***Case Series*** *is an interesting half-breed, somewhere between a retrospective cohort study and a case report. A case series design is similar to the case report, only involving more than one individual. The case series may involve the documentation of a rare disorder in a group of people, or may actually be a “how we do it” study, wherein a given procedure that has been performed on a number of patients is described, and commonly advocated. The IRB will use this protocol to make their determination. Please reference sections in this document to complete the application.*

**Title**

(Descriptive title; keep it tight, no 100 word titles)

**Version Date**

(e.g., the date the protocol was created)

**Significance/Background:** Using the literature, establish any previous work related to your research question. This section should describe the gaping hole in the literature and how your specific aims will attempt to address it. **Make sure to cite your references in this section!**

***Example:***

*Patients who develop velopharyngeal incompetence (VPI) while having their cleft palate repaired suffer from various anatomical disarrangements resulting in severe speech pathology.1, 2 Numerous surgical procedures have been proposed for the correction of VPI due to cleft palate repair or other less common etiologies (e.g., surgical trauma, VPI secondary to congenital malformation without cleft palate).3-6 However, these procedures are associated with various complications and diverse results.7-10 The Double Opposing Buccal Musculomucosal Flap (DOBMF) procedure was first described by Hill et al.11 though the technique has been used by the primary author for over a decade. Our goal is to evaluate the DOBMF procedure through the use of our extensive patient information collected over the last 15 years.*

**Objective(s):** Identify the specific aim(s) for your study.

***Example:*** *To determine the outcomes associated with the DOBMF for the repair of secondary VPI.*

***Primary Outcome Variable(s):***Describe any outcome variables for the study.

***Example:*** *Incidence of pulmonary emboli as determined from chest CTA, total number of CTAs ordered.*

***Setting/Resources for the Study:*** Describe where the research will take place. This includes both the setting for the research, as well as the location of any of the patient records to be obtained. You will also need to describe the capability of the investigators to perform the research, as well as the timeframe for the study.

***Example:*** *The Surgical Plastics, PC will be the setting for this research. The electronic medical records will be accessed by the investigators in order to collect the data for the study. The investigators have all participated in research at General Hospital previously and have successfully completed the CITI program. The timeframe set for this study is one year.*

***Study Design:*** Describe the study design.

***Example:*** *Retrospective case series*

***Study Subjects:*** Describe where you will obtain your subjects, over what time period and the specific inclusion and exclusion criteria used.

***Example:*** *All patients who have undergone the DOBMF by W. Norple, MD from 1/1/93 to 7/15/08 at Surgical Plastics, PC.*

***Study Procedures:*** This section basically describes methods for obtaining your data and descriptions/definitions of your variables.

***Example:*** *Data to be collected from a retrospective chart review will include: patient demographics, pre-operative analysis (i.e., speech assessment, nasopharyngoscopy and/or videoradiography), operative technique and post-operative course. Complications, post-operative speech analysis and mean length of follow-up will also be noted (see attached data sheet for complete list).*

***Statistical Plan* *(please don’t struggle with this section, staff are available to help write this up)***

***Sample Size Determination:*** Describe the statistical methods for determining the sample size for the study (reason for choice of sample size).

***Example:*** *As this is an observational study, no formal sample size analysis has been conducted. We anticipate reviewing the records of 15 patients.*

***Statistical Methods:*** Use this section to provide a thorough description of the statistical tests that will be used in the analysis of your data. No statistical comparisons are planned for the data.

***Example:*** *Summary statistics will be calculated.  Quantitative data will be expressed as the mean+SEM and nominal data will be expressed as a percentage.*

***The next three sections should be left as is for IRB submission***

***Risks to Subjects:*** This study is based on retrospective data, the only possible risk would be loss of confidentiality.

***Potential Benefits to Subjects:*** This study is based on retrospective data, there will be no benefit to the study subjects.

***Confidentiality and Management of Data:*** Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Patient data will be entered into a password protected electronic spreadsheet. Only the investigators will have access to the file/password. No identifiable data will be collected and a correlation tool will not be used. Electronic records will be stored for five years after study conclusion on the PI’s laptop computer, after which time they will be deleted.

***References:*** Use this section to provide all of the references used throughout your study. Pick a format from your favorite journal and use it consistently.

***Example:***

1. *Peat B, Albery E, Jones K, Pigott R: Tailoring Velpharyngeal Surgery: The Influence of Etiology and Type of Operation. Plast Reconstr Surg 1994:93:948-953.*

2. *Orticochea M: A Review of 236 Cleft Palate Patients Treated with Dynamic Muscle Sphincter. Plast Reconstr Surg 1983:71:180-188.*

*3. Ren Y, Wang G: A Modified Palatopharyngeous Flap Operation and its Application in the Correction of Velopharyngeal Incompetence. Plast Reconstr Surg 1993:91:612-617.*