Official Title of study: Assessment of Outcomes Following Bariatric Surgery for Mississippi State Employees

NCT: 41165

Date of Document: Created April 05, 2010; uploaded May 3, 2018

Form: IRB application (study protocol and statistical analysis plan)

The University of Mississippi
Office of Research and Sponsored Programs
Division of Research Integrity and Compliance – Institutional Review Board
100 Barr Hall – University, MS 38677
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APPLICATION TO CONDUCT RESEARCH WITH HUMAN SUBJECTS
~ Instructions ~

- Use the most recent version of this form (http://www.olemiss.edu/depts/research/compliance/compliance_forms.html#irb).
- Do not submit a handwritten form. Prepare as a Word document, using no less than a 10 point font. [Note that, as this is a protected form, you cannot use Spell Check. It is best to prepare text in another document first, then cut and paste.]
- Answer all of the questions on this form completely. (If you have questions about this form, please contact the DRIC office at 662-915-7482 or irb@research.olemiss.edu.)
- For examples of Abstracts, go to http://www.olemiss.edu/depts/research/compliance/human/sample_abstracts.html.
- For examples of Procedures, go to http://www.olemiss.edu/depts/research/compliance/human/sample_procedures.html.
- Complete and attach all supporting documentation and all appropriate appendices.
- Complete the checklist that accompanies this form to assure all requirements for submission are completed. *Incomplete submissions will not be reviewed.*
- E-mail the completed form with attachments to irb@research.olemiss.edu. Fax the signature page to 662-915-7577, or mail or bring it to the Office of Research and Sponsored Programs, Division of Research Integrity and Compliance, 100 Barr Hall, University, MS 38677.

CHECKLIST

- ☐ All personnel have completed the appropriate CITI course. (Do NOT submit completion certificates.)
- ☐ All questions on the application have been completed and it has been proofread for consistency and accuracy.
- ☐ All supporting documents (consent forms, assent forms, surveys, interview questions, scripts, advertisements, etc.) are attached. All appropriate appendices are completed and attached.
- ☐ Approval of another committee or another institution, if applicable, is attached.
- ☐ Complete copy of the grant proposal, with pages pertaining to human subjects highlighted, if applicable, is attached.
- ☐ Departmental signatures (and signature of advisor for student research) have been obtained.
- ☐ A copy of this application has been made for the investigator's records.

☐ **List all personnel involved with this research who will have contact with human subjects or with their identifiable data. All personnel listed here must complete CITI training before this application will be processed.**

NAME	FACULTY OR STAFF	GRADUATE STUDENT	UNDERGRAD STUDENT	ROLE ON PROJECT
Katie McClendon	☒	☐	☐	Principal Investigator
Whitney Byars	☐	☐	☐	Oxford Surgical and Bariatric Clinic, LLC site manager
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	

If more space is needed to list project personnel, please submit Appendix A found on the ORSP Compliance Forms page.

OFFICE USE ONLY

APPLICATION TO CONDUCT RESEARCH WITH HUMAN SUBJECTS

ABSTRACT: **Briefly summarize your project using non-technical, jargon-free language that can be understood by non-scientists.** Include: (1) a statement of the research question and related theory supporting the reasons for, and importance of, the research; (2) the ages and characteristics of your proposed subjects and how you will recruit them; (3) the research design; and (4) a description of the procedure(s) subjects will undergo. Limit to the space below, using no less than a 12 point font. See Instructions (page 1) for a link to examples.

1. Objective: to assess the health and economic outcomes (weight lost, change in control of chronic diseases such as diabetes, quality of life, work productivity, health care cost, etc) associated with bariatric (weight-loss) surgery for 200 severely obese patients who undergo bariatric surgery as part of the Mississippi State Employees' Life and Health Insurance Plan's Obesity Treatment Program (OTP).

2. Patient Characteristics: Inclusion criteria: Eligible bariatric surgical candidates who are enrolled in the OTP (100 patients per year for 2 years). The Plan's criteria includes, but is not limited to 1) enrollment in the plan for at least 12 consecutive months prior to September 1, 2009; 2) completion of the HealthQuotient health risk assessment through the Plan's wellness and health promotion program; 3) a Body Mass Index (BMI) of >40 kg/m2, or a BMI >35 kg/m2 with two or more co-morbidities such as diabetes, hypertension, sleep apnea or asthma; 4) two or more physician-supervised weight loss attempts within the last 24 months; 5) age 18 years or older; and 6) consent to provide personal and medical information to the Plan. Prior to surgery, each site administers a pychiatric evaluation to ensure the patient is pychologically stable for surgery. Exclusion criteria: any patient who does not meet criteria above or who declines to participate. Surgeries will take place only at Certified Bariatric Surgery Centers of Excellence (COE), of which, there are currently 3 in the state. The 3 COEs exist with 4 outpatient medical offices (1 COE is composed of 2 independent surgeon practices) Patients will be recruited at each site once they are approved by the OTP.

3. Design: prospective, observational, multi-center, longitudinal study of outcomes and resource utilization associated with OTP. Estimates of obesity and comorbidities' impact will be obtained from the outpatient medical office for the COEs. Medical charts, databases and medical/pharmacy claims will be the source of information. Surveys on quality of life, productivity, and patient satisfaction will be administered directly to patients. Database claim information will be obtained in future and is not a part of current IRB application.

4: Procedures: After obtaining informed consent, patients will be administered surveys at baseline, as well as at follow-up visits. Additional data will be obtained via patient charts, databases, and medical/pharmacy claims.

1. PROJECT TITLE: **Assessment of Outcomes Following Bariatric Surgery for Mississippi State Employees**

   If student project: ☐ dissertation ☐ thesis ☐ other:

   Date dissertation or thesis proposal approved by committee: (committee approval required)

2. PRINCIPAL INVESTIGATOR: ☒ Dr. ☐ Ms. ☐ Mr. **Katie McClendon**

   Department: **School of Pharmacy, Dept Pharmacy Practice** Work Phone: **601.984.2638**

   Mailing Address: **2500 North State Street, Office Annex I**
   Jackson MS 39225 Home Phone: **601.668.8811**

   E-Mail Address: **kmcclendon@sop.umsmed.edu** Fax Number: **601.984.2751**

   CO-INVESTIGATOR(S): **name** **name**

3. RESEARCH ADVISOR: (required for student researchers)

   Department: Work Phone:

   E-Mail Address: Fax Number:

4. FUNDING SOURCE:

Is there funding for this project? ☒ Yes ⇨ ☐ No

If Yes, is the funding:

Internal: ☐ ORSP Faculty Research Program
☐ Other:

External: ☐ Pending/Agency:
☒ Awarded/Agency: **Allergan**

5. ANTICIPATED BEGINNING AND ENDING DATES OF HUMAN SUBJECTS CONTACT:

Beginning Date: **04/10/2010 (as soon as approved)**
Ending Date: **12/31/2013**
Not Applicable: ☐

RESEARCH METHODOLOGY/PROCEDURES

6. CHECK ALL PROCEDURES BELOW THAT APPLY TO YOUR STUDY:

☒ Pre-existing data ⇨ ⇨ ⇨

Source of data: **Patient medical charts, BOLD Database, MS State Employee medical and pharmacy claims. Claims information not part of this IRB application.**

Do data have identifiers? ☒ Yes ☐ No

☐ Observation
☐ Oral history
☐ Interview
☐ Focus group

☒ Questionnaire or Survey ⇨

Anonymous? ☐ Yes ☒ No

Distribution:
☐ Internet
☐ Mail
☐ E-mail
☒ In person
☐ Other:

Anonymous or Confidential?
Anonymous means (1) the investigator cannot associate a subject with his/her data and (2) the data cannot identify a subject. Examples: Surveys with no names handed to an investigator are not anonymous; surveys placed by the subject in a group data envelope can be anonymous; surveys with no names and with demographic data that can identify a subject (e.g., the only African-American in a class) are not anonymous.

☐ Experiment/manipulation
☐ Treatment study
☐ Other:

☐ Exercise ⇨ ⇨ ⇨ ⇨

☐ Moderate
☐ More than moderate

☐ Videotaping
☐ Audio recording

☐ X-rays ⇨ ⇨ ⇨ ⇨

E.g. DEXA ~ contact Health & Safety for training requirements.

☐ Collection/use of blood, urine, other bodily fluids, or tissues ** ⇨ ⇨ ⇨

Has IBC application been submitted? ☐ Yes ☐ No
If Yes, has IBC application been approved? ☐ Yes ☐ No

** Requires IBC approval; see http://www.olemiss.edu/depts/research/compliance/compliance_forms.html#ibc. Contact Health and Safety for training requirements.

☐ Use of drugs, biological products, or medical devices

7. DECEPTION OR OMISSION OF ELEMENTS OF CONSENT:

Do any of the following apply to your study?

☐ The study uses surreptitious videotaping.
☐ The study gives subjects deceptive feedback, whether positive or negative.
☐ The study uses a research confederate.
☐ The study has misleading or deceptive:
(1) study descriptions; (2) procedure explanations; and/or (3) survey instructions/rationales.

If you checked any of the above, please complete Appendix D.

PARTICIPANT INFORMATION

8. SUBJECT CHARACTERISTICS: Number: **200** Age Range: **18 &up** If under 18, parental consent is required.

9. BRIEFLY DESCRIBE SUBJECT POPULATION: **Obese adults with state insurance**
E.g. 2nd grade students, college students, etc. Justify exclusion of any racial or gender group.

10. POTENTIALLY VULNERABLE SUBJECTS INVOLVED:
Check all applicable groups.

☐ Children/adolescents[1]
☐ Mentally ill – outpatients
☐ Mentally ill – inpatients
☐ Cognitively impaired
☐ Elderly, if institutionalized
☐ Pregnant females
☐ Prisoners[2]
☐ HIV+
☐ Other:

[1] Complete Appendix B if applicable.

[2] Complete Appendix C.

11. RECRUITMENT PROCEDURES:

a. How will you recruit subjects? Check all that apply:

☐ Psych PSPM
☐ UM bulletin boards, where:
☐ Class announcements
☐ Letters to parents/guardians
☐ E-mail – specify groups:
[Mass e-mails to UM groups must: 1) be in plain text; 2) state "This study has been approved by UM's Institutional Review Board (IRB); and 3) be limited to 200 words.]
☐ Radio/TV/newspaper ads
☒ Other: **Patients who are approved for surgery at 4 sites as part of OTP will be enrolled. This application only pertains to Oxford Surgical & Bariatric Clinic,LLC**
[List all recruitment sites.]

Recruitment ad/e-mail/oral announcement is attached: ☐ Yes ☐ No

b. Are subjects in a subservient power relationship to investigators or to parties with an interest in the research, such as students in an instructor/investigator's class or employees of the investigator?

☐ Yes ☒ No

If Yes, how will you ensure that their participation is truly voluntary?

c. Describe incentives for subjects, if any (money, drawing, class points, etc.).

☒ No incentives

d. List pro-rating for incentives for study drop-outs. ☒ Not applicable

12. CONSENT PROCEDURES:

Check all that apply.

- ☐ Oral (attach script)
- ☐ Information letter – used in survey research (attach)
- ☒ Informed consent form (attach)
- ☐ Assent form for children or subjects with intellectual disabilities (attach)
- ☐ Not applicable

If you plan to enroll non-English speaking participants, the consent form and assent document(s) must be translated into the appropriate language(s) and included with this submission.

For subject populations where competence to consent is highly questionable (e.g. some psychiatric populations), explain how competency will be determined and by whom.

- ☐ Request waiver of *written* consent – justify:
- ☐ Request waiver of consent – justify:

13. WHERE WILL THE STUDY BE CONDUCTED?

Check all that apply.

- ☐ UM campus
- ☐ Local community: elementary/secondary school(s) or child care facility[1]
- ☒ Local community: other – specify: **4 physician offices associated with 3 Certified Bariatric Surgery Centers of Excellence in Mississippi (Jackson, Oxford, Pascagoula). This application only pertains to Oxford Surgical & Bariatric Clinic,LLC.**
- ☐ Another U.S. location – specify:
- ☐ Another country[2] – specify:
- ☐ Not applicable

[1]Complete Appendix B.

[2]Complete Appendix E.

- ☐ Approval letter from another IRB attached
- ☐ Approval letter from other organization attached

14. DESCRIBE ALL POSSIBLE RISKS TO SUBJECTS.

LIST STEPS TO MINIMIZE RISKS, INCLUDING EXPERIMENTER AND RESEARCH ASSISTANT TRAINING/EXPERTISE. For example, an emergency plan to handle potential adverse events for traumatic experience surveys or psychology research with children.

a. Physical: **Patients have already chosen to receive surgery, which has risks, but this study doesn't increase risk.** ☒ n/a

b. Emotional: **Surveys ask personal information, which may cause mild psychological stress, but no more than encountered in day-to-day life** — **Surveys will be administered at medical site, where patients could discuss with medical personnel. Patients will also be reminded that information shared is confidential.** ☐ n/a

c. Social/interpersonal: **Surveys ask personal information, which may cause mild psychological stress, but no more than encountered in day-to-day life** — **Surveys will be administered at medical site, where patients could discuss with medical personnel. Patients will also be reminded that information shared is confidential.** ☐ n/a

d. Occupational: **While subjects are employees, spouses, or retires of the State, all medical information is confidential, so there should be no occupational risk.** ☒ n/a

e. Financial: ☒ n/a

f. Legal: ☒ n/a

g. Other: ☐ n/a

15. WHAT ARE THE POTENTIAL BENEFITS, IF ANY, TO SUBJECTS (e.g. recognition of health risks, reduced stress, increased physical fitness, etc.) POTENTIAL BENEFITS DO NOT INCLUDE INCENTIVES OFFERED FOR PARTICIPATION.

Patients who have bariatric surgery may have improved health, quality of life, and improved productivity at work. The administration of surveys, however, is expected to have minimal benefit to the subjects enrolled, however, by doing surveys, patients may recognize improved quality of life.

16. HOW WILL YOU MAINTAIN DATA CONFIDENTIALITY?

☐ All data are anonymous (go to next section).
☒ Data are confidential.
☐ Data kept in locked file cabinets.
☒ Data in locked room.

When will data be de-identified? **at time of collection** ☐ n/a

Anonymous or Confidential?
Anonymous means (1) the investigator cannot associate a subject with his/her data and (2) the data cannot identify a subject.

THE IRB ENCOURAGES PERMANENT RETENTION OF DATA FOR POTENTIAL FUTURE USE BECAUSE THIS IMPROVES THE COST/BENEFIT RATIO.

PROJECT DESCRIPTION

17. DESCRIBE YOUR PROJECT IN THE SPACES BELOW. Spaces will expand as you enter text.

a. Problem statement (including specific aims of your project):

To assess the health, humanistic and economic outcomes associated with bariatric surgery for 200 severely obese patients who have State insurance and who undergo bariatric surgery as part of the Obesity Treatment Program (OTP).

b. Brief literature review that points to a need for this research:

Mississippi has the highest rate of adult obesity in the nation at 32.8% in 2008, whereas, 10 years prior, the rate was 22.8%. Obesity has far-reaching effects on the health, health care resource use, and productivity of the population. Obesity-related co-morbidities and complications include coronary artery disease (CAD), hypertension, type 2 diabetes mellitus (T2DM), cancer, non-alcoholic fatty liver disease, dyslipidemia, and sleep apnea which increase the morbidity, mortality and cost of care associated with obesity. Increases in obesity in the US population parallel a substantial share of growth in health spending and continues to impose an economic burden on both public and private payers.

Studies currently exist which evaluate the costs and benefits of bariatric surgery on an obese population, but little information is available on a population with obesity rates as high as seen in Mississippi.

Additionally, in 2009, the State of Mississippi passed legislation that authorized bariatric surgery as a covered health benefit for state employees for a select obesity program. Continued coverage past 2011 will be contingent on outcomes from the project and funding availability.

As a result of this legislation, Mississippi's State and School Employees' Life and Health Insurance Plan (SSELHI Plan) will provide a two-year Obesity Treatment Program (OTP) for the treatment and management of obesity and related conditions. Under the OTP, the Plan will provide benefits for medically necessary bariatric procedures at certified Centers of Excellence (COE) in Mississippi for qualifying participants.

c. Description of procedures:

After approval for surgery by the OTP, patients will be invited to participate in this study at the physician office associated with a COE. This application is for the Oxford Surgical & Bariatric Clinic, LLC. After completion of Consent Form, patients will be asked to fill out surveys and their providers, medical staff and/or PI will assist in filling out data collection form at initial and follow-up visits. No direct intervention to the patient will occur. Some patients have already had surgery--for these patients will have the surveys administered at next follow-up, and chart reviews will be done to fill out Initial Visit and Follow-Up Visit Data Collection Forms. Database claim information is not part of this IRB application, but will be

done in future to obtain economic outcome information.

d. Measures:

SURVEY/TEST/QUESTIONNAIRE (e.g. WAIS)

	NAME AND ACRONYM	IS THERE PUBLISHED PSYCHOMETRIC SUPPORT?
1	**Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI: GH)**	☒ Yes ☐ No
2	**Impact of Weight / Quality of Life-Lite (IWQOL-Lite)**	☒ Yes ☐ No
3	**Patient History Survey**	☐ Yes ☒ No
4	**Patient Satisfaction Survey**	☐ Yes ☒ No
5		☐ Yes ☐ No

OTHER MEASURES (e.g. heart rate)

NAME

1 **Prevalence of hypertension, control of hypertension (as measured by blood pressure) and use of medication for hypertension (drug[s], dose)**

2 **Prevalence of type 2 diabetes mellitus (DM), control of DM (as measured by A1c) and use of medication for DM (drug[s], dose)**

3 **Prevalence of dyslipidemia, control of dyslipidemia (as measured by lipid levels) and use of medication for dyslipidemia (drug[s], dose)**

4 **Prevalence of sleep apnea and sleep apnea score**

5 **Prevalence of other obesity-related complications, including but not limited to CAD, asthma, gastroesophageal reflux disease (GERD) and control of these diseases**

6. Serum creatinine and liver function enzymes, when available in medical charts
7. Incidence of nutritional deficiencies and use of medication to treat deficiencies
8. Incidence of device or surgery-related adverse events
9. Outpatient medication costs*
10. Hospitalization costs*
11. Office visit costs*
12. Emergency room costs*

*these items will be part of research in future and are not part of current IRB application.

e. Provide a numbered step-by-step list of all procedures, starting with recruitment. Elaborate on more complex items. Attach scripts of procedural instructions to subjects. See Instructions (page 1) for examples.

1 **Mississippi's State and School Employees' Life and Health Insurance Plan (SSELHI Plan) will determine which 200 patients will have surgery as part of the Obesity Treatment Program (OTP). 100 patients were approved in 2009, and 100 more will be approved in 2010. Patients approved for the OTP will work with the surgery team to chose the type of surgery best for the patient. Once the patient is approved for the OTP, then their participation with this study can begin.**

2 **At the initial visit for surgery consultation, the patient will be asked if they are willing to participate in this study. If patient consents, then they will fill out the consent form with the assitance of someone at the COE (Whitney Byars). This person has been trained in admisistration of surveys by the PI. Once the Consent Form has been signed, the patient will answer surveys (Patient History Survey, WAPI: GH, IWQOL-Lite). After this visit, medical personnel in the COE (Whitney Byars, with the assistance of the PI when available), will fill out the Initial Visit Data Collection Form. The information for the Initial Visit Data Collection Form will come from the patient's medical record and/or the BOLD database (a database all COEs use to collect information on all surgery patients at the site).**

If the patient has had surgery already, the Patient History Survey will be administered to the patient at the

next available visit.

3 **Soon after the patient has surgery, the Peri-surgery Data Collection Form will be filled out by medical personnel at the physican's office (Whitney Byars). If needed, PI will assist in completion of this form.**

4 **At follow-up visits near 6 months, 12 months, and 24 months post-surgery at the physician office, the patient will fill out the IWQOL-lite, WPAI:GH, and Patient Satisfaction surveys. After these follow-up visits, medical personnel at the COE (with the assistance of PI when available), will fill out the Follow-up visit Data Collection Form. Information for this form will also be found in the patient chart and/or BOLD database.**

5 **If the patient has an adverse event at any time during the study, an adverse event form will be filled out by medical personnel and/or PI.**

6. At study closure, or if patient wishes to withdraw from the study at any time, the Withdrawal/End of Study form will be filled out.

7. Each patient will also have a State Employee Bariatric Surgery Project Checklist, which will be filled out by Whitney Byars to ensure study methods are followed correctly.

8. After the patient has signed the consent form, study personnel will collaborate with CareAllies, which serves as the disease management program for the Mississippi State and School Employees' Life and Health Insurance Plan State of Mississippi. Via this collaboration, medical and pharmacy claims will be reviewed for the patient to collect information (costs) of pharmacy utilization, medical visits, emergency room visits, and hospitalizations.* This part of the study is not a part of the current IRB application, but will be done at a later time.

f. Data analysis methods:

Statistical analysis: Descriptive statistics will be reported for each measure at baseline and at the 6, 12, and 24 month followup periods. We will use a generalized linear model for repeated measurements (generalized estimating equations) to assess the effect of bariatric surgery across followup periods. This approach will also be used to assess the effect of surgery type (Roux-en-y versus banding) while controlling for the effect of other variables. An alpha of 0.05 will be used to determine statistical significance.

g. Debriefing and/or feedback on test results (procedures, forms, scripts, and statements if applicable):

N/A

ASSURANCES ~ CONFLICT OF INTEREST AND FISCAL RESPONSIBILITY

Do you or any person responsible for the design, conduct, or reporting of this study have an economic interest in, or act as an officer or a director of any outside entity whose financial interests may reasonably appear to be affected by this research?

☒ YES ⇨ ⇨ If Yes, please explain any potential conflict of interest.

☐ NO **Each surgery office may have economic interest in surgery improving outcomes, however, PI will monitor activity at each site to ensure integrity of project. The PI has no financial interest in the outcome of this study.**

Do you or any person responsible for this study have existing financial holdings or relationships with the sponsor of this study?

☐ YES ⇨ ⇨ If Yes, please explain any potential conflict of interest.

☒ NO

☐ N/A

SIGNATURES

PRINCIPAL INVESTIGATOR, RESEARCH ADVISOR (IF APPLICABLE) AND DEPARTMENT CHAIR MUST SIGN BELOW

PRINCIPAL INVESTIGATOR'S ASSURANCE

I certify that the information provided in the application is complete and correct. As Principal Investigator, I have the ultimate responsibility for the protection of the rights and welfare of the human participants, conduct of the research, and the ethical performance of the project. I will comply with all UM policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of participants in human research, including, but not limited to the following:

- The research will be performed by qualified personnel according to the approved research protocol;
- No changes will be made in the research protocol or informed consent document(s) until approved by the IRB;
- Informed consent will be obtained from the participants, if applicable and appropriate;
- Adverse events and/or unanticipated problems will be reported to the IRB as required.

I certify that I, and all key personnel, have completed the required initial and/or refresher CITI courses in the ethical principles and regulatory requirements for the protection of human research participants.

Natal McClendon, PhD 4/5/10

Signature of Principal Investigator Date

RESEARCH ADVISOR'S ASSURANCE (REQUIRED FOR STUDENT PROJECTS)

As the research advisor, I certify that the student investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular research in accordance with the approved protocol.

- I agree to meet with the investigator on a regular basis to monitor research progress;
- Should problems arise during the course of the research, I agree to be available, personally, to supervise the investigator in solving them;
- I will ensure that the investigator will promptly report adverse events and/or unanticipated problems to the IRB as required;
- If I will be unavailable, for example, on sabbatical leave or vacation, I will arrange for an alternate faculty member to assume responsibility during my absence and I will advise the IRB by letter or e-mail of such arrangements; and
- I have completed the required initial and/or refresher CITI courses in the ethical principles and regulatory requirements for the protection of human research participants.

Signature of Research Advisor* Date

*The research advisor must be a UM faculty member. The faculty member is considered the responsible party for the ethical

performance and regulatory compliance of the research project.

DEPARTMENT CHAIR'S ASSURANCE

As department chair, I acknowledge that this research is in keeping with the standards set by our department and I certify that the Principal Investigator has met all departmental requirements for approval of this research.

Leigh Ann Ross 4/5/10

Signature of Department Chair/Dean* Date

*If the Principal Investigator is also the department chair, this signature must be that of the Dean.

OFFICE USE ONLY

- ☐ Administrative Review
- ☐ Expedited Review: Approval expires _____
- ☐ Full Board Review: Approval expires _____

_____

Signature Date

- ☐ IRB Coordinator
- ☐ IRB Chair
- ☐ IRB Member

+ + + + + ATTACH (INSERT) ADDITIONAL REQUIRED DOCUMENTS HERE + + + + +
(all will be sent as separate documents)