

**INVESTIGATOR STUDY PLAN - REQUIRED
07-15-2014**

1) Study Title

A Methodological Study to Assess Mental Disorders for NCS Birth Parents

2) IRB Review History

NA-no external IRB

3) Principal Investigator

Thomas McLaughlin, ScD.

4) Objectives

The Parental Mental Health Formative Research Project (LOI#9) is developing a brief questionnaire to assess parental mental health that is a major driver of their children's behavioral and mental health. The questionnaire developed by the NCS Mental Health Working Team will be administered by telephone with an expected duration of approximately 10 minutes. Questionnaire responses indicative of mental illness will be compared to a gold standard-the Composite International Diagnostic Interview (CIDI). The CIDI will also be administered by phone and is estimated to take 30 minutes to complete. To further compare results using a simple evidence-based biological marker of cumulative stress consisting of determination of chromosomal telomere length, parents will be asked to provide a saliva sample.

5) Background

Several research studies have already established the evidence that commonly found mental health disorders in parents (particularly pregnant women) are likely to yield to children's mental and behavioral health problems. These include mood disorders (major depressive disorder, bipolar disorder), anxiety disorders (generalized anxiety disorder, panic disorder, post-traumatic stress disorder), and impulse-control disorders (adult attention/deficit hyperactivity disorder, intermittent explosive disorder). All of these disorders other than bipolar disorder are commonly occurring disorders in the general population.^{3,4} In comparison, bipolar disorder has a prevalence of only about 1% for Bipolar-I and another 1-2% for Bipolar-II, but has a clinically significant sub-threshold spectrum that represents approximately 5% of the US population⁵. Overall, parental mental disorders are powerful risk factors for children's mental and behavioral disorders, making it critical to obtain accurate estimates of parental mental disorders in National Children Study (NCS) baseline assessments. However, these disorders are usually assessed and diagnosed using very lengthy and complicated instruments. In recent years chromosome telomere length has been identified as a biological marker of cumulative stress and biological aging, and may be as or even more valid than psychological measures. A quick, inexpensive assay for evaluation of chromosomal telomere length using saliva cells is now available. The assay does not involve or rely on analysis of genes but is a measure of the physical length of the ends of chromosomes. For purposes of the NCS that will be following 100,000 kids and their parents for 21 years, the potential value of a simple inexpensive measure of toxic stress and possibly declines in health status that can be collected quickly is immense.

6) Inclusion and Exclusion Criteria

Study subjects will consist of adults of age 18 and older, pregnant women at any stage of gestation and the male partners of pregnant women. Postpartum mothers and fathers will also be included. Postpartum is defined as four weeks following birth. The subjects must be English speaking to participate, reside in Worcester County, MA, and will not already be enrolled in the National Children's Study. No minors, adults unable to consent or prisoners will be included in the study.

7) Study-Wide Number of Subjects

The total number of participants to be recruited is the number required to obtain 1,200 completed PMHS interviews with an expectation that the number of mother interviews to father interviews would be 2:1. We will use clinical sites, prenatal classes, nutrition programs that we have identified but are not using for PBS or have used in other formative research involving pregnant parents. That is, those recruited will be non-NCS participants so as not to increase patient or even clinical burden.

Participants will have to understand English though it need not be their first language since there is no budget at present for other languages.

In practice, a larger sample size tends to obtain a better level of precision in making statistical inferences about the population. It also allows for oversampling of small subgroups of interest, such as race or ethnicity. For the second-stage clinical reappraisal interview using the CIDI, the sampling methodology will account for the population prevalence of the various psychiatric illnesses. As such, all PMH screen positives for bipolar disorder and schizophrenia will be selected as these are rare disorders in the general population. Depression and anxiety, being the most prevalent conditions, will be selected using a stratified sampling method to include all subgroups identified above.

The goal of the analyses is to assess the accuracy of mental disorder screens for pregnant women by comparing the screening responses to a gold standard-the CIDI. The methods of these activities rely upon the McNemar chi-square tests at the aggregate level and are under the receiver operating characteristic curve (AUC) and kappa approaches at the individual level. We will use stepwise logistic regression models to evaluate any significant differences in concordance between screening scales and clinical diagnoses based on respondents' socio-demographic characteristics. We can develop separate calibration rules to adjust the estimates of predicted probability of diagnosis from screen scale scores.

An estimated 1,200 participants will be utilized in the above analyses with 1,200 of the parents will receive one questionnaire and then a subset 400 of the 1,200 will receive a second questionnaire (CIDI). The sample sizes required for the 80% or 90% power required to detect Kappa values significantly different from 0 for a two-tailed test for null at a value of .60 is 149 and 200, well within our targeted sample size.

Through oversampling, we will target the racial and ethnic makeup of the final study cohort as follows.

B.1 IRB Protocol 07152014 Amended
 Parental Mental Health

Race	What is your race? (One or more categories may be selected) a. <u>933</u> White b. <u>133</u> Black or African American c. <u> </u> American Indian or Alaska Native d. <u>67</u> Asian Indian e. <u> </u> Chinese f. <u> </u> Filipino g. <u> </u> Japanese h. <u> </u> Korean i. <u> </u> Vietnamese j. <u>67</u> Other Asian k. <u> </u> Native Hawaiian l. <u> </u> Guamanian or Chamorro m. <u> </u> Samoan n. <u> </u> Other Pacific Islander
Ethnicity	Are you Hispanic, Latino/a, or Spanish origin (One or more categories may be selected) a. <u>750</u> No, not of Hispanic, Latino/a, or Spanish origin b. <u>12</u> Yes, Mexican, Mexican American, Chicano/a c. <u>386</u> Yes, Puerto Rican d. <u>5</u> Yes, Cuban e. <u>44</u> Yes, Another Hispanic, Latino/a or Spanish origin

8) Study-Wide Recruitment Methods

The UMASS NCS Study Center will recruit parents from throughout Worcester County utilizing NCS Community Advisory Board, birth education classes, and advertisements on community message boards.

PMH staff will negotiate with prenatal providers and hospitals for permission to talk with potential participants in person in practice offices and in post-partum rooms after delivery in hospitals. Study staff will ask prenatal providers to have the receptionist hand a Study Card and brochure to each pregnant woman presenting for care. The Study Card serves as an eligibility screener, to document interest, and to collect contact information for completion of interviews and the mailing of incentives. PMH Interviewers will approach women who are holding the Card, explain the study, complete an eligibility

screening, and conduct the informed consent process in person. Likewise in hospitals a similar procedure will be used except that new mothers and fathers will be identified by their presence in a post-partum room at the hospital. Using a partial waiver of HIPAA Authorization, Interviewers will pre-screen Labor and Delivery floor admissions in order to avoid contacting women who would be ineligible according to the information available in the electronic/paper records. In lieu of a HIPAA waiver, having hospital staff approach women is not a practical approach because floor nurses are busy with the care of all of the patients to which they are assigned on a given day. Asking a nurse to contact the woman to ask permission to speak with us interrupts the flow of the nurse completing his/her own work. With often several studies occurring on the Labor and Delivery floor at any one time, this request adds a burden to the work of an already-busy nurse and could not practically be carried out. Before initiating our work in the Post-partum areas, which would include pre-screening using patient records, Study leaders review procedures with and gain permission from facility executives, nurse managers, and managing physicians who are responsible for the care and well-being of the patients in their area.

In the event that the individual may reconsider enrollment, the Study Card information will be retained for the duration of the study. If the individual requests that their information be deleted, the study will honor their request.

Eligible women and men (1) can self-select into the study by calling the study phone number. This information will be available through advertisements on message boards or materials (e.g. flyers, brochures in public locations); after study staff provides a verbal informed consent by telephone, printed consent documents will be mailed to the participant for signature, and an interview appointment will be scheduled upon receipt of the signed consent documents by the Parental Mental Health Study office, or (2) will be informed of the project by a brief presentation by a NCS staff person held at various community locations. If interested, the parent will be verbally consented by the NCS staff member and her contact information will be obtained.

Once a participant is enrolled and consented, a trained, PMH interviewer will call the parent from a land-line telephone with

headphone to conduct the interview. . The woman will be verbally re-consented prior to the administration of the survey. A script will not be used for making or answering calls. Individuals calling in to the study office will include those contacting the study for the first time to inquire about participation, as well as those who have already spoken to study staff and are at various stages in the recruitment, enrollment, and interview completion process. Outgoing calls will also be completed for recruitment, enrollment, and interview activities. For this reason, rather than having the Interviewers use a script for fielding calls, Interviewer training will include mock interviews and scenarios to teach techniques for answering calls and conducting interviews.

All recruitment (and data analysis) will occur through the NCS Study Center in Worcester Co. Key personnel for the team is already on board and these will be added to through the hire of per diem recruiters and interviewers. Personnel for training and use of study instruments currently exist in-house. Analytic methods and programs are being adapted to the study instruments, most especially since we changed from the SCID to the CIDI as the gold standard instrument, thus requiring revision of the programs.

9) **Study Timelines**

The study duration is from September 26, 2013 through September 25, 2015. Subject enrollment will begin in February 2014 and ending February 2015. Subjects will be enrolled in the study for the maximum of 3 weeks. Analyses will be on-going throughout the duration of the project. From March to September 2015, the analyses will be finalized and a report completed.

10) **Study Endpoints**

1. Test the feasibility of implementing a short, telephone mental health screen.
2. Test the validity of the PMH screen against the gold standard, the CIDI.

11) **Procedures Involved**

There are three parts to this study:

1. The Parental Mental Health Screen
 - a. All pregnant women and fathers of the babies who agree to participate in this study will provide a phone number to the research assistant and they will schedule a time for a telephone call.
 - b. At the agreed upon time, the research assistant will call the pregnant parent. The research assistant will ask the parent a series of questions from the PMH Screen. This call will last approximately 10 minutes.

2. The Composite International Diagnostic interview (CIDI)
 - a. One-third of the parents in the study will be randomly chosen to participate in a second phone call. This time questions from a mental health screening instrument called the Composite International Diagnostic interview will be asked. This phone call will last approximately ½ hour.
3. Collection of a saliva sample
Following consent in the provider location, all participants who consent to have a saliva specimen collected will be asked at that time to allow the interviewer to provide directions for providing a saliva sample. Participants will fill the collection tube to the fill line. The DNA from the saliva sample will be extracted and DNA telomere length will be measured. Saliva samples will not be collected from participants who are not consented in person.

To reschedule missed appointments, Interviewers will continue to attempt to contact participants who cannot be reached at the time of their initial appointment interview. On 5 additional occasions at different times of day and days of the week, interviewers will use phone numbers and email addresses provided by the participant at the time of consent to call, email, and text them.

Interviewers will administer both the PMHS and the CIDI via REDCap. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. The UMass NCS Center staff will use FISMA compliant laptops to enter the data into REDCap.

Both the PMH screen and the CIDI will be entered directly into the REDCap system as the interview is conducted by phone in real time (Computer assisted telephone interview).

Study cards and consent forms will be stored in a locked cabinet in a locked office and only accessed by study staff. The documents will be kept for a minimum of seven years after the date of the last publication. Both of these activities will be conducted by the PMH interviewers and research assistants. Data from the Study cards will be entered into a tracking database, FoxPro, to aid in the study management process.

Daily, diagnostic algorithms will be run in REDCap using the data from REDCap PMH database. Upon completion, a second

analytical program will be implemented to obtain a subsample for participation in a second-stage clinical reappraisal interview using the CIDI. The CIDI will be administered as a telephone interview.

Participants will receive a monetary token of appreciation of \$25 for completing the Parental Mental Health Screen. If chosen to participate in the CIDI, participants will receive an additional monetary token of appreciation of \$25.

Fifteen percent of all interviews will be selected for validation of completion and quality assurance. Following completion of selected interviews, participants who completed the interviews will be called by study staff and asked a series of questions using a script. Responses will be entered into the REDCap database.

12) **Data and Specimen Banking**

Study data (questionnaire responses) will be entered and transmitted electronically using the secured encrypted internet-based REDCap data platform accessed on NCS approved computers. The UMASS NCS study center intends to keep the de-identified research data for those who do not enroll in the study at a minimum until the analysis of the information is completed and for the minimum period of 3-7 years as required for NIH studies. All data of enrollees will be retained by the UMass study center and will also be transferred as stipulated by contract to NORC and the National Children's Study Program Office.

Saliva samples will be stored temporarily in a locked storage room at the UMMS Chang Building, 222 Maple Avenue, Shrewsbury until they are shipped for analysis of telomere length to an analytical laboratory. The stored and shipped samples will be labeled with the participant's identification number. No other identifying information will be kept with the samples. The Chang Building is a locked FISMA-compliant building accessible only to authorized persons via a badge swipe or to visitors admitted by authorized personnel. The storage room is accessible only to key study staff and facilities personnel. Samples will be shipped via FedEx to the analytical lab for analysis. They will be destroyed according to analytical laboratory protocols once the analysis is completed.

Specimen tracking data and analytical results will be entered into the study REDCap database and FoxPro tracking database.

13) **Data Management**

Each study subject will be assigned a subject identification code consisting of two elements to identify the interviewer and a subject number. The UMass Center will maintain a separate database, the FoxPro tracking database, to link subject identification codes with each subject's name and telephone number.

Interviewers will enter a specified username and password provided by the UMASS NCS center to gain access to the study survey, made available on the secured, encrypted web-based Research Electronic Data Capture (REDCap) platform, developed by the UMASS NCS center. Interviewers will then use the study survey to administer the interview questions, entering subjects' responses as each response is given where it is stored electronically on the secured, encrypted REDCap data platform.

Subjects' names, addresses, email addresses, birthdates, and telephone numbers will be stored in the FoxPro tracking database secured according IRB and NCS confidentiality requirements. For security measures related to data, the baseline technical requirement per NCS is that laptops and other computing devices used in the data collection process should:

- Be equipped with FIPS 140-2 compliant full disk encryption
- Be hardened to the specifications set forth in the DISA STIGS <http://iase.dis.mil/stigs/index.html>

14) **Provisions to Monitor the Data to Ensure the Safety of Subjects**

There is a very rare likelihood of potential risks to subjects, which may include: 1) experiencing minor discomfort related to the standard procedures of responding to the potentially sensitive and personal questions included on the questionnaires, and 2) minor risk of potential breach of confidentiality. To protect against the risk of discomfort, the informed consent process will prepare participants in advance as to the nature of the questions they will be asked. Participants will be advised that their responses to questions are voluntary and that they may choose to refuse to answer any of the questions. Interviewers will all be trained in conducting mental health interviews – and specific training will include how to alleviate participant discomfort and/or address any discomfort and how to respond to indications that subjects need mental health services. Though danger to self or others is expected to be a very low risk in the study population, interviewers trained in the use of a previously approved risk assessment protocol will contact the Project Manager, Study Psychologist, or the PI and discuss the safest course of action for emergent care if necessary. (Also, please see below in the section **Access to Emergency Mental Health Specialty Care** for additional details.) Participants who ask for support for issues raised during the screening interview will be directed to the local study manager for assistance seeking services. Following participation in the screening interview, all participants will be provided with a list of local resources, including mental health resources, should they desire to pursue support for any of the issues raised.

Safety Plan: Access to Emergency Mental Health Specialty Care. A worrisome problem any mental health study is assuring immediate access to specialty mental health services for patients who might become dangerous to themselves or others without any mental health care benefit. Fortunately, the study site at UMass Memorial is Central Massachusetts' leading resource for

providing vital mental health services in both outpatient and inpatient settings for adults as well as children. Emergency Mental Health Services (EMHS) are available to individuals regardless of their insurance or ability to pay. In the current year, more than 6,000 psychiatric evaluations will be handled by staff in the UMass Emergency Department. The EMHS team sees patients in crisis, such as those who may be planning to commit suicide or overdosed on drugs, or patients who are feeling overwhelmed by events in their life. EMHS personnel can mobilize the mental health team to go to other hospitals or facilities in the Worcester area in the event a patient needs an emergency evaluation. When a patient comes or is sent to the emergency room, medical needs, if any, are met first. Once the patient's medical condition is stabilized, EMHS staff conduct a full mental health evaluation and develop a care plan for the patient that can involve discharge and arranging for outpatient services, being admitted for more intensive treatment, or being moved to a crisis stabilization unit. Patients in crisis stabilization units, located throughout the Central MA, stay for one to five days and receive intense, targeted treatments. A multidisciplinary team, including nurses, social workers, trained crisis counselors, psychiatric residents and attending psychiatrists operates EMHS 24/7. The goal of care is to stabilize the patient, identify the crisis and determine effective treatment, allowing the patient to return home.

15) **Withdrawal of Subjects**

The study is voluntary. A subject can withdraw at any time without any impact upon her prenatal care.

16) **Risks to Subjects**

This study involves no more than minimal risk. The participant may experience discomfort associated with this study when asked about emotional, behavioral, or substance use difficulties. There is also a risk of lost or exposed personal information. To protect against potential breach of confidentiality, access and use of the participants' names, telephone numbers, addresses, email addresses, and birthdates, will be managed, accessed, and stored on secure, encrypted computer data bases with any physical copy to be stored in a locked file in accordance with the NCS-approved security plan.

With regard to the saliva collection, because genetic information is unique to the individual, there is a small chance that someone could trace research results back to the participant. The risk of this happening is very small, but may grow in the future. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except

those with fewer than 15 employees, to discriminate against individuals based on their genetic information. However, it does not protect against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If participants do not share information about taking part in this study, this risk will be reduced.

17) **Potential Benefits to Subjects**

There are no benefits to the subjects as a result of participating in the study.

18) **Vulnerable Populations**

Pregnant women are being recruited for this study. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.

19) **Multi-Site Research**

UMMS is the only location of this study.

20) **Community-Based Participatory Research**

N/A

21) **Sharing of Results with Subjects**

The results of the tests will not be shared with the subjects or their medical/clinical providers with one exception: If a woman or man is experiencing significant, psychological distress, the results will be shared directly with the person and the Emergency Mental Health Services (EMHS)

22) **Setting**

The recruitment will take place in the community at prenatal provider practices, in hospitals and at childbirth education classes. The interviews will be conducted by phone. The NCS located at the Chang building has a designated call center where the interviews will be conducted. Data analyses will take place at the Chang or on the UMass Medical school campus.

23) **Resources Available**

This project is funded through a NICHD – NCS -Sub award. There are adequate resources and facilities to carry out this research, including staff, funding, space, recordkeeping capability, and resources to address serious adverse events.

- **Thomas McLaughlin ScD**, Professor of Pediatrics, Psychiatry, and Quantitative Health Sciences and past Co-Principal Investigator of the UMass NCS-Center, will serve as the Lead Investigator on this project

and will be responsible for successful implementation and timely completion of all aspects of the proposed research. He is a mental health researcher who has conducted NIH and foundation research funded work in diverse populations: Medicaid patients with schizophrenia, bipolar disorders and since 1992 mental disorders in primary care. He has conducted randomized controlled trials, epidemiologic studies, clinical research and health services research. Presently he is focused on adolescent depression and leads the development of a mental health research program for the National Children's study. He is well experienced in information security training, operationalization and monitoring of sensitive data such as psychiatric information and sequestering of these data with access approved by the IRB and the PI. He is well versed in the development of safety nets especially suicide protocols aimed at reducing risk in study subjects. Typically his studies develop safety protocols that exceed federal standards. He has numerous publications in the area of mental health.

- **Onesky Aupont, MD, MPH, PhD**, Assistant Professor, Department of Pediatrics will serve as Co-Principal Investigator for the Parental Mental Health Study
- **Project Manager** will have primary responsibility for overseeing proper implementation of the proposed work; will maintain the daily operations of the study, and will place saliva samples in temporary storage and ship samples for analysis.
- **Study Coordinator** will have primary responsibility for engaging medical provider offices as participant recruitment locations and for maintaining compliance with FISMA security requirements. The Study Coordinator will also place saliva samples in temporary storage and ship samples for analysis.
- **REDCap Expert** is responsible for maintaining the web interface for the administration of the MH screening scales for the study in the REDCap system; for receiving all data from the REDCap data platform and checking reliability of the data; for providing ongoing trouble shooting through the duration of the project; with Dr. McLaughlin will be responsible for the specification of all the necessary explanatory statistical models and the interpretation of results.
- **Clinical Psychologist** will provide training to the CIDI Interviewers on conduct of the CIDI Interview, develop and provide training to all Interviewers on recognition and management of mental health emergencies, serve to triage mental health emergencies, conduct quality review of CIDI Interviews

- **Project Assistant** will provide administrative assistance with study activities including triaging incoming calls on the study toll-free number
- **7 PMH Interviewers** will recruit/consent/conduct PMHS telephone PMH interviews with consented subjects. They will collect saliva samples, delivering them to the Chang building for storage.
- **2 CIDI PMH Interviewers** will conduct CIDI telephone interviews with consented subjects

In the original application, clinical interviewers were required as part of the protocol due to the training and licensing requirements to administer the SCID. The revised project does not include the SCID; it has been replaced with the CIDI that was developed for field use by trained lay investigators. The CIDI is a comprehensive, fully-structured interview designed to be used by *trained lay* interviewers for the assessment of mental disorders according to the definitions and criteria of ICD-10 and DSM-IV. It is intended for use in epidemiological studies and has been used extensively for decades in multiple international settings.

Interviewers will be trained in the administration of all instruments by the Project Manager, REDCap Expert, clinical psychologist, and the PI. The CIDI training session is 54 hours. The materials will be provided by Dr. Kessler. The PMH training program was developed at UMass in collaboration with the University of Michigan. The training program for PMH is 24 hours. The final piece of the training will include a course on crisis intervention. It will include how to identify a person and crisis and how to respond. The total amount of training staff will undergo is two weeks and 1 day.

Recruiters and interviewers will all be trained in conducting mental health interviews – and specific training will include how to alleviate participant discomfort and/or address any discomfort that occurs.

24) **Prior Approvals**

This study has been previously approved by the UMass IRB.

25) **Recruitment Methods**

See Study-Wide Recruitment Methods

26) **Local Number of Subjects**

UP to 1,200 participants are planned to be recruited.

27) **Confidentiality**

See Data Management

28) **Provisions to Protect the Privacy Interests of Subjects**

NCS staff undergoes training and certification in maintaining confidentiality and security of participants' data. Subjects' names and telephone numbers will be stored in the FoxPro tracking database and secured according to IRB and NCS confidentiality requirements. Interviewers will make each phone call from an appropriate setting in accordance with NCS and institutional requirements and standards for maintaining patient confidentiality. PMH Study staff will enter information from Study cards into a FoxPro tracking database kept in a secure UMass network shared drive accessible only to PMH Study staff. Access to laptops is password protected and a separate FoxPro log-in, available only to study staff, will be needed to access the FoxPro database

29) **Compensation for Research-Related Injury**

In the unlikely event of injury, no funds have been set aside for coverage. As of March 2014, UMMS is no longer responsible for coverage.

30) **Economic Burden to Subjects**

None

31) Consent Process

The parent will sign an informed consent form prior to receiving a phone call from the PMH interviewer. At the time of the call, the PMH interviewer will verbally re-consent the parent prior to administering the PMH questionnaire. If a respondent is selected for the second-stage clinical reappraisal interview using the CIDI, the CIDI interviewer will verbally re-consent the parent prior to administering the CIDI.

For individuals calling in to self-select into the study, study staff will conduct a verbal informed consent by telephone, then will mail a consent document and consent signature page for the individual to sign and return by mail prior to scheduling the PMH interview call.

32) Process to Document Consent in Writing

Eligible parents (1) can self-select into the study by calling the study phone number. This information will be available through advertisements on message boards or materials (e.g. flyers, brochures), or (2) will be informed of the project by a brief presentation by a NCS staff person held at various recruitment venues. If interested, the expectant parent(s) will be consented and their contact information will be obtained.

Consent process for (1) if the expectant parent self-selects into the study by telephone, they will be verbally consented by phone, then consent materials will be mailed to them with a request to return the signed signature page in an enclosed postage-paid addressed envelope. (2) The NCS staff member will be present at various locations within the community, where they will give presentations about the study. This will take place at birth education or parenting classes. Parents who are interested in participating in the study can approach the NCS staff member, who will then begin the consent process. Parents will receive a copy of the informed consent.

33) Drugs or Devices

N/A