The PRACTICE:
A UNLV Community Mental Health Clinic

The Partnership for Research, Assessment, Counseling, Therapy and Innovative Clinical Education

Research Policies & Procedures

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I. THE PRACTICE RESEARCH OVERVIEW

A. Vision & Mission
The PRACTICE Mission Statement: The Partnership for Research, Assessment, Counseling, Therapy, and Innovative Clinical Education, referred to hereafter as The PRACTICE, is a collaborative endeavor between the College of Education and the College of Liberal Arts at the University of Nevada, Las Vegas (UNLV). The PRACTICE serves as a teaching, training, and research clinic for faculty members and graduate students within the two colleges. The PRACTICE centralizes the research and clinical teaching functions of our faculty experts who specialize in a number of clinical arenas.

The PRACTICE is dedicated to the integration of research and clinical practice. Therefore, The PRACTICE delivers empirically based services, utilizes data for Quality Assessment and Quality Improvement (QA/QI), and partners with researchers to conduct relevant research. The PRACTICE aspires to be a major contributor to UNLV’s Tier 1 initiative.

B. General Informed Consent Regarding Research Practices
All patients or patients’ legal guardians at The PRACTICE complete an informed consent prior to receiving services. The consent contains the following clause regarding research:

Research: The PRACTICE supports behavioral, cognitive, and mental health research by UNLV faculty and graduate students. We routinely collect and analyze data to help improve the quality of our services or contribute to the research mission of the university. In addition, UNLV faculty and graduate students might contact you to discuss participation in a specific research study. Your chart may be reviewed by The PRACTICE’s research clinician to determine your eligibility for particular studies. You will have the opportunity to choose whether or not you would like to participate in such a study. Your choice to participate in the study will not affect any services you receive at the clinic. Any reporting of research results will not include information that could identify you.

C. Organizational Structure of Research Oversight
The organizational structure of research oversight may be found in Appendix A.

D. Overview of Research at The PRACTICE
Anyone interested in conducting research at The PRACTICE begins by submitting an Application to Conduct Research at The PRACTICE (Appendix B). The PRACTICE’s Research Coordinator conducts an initial review and may ask for clarification, additional information, etc. from the researcher. The Research Coordinator may also provide initial feedback regarding the application’s likelihood of approval and suggest possible revisions to increase the likelihood of approval. Currently, the Research Coordinator and Clinic Director/s discuss the Application to Conduct Research at The PRACTICE and provide approval. Documented approval from the Research Coordinator or Clinic Director must be obtained prior to conducting research at The PRACTICE. The PRACTICE is currently developing a Research Committee; once this committee is functioning, it will be tasked with reviewing final Applications to Conduct Research and providing written approval. Research proposals are reviewed on the following factors:

- Feasibility & resource utilization
- Contribution to scientific knowledge base
- Benefit & risk to The PRACTICE’s patients
- Priority in comparison to other ongoing research projects

All research conducted at The PRACTICE must undergo oversight by the Institutional Review Board (IRB) of UNLV’s Office of Research Integrity either by obtaining approval or exemption. Verification of IRB oversight must be provided to The PRACTICE before any research project is initiated at The PRACTICE. More information can be found at: https://www.unlv.edu/research/ORI-HSR.
Research projects at The PRACTICE can be conceptualized as existing along a continuum of the degree to which interaction with patients occurs and deviates from standard delivery of services.

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<td>Using The PRACTICE for Non-patient Research Activities</td>
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The more that research deviates from standard delivery of services, the more oversight is necessary. Different procedures exist depending on the nature of the research project. Please review the procedures for the type of research you plan to conduct at The PRACTICE.

II. USING THE PRACTICE FOR NON-PATIENT RESEARCH ACTIVITIES

A. Overview of The PRACTICE’s Resources for Research

1. Space - The PRACTICE has private rooms with videorecording capabilities that may be used for approved research purposes. Large rooms comfortably seat 3-4 persons and small rooms comfortably seat 1-2 persons. Each room contains a closed-network computer and has UNLV wi-fi access. The PRACTICE has a large innovative clinical education room with 2 projectors and a smart board. The PRACTICE has a small conference room; its use must be coordinated with the adjoining telemental health rooms. The PRACTICE has limited confidential storage areas.

2. Human Resources – The PRACTICE has front desk coverage during operating hours. The PRACTICE’s services are typically offered by trainees under the supervision of licensed clinical psychologists and licensed school psychologists. The PRACTICE currently has three post-doctoral fellows in psychology, four mental health counseling graduate students, 15 school psychology doctoral students, 11 clinical psychology doctoral students, one social work graduate student, and two undergraduate student interns. Seven of these students serve as graduate-assistants at The PRACTICE.

3. Additional Resources – The PRACTICE has a psychological assessment library.

Note: This list may not be exhaustive and is subject to change.

B. Current Procedures

The following procedures should be followed by those who wish to conduct research at The PRACTICE that does not involve The PRACTICE’s patients. Specifically, research covered in this section would include research that does not recruit patients from The PRACTICE, utilize data from patients at The PRACTICE, or intervene with patients at The PRACTICE.
1. Complete Application to Conduct Research at The PRACTICE (Appendix B).
2. Once application is approved, The PRACTICE and researcher may need to draft and agree to a Data Use Agreement (DUA). However, this is rare with this category of research.
3. The PRACTICE will then provide you with a Letter of Authorization for Resource Utilization to Conduct Research at The PRACTICE. In most cases, you may have already have IRB approval and utilization of The PRACTICE’s resources will not need an IRB modification. This letter of authorization will be sufficient for you to begin research. It will include stipulations that you must follow as you utilize The PRACTICE to conduct research. Failure to comply with stipulations will terminate your agreement with The PRACTICE, and may lead to more serious consequences, particularly if ethical violations are believed to have occurred. If you need a letter of authorization from The PRACTICE for your IRB application, please notify us so that we can provide you with the appropriate letter.
4. Prior to beginning research at The PRACTICE, provide your IRB approval to The PRACTICE.
5. Coordinate with The PRACTICE to reserve resources for your research.

III. ARCHIVAL RESEARCH AT THE PRACTICE

A. Overview of The PRACTICE’s Archives
The PRACTICE collects and stores patient data related to routine clinical services within the patient’s Electronic Medical Record (EMR). The PRACTICE currently uses Titatanium Software (Ti) for these purposes as well as scheduling. Data that is stored within this system on “Data Forms” can be easily extracted without Personal Health Information (PHI). Additional data is stored within patient’s clinical records, but must be manually extracted. The PRACTICE complies with the HIPAA Privacy Rule and HIPAA Privacy Rule’s De-Identification Standards.

B. Data Kept in Data Forms
1. Patient Information
   - PRACTICE Intake Form – Non-PHI information includes ethnicity, sexual identity, relationship status, occupation, year or grade in school, and medications currently taking.
   - PRACTICE Checklist of Concerns (Adult and Child versions) – presents a list of common presenting problems for psychotherapy
   - Insurance Survey – asks patient about health insurance status
   - AUDIT – assesses adults alcohol use
   - Group Readiness Questionnaire – assesses adults readiness for group
   - Social Work Needs Assessment – assesses common domains of social need
   - Diagnosis – DSM 5 and ICD 10 Diagnoses

2. Patient Outcome Monitoring (This list may not be exhaustive and is subject to change.)
   Administered Every Session
   - Adult Outcome Rating Scale – analog scales that measure patient functioning
   - Adult Session Rating Scale – analog scales that measure patient’s experience of session
   - ORAL Outcome Rating Scale for Telemental health– analog scales that measure patient functioning
   - ORAL Session Rating Scale for Telemental health– analog scales that measure patient’s experience of session
   - Child Outcome Rating Scale (Child & Caregiver versions) – analog scales that measure patient functioning
   - Child Session Rating Scale (Child & Caregiver versions) – analog scales that measure patient’s experience of session
   - Young Child Outcome Rating Scale– analog scales that measure patient functioning
   - Young Child Session Rating Scale– analog scales that measure patient’s experience of session
Administered Periodically (PRACTICE policy requires at intake and every 4 sessions)
- DASS-21 – general indicator of distress and symptomology for adults. Form reports scores and range (e.g., normal, very severe).
- SDQ initial & follow-up (parent 2-4 year old version, parent 4-10 year old version, parent 11-17 year old version, self 11-17 year old version) - assesses common domains of child psychopathology. Form reports scores and range (e.g., average, high).

Administered Based on Clinical Need
- Suicide Risk Assessment (previously used) – has been used to assess suicide risk when a patient expressed suicide risk in session. PRACTICE policy required usage of this form until Fall 2015.
- Suicide Status Forms (currently used; initial and tracking) – current form to utilize as part of Collaborative Assessment and Management of Suicidality (CAMS) which became PRACTICE policy in Fall 2015.
- Adult Mental Status Evaluation Checklist
- Child Mental Status Evaluation Checklist

3. Group Psychotherapy
- Group Outcome Rating Scale (administration not enforced) – has been used in the past to evaluate Adult DBT Skills Group participants
- Group Session Rating Scale (administration not enforced) – has been used in the past to evaluate Adult DBT Skills Group
- Adult Attachment Scale – an attachment assessment administered to adult process group participants
- IIP-C 64 – an interpersonal assessment administered to adult process group participants
- FFMQ – a mindfulness measure administered to adult DBT group participants

4. Assessment Clinic
- Assessment Instruments – Completed for every PATC case which summarizes which assessments were administered. Does not include actual test data (e.g., scores).

C. Data Existing in the Clinical Records
The following list contains information typically found in the clinical record. This list is not exhaustive and more specific inquiries can be submitted to The PRACTICE. There is currently no search capacity for clinical records; data must be manually found and extracted from clinical records. Anyone who wishes to access clinical records for research purposes must be appropriately credentialed and provide certification of HIPAA training.

1. Counseling/Therapy
- Progress notes from all sessions (individual, group, social work as applicable)
- Case management & other clinical documentation notes (e.g., phone call attempts, communication with other providers)
- Treatment Plan (drafted between 3 & 4 session) & Treatment Plan Updates (every 90 days)
- Case Summary (drafted between 3 & 4 session)
- Termination Summary (once patient terminates treatment)

2. Assessment
- Psychological Testing Report
- Progress notes from all assessment sessions
- Collateral information
- Raw Data kept in paper files

If you intend to collect data from existing clinical records:
- Ensure that none of the data is considered an Identifier under HIPAA.
• Specify who will access the data and their qualifications (e.g., completed HIPAA training? level of education? current or previous staff at the clinic?). Access to data should be as limited as possible so specify how you will only access the data necessary for your research, how as few people as possible will view the data before it is deidentified, etc.

D. Current Procedures
1. Complete Application to Conduct Research at The PRACTICE (Appendix B).
2. Once application is approved, The PRACTICE and researcher may need to draft and agree to a Data Use Agreement (DUA).
3. The PRACTICE will then provide you with a Letter of Authorization (or Letter of Authorization for Archival Research) to Conduct Research at The PRACTICE which you will need for your IRB application.
4. Obtain IRB Approval for your research project and provide to The PRACTICE.
5. The data will then be released to you by The PRACTICE OR the designated member of your research team will run the necessary report to extract the data from Ti for you to use (depending on your approved procedures).

E. Anticipated Procedures
The PRACTICE is currently developing an IRB application to approve research with deidentified data. Once this general approval is obtained, individual research projects utilizing deidentified data will no longer need separate IRB approval.

IV. RECRUITING PARTICIPANTS AT THE PRACTICE

A. Description of The PRACTICE’s Patient Population
The PRACTICE provides sliding scale services to the community. The PRACTICE serves children, adolescents, adults, and older adults. In terms of race/ethnicity, The PRACTICE’s patient population is approximately 50% Caucasian, 15% Hispanic/Latino, 15% bi- or multi-racial, and 10% African American. Less than 10% of The PRACTICE’s patients are Asian American/Pacific Islander or Native American. Patients present to The PRACTICE with complex and serious concerns most commonly including depressive and anxiety disorders, bipolar disorder, and psychotic disorder. The vast majority of The PRACTICE’s patients report annual household incomes below $20,000. Approximately 20% of patients are uninsured.

B. Allowable Recruitment Activities
Recruitment activities can be conceptualized to exist along a continuum ranging from general to specific targeting.
The more specific recruitment targeting is, the more procedures will be scrutinized to ensure protection of privacy and prevent undue influence to participate in research of The PRACTICE’s patients. General recruiting will also be limited so as to retain a therapeutic environment at The PRACTICE and prevent inundating The PRACTICE’s patient with research recruitment.

C. Current Procedures
1. Complete Application to Conduct Research at The PRACTICE (Appendix B).
2. The PRACTICE will then provide you with a Letter of Authorization (or Letter of Authorization for Archival Research) to Conduct Research at The PRACTICE which you will need for your IRB application.
3. Obtain IRB Approval for your research project and provide to The PRACTICE.
4. Provide your recruitment materials to The PRACTICE with instructions for distribution consistent with IRB Approved Procedures.

V. CLINICAL TRIALS AT THE PRACTICE

Research conducted on The PRACTICE’s patients that deviates from standard delivery of services will be allowed when it evaluates intervention/s effect/s on health outcome/s. Such research will be held to the highest standards.

A. Role of Clinical Trials
Clinical trials allow The PRACTICE to contribute to the development of innovative, effective, and culturally sensitive interventions. The PRACTICE embraces opportunities to serve as a site for clinical trials while also adamantly protecting the well-being of its patients.

B. Registering of Clinical Trials
The PRACTICE is dedicated to high-quality research and therefore strongly encourages clinical trials meet the Spirit Guideline for clinical trial research design and the Consort Guideline for clinical trial reporting. Furthermore, The PRACTICE may require clinical trials to register at www.clinicaltrials.gov.

C. Current Procedures
1. Complete Application to Conduct Research at The PRACTICE (Appendix B).
2. Once application is approved, The PRACTICE and researcher may need to draft and agree to a Data Use Agreement (DUA).
3. The PRACTICE will then provide you with a Letter of Authorization (or Letter of Authorization for Archival Research) to Conduct Research at The PRACTICE which you will need for your IRB application.
4. Obtain IRB Approval for your research project and provide to The PRACTICE.
5. Coordinate closely with The PRACTICE’s Research Coordinator throughout the duration of your project.

D. Availability of Financial Support for Clinical Trials
The PRACTICE has created a small budget to offer financial incentive to participants of clinical trials at The PRACTICE. Researchers conducting clinical trials at The PRACTICE may request access to this budget by submitting an Application for Clinical Trial Financial Support (Appendix C). Clinical trials that are officially registered at www.clinicaltrials.gov and meet Spirit Guideline for clinical trial research design and student-led projects will be given priority.

Once budgeting to offer payment to participants of clinical trials at The PRACTICE has been approved, the following procedures need to occur before money can be paid to participants:
1. A payment voucher must be filled out.
2. Approved IRB paperwork must be attached to the payment voucher.
3. The Clinic Director must review and sign the payment voucher and IRB approval.
4. The Dean of the College of Education must sign.
5. The Office of Research Integrity must provide final Approval.
6. Approved paperwork is provided to Accounts Payable.
7. Accounts Payable issues a check to the Principle Investigator.
8. The Principle Investigator must CASH the check.
9. The researcher/s provide cash payment to participants according to the IRB approved payment procedures. Failure to obtain appropriate approval at any step or failure to follow these procedures exactly will prevent payment.

VI. OTHER TYPES OF RESEARCH AT THE PRACTICE
When a research project does not fall into one of the existing research types, the researcher should refer to the section which most approximates the desired research. The PRACTICE will attempt to review the research using procedures that approximate those outlined for existing research types.
Provost
Diane Chase

Dean CoEd
Kim Metcaff

Executive Associate Dean CoEd
Danica Hayes

Dean CoLA
Jennifer Keene

Associate Dean CoLA
Denise Tillery

Institutional Review Board
Membership Varies

Research Committee
UNDER DEVELOPMENT

Director
Michelle Paul

Assistant Director of Clinical Services and PK-12 Outreach
John Nixon

Assistant Director of Clinical Services and Research
Noelle Lefforge

Postdoctoral Fellow
Amelia Black
Carolina Meza-Perez

Research GA
UNDER DEVELOPMENT

Others Conducting Research
TBD
Appendix B.

Application for Research at The PRACTICE

If you are interested in conducting research at The PRACTICE, submit this application to The PRACTICE Research Coordinator, Dr. Noelle Lefforge, at noelle.lefforge@unlv.edu or drop the application off at the office located in the Carlson Education Building room 226. The review process will take approximately one week. The PRACTICE Research Review Team will review your application and provide a response by email. Please feel free to follow up with Dr. Lefforge if you have not heard back within one week of submission. You may be contacted for additional information, your prompt response is appreciated and will expedite the review process.

For research involving The PRACTICE patients or patient data: If your study is approved, you will receive a Letter of Authorization to Conduct Research at The PRACTICE to submit with your IRB Proposal. Your IRB approval must be submitted to The PRACTICE Research Coordinator and verified before you conduct your research at The PRACTICE.

For research not involving The PRACTICE patients or patient data: If your study is approved, you will receive a Letter of Authorization to Conduct Research at The PRACTICE with stipulations for usage of The PRACTICE resources. You will be able to proceed once you receive this authorization. Your review and authorization will very likely follow an expedited timeline.

Primary contact person for the study

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Other individuals involved in the study (you must name anyone who will interact with The PRACTICE):

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Briefly describe the purpose and procedure of your study (you may limit your description of your procedure to the part that is relevant to utilizing The PRACTICE).

Click here to enter text.

Do you intend to recruit patients from The PRACTICE for your study? Yes ☐ No ☐

If yes, please describe your recruitment process:

Click here to enter text.
Do you intend to use The PRACTICE space for your study? Yes ☐ No ☐
If yes, please describe your space needs (e.g., number of hours and days in the clinic, number of rooms needed, etc.).
Click here to enter text.

Do you intend to access patient treatment records for your study? Yes ☐ No ☐
If yes, please specify the type of information you will need and the purpose for accessing client treatment records:
Click or tap here to enter text.

Will you be utilizing other clinic resources for your study? Yes ☐ No ☐
If yes, please indicate the types of resources you will need (e.g., recording devises, one-way mirrors, office supplies, front desk staff members, etc.):
Click here to enter text.

Does your study pose any risks to the participants? Yes ☐ No ☐
If yes, please describe the risks involved in participating in your study:
Click or tap here to enter text.

Does your study offer any potential direct benefits to the participants? Yes ☐ No ☐
If yes, please describe the benefits involved in participating in your study:
Click or tap here to enter text.
Appendix C.

Application for Clinical Trial Financial Support at The PRACTICE

Researchers conducting clinical trials at The PRACTICE may financial support for their research from The PRACTICE. Financial support is primarily intended to provide payment to clinical trials’ participants. Clinical trials that are officially registered at www.clinicaltrials.gov and meet Spirit Guideline (http://www.spirit-statement.org/) for clinical trial research design will be given funding priority. *If applicable, please attach verification of registration and a completed Spirit Checklist with your application.*

Please submit this application to The PRACTICE Research Coordinator, Dr. Noelle Lefforge, at noelle.lefforge@unlv.edu or drop the application off at the office located in the Carlson Education Building room 226. The PRACTICE Research Committee will review your application and provide a response by email; if the Research Committee is not in session, your application will be reviewed by both The PRACTICE Director and Assistant Director. If you have not received a response within 10 business days, please follow-up with Dr. Lefforge. The PRACTICE might contact you for additional information. Your prompt response is appreciated and will expedite the review process.

Please see The PRACTICE’s Research Policies and Procedures for additional information on processing awarded funds.

**Principle Investigator:**

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**Other individuals involved in the study:**

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Briefly describe your current recruitment methods. Include a description of any problems you have encountered and what you have attempted to do to overcome barriers to recruitment.
Click here to enter text.

Is your project funded by any source? Yes ☐ No ☐
If yes, please describe.
Click here to enter text.

Is your study registered with www.clinicaltrials.gov? Yes ☐ No ☐
If yes, be sure to submit verification of registration with this application.

Does your study meet Spirit Guidelines for research design? Yes ☐ No ☐
If yes, be sure to submit completed Spirit Checklist with this application.

Why should your project be considered for financial support from The PRACTICE (e.g., how would funding contribute to the successful completion of the project, how does funding this project contribute to The PRACTICE’s mission, who would funding of this project benefit)?
Click here to enter text.