Rheumatoid Arthritis (RA) is a chronic autoimmune disease that can have drastic effects on the functional abilities of the afflicted person. For many years the standard recommendation of bed rest was utilized during exacerbations of the illness, which unfortunately, results in severe aerobic de-conditioning and muscle atrophy.

Recent studies have shown that persons with RA can tolerate exercise training, including aerobic and strength training without adverse effects. In fact, several studies suggest that measures of activity such as the number of swollen joints and duration of morning stiffness may actually decrease with exercise. There is additional research in healthy individuals that suggests exercise lowers the levels of some markers of inflammation. The mechanism responsible for a decrease in inflammatory status in response to exercise is still unknown, and currently knowledge of the immune changes in response to exercise is primarily limited to healthy individuals.

Laura Bilek, PT, PhD, Department of Physical Therapy Education is conducting a research study to determine the impact of exercise on disease activity and the immune system in persons with RA. Forty subjects with RA and 40 matched controls will undergo a 4-week control period followed by a 12 week exercise period consisting of aerobic and strength training individually prescribed and followed by an exercise professional at the UNMC Fitness Center in the Center for Healthy Living. To determine if disease activity decreases with exercise, disease activity will be determined by assessing each of the American College of Rheumatology core set of activity measures and biophysiolegic markers.

Please contact the research study coordinator, Deb Meyer 559-3458 with any questions or to enroll.
Clinical Trials Participation

A new poll from Harris Interactive indicates that although only 10% of Americans have actually participated in a clinical trial, more than three-quarters (77%) say if asked they would consider participating. The survey of more than 2,000 U.S. adults was conducted in May, 2003. Participants indicated a variety of reasons for participating in a clinical trial, including advancing medicine (54%), helping others (46%), extra money (42%), and obtaining better treatment (40%). Only 5% mentioned that having a life-threatening illness was a reason for participation.

Most people surveyed believe they’ve never had the opportunity to participate in a clinical research study. Only 16% of those surveyed reported having had the opportunity. Of those who believed they’d had the opportunity to participate, a full 63% actually signed up for the trial.

It is clear from this data that the most important thing investigators can do to drive participation in trials is to make opportunities more obvious to potential participants.

NIH Data Sharing Plan

Starting October 1, 2003 receipt date "investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible. This is part of the NIH's long-standing policy to share and make available to the public the results and accomplishments of the activities that it funds.

The NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local state and federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plan.

Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will oversee the data sharing policy.

NIH Progress Report Notification On-Line

Historically the NIH sent an institutions sponsored programs office pre-printed face pages as a reminder of specific progress reports that were due. In August 2002, NIH announced that they will no longer be mailing these out. At that time, Sponsored Programs Administration (SPA) modified the notification process.

Approximately six-weeks before the progress report due date, SPA sends an email reminder to the principal investigator (PI) and departmental administrator. Progress Reports should continue to be submitted to SPA for review, institutional signature, and mailing. PI’s interested in checking the due date of their progress report can log on to the NIH website http://era.nih.gov/ userreports/pr_due.cfm using UNMC’s Profile Number (IPF) which is 0578104. The website lists the name of the PI, NIH grant #, & due date of the report. Typically, this information covers a three month period and grants are removed from the list as NIH receives the progress report.

Clinical Research Symposium

The Clinical Research Symposium will be held September 15-19, 2003 and January 19-23, 2004. The course includes didactic sessions on the ethics of clinical research, the process of informed consent, and basic principles of study design and statistical analysis. The participant will also write a sample grant and IRB document including a patient consent form over the two week course. Call 9-7685 to get a copy of the schedule or to register. The registration fee is $25 for the 2 weeks.