

# Application for IRB Approval

**General Instructions:** All information should be typed or legibly printed. Do not leave any spaces blank; if a section does not apply to your study, please indicate "N/A". Specific sections of the investigator brochure, study protocol, informed consent or other documents may be *referenced* to provide supplemental or substantiating information, but may not be utilized *in lieu* of completing the requested responses in the application form.

No action will be taken until a completed application packet is submitted, including the application fee if applicable.

**Emergency use** is defined as the one time use (or course) of an investigational drug, biological product, or device with one human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. This form must be completed and submitted within 5 working days of incident.

**Compassionate use** is defined as the use of an investigational device, drug, or biological product with an ongoing clinical trial already approved as the only option available for a patient(s) faced with a serious, albeit not life threatening condition.

**Treatment use** is defined as use of a promising new therapeutic or diagnostic device for patients with serious or immediate life-threatening disease or conditions for which no comparable or satisfactory alternative device, drug or other therapy exists, as early in the device development process as possible, i.e., before general marketing begins, and to obtain additional data on the device's safety and effectiveness.

## CHECKLIST

### I. Basic application components:

**Face Sheet**

**Study Description**

**Confidentiality Statement(s)** for non-WHS employees (duplicate as necessary)

**Behavioral or Biomedical Study Agreement (Contract) or Individual Investigator Agreement**

### II. Additional required documents:

(for every investigator and other research personnel) **signed Curriculum vitae**

(for every investigator and other research personnel) copy of **Certificate of Completion** of the "Requirement for Education on the Protection of Human Subjects," which can be obtained at <http://cme.nci.nih.gov> or direct access site <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

One copy of the **complete study protocol**, including all surveys, evaluations, press releases, etc.

One copy of the **informed consent** and **HIPAA consent** with Washoe Health System/Washoe Medical Center header and WHS/WMC contact info under questions document

### III. Components specific to certain types of studies:

**\$2,000 Fee** for processing made out to Washoe Medical Center IRB; please see memo for waiver request.

If **study monitors** are to be used; a protocol outlining the study monitors' activities within Washoe Medical Center must be developed and signed by all investigators.

One copy of all advertising/recruiting literatures, etc.

For **drug or device studies**, one copy of the investigator's brochure and/or device manual

For **device studies**, one copy of the investigational device exemption (IDE) form with IDE number

For **drug studies**, one Notice of Claimed Exemption for a new Drug (IND) with IND number

If **deferred approval** is requested, letter from external IRB indicating approval (CIRB only).

Note: The Investigator must provide this IRB with all items in the checklist above, as well as ongoing reports (e.g., amendments, reports of adverse events, annual reviews, etc.).

### Return With Original Signature(s) To:

**Sally Sue Broili, MT(ASCP), Administrative Coordinator IRB**  
**Washoe Medical Center**  
**77 Pringle Way X19**  
**Reno, NV 89502**

### For further information:

**Phone:(775) 982-5760**  
**FAX: (775) 982-4575**  
**ssbroili@washoehealth.com**

Renown Regional Medical Center  
 Institutional Review Board  
**APPLICATION FOR APPROVAL TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS**

**IRB APPLICATION FACE SHEET**

1. TITLE OF PROJECT: Bariatric surgery in patients with Body Mass Index 30 to 35  Protocol: Proposed start date: <u>9/1/2009</u> Proposed end date: <u>9/1/2012</u> Estimated total number of subjects: <u>500</u>	
2. PRINCIPAL INVESTIGATOR: Name, address, phone, fax, e-mail  Kent C. Sasse MD, FACS Western Surgical Group 645 N Arlington Ave. Suite #525 Reno, NV 89503 775 323-7500 <a href="mailto:Ksasse@westernsurgical.com">Ksasse@westernsurgical.com</a>	1. CO-INVESTIGATOR(S): complete address(es), e-mail  Dionne Lim MPH, BA Western Surgical Group 645 N Arlington Ave. Suite #525 Reno, NV 89503 775 323-7500 <a href="mailto:Dlim@westernsurgical.com">Dlim@westernsurgical.com</a>
4. APPLICANT/SPONSORING ORGANIZATION: (contact person(s), complete address, phone, fax, e-mail)  Dionne Lim MPH, BA Western Surgical Group 645 N Arlington Ave. Suite #525 Reno, NV 89503 775 323-7500 <a href="mailto:Dlim@westernsurgical.com">Dlim@westernsurgical.com</a>	5. PERFORMANCE SITES: (include all)  Western Surgical Group 645 N Arlington Ave. Suite #525 Reno, NV 89503
6. INVESTIGATOR ASSURANCE: I accept responsibility for the scientific conduct of the research and I agree to provide information and/or progress reports to the IRB of Washoe Medical Center as requested. I verify that all responsible investigators are appropriately credentialed to do the services provided and the work undertaken in this protocol.  Signature of Principal Investigator: _____ Date: _____	
7. CONFLICT OF INTEREST: All investigators are responsible for declaring any real or potential conflict of interest in regard to their research. Potential conflicts of interest include any consulting relationship or financial interest in a company sponsoring research you are involved in, which would include stocks, joint ventures, or patents.  A. Do any of the investigators have a real or potential conflict of interest? <input type="checkbox"/> YES* <input checked="" type="checkbox"/> NO  B. Will any of the investigators receive payment, either financial or in-kind (other than routine billing for direct care services rendered) related to participation in this study? <input type="checkbox"/> YES* <input checked="" type="checkbox"/> NO  C. If YES to either of the above, is this information included on the consent form? <input type="checkbox"/> YES <input type="checkbox"/> NO*  * Please attach additional sheet with explanations.	
8. Research involves the use of: (check all that apply) <input type="checkbox"/> Investigational Device <input type="checkbox"/> Investigational Drug, Phase (circle): I II III IV <input type="checkbox"/> Emergency Use Exemption <input type="checkbox"/> Compassionate Use Exemption <input type="checkbox"/> Humanitarian Use Exemption <input type="checkbox"/> Treatment Use Exemption <input type="checkbox"/> Cohort <input type="checkbox"/> Case-Control Study <input type="checkbox"/> Survey or Cross-Sectional Study <input type="checkbox"/> Case Series <input type="checkbox"/> Case Reports <input type="checkbox"/> Investigational Procedure (type): _____ Other: _____	

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**Signatures in this section required FOR EMERGENCY USE OR COMPASSIONATE USE EXEMPTED STUDIES only: All exempt studies must complete the Statement of Exemption Form in addition to the application.**

\_\_\_\_\_  
WMC Administrator (Print name: \_\_\_\_\_) Independent Physician: (Print Name: \_\_\_\_\_)

**IRB ACTION ON PROTOCOL & INFORMED CONSENT**

DATE RECEIVED: \_\_\_\_\_ IRB #: \_\_\_\_\_ Requires review fee:  NO  YES: Date Payment Received: \_\_\_\_\_

TYPE OF REVIEW:  Regular  Expedited  Administrative (including Emergency Use Exemption)  
 Deferred from Institution: \_\_\_\_\_ Approval date: \_\_\_\_\_ Exp date: \_\_\_\_\_

DATE REVIEWED: \_\_\_\_\_  
 Approval as submitted (IRB approval expires on: \_\_\_\_\_)  
 Approval deferred pending receipt of additional information (below)  
 Disapproved, for reason below:

Signature of Chairperson: \_\_\_\_\_ Date: \_\_\_\_\_

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**STUDY DESCRIPTION**

1. Will study Data Extractors or Monitor(s) be utilized?  NO  YES (please complete the section below)  
(attach pages as needed to list additional personnel)

Name of person Dionne Lim

Street Address 645 N. Arlington Ave. Suite #525. Reno NV 89503

Telephone Number (775) 323-7500 E-mail dlim@westernsurgical.com

Monitor Protocol Attached  YES  NO

2. Will personnel other than the investigators conduct interviews or perform procedures within the hospital?  
 NO  YES (please complete the section below) (attach pages as needed to list additional personnel)

Name of person \_\_\_\_\_

Street Address \_\_\_\_\_

Telephone Number \_\_\_\_\_ E-mail \_\_\_\_\_

Procedural Protocol Attached  YES  NO

3. Drug and Device Information (skip to part 4 if no drugs or devices will be used in the study):

A. For studies involving drugs:

**STUDY DRUG INFORMATION**

Generic name and trade or brand name \_\_\_\_\_

Name of manufacturer \_\_\_\_\_

Proposed therapy:  New Drug  New Therapeutic Application for Approved Drug IND No.: \_\_\_\_\_

***Pharmacological information such as dose schedule, route of administration, duration of therapy, indications, contraindications, potential adverse effects, detoxification, etc., should be included in the attached study protocol documents.***

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B. For studies involving devices:

**STUDY DEVICE INFORMATION**

Name of the experimental medical device \_\_\_\_\_

IDE No.: \_\_\_\_\_

*Device information such as method of application or insertion, duration of therapy, indications, contraindications, potential adverse effects, etc., should be included in the attached study protocol documents.*

*Federal regulations require that Institutional Review Board membership include individuals with varied backgrounds and education. Therefore, the summary information below should be written in terminology understandable to non-scientific persons.*

**4. Background** (must be summarized here; attached documentation does not substitute for this summary)

Summarize the background of the proposed study including the results of any previous research: Bariatric surgery has become an accepted standard of care practice for patients who meet the National Institutes of Health criteria. This includes people with a Body Mass Index (BMI) over 40 kg per meter squared and people with a BMI between 35 and 40 kg per meter squared who also have an identified comorbid condition caused by or due to their obesity. The most common of these conditions include diabetes mellitus, hypertension, hyperlipidemia, obstructive sleep apnea, degenerative joint changes and chronic dyspnea, among others. Bariatric surgery in patients with a BMI of 30 to 35 is increasingly performed. Several studies have demonstrated similar safety and efficacy outcomes. Actuarial data demonstrates that patients with a BMI over 30 do indeed experience a significantly shortened life expectancy than their counterparts with normal weight. Patients with a BMI of 30-35 also suffer a disproportionately high incidence of hypertension, diabetes, hyperlipidemia, heart disease, obstructive sleep apnea and degenerative joint disease. Thus, while a patient with a BMI of 32 may not be able to lose the same overall amount of weight as a patient with a BMI of 42, it is believed that those patients may experience significant health improvement as a result of even modest weight loss.

**5. Objectives** (must be summarized here; attached documentation does not substitute for this summary)

Summarize the objectives of the study: The objectives of this study will consist of a review of the clinical records of patients with BMI 30-35 who are undergoing or have undergone bariatric surgery and aims to report the outcomes associated with bariatric surgery. Endpoints to be observed will include perioperative consultations and adverse events. They will also then include weight loss and resolution or development of comorbid conditions over the years of the study. We typically gather such data at approximately one month, three months, six months, nine months and twelve months after surgery, and then annually thereafter.

**6. Subject Selection** (must be summarized here; attached documentation does not substitute for this summary)

Summarize the criteria for selection and exclusion of subjects: The subject will consist of all patients with BMI 30-35 who are undergoing or who have undergone a laparoscopic adjustable gastric banding/laparoscopic Roux en Y gastric bypass operation performed by a bariatric surgeon with Western Bariatric Institute.

A. Will any special populations be included in the study?  NO  YES (indicate type below)

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Minors  Pregnant Women  Mentally Retarded/Disabled  Prisoners  Other: \_\_\_\_\_

If YES, Justify the inclusion of subjects from one of the above mentioned special populations:

\_\_\_\_\_  
\_\_\_\_\_

**B. Specify (a) source of participating subjects (hospital, clinic, institution, general population, etc.) and (b) method of recruiting such subjects:**

Patients with BMI 30-35 who are undergoing and have undergone laparoscopic Roux-en-Y gastric bypass/laparoscopic adjustable gastric banding surgery procedure performed by a bariatric surgeon with Western Bariatric Institute.

**C. Will subjects receive any compensation, either monetary or other?  NO  YES:**

If monetary, how much \_\_\_\_\_ If other, please specify \_\_\_\_\_

**D Will subjects be asked to assume any out-of-pocket costs for participating in the proposed study?  YES  NO**

**E. Please indicate the source of payment (subject vs other payor) for drug(s) or device(s) used in the proposed study:**

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

Drug/Device: \_\_\_\_\_ Payment source:  Subject Other: \_\_\_\_\_

**F. Describe the complete process of informed consent** (including who will perform the consent, a summary of the steps involved in the process of informed consent, and circumstances wherein repeated written informed consent may be necessary during the course of the study). *Note: If the investigator delegates the function of verbal presentation and discussion to other members of the research team, the investigator must be sure they have sufficient knowledge of the protocol to answer questions appropriately—this delegation should be approved by the IRB. (Attach additional pages as necessary)*

As this is both a prospective and retrospective study, no informed consent is required. In the future, the researchers may ask patients to take part in other research studies about bariatric surgery. They can take part in future studies at the same time that they are taking part in this study. If subjects decide not to have bariatric surgery, or if the surgery does not occur for other reasons, they will no longer be part of this research study. All information of patients will be kept completely confidential.

Additional pages attached

**7. Clinical Monitoring**

Summarize clinical observations/examinations, surveys, phone contacts, laboratory tests, imaging studies, etc., to be performed on subjects: *(Attach additional pages as necessary)*

No additional laboratory tests, imaging studies, etc., are anticipated for any subjects. The examinations, phone contacts and/or surveys would be minimal and are already part of Western Bariatric Institute's ongoing follow up protocol.

Additional pages attached

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**8. Risks to Subjects**

**A. List any potential RISKS including physical, psychological, social, legal or ethical and assess the likelihood and seriousness of such risks. Include the anticipated frequency of each complication. (Attach additional pages as necessary)**

It is believed that this type of study, consisting of reporting of clinical outcomes of patients without any identifying information, would result in minimal risks to research subjects. Subjects are clinical patients of Western Surgical Institute and participate in a program of ongoing lifelong care, which would not change as a result of this study. Subjects consent to a clinical protocol involving certain amount of communication over the years. It is anticipated that annual contact would be sufficient and would consist of a brief conversation and possible questionnaire. It is believed that there is an exceptionally low likelihood of physical, psychological, social, legal or ethical risks involved from this type of communication and conversation. Safeguards exist in the office to protect patient and subject privacy. As the study is conducted under the auspices of an existing clinical practice devoted to bariatric surgery and lifelong follow-up care., stringent safeguards and privacy policies currently in existence would be rigorously applied.

\_\_\_Additional pages attached

**B. List procedures for protecting against or minimizing potential risks: (Attach additional pages as necessary)**

Procedures for protecting and minimizing the risk will include a strict compliance with HIPAA privacy policies and regulations. A minimum number of personnel in the department would have access to these records and any identifying information will be excluded from data collection and collation. Patient information and demographics will be kept in a secure location in accordance with privacy policies. Electronic database management will occur under strict privacy safeguards. (see attached)

\_\_\_Additional pages attached

**C. Describe procedures for managing adverse events: (Attach additional pages as necessary)**

Adverse events will be managed by communicating the details of the adverse event by the nurse to the principle investigator. The event will be managed at the discretion of the principle investigator with appropriate treatment of emergent and non-emergent medical issues.

\_\_\_Additional pages attached

**9. Benefits to Subjects**

Summarize potential benefits to be gained (a) by the study subjects themselves, or (b) to the generalizable fund of knowledge:

Benefits to the subjects would be the knowledge that they are participating in a study with potential benefit to a number of people worldwide. Some benefit may accrue to patients who come in contact with training health care professionals including registered nurse and physicians as a result of the study. While it would not be an advertised component of the study, it is believed that such contact may result in identification of medical issues in this high risk morbidly obese population. The generalizable fund of knowledge is expected to grow considerably as a result of this study.

**10. Benefit/Risk Statement**

Describe why the potential benefits outweigh potential risks:

It is believed that the benefits of the study are significant, especially with regard to the potential gain of knowledge by the subject. It is believed that individual subjects may benefit from increased exposure to an expert center dealing with problems of morbid obesity and bariatric medicine. It is also believed that the risk to subjects is exceedingly small, as it consists of informational contact over a prolonged period of time that is already a standard part of the clinical program. Reporting will include aggregate statistics and no personal identifying information, and thus presents minimal risks.

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**AGREEMENT**

By making application for this investigational study, I accept, and intend to diligently comply with all federal guidelines as well as Washoe Health System policies, procedures and regulations as they apply to investigational studies.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

Kent C. Sasse  
\_\_\_\_\_  
Typed or Printed Name of Principal Investigator

\_\_\_\_\_  
Signature of Co-Investigator

\_\_\_\_\_  
Date

Dionne C. Lim  
\_\_\_\_\_  
Typed or Printed Name of Co-Investigator

\_\_\_\_\_  
Signature of Co-Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed or Printed Name of Co-Investigator

\_\_\_\_\_  
Signature of Co-Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed or Printed Name of Co-Investigator

\_\_\_\_\_  
Signature of Co-Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed or Printed Name of Co-Investigator



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**STATEMENT OF CONFIDENTIALITY  
for  
Research Principle Investigators**

I am responsible for complying with the following research confidentiality practices and for becoming familiar with all Washoe Health System (WHS)/Washoe Medical Center (WMC) Confidentiality Policy and Procedures:

1. I understand that all WHS/WMC information will be treated as confidential and will be used only as required in the performance of my research. This includes, but is not limited to, information concerning WHS research participants. I will not disseminate this information to persons who are not authorized to receive it. I will not knowingly obtain, use, or possess any WHS/WMC information for which I am not entitled or authorized.
2. I will protect the confidentiality of all research patient information, whether communicated verbally, written or electronically. I understand that the unlawful duplication of records or misuse of software by me may constitute a violation of federal copyright laws and could result in fines or criminal prosecution for which I may be liable.
3. I will discourage others from disseminating any confidential or proprietary research information, whether patient information or WHS/WMC information.
4. WHS/WMC owned computer equipment or other computing resources to which I have access are to be used for business only. Unauthorized use of computer equipment is prohibited. Management reserves the right to review any files, programs, records, or other physical electronically managed information stored or processed through company computer equipment.
5. Breaches in security, which I may observe or have knowledge of, should be reported to the information Security Manager in Information Resources.
6. I further agree to abide by all Federal and State laws as well as applicability of Washoe Health System policies and procedures regarding protection of participants/patients including the HIPAA Privacy and Security Rule.

My signature below is evidence that I have read and understand my responsibilities for safeguarding the medical records, confidentiality and information assets of WHS/WMC in regards to my practice of research.

\_\_\_\_\_  
Date

\_\_\_\_\_  
NV License Number or  
Social Security No.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name