**Delete all sections in Blue or Red prior to submi**s**sion to the IRB**

**IMAGING / DATA BANK TEMPLATE**

**Sections that are not applicable can be filled in simply with “not applicable.”**

|  |  |
| --- | --- |
| Title: | **Complete Title** |
|  |  |
| Protocol No: | **XXXX-XXX** |
| Protocol Date: |  |
| Amendment 1 Date:  | Amendment 4 Date:  |
| Amendment 2 Date: | Amendment 5 Date: |
| Amendment 3 Date: | Amendment 6 Date: |
| **Sponsor** (if applicable)Sponsor NameAddressCity, State, ZipCountry |
| **Study Principal Investigator** Office AddressCity, ST, ZIPPhone XXX-XXX-XXXXemail: XXXXX@XXX.XXX |

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Appendix 10

Abbreviations and Definitions of Terms

|  |  |  |
| --- | --- | --- |
|  |  | Insert and delete terms as relevant |
| °C |  | Degrees centigrade |
| AE |  | Adverse event |
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Abstract

Context: (Background)

* Include 1 - 3 sentences about the clinical importance of the condition and the importance of the research question.

Objectives: (primary and important secondary objectives)

* State the precise objective or study question
* If more than 1 objective, limit to only the key secondary objectives.

Study Design:

* Basic design: Prospective data and/or imaging bank
* Organizational Structure
* Potential Future Use

Setting/Participants:

* The setting including location (referral or community center) and level of care (inpatient or outpatient)
* The number of sites,
* The number and description of participants including key eligibility criteria

Data/Imaging Collection Procedures and Frequency:

* Main study outcome measures (assessments of primary and key secondary endpoints)

# Background Information and Rationale

The background and rationale should be no more than 3 pages

## Introduction

Provide background information to orient the reviewer (who may not be familiar with your specialty) to the issue under investigation. Provide a brief overview of the following:

* Rationale for developing the bank including information about the disease or condition, the target population and the unmet need and value of the desired data for future research.
* Potential future uses of the data/images
* Cooperating investigators or cooperative group(s)
* Funding sources
* Organizational structure

## Compliance Statement

This study will be conducted in full accordance with all applicable University of California, Los Angeles (UCLA) Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (unless a waiver is granted), and will report unexpected problems in accordance with the UCLA IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

## Relevant Literature and Data (If Applicable)

Provide a concise summary, identifying issues that this study will address. Point out any sources that would be especially useful in providing an overview of the subject.

# Study Objectives

*State the objectives of the data/imaging storage.*

The purpose of this study is to provide a mechanism to store data, images, etc. to support the conduct of future research about XXXXXXXXXX.

## Primary Objective (or Aim)

The primary objective of this study is to provide a mechanism to store the following information about subjects with DISEASE or CONDITION. This can include storage of data for subjects who will serve as controls for such research as well as….

## Secondary Objectives (or Aim)

The secondary objectives are to: ….

* List any additional objectives
* Etc.

# Investigational plan

## General Schema of Study Design

Provide an overview of study including a general description of the participating sites, the nature of the data and images and the mechanisms for protections.

### Description of the Collecting Sites (for multi-center research where UCLA will be the lead site)

A listing of the various sites that will be providing images/data to the bank. Information should include the policies and methods governing how the bank will ensure that each investigator is qualified, that the local IRB has an FWA registration number (Federal Wide Assurance) with OHRP (Office of Human Research Protections) and that the IRB approval is issued before the site begins participation in the research. The latter can be ensured by requiring a copy of the IRB approval letter and subsequent continuing approval letters.

### Overview of the Data/Imaging Collection

Provide an overview of the methods that will be employed for the data/imaging (e.g., database, interviews, physical examinations, procedures, etc). The specifics will go in Sections 4.

## Study Duration, Enrollment and Number of Sites

### Duration of Study

Duration applies to the subject’s participation, i.e., how long will they be followed in the bank.

### Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at approximately XX investigative sites in the United States and XXXX.

Recruitment will stop when approximately XXX subjects are ….. It is expected that approximately XXX subjects will be enrolled (identified for further review) to produce XXXX evaluable subjects.

## Study Population

Even if the study is retrospective, the study population must still be defined using inclusion and exclusion criteria.

### Inclusion Criteria (examples)

1. Males or females age 0 to 16 years.
2. Tonsillectomy (with or without adenoidectomy) between 1/1/1995 and 12/31/2005.
3. Completed operative note
4. Additional criteria as required
5. Parental/guardian permission (informed consent) and if appropriate, child assent. (Include ONLY if waiver of informed consent is not appropriate).

### Exclusion Criteria (examples)

1. Previous tonsillectomy, here or elsewhere
2. Named craniofacial syndrome

# Study Procedures

This section should list the data elements and images that will be collected as part of the data/image bank.

**Research Data Sources**:

Existing research data: If data are from research sources, for example for reanalysis of existing research data, provide the original IRB number and provide the section of the consent form that allows this use.

New research data: If the data collection is prospective from this or a related protocol, then either the protocol should be referred to or this submission must contain all of the details of the research activity to permit approval. This information could come from medical history, physical examination, laboratory, radiological, pathology, questionnaires or other psychological tools, etc. that were performed specifically for the purposes of this bank.

## Data Collection Procedures

Provide an overview for how the data will be identified, and collected.

If the data is being collected from routine care, it is important to completely justify that the data are available from non-research sources as opposed to surveys, questionnaires or medical history targeted specifically for the study.

### Data Collection

Detail where the data will come from. Will it come from medical records or will there be additional procedures such as history, physical exam, questionnaires, surveys, psychological exams etc., that are not part of routine clinical or existing research protocol.

For example, “CareConnect will be queried for demographic information, admission dates and discharge diagnoses. Surgical approach will be abstracted from the Operative Note. Indications and recovery information will be obtained from the office chart.”

Who will perform the data collection? If the data is abstracted from electronic records, who will perform this operation and will all PHI be stripped from the dataset prior to inclusion in the bank?

### Data Elements

Describe the data elements to be obtained from each data source. The data elements can be listed here or CRF pages included as an appendix to the protocol. Database owners will often need to provide the data to the investigator. They generally want to know that the IRB has approved the use of the data. Without a specific listing of the data fields, there is ambiguity.

### PHI Elements Collected

List of any personally identifiable health information that will be collected (any of the 18 HIPAA identifiers that will be recorded as part of the research). The elements that will be maintained at the site by the collector should be listed separately from the PHI elements that will be sent to the bank.

## Imaging

Provide a brief overview of the images to be collected. Will research procedures be performed at the same time as clinical procedures?

### Procedures

For each type of image that will be collected provide (a) a description of the study procedures, (b) the schedule of timing of imaging and if it will be collected more than once, and (c) where the images will be stored.

# BANK ADMINISTRATION

A Bank is organized to facilitate future use so this information is critical for understanding the human subjects issues. To be maximally beneficial for future research, policies and procedures need to be in place describing how the Bank will operate, how it will release data/images, and how the data/images will be identified when released. The identifiers associated with released data/images will determine whether or not IRB approval will be needed for subsequent research.

## Study Organization

Describe the overall organization and structure of the bank.

Describe the Policies and Procedures (written) for granting access for future use.

Describe how decisions will be made for granting access to investigators for future uses of the materials in the bank? How will the bank make these determinations?

Describe procedures and policies for distributing data for future research. There are usually three conditions for release of data: (1) without identifiers (no IRB approval needed and no HIPAA authorization or waiver), (2) with a limited data set (usually without IRB approval but with a Data Use Agreement executed by recipient and bank), or with identifiers (requires IRB approval and usually will require waiver of consent and HIPAA). See Section 5.3

## Data Collection and Management

Describe the system for maintaining primary records (source documents) and case report forms and for entering the data into any computerized systems. Address the following:

### Computer Systems

Describe the computer systems, facilities and equipment. Describe the backup plan and recovery plans. Describe the password protection and data encryption systems that will be in place. What are the plans for restricting and controlling access to the research data.

### Confidentiality of Subjects:

Describe the methods for ensuring the privacy of subjects and the confidentiality of their data/images.

Describe the coding scheme for data/images. Who will generate the code? Will the code include any elements of PHI (e.g., initials or dates). How will the data be linked back to subjects? Will the collecting site retain the link to PHI or will the Bank possess the PHI and have access to the link between data/images and subjects:

If PHI will be sent to the Bank it must be listed in the informed consent document and this must be justified.

Include descriptions or attach copies of Policies or Procedures related to use or disclosure of PHI for research purposes. If data/images will be anonymized (all PHI removed) describe how that will be done and by whom. that will be used to anonymize or de-identify data prior to future use.

#### Certificate of Confidentiality

If a certificate of confidentiality will be obtained, then that information should be provided. Delete this section if a certificate of confidentiality will not be obtained.

## Imaging Collection and Management

Describe the system for collecting, storing and distributing data/images.

Confidentiality. How will you ensure the confidentiality of the images, from collection through use. Describe the Code/ID number assignment and the maintenance of the linkage (if any) between the data/images and the subject’s PHI. Data/images that are linked to a Master List are “coded” or “linked”. Data/images that cannot be linked back to the donor because no PHI is ever attached are “anonymous”. Date/images that have the linkage removed are said to be “de-identified” or “anonymized”.

Storage. Where will the data/images be stored? If samples are going to more than one location, list each location and the person responsible at that location. How will the data/images be tracked? Describe the storage facilities and equipment.

Security. Describe plans for controlling access to data/images and limiting use to the purposes outlined in the consent document.

**NOTE: Maximizing the Future Use of Bank Materials**

Future use of data/images by recipient investigators can be subject to IRB oversight. Careful planning for the Policies and Procedures (SOPs) for the Bank can minimize the obstacles for future use and will maximize the usefulness of the materials collected.

If data/images will be provided to investigators without any elements of PHI and the Bank has a clear policy prohibiting release, then the future use of data/images will not require IRB oversight for recipient investigators.

If the data/images will be provided to investigators with a limited dataset (dates and city, state and zip code) then the procedures for obtaining a data use agreement between the Bank (the provider) and the recipient investigator should be described.

Other examples where IRB oversight would not be required include:

* Future use of identifiable data/images only in accordance with terms specified in the consent form and HIPAA authorization;
* An “honest broker” at the Bank who removes all PHI to anonymize the materials before sending them on to the recipient investigator. The honest broker may not be a member of the study team;
* Bank receives only de-identified data/images;
* Receipt of coded data/specimens with agreements in place with the providers of the data/specimens to not provide any PHI;
* Receipt of limited dataset information with either agreements to limit future use to the requirements of the data-use agreement or de-identification of the dataset before provision to investigators
* Receipt of identifiable information with policies and procedures in place to (a) never share any PHI with investigators as required by the IRB, state law, federal government (de-identify prior to release) or (b) provide only a limited dataset with an appropriate data-use agreement.

## Providing Results to Subjects

Describe the plans, if any for reporting research results to subjects and results of any incidental findings that clinically significant. Who will meet with the family? What are their qualifications for discussing the implications of the findings? What are to plans to communicate results to others (e.g., family physician)?

Research (non-validated) test results that are of uncertain clinical significance should not be reported back to families and should not be reported to physicians or included in the medical record without subject consent.

## Recruitment Strategy

For a purely retrospective study describe the case ascertainment procedures to identify eligible subjects (records).

Describe the approach to recruiting prospective subjects. Where will they come from? How will the investigator identify prospective subjects? Will the subjects come from the investigator’s patients or will they be patients of other care providers? If the prospective subjects are not patients of the investigator who will first approach the subjects and by what method (in person, via mail, via telephone contact?) Will advertising be used (submit copy to IRB for approval)? Will there be sufficient subjects to achieve the study goals?

## Informed Consent/Assent

Describe the process for obtaining informed consent and child assent or state that a waiver of consent will be received.

## Confidentiality

Include a statement that all data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. Describe the safeguards to maintain subject confidentiality (you may say, “Safeguards are described under Data Collection and Management,” if no additional detail is required. An important point: If the investigator leaves the institution and takes the data, or shares the data with an outside colleague, additional HIPAA requirements must be satisfied.

# SAFETY MANAGEMENT

The template language below assumes that the bank is a minimal risk study. If the risks of study procedures are greater than minimal, please see the IRB website for Serious Adverse Event reporting requirements.

## Clinical Adverse Events

Unanticipated problems involving risks to subjects and others will be monitored throughout the study.

## Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study these will be reported to the IRB in accordance with UCLA IRB Guidance and Procedure: Post-Approval Reporting Requirements (PAR) for Investigators: Reporting of Unanticipated Problems, Including Adverse Events as well as Protocol Violations, Deviations and Incidents and the Reporting of Updated Study Safety Information.

# PUBLICATION

Describe the plans for publication and presentation. ***Note that the inclusion of illustrative cases in such reports may result in disclosure of identifiable information****.* Consider this eventuality. If the UCLA investigator will not have access to the complete data set, or if this is multicenter study, describe how publication will proceed.

# References (IF APPLICABLE)

If a grant application is included in the submission, you may refer the reviewer to its References section.

Appendix

* Attach a listing of data elements from each data source.
* Attach any case report forms. (If applicable)