bartlett Publishers, 2001.
- **A Quick Guide to Clinical Trials: For People Who May Not Know It All**. Rockville, Md.: BioPlan Associates, 2008.
- Rozovsky, Fay A. **Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance**. San Francisco: Jossey Bass, 2003.

- Woodin, Karen E. **The CRC's Guide to Coordinating Clinical Research**. Boston: CenterWatch, 2004.

**The information contained in this message is presented for the purpose of educating and informing you about paralysis and its effects. Nothing contained in this message should be construed nor is intended to be used for medical diagnosis or treatment. It should not be used in place of the advice of your physician or other qualified health care provider. Should you have any health care related questions, please call or see your physician or other qualified health care provider promptly. Always consult with your physician or other qualified health care provider before embarking on a new treatment, diet or fitness program. You should never disregard medical advice or delay in seeking it because of something you have read in this message.**