



RUSH UNIVERSITY
MEDICAL CENTER

PARKINSON NEWSLETTER

Regulation of Human Research in the United States

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Part 1: Human Subjects Protection



The history of protection of human subjects in research began with one of the most sordid epochs in human histo-

ry. In 1947, 26 Nazi physicians were tried in Nuremberg, Germany, for research atrocities performed on concentration camp internees. The Nazi War Crimes Tribunal issued the Nuremberg Code, a ten-point treatise. The Nuremberg Code introduced the principles of informed consent and absence of coercion in research, and stressed human research should be scientifically sound and beneficent to participants.

The 10 items of the Nuremberg Code are:

1. Voluntary consent is essential; the duty for ascertaining quality of consent rests with the person who initiates or directs the study.
2. The experiment should be designed so that it may yield fruit-

ful results for the good of society

3. The design should be based on animal experiments or knowledge of the disease so that the results will justify the performance of the experiment.

4. The design should avoid unnecessary physical and mental suffering and injury.

5. No experiment should be conducted when there is reason to believe death or disabling injury may occur, unless the experimenter is also the subject of the experiment.

6. The degree of risk should not exceed the degree of humanitarian importance of the problem to be solved.

7. There should be proper preparations to avoid even remote possibilities of injury, disability or death.

8. The experiment should be conducted by scientifically qualified persons.

9. Human subjects should be at liberty to stop participation if continuation of the experiment seems impossible.

10. The person in charge of the experiment must be prepared to terminate the experiment if continuation is likely to result in injury, disability or death of a subject.

(Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182)

In 1964, The 18th World Medical Assembly met in Helsinki, Finland

and issued recommendations to guide physicians in human biomedical research. The Declaration of Helsinki expanded the principles expounded in the Nuremberg Code in several ways:

- ♦ recommending each research study be guided by a written experimental protocol outlining all study procedures and protections
- ♦ encouraging safeguards for maintaining the integrity and privacy of research subjects
- ♦ requiring preservation of the accuracy of scientific results in any research publications
- ♦ protecting against coercion by recommending particular caution in situations when the potential research subject is in a dependent relationship to the study investigator, recommending that in such a circumstance the consent be obtained by an independent person
- ♦ outlining the procedures for consent by a legal guardian when the potential research participant is not legally competent to consent (or is a minor child)
- ♦ assuring the best proven diagnostic and therapeutic methods be applied to every study participant (even control subjects)
- ♦ protecting the subject's ability to refuse to participate without incurring any repercussions

(Continued on Page 2)

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The next dreary chapter of this story was revealed by a whistleblower, Peter Buxton, a venereal-disease investigator for the Public Health Service, in 1972. Since 1966, Buxton, had vainly petitioned the Division of Venereal Diseases and Centers for Disease Control to stop the Tuskegee Syphilis Study, a study he believed was unethical. The Tuskegee Syphilis Study enrolled 399 African American sharecroppers with syphilis and 201 control subjects into an observational study of untreated syphilis in 1932. They were not told they had syphilis; rather, they were told they had "bad blood." Although penicillin became the accepted treatment for syphilis in the mid 1940's, the study subjects were not treated and they were prohibited from seeking treatment outside the study. During the course of the study, they were routinely misled about the nature of their participation, including being told research spinal taps were "special free treatment," and sometimes offered ineffective treatments. By the end of the study in 1972, 128 subjects had died from syphilis or its complications, and 40 wives and 19 newborns had contracted the infection. Finally, having exhausted official channels, Mr. Buxton went to the press in the 1970's. On July 25, 1972, a story about this study appeared in the Washington Star. The next day, the story made the front page of the New York Times. Congressional hearings led to the termination of the study and reparations for survivors and their families.

In 1974, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established and Congress passed the National Research Act. This act required every institution performing research set up an Institutional Review Board (IRB) charged with the responsibility of local human research oversight. Each IRB must include at least 5 members of varying background, including one member from the community who is not affiliated with the institution and one non-scientist. Additional expertise is required for research in vulnerable populations such as children and prisoners. The IRB reviews and approves every human research study before any research can start and performs an annual review of the study until it has been completed.

Another outcome of the failed Tuskegee experiment was the preparation of The Belmont Report,

which outlined 3 principles that must guide human research:

Respect for persons (autonomy and entitlement to protection from risks), beneficence (protection from harm and maximization of potential benefits) and justice (fairness in distribution of risk and potential benefits).

In addition, federal law described ten required components of informed consent:

1. A statement that the study involves research, and an explanation of the purpose of the research and the procedures that will occur
2. A description of foreseeable risks and discomforts
3. A description of benefits to the subject and to others
4. A disclosure of alternatives to participate
5. A statement regarding confidentiality
6. An explanation of potential compensation (if any) or medical treatment (if any) to be provided in the event of a research-related injury
7. Contact information for questions or concerns
8. A statement that participation is voluntary
9. A statement of possible risks to the fetus or embryo
10. Anticipated circumstances under which the subject's participation may be terminated by the investigator
11. Any additional costs that might result from participation in the study
12. Consequences if the subject withdraws from the study
13. A statement that significant new findings that might influence the subject's willingness to continue participating in the study will be communicated to the subject
14. The approximate number of subjects expected to participate

Informed consent does not end with signing the consent form; rather it is a process of verbal and written communications between the investigator and study subjects that continues even after all the study procedures have been completed.

In Our Next Issue

Part 2: The Food and Drug Administration

The Rush Parkinson's Disease Symposium 2010

Friday, May 21, 2010

12:00 pm to 4:30 pm

(Registration/sign-in begins at 11:00 am)

Hyatt Regency Hotel - O'Hare

Announcing the 10th Patient/Caregiver Symposium entitled: "The Rush Parkinson's Disease Symposium 2010" which will be held on Friday, May 21, 2010 from noon to 4:30 p.m. at the Hyatt Regency Hotel - O'Hare, 9300 W. Bryn Mawr Road, Rosemont, IL. This Patient/Caregiver Conference is sponsored by the Movement Disorder Section of the Department of Neurological Sciences at Rush University Medical Center in Chicago and the Parkinson's Disease Foundation (PDF). The moderators of the conference are Dr. Katie Kompoliti and Dr. Christopher Goetz. The conference is directed to the education of Parkinson's disease patients and their caregivers. The overall goal is to provide an understanding of the roles of the various drugs and surgical techniques in the approach to specific problems experienced by the Parkinson's disease patient. Refer to the newsletter insert for a preliminary agenda and topics to be presented.

The last conference of this type was held in May of 2009 and had full attendance. Admission to the conference is free, but seating is limited. Advanced registration is required. In order to reserve your seat, please complete the registration form on page 3 of this newsletter and send it to us.

On the day of the conference, **sign-in will begin at 11:00 a.m.** The conference will be held in the Rosemont Ballroom of the Hyatt Regency Hotel. The hotel has an adjoining parking garage with a discounted self parking charge of \$10.00. Valet parking is also available at the prevailing rate.

CANCELLATIONS:

After reserving your seat, if for any reason you find you cannot attend the conference, please contact our office at 312-942-8002 so that we may open your seat(s) up to other patients/caregivers.

The conference is partly supported by the following: The Parkinson's Disease Foundation.

(Complete form, detach and return)

REGISTRATION FORM

(Please print or type)

I would like to attend the Parkinson's Disease Patient/Caregiver Conference

Name (1): _____

Name (2): _____

Address: _____

City: _____ State _____ Zip _____

Phone Number (_____) _____

Number of persons attending: _____

Please mail your completed registration form to:

Ms. Teresa Chmura
Rush University Medical Center
Department of Neurological Sciences
1725 W. Harrison Street, Suite 755
Chicago, IL 60612

Fax: (312) 563-2684 / Phone: (312) 942-8002

From O'Hare International Airport:

Take I-190 East to River Road South Exit. Hotel is on the left side.

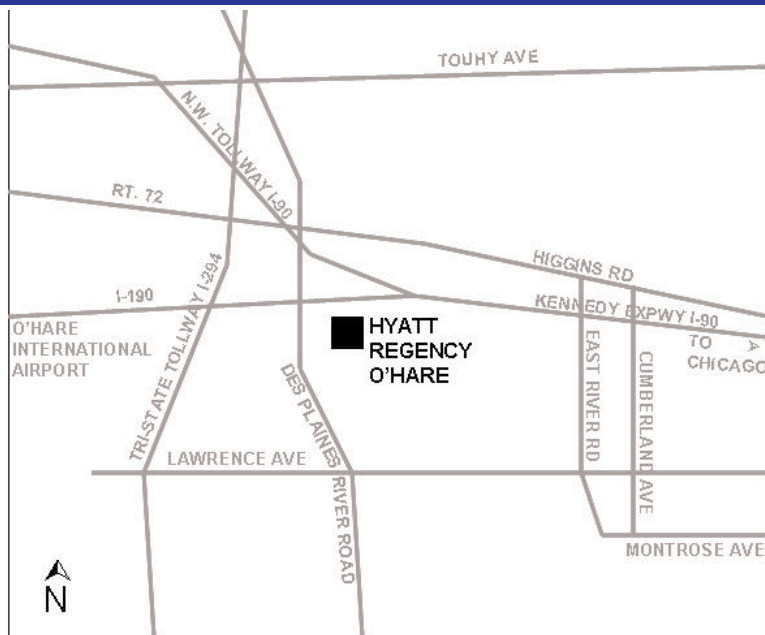
From Midway Airport:

Take Cicero Avenue North to I-55 South to I-294 North. Follow directions to O'Hare. Exit River Road South. Hotel is on the left.

Venue: Hyatt Regency Hotel - O'Hare

Address: 9300 W. Bryn Mawr Rd.,
Rosemont, IL 60018

Phone: 847-696-1234



Monthly Educational and Support Program

WHEN: Second Saturday of each month, 10:00 am to 12:00 noon

LOCATION: Oak Park Hospital (Back of Cafeteria)

March 13: Dr. Cynthia Comella May 8: Dr. Katie Kompoliti
April 10: Dr. Christopher Goetz June 13: TBD

The Movement Disorder Group
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Supported by the Parkinson's Disease Foundation

**Your invitation to the
PD Patient/Caregiver
Symposium is included in
this issue (see page 3)**