School of Dentistry Policy on Administrative Screening of Potential Subjects for Dental School Research

INTRODUCTION

The enrollment of patients in UNC Chapel Hill human subjects research must be in accord with approval of the University IRB, all University policies and the relevant federal regulations. Among the relevant federal regulations are 45 CFR 46.111a (3) and 21 CFR 56.111a (3), which assert that selection must be equitable. University policy includes embrace of the ethical principles of the Belmont Report, which states that, as a matter of social justice, the benefits of research should not be unfairly withheld from segments of the population. This would include segments defined by their financial position.

Individuals who participate in clinical research at the School of Dentistry (SOD) are subject to the relevant rules and regulations of the SOD patient care system in which the research is conducted. This includes registration in the Electronic Patient Record (EPR) and adherence to applicable sections of the School Patient Rights & Responsibilities. SOD policy allows for denial of treatment to patients who do not fulfill their financial obligations. Since this conflicts with regulations governing selection of subjects for research, the objective of this policy is to explain the distinction between application of a Financial Lock to participation as a patient at the SOD versus its application to participation as a research subject at the SOD.

PRINCIPLES

1. Individuals who are screened for study acceptance are assigned record numbers in EPR, whether or not they are accepted.

2. Former patients who have been dismissed from the SOD through an Administrative Lock (e.g. for inappropriate behavior or excessive missed appointments) are ineligible for participation in research studies.

3. A Financial Lock (e.g. for not paying for services received in Student Clinics or Dental Faculty Practice) on a former patient does not make that patient ineligible for participation in research studies.

APPLICATION

1. Dental Research staff and faculty who are involved in human subjects research shall be trained in use of the EPR. Current personnel shall receive this training by April 14, 2004. Thereafter, new personnel shall receive this training as soon as possible upon commencing employment.
2. When an individual is screened for potential study acceptance, a patient record number is created in the EPR. If the subject is accepted into a study, a dental chart is created. If the individual is not accepted, a dental chart is not created; however, the record number remains in the EPR.

3. Dental Research staff shall check the EPR for administrative dismissals. When entering the name of an individual being screened for a research study in the Patient Information Module, the Patient’s Status screen will automatically display if the individual has been previously dismissed from the SOD (e.g. Administrative Lock or Financial Lock). An Administrative Lock shall exclude the individual from participating in the SOD study; however, an individual shall not be excluded from participation in an SOD study based solely on a Financial Lock.

4. Former patients who have been placed on Administrative Lock may appeal to the Associate Dean for Clinical Affairs or the Director of the Dental Faculty Practice for reinstatement.

Referral of a potential research subject for patient care:

5. When a potential subject does not meet the research study criteria and disease is present, faculty or support staff shall advise the individual to seek professional care. A form shall be provided to advise the individual of the presence of disease, the need to obtain professional care, and the need to seek treatment within a specified amount of time. This shall be documented in the individual’s information file.

6. Information about the School’s clinics (predoctoral, graduate student, faculty practice) shall be available for all subjects who are screened or are selected; however, it should always be made clear to potential or existing research subjects that their ability to obtain treatment from the SOD is not conditioned on their willingness to participate in research.

7. Unless previously placed on Administrative Lock, individuals may be referred to the Dental Faculty Practice or may apply for admission to the predoctoral or graduate clinics. The individual should not be given assurances about receiving treatment, and should not be escorted to a treatment area. Each clinical area has its own process and criteria for admission. The individual should be made aware that there is cost associated with treatment, and payment is due at the time of treatment.

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Department Chairs Committee
UNC School of Dentistry