



*SCHOOL OF SOCIAL WORK*

**SWK 595: ADVANCED GENERALIST PRACTICE-INTEGRATIVE SEMINAR**  
**Tuesday 6:00-9:00 p.m.**  
**Mesaquite Metroplex Campus**

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**Instructor:** Dr. Linda Openshaw  
**Office:** 310 Henderson, & Mesquite Metroplex campus Room 129  
**Office Hours:** Commerce Hours: M, W, F 11:00-3:00 p.m.  
Mesquite Metroplex Campus: Tuesday 1:00-2:00 & 5:00-6:00 p.m.  
**Office Phone:** 903 468-6095  
**E-Mail:** Linda.Openshaw@tamuc.edu

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**COURSE DESCRIPTION:**

This seminar requires students to integrate content from all their social work coursework. The student applies knowledge, values, and skills gained in their graduate program to a specific intervention or evaluation undertaken in the concurrent field practicum placement. Critical thinking skills, self-assessment, and practice evaluation requirements are developed and demonstrated in a major paper. Students must take this course during their final semester in which they plan to graduate. Prerequisites: SWK 595; Concurrent enrollment in final semester of field.

**GOAL & COMPETENCIES:**

**1. Prepare MSW graduates for professional advanced generalist practice that reflects application and integration of critical thinking, theoretical frameworks, and differential interventions. Graduates will be able to demonstrate the following competencies:**

C 1.1 Apply critical and independent analysis of practice situations and effectively communicate their judgments, reasoning and decision-making processes (2.1.3)

C 1.2 Apply and contribute to evidence-based and best practice approaches to continuously assess and improve the efficacy and effectiveness of practice (2.1.6)

**2. Enable MSW graduates to apply ethical reasoning to advance equality, justice, and social change. Graduates will be able to reflect the following competencies:**

C. 2.2 Apply social work ethical principles to resolve dilemmas and create positive change among individuals, families, groups, organizations & communities (2.1.2)

C. 2.3 Demonstrate the ability to build strengths based on mutual engagement with diverse populations (2.1.4)

**COURSE OBJECTIVES:**

This course is designed to provide the student with the opportunity to integrate the knowledge, values, and skills of advanced generalist practice in social work. The student is expected to select a social work assignment from the field practicum and conduct an assessment of the client system, develop a plan of intervention, program evaluation, or needs assessment and to implement the plan in accordance with appropriate values, knowledge, and skills, and evaluate the effectiveness of the intervention. The student will conduct an assessment of his/her success in achieving the defined goals with the client system, identify strengths and areas of needed growth in professional knowledge and skills, and outline a program of post-graduation professional development

1. Students will demonstrate the ability to apply the problem solving process to generalist practice intervention with client systems at all levels, taking in to account the rural or urban practice context.
2. Students will demonstrate the values and skills needed for autonomous practice.
3. Students will demonstrate the knowledge and skills needed to provide leadership in social work organizations.
4. Students will demonstrate an understanding of the importance of evidence-based knowledge and methods in designing interventions that take into account the rural or urban context.
5. Students will demonstrate an understanding of social work values and ethics in professional interventions with clients and colleagues and demonstrate effectiveness in taking into account cultural difference among clients and colleagues.
6. Students will demonstrate an ability to critically analyze social policies as these influence practice in the field agency.
7. Students will demonstrate the ability to assess and develop social policies that can enhance the client's well being in situations similar to those addressed in the field practicum.
8. Students will develop a plan for continuing professional development that takes into account the successes and problems encountered in the field practicum experience.

## **STUDENT LEARNING OUTCOMES:**

1. Student will conduct an independent research project.
2. Student will develop the skills to collect and analyze data
3. Student will utilize evidence-based practice literature
4. Student will use constructive feedback from the instructor to produce a major paper
5. Student will report the results of their research project to the class
6. Student will integrate the experience of the social work curriculum into the completion of this project.
7. Student will discuss the impact of agency and social policies on conducting research.

## **RELATIONSHIP TO OTHER COURSES:**

### **TEXTS:**

American Psychological Association. (2001) *Publication manual of the American Psychological Association* (6<sup>th</sup> ed.). Washington, D.C.

Salkind, Neil J. (2013). *Statistics for People Who (Think They) Hate Statistics* (3<sup>rd</sup> ed.) Sage Publications, Inc., Los Angeles.

### **GRADING:**

### **OVERVIEW OF ASSIGNMENTS:**

The grade for this course will be based on the final integrative paper and presentation of the research process and findings.

**Before beginning your research project:** Students will submit a proposal describing his or her project on the revised university internal review form (IRB) within the first two weeks of the semester. The IRB request must be signed by the student's field instructor, or person at the field placement who can approve the research. The instructor will review the IRB form to determine that no person or agency will be at risk as a result of the project. Once the IRB clearance has taken place the student will be given permission to begin the research project.

## **INTERGRATIVE PAPER (100 Points):**

### **Guidelines:**

1. The final paper must be typed or word-processed. The paper must be double spaced and must follow the format set forth in the most recent Style Manual of the American Psychological Association. APA format includes: title page, an abstract, table of contents, and an appendix.
2. The paper is expected to be clearly legible, utilize a standard typeface (e.g., Times New Roman), and size 12 font. Papers must be free of spelling, grammatical, typographical, and punctuation errors. **It is the student's responsibility to ensure that papers have proper syntax and grammar. Grades will be significantly lowered if such errors exist.**
3. The text of the paper is to be no less than twenty-five pages in length. This excludes all cover sheets, tables of contents, appendices, features, displays, or reference list.
4. Students must include at least 15 references from current (within the last 7 years) professional literature. Twelve of the reference must be journal articles. Resources for paper preparation are available in the Databases include PsycLit, ERIC, Sociofile, and Dissertation Abstracts. These materials may be checked out through the library reference desk. The library also has computer labs available for paper preparation. Schedules of computer time availability can be secured from the library.
5. **Power Point Presentation (25 points)**
  - A. Students will present their papers during class at the end of the course. Students may invite another faculty member or his or her field instructor to the presentation.
  - B. Students must present at their assigned day and time.
  - C. Students must be present for the all classmate presentations. Absences will result in a lowered presentation grade.

## **OUTLINE OF REQUIRED ELEMENTS FOR INTEGRATIVE PAPER**

**This outline applies to general intervention or program evaluation research; some aspects of the outline may not apply to your specific paper.**

### ***I. Introduction & Agency Description:***

- A. Hypothesis (State your research question).

- B. Explain how you became interested in this particular topic. Provide any relevant background experiences describing the selection of the project or client population. These experiences can be personal or professional.
- C. Describe the agency where research project will occur:
  - 1. Physical location
  - 2. Background information:
    - a. Involvement with community
    - b. Demographic information of client population
    - c. Management structure
  - 3. Agency Assessment:
    - a. Strengths
    - b. Resources
    - c. Areas for improvement
  - 4. Diversity Issues
- D. Agency's motivation to support project:
  - 1. Positive motivators (incentives).
  - 2. Negative motivators (disincentives).
- E. Describe the data/observation sources and processes used to make these assessments. What information did you use to assess the agency where your research will take place?

**II. Goals/proposed outcomes:**

- A. Specify the specific problems selected for the project. What are you hoping to learn?
- B. Describe your expected outcomes for your project. What do you expect to find?
- C. Describe the expectations of the agency.
- D. Describe any possible issues between the agency and possible results of your research project.

**III. Literature Review**

- A. Introduction and general findings in this area of study
- B. Significant findings relevant to this study, key terms or variable definitions
- C. Application and discussion of any applicable theories
- D. Gaps in the literature

E. Review should lead directly to your research question; place research question at the end of the review

F. 15 current (within past 7 years) references

#### ***IV. Methods***

A. Design

1. Which design will be used?
2. Why this design?

B. Measurement

1. All variables defined and operationalized (how will you measure them?).
2. If treatment or intervention involved, describe treatment or intervention
3. Measures: Discuss reliability and validity
4. Supporting information, i.e. other studies, studies demonstrating reliability and validity?
5. Copies of measures in Appendix

C. Sample

1. Sampling strategy: Purposive vs. nonpurposive
2. Inclusion and exclusion criteria

D. Procedure

1. Informed consent procedures? Did you need permission from supervisors or stakeholders?
2. What sources of data will be used? How will be data obtained? By Whom? When?
3. Is study procedure clear and complete?
4. Were there any changes to the procedure during the course of the study?

E. Ethical Issues

1. Any ethical issues that arose during the course of the project?
2. Describe Informed Consent process.

#### ***V. Results & Discussion:***

A. What statistical tests were used?

1. Why were they used?

2. What were the statistical results? What was significant? What was not significant?
- B. Discussion
1. Relate results to what is known, or not known, from literature.
  2. Were outcomes expected or unexpected?
  3. What are implications of results, i.e. how do results impact agency or treatment/
5. Limitations
1. What were the limitations of the project?
  2. How could you improve the project in the future?

This section must be a comprehensive overview of learning from each sequence as it applies to this research project

- A. Identify the contribution made to your research project by each of the following:
1. HBSE foundation content courses.
  2. Social policy and programs foundation courses.
  3. Social work practice courses.
  4. Research courses.
  5. Other courses or professional development experiences.
  6. Study of social oppression, the impact of cultural diversity, and the effects of social injustice present in this case.
- B. Identify goals for your future professional development in:
1. Knowledge base.
  2. Practice skills.
  3. Values and ethics.
  4. Understanding the effects of cultural diversity, oppression, and social injustice on client system functioning

***VIII. Appendix:***

- A. Include original signed IRB form, consent form, and any measures used in the project.

**CLASS ATTENDANCE AND PARTICIPATION:**

Students are expected to attend class, reflecting responsibility which is inherent in the development as a social work professional. Roll will be taken regularly. Students are expected to be on time and prepared to participate when class begins as well as be present throughout the entire class meeting. Classroom exercises, discussions, role plays, guest speakers and other in-class experiential exercises are essential for a student's professional learning and continued development of self-awareness. Tardiness (or early departure) of more than 15 minutes will count as .5 absence (2 tardies/early departures = 1 absence). A student is considered absent if

he/she arrives more than 30 minutes late to class, leaves 30 or more minutes early or does not come to class.

The following penalties for absences (unexcused, or excused, according to university policy) will be administered:

Weekly	Up to 2 absences No penalty	3 absences 1 letter grade drop	4 absences Class grade of "F"	
Bi-weekly	Up to 3 absences No penalty	4 absences 1 letter grade drop	5 absences 1 letter grade drop	6 absences Class grade of "F"
Summer 10-week	Up to 1 absence No penalty	2 absences 1 letter grade drop	3 absences Class grade of "F"	

**ONLINE OR WEB-ENHANCED CLASSES:** Just as students are required to attend face-to-face classes, students are required to log in and participate in online components. To receive credit for attendance online via eCollege, students must log in and complete assignments in a timely manner. Not logging in to eCollege (which can be monitored by the instructor) and completing assignments online during the appropriate time is the equivalent of an absence for each week this occurs.

Final evaluation and grades depend on both presence and participation. Students' grades will be significantly impacted by inadequate participation or lack of required time commitment each week. Students are expected to spend a comparable amount of time in the online learning environment as they would in class (3 hours a week in the classroom). In addition, just as in traditional F2F classrooms, students are expected to spend time reading and studying class materials.

**NOTE: PROBLEMS WITH YOUR INTERNET CONNECTION AND/OR COMPUTER ARE NOT CONSIDERED AS REASONS FOR LACK OF PARTICIPATION.** You have access to the university's computer labs (in the social work department AND other campus facilities, including the library) as well as local libraries and other access to computers and ISPs. If you believe that you are unable to fulfill the requirements for the course you should talk with your instructor about the possibility of dropping or withdrawing.

Class participation has three components: (1) Appropriate interactions with classmates, (2) Attentiveness, and (3) Active involvement in class activities. Evaluation of class participation is based on instructor observation. Students will be given feedback if problems are evident.

**POLICY ON DUE DATES:**

**POLICY ON PLAGIARISM AND CHEATING:**

Every student is expected to do his/her own work. Law, ethical standards, university policy, and departmental policy demand that students refrain from plagiarism and any form of cheating. Plagiarism is the "Act of appropriating the literacy composition of another, or parts of passages from of his [or her] writings, or the ideas or language of the same, and passing them off as the

products of one's own mind." (Black's Law Dictionary, Abridged Fifth Edition, 1983). When using others' words, phrases, or ideas in writing, the original author should be given proper credit.

Cheating may take different forms. These include, but are not limited to, copying others' answers during an exam, using notes or other forms of help during an examination or quiz, except when explicitly permitted by the instructor, giving or receiving help on exams or assignments, or submitting work for one class which has already been submitted for another class for credit. Use of citations from the Internet without paraphrasing content AND proper referencing is regarded as plagiarism. Professors have the right to use electronic review programs (such as Turn It In") to identify plagiarism.

The department does not tolerate plagiarism or cheating. A student found to be engaging in such illegal and unethical conduct may receive a failing grade in the course and may be subjected to further disciplinary proceedings. Any assignment or exam that lacks honesty will be given a grade of "0".

### **ACCEPTABLE CLASSROOM BEHAVIOR:**

“Students at Texas A&M University-Commerce are expected to obey all federal, state, and local laws, in addition to the regulations of the University. The standards of Student Conduct including disciplinary rules and procedures are designed to provide and conform to the basic tenets of due process, as developed by institutions of higher education. As such, the University distinguishes these procedures and regulations as an educational and growth process which is not intended to conform to adversary proceedings as in a court of law. (Student’s Guide Book, 2011, p. 35).

### **CODE OF CONDUCT FOR SOCIAL WORK STUDENTS**

The Department of Social Work expects all social work students to conduct themselves in an ethical, professional manner. Professional ethics are at the core of social work. The profession articulates its basic values, ethical principles, and ethical standards as set forth in the *NASW Code of Ethics* to guide social workers’ conduct. The *Code* is relevant to all social workers and social work students, regardless of their professional functions, the settings in which they work, or the populations they serve. Accordingly, we expect social work students to demonstrate courtesy, respect and support for fellow students, instructors, clients, and all other persons.

All students enrolled in BSW or MSW classes are expected to observe the tenets of the NASW Code of Ethics and the Social Work Student Code of Conduct. Our Code of Conduct is reflective of professional and academic expectations – a student who cannot demonstrate appropriate behaviors will not be appropriate for practice in the social work profession. Students who violate these Codes may be asked to meet with appropriate Social Work faculty (instructors or Program Directors). In addition, the department’s Academic and Professional Issues (API) Committee is responsible for dealing with student issues when requested by faculty.

## STUDENTS WITH DISABILITIES

It is the policy of Texas A&M University-Commerce and the Social Work Department to do everything we can to accommodate students with disabilities, pursuant to federal and state law, and the University's commitment to providing equal opportunities. Any student with a disability who needs accommodation, for example, in accessibility, seating placement or in arrangements for examinations should not hesitate to inform the instructor. If required, large type, Braille or cassette recordings of syllabus or assignments can be provided.

Students with conditions that require special attention or accommodation should contact the Director of Disability Resources & Services at 903-468-5150 (located in the Library, Room 132).

The following outline is provided as a guide though variations may occur. Assignments are due at the beginning of the class period.

WEEK	DATE	CLASS MEETING	TOPIC	ASSIGNMENTS DUE	COMP. & LINK TO SLO
1	1/15/13	Online	Syllabus; Introduction; IRB FORM	Please e-mail an overview of your project to the instructor. Text, Ch. 1 and 2 <b>Graduation applications accepted January 15-February 1, 2013</b>	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
2	1/22/13	Online	IRB & Discussion of Sections I & II	Please e-mail completed IRB due to the instructor. Text, Ch. 3 and 4	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
3	1/29/13	In-Class Discussion from textbook Chapter 1	Sections I, II & III	Text, Ch. 5 and 6 <b><u>Graduation applications due February 1, 2013</u></b>	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
4	2/5/13	<b>No Class</b>	Begin collecting data		
5	2/12/13	In-Class	Section III & textbook chapters 2 & 3	Sections I & II due Text Ch. 7 and 8	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.

6	2/19/13	In-Class	Section IV Textbook chapters 4 & 5	Section III due Text Ch. 9 and 10	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
7	2/26/13	In-Class	Section V Chapters 6&7	Text Ch. 11 and 12	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
8	3/5/13	In-Class Brian Brumley Test taking strategies for licensure and comprehensive examination			Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
9	3/12/13	<b>NONE</b>	<b>SPRING BREAK</b>		
10	3/19/13	Comprehensive Exam in Mesquite during class time 6:99p.m.		<b><u>Multiple Choice Comprehensive Examination Scheduled: 3/19/13 6:00p.m. Mesquite Metroplex Campus</u></b>	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
<b>REMINDER: Comprehensive Exam Forms due to Graduate School: 3/22/13</b>					
11	3/26/13	In-Class		Section IV Due Text Ch. 13 and 14	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
12	4/2/13	In-Class		Text Ch. 15 and 16	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
13	4/9/13	In-Class		Text Ch. 17 and 18	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
14	4/16/13	In-Class		Section V Due Text Ch. 19, 20, and 21	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.

15	4/23/13	Class Presentations Begin		<b>PRESENTATIONS</b>	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.
16	4/30/13	In-Class		<b>PRESENTATIONS &amp; FINAL PAPER DUE</b>	Comp 1.1-1.4, 2.1-2.3, 3.1-3.4, SLO 1-7.

\*\* Schedule subject to revisions – changes may be made at the discretion of the instructor

All corrections due and final paper must be turned into professor by 6:00pm, Electronic copy must be e-mailed to Pamela.Hammond@tamuc.edu by 6:00pm, April 30, 2013.

## APPENDIX A

Internal Review (IRB)—Description of Proposed Research  
Department of Social Work-Texas A&M University-Commerce  
Integrative Seminar SWK 595

Student Name: \_\_\_\_\_

Date: \_\_\_\_\_

### *Purpose and Potential Benefit:*

Summarize the background, rationale, nature, and significance of the proposed research.

### *Location of Study:*

Identify all sites at which research will be conducted.

### *Dates of Study:*

Include month/day/year of start and estimated end dates of study. Any research that extends beyond a one-year period must obtain IRB approval for continuation.

### *Subjects:*

Include estimated number and description of types of subjects (e.g., normal volunteers, pregnant women, and students), age, gender, inclusion and exclusion criteria for subject selection, and source of subjects (including any referral sources).

### *Methods and Procedures:*

This should include but not be limited to details on subject recruitment, apparatus, procedure, copies and descriptions of all instruments (including reliability, validity, and permission for use or copyright information, if applicable), nature and type of evaluation(s), subject's time commitment, proposed follow-up, debriefings when indicated, and any other information necessary to evaluate the methodological soundness of the research. If there are significant benefits that are available to subjects because of inclusion in the research, then the issue of exclusion of potential subjects should be addressed.

### *Participant Payment or Costs:*

Indicate whether the subjects will be offered an incentive to participate in the student and if so, in what for (e.g., cash, meals, taxi fare, etc.) and in what amount.

### *Subject Confidentiality:*

Indicate the extent to which confidentiality of records identifying subjects will be maintained. Be specific—how will confidentiality be protected and where will the records be maintained? Who will have access to the records?

*Potential Risks to Subjects:*

Specify any risks (physical, social, psychological, emotional, legal); indicate precautions instituted to minimize risks; and describe procedures to be followed in the event of problems. Specify the results of pilot work or the work of others with similar procedures.

*Risk/Benefit Ratio:*

Specify or estimate the level of risk in relation to anticipated benefits.

Student Signature

Date

\_\_\_\_\_

\_\_\_\_\_

Field Instructor or Agency Representative

Date

\_\_\_\_\_

\_\_\_\_\_

Department IRB Chair

Date

\_\_\_\_\_

\_\_\_\_\_

IRB Member and/or 590 Instructor

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

From: TAMU-Commerce IRB Form

## APPENDIX B

### Sample Informed Consent Document

- Paragraphs like this one are reminders for you, the writer. Do not include them in your form unless they contain

language that applies to the study.

- Use a 12 pt font for this document.
- Write the document in the 2nd person (i.e., you) and keep the pronoun usage consistent throughout the document.

- **Use understandable, non-technical language at an 8th-grade or lower reading level.**

**TITLE OF RESEARCH:** Protocol for the Evaluation of the Safety and Efficacy of Trimycin vs. Hydrochlorothiazide in the Treatment of Essential Hypertension

**INVESTIGATOR:** Dr. John Doe

**SPONSOR:** Texas A&M University--Commerce

- **You/Your Child:** For studies involving minors, do not use “you/your child” throughout the form. Instead, use “you” and insert the following text after the Sponsor and before the Explanation of Procedures:

For Children/Minors (persons under 19 years of age) participating in this study, the term *You* addresses both the participant (“you”) and the parent or legally authorized representative (“your child”).

### Explanation of Procedures

- Explain the purpose of the study in nontechnical language.
- Describe the procedures to be followed.
- Include an estimate of the amount of time involved in study participation.
- Include a statement indicating that the study involves research.
- Identify all procedures that are experimental.
- Include the name of the sponsor if the research receives any funding.
- If applicable, explain what a Pilot, Phase I, II, III, or IV drug study is.
- Include the total number of participants to be enrolled.

We are asking you to take part in a research study. This research study will test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the U.S. Food and Drug Administration (FDA). Wise Drug Company, the company that makes Trimycin, is paying for the study. People who enter into the study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is the FDA approved drug that most people take now to lower blood pressure. Trimycin is approved in Europe, but has not been approved in the United States. More than 200 people in other research studies in the United States have safely used Trimycin. This is a Phase III study. A Phase III

study is a research study that looks at a large number of patients receiving a common or routine treatment.

If you enter the study, all your current blood pressure medicines will be stopped for one month. During this time, you will be given pills called placebos. A placebo does not have any active medicine, so it should not have any effect on your blood pressure. However, this placebo might cause your blood pressure to lower. The study staff will need to watch your blood pressure closely while you are not on any medicine for your blood pressure. Your blood pressure will be watched to make sure it does not rise so high that you need immediate treatment. You will need to come for office visits 3 times during the first week. You will need to come for office visits two times per week during weeks 2, 3, and 4. If your blood pressure is in the range required after week 4, you will be entered into the study. If your blood pressure is not in the range required after week 4, you will not be entered into the study and will receive standard care for your blood pressure. If you are entered and complete the entire study, you will be in the study for 6 months.

If you qualify for the study, you will be randomly picked (like the flip of a coin) by a computer to receive either Trimycin or Hydrochlorothiazide. You will take the medicine once a day by mouth. This will be a double-blind study. This means neither you nor your doctors will know which medicine you are taking. If medically necessary, the doctor can find out which drug you are taking.

These tests will be made during the study: lab blood tests, urine tests, weight measures, resting electrocardiogram, heart rate, and blood pressure. (An electrocardiogram measures the electrical activity of the heart.) You will be asked to come back to the clinic for 20 weekly visits. At each visit you will be asked if you have had any bad reactions and how you are feeling on the drug.

- If drug screening is part of the protocol, include a statement such as

If you have used an illicit (street) drug(s) within the past 3 months, we ask that you not participate in this project.

## Risks and Discomforts

- Include any foreseeable risks or discomforts to the participant.
- When possible, quantify the risks involved (e.g., *common*, *rare*, percentages).
- If the study involves a placebo,
  - define placebo (not as *treatment* or *medication*)
  - describe what complications may result
  - describe the precautions that will be taken to protect the participant during this time.

You may have some side effects from taking these drugs. The side effects of Trimycin are headaches, feeling drowsy, and feeling tired. About forty percent (40%) of people who take Trimycin have reported feeling drowsy and tired. About twenty percent (20%) of people who take Trimycin have headaches. Hydrochlorothiazide can cause the following side effects: low blood potassium; a rise in blood uric acid and blood sugar; and a lowering of red and white blood cells. About eighty percent (80%) of people who take Hydrochlorothiazide have these problems. There may also be risks that are unknown at this time. You will be given more information if other risks are found.

## Benefits

- State any potential benefits to the participant or to others that may reasonably be expected from the research.

- If there is no potential for direct benefit to the participant, that should also be stated.
- **Do not include** medication, treatment, devices, or compensation information.

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat high blood pressure in the future.

## Alternatives

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- One alternative is always possible: to not participate in the study.

There are many other drugs that are used to treat high blood pressure. Some examples of these drugs include Betasan, Enapror, and Ditserin. Dr. Doe will discuss these other drugs with you.

## Confidentiality

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- Include the extent to which confidentiality of participants will be maintained.
- If the federal government or any other sponsor will have access to the participants' records, this should be included.
- Include the UAB IRB in this section.

Information obtained about you for this study will be kept private to the extent allowed by law. However, the following groups will be able to view your medical records and have access to private information that identifies you by name: your doctor; people on behalf of Wise Drug Corporation; the U.S. Food and Drug Administration (FDA); the Office for Human Research Protections (OHRP); and the Institutional Review Board (IRB). The results of the treatment may be published for scientific purposes. These results could include your lab tests and X-rays. However, your identity will not be given out.

## Refusal or Withdrawal without Penalty

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- Include the consequences of a participant's decision to withdraw from the research.
- Include procedures for orderly termination of participation by the participant.

Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. **If you decide not to be in the study, you will not lose any benefits you are otherwise owed.** You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

## Cost of Participation

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- Specify if any costs to the participant might result from the research (e.g., for tests, drugs, biologics, or devices).
- If there is no cost to the participant, this should be stated also.

There will be no cost to you from taking part in this study. All drugs, exams, and medical care related to this study will be provided at no cost during the six-month study period. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

## Payment for Research-Related Injuries

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- State the name of the sponsor(s).
- Include whether or not the sponsor will pay for compensation to injured research participants, or pay for medical treatment of research-related injuries.
- **Note:** If the sponsor will pay participants for either compensation or treatment for research-related injuries," the IRB must be provided with "sponsor verification" either in the form of a letter signed by the sponsor with the same wording given in the consent form or a model consent form included in the protocol and listed in the Table of Contents of the protocol with the same wording. Do not submit a copy of the indemnification letter as the verification. Include information regarding what medical treatment will consist of if injury occurs and where further information may be obtained.

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge. The sponsor will not provide other payment for harms that may result from the study, for instance, lost wages.

## Questions

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- Include a specific name and number for each person(s) that participants can contact regarding
  - the research
  - any research-related injury and
  - compensation or payment for medical treatment.
- Also include a specific name and number for
  - questions regarding research participants' rights,
  - questions or concerns or complaints about the research in case the research staff cannot be reached or the participant wishes to talk to someone independent of the research staff. The IRB recommends that Ms. Sheila Moore's name and number be included for this purpose.

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. John Doe. He will be glad to answer any of your questions. Dr. Doe's number is 205-934-3810. Dr. Doe may also be reached after hours by paging him at 205-934-3411 (beeper 9999).

## Legal Rights

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You are not waiving any of your legal rights by signing this informed consent document.

## Signatures

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- If the research involves children (i.e., individuals younger than 19 years of age)
  - See "Children" under General Information in the IRB Guidebook.
  - See Sample Signature Page for Research Involving Children, below.

**Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.**

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### Signature of Participant

**Date**

- If the IRB has approved the research for the involvement of adults unable to consent, include a signature line for the Legally Authorized Representative. In accord with UAB Office of Counsel, if an individual is not capable of providing informed consent, the IRB allows that it may be obtained from the individuals listed below in priority order:
    - Judicially appointed guardian or individual named in a durable power of attorney;
    - Spouse;
    - Sons or daughters over 19 years of age;
    - Either parent;
    - Brother or Sister over 19 years of age;
    - Other nearest kin over 19 years of age.
- 

### Signature of Investigator

**Date**

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### Signature of Witness

**Date**

- The consent process must include a witness unless the PI requests and justifies, and the IRB approves a waiver of the requirement.
  - The person administering the consent (e.g., study coordinator) cannot sign as the witness.
- 

### Signature of person obtaining consent (if other than the investigator). Date

- All persons who discuss or obtain informed consent must be listed in the HSP.
- If the investigator will not conduct the informed consent discussion and obtain the signature, include a signature line for the "person obtaining consent."

## Sample Signature Page for Research Involving Children

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate.

You will receive a copy of this signed informed consent document.

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Signature Of Parent Date  
Or Legally Authorized Representative

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Signature of Investigator Date

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Signature of Witness

### Assent of Child

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\_\_\_\_\_ **[Name of Child]** \_\_\_\_\_ (name of child/minor) has agreed to participate  
in research titled \_\_\_\_\_ **[Title of Project]** \_\_\_\_\_.

---

Signature Of Child  
Date

### Waiver of Assent

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The assent of \_\_\_\_\_ (name of child/minor) was waived because of:  
Age \_\_\_\_\_  
Maturity \_\_\_\_\_  
Psychological state of the child \_\_\_\_\_

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Signature of Parent or Date  
Legally Authorized Representative

(Consent Form Adapted from the University of Alabama 2/08)



