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Apex Innovative Sciences
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CONTACT INFORMATION:

Site Selection and Information:
Bobbie Theodore, Alliance Director
Tel. (916) 803-7149 (cell)
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Email: clinicaltrials@alliancesites.com

Site Contact:
Mitchell Hassman, MBA, Director of BD
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Fax (856) 306-6590
Email: mrhassman@hritrials.com

AFFILIATIONS:

Berlin Medical Associates
175 Cross Keys Rd, Suite 300A
Berlin, NJ 08009

Comprehensive Clinical Research
175 Cross Keys Road
Berlin, NJ 08009

EDUCATION:

2013 - 2019 Doctorate of Clinical Psychology
LaSalle University, Philadelphia, PA

2013 - 2015 Master of Arts, Clinical Psychology
LaSalle University, Philadelphia, PA

2011 - 2013 Master of Arts, Psychology
Columbia University, New York, NY

2007 - 2011 Bachelor of Arts, Psychology
St. John's University, Queens, NY

INTERNSHIP:

07/2018 - 07/2019 Clinical Psychology Internship
Pennsylvania Counseling Services & Crossroads Renaissance: Lebanon, PA

LICENSURE:

2020- Present Licensed Psychologist New York #024166

PROFESSIONAL EXPERIENCE:

Director of Addictions and Pain Management Research, Sub-Investigator, Rater
07/2019 – Present
Apex Innovative Sciences
Hassman Research, Institute, LLC, Berlin and Marlton, NJ

Clinical Psychology APA- Accredited Internship, Drug and Alcohol Clinician
07/2018 - 07/2019
Pennsylvania Counseling Services & Crossroads Renaissance, Lebanon, PA

Psychometrician, Psychology Practicum, 09/2016 -10/2017
Bancroft NeuroRehab, Resnick Center Mt. Laurel, NJ

Master's Level Clinician, Psychology Practicum, 07/2015 - 07/2016
University of Pennsylvania Psychiatric Center, Philadelphia, PA

Dissertation Research: Principal Investigator, 09/2014 – 05/2018
New York State Psychiatric Institute, Columbia University, New York, NY

Research Assistant, 09/2014 - 2017
LaSalle University, Marriage and Family Counseling Department, Philadelphia, PA

Master's Level Clinician, Psychology Practicum, 06/2014 - 06/2015
NHS Human Services: Mt. Airy, PA

Emotion Regulation Clinic, Master's Level Clinician, 05/2014 - 05/2017
LUCPS: LaSalle University Community Psychological Services, Philadelphia, PA

Peripartum Depression Clinic, Master's Level Clinician, 05/2014 - 05/2017
LUCPS: LaSalle University Community Psychological Services, Philadelphia, PA

Intake Clinician, 08/2013 - 08/2014
LUCPS: LaSalle University Community Psychological Services, Philadelphia, PA

Focus Group Leader, 10/2012 - 01/2013
Teachers College, Columbia University, Office of School and Community Partnerships, Partnership Schools Consortium, New York, NY

Psychometrician, 09/2012 - 02/2013
Neurorehabilitation & Neuropsychological Services, P.C., Massapequa, NY

Psychometrician/Research Assistant, 06/2012 - 06/2013
New York State Psychiatric Institute, New York, NY

PROFESSIONAL EXPERIENCE (*continued*):

Mental Health Lecturer/Data Analyst, 01/2012 - 06/2013
Columbia University, Clinical Psychology and Health Department, Think Smart Project, New York, NY

Psychometrician/Research Assistant, 9/2011-06/2012
New York State Psychiatric Institute, Substance Treatment and Research Services (STARS) Clinic, New York, NY

Research Assistant, 06/2010 - 09/2010
St. John's University, Department of Psychology, Queens, NY

INVESTIGATOR EXPERIENCE:

Phase I-IV • Addiction • Attention-Deficit/ Hyperactivity Disorder • Bipolar Disorder Depression • Healthy • Opioid Use Disorder • Schizophrenia or Schizoaffective Disorder

CLINICAL TRIAL EXPERIENCE:

Phase I Addiction

A Phase Ib, Randomized, Double-blind, Placebo-controlled, Ascending-dose Study of XXX to Treat Symptoms of Acute Opioid Withdrawal in Patients with Opioid Use Disorder who are Physically Dependent on Opioids

Phase I Depression

A Phase I/II Two-Part Study of XXX as an Adjunctive Therapy in Subjects With Major Depressive Disorder

Phase I Healthy

A Phase I, Randomized, Double-blind, Double-dummy, Active- and Placebo-controlled, Crossover Study to Assess the Abuse Potential of XXX Relative to Buprenorphine and Placebo in Healthy Experienced Recreational Drug Users

A Phase I, Single Ascending Dose, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Adult Subjects

A Phase I randomized, double-blind, double-dummy, active- and placebo-controlled, crossover study to assess the abuse potential of XXX relative to ketamine and placebo in healthy experienced recreational drug users.

A Phase I Study to Evaluate the Pharmacokinetic Profiles of Modified Release (MR) Formulations of XXX in Healthy Adult Subjects

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I Study to Evaluate the Effects of XXX , on the Pharmacokinetics, Safety, and Tolerability of XXX

A Randomized, Placebo controlled, Double-blind, Double-dummy Threeway Cross over Trial to Investigate the Effect of XXX and XXX on Ketamine-induced Cognitive Deficits in Healthy Male Subjects

A Phase I, Double-blind, Sponsor-open, Placebo-controlled, First-In-Human Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Ascending Dose of XXX in Healthy Subjects

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part B MAD)

A Phase I, Randomized, Double-Blind, Placebo-Controlled, Combined Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX Oral Solution in Healthy Subjects (Part A SAD)

A Phase I, Randomized, Double-blind, Placebo-controlled, Single-Ascending-Dose Trial to Evaluate the Safety, Tolerability, Immunogenicity, and Pharmacokinetics of Intravenous XXX in Normal Healthy Volunteers

A Double-blinded, Placebo-controlled, Sequential Cohort, Single-dose Escalation, Phase I Study to Evaluate the Safety and Single Dose Pharmacokinetics of XXX, a Reactive Species Decomposition Accelerant, in Healthy Volunteers - A First in Human Clinical Study

A Phase 0, Multi-Center Study in Schizophrenic Patients and Healthy Volunteers to Validate XXX Biomarkers for Use in Therapeutic Trials

A 2-Part, Phase I, Study of XXX Pharmacodynamics and Pharmacokinetics Alone and in the Presence of XXX or XXX

Phase I Schizophrenia

A Phase I, Pilot, 4-Week, Randomized, Double-Blind, Placebo-Controlled, Inpatient, Multicenter Study of the Safety, Population Pharmacokinetics, and Exploratory Efficacy of XXX in Acutely Psychotic Adult Subjects With Schizophrenia

A Phase I/II, Multiple Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of XXX Extended Release Capsules in Subjects with Schizophrenia, Schizoaffective Disorder

A Phase Ib Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Doses of XXX in Subject with Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I Randomized, Single-dose, Crossover Study of the Effects of XXX on Electrocardiogram (ECG) Intervals in Subjects with Schizophrenia

A Phase I/II Study to Evaluate the Safety, Tolerability, Efficacy and effects on Neurophysiological Biomarkers of XXX Oral Treatment in Subjects with Schizophrenia and Normal Healthy Volunteers

A Phase I, Single Ascending Dose and Multiple Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX for Extended-Release Injectable Suspension for Subcutaneous Use, in Healthy Subjects and in Patients with Schizophrenia or Schizoaffective Disorder

A Phase I, Open-label, Randomized, Single Ascending Dose Trial to Determine the Pharmacokinetics, Safety, and Tolerability of XXX Long Acting Injectable in Adult Subjects with Schizophrenia

A Safety/Tolerance Study to Evaluate a New Titration Scheme in Patients With Bipolar I Disorder or Schizophrenia

A Phase I, Open Label, Parallel-Design, Single Dose Study to Assess the Relative Bioavailability of XXX Extended-Release Suspension for Subcutaneous Administration XXX, in Vials compared to Prefilled Syringes, in Patients with Schizophrenia or Schizoaffective Disorder

Phase I Other Indications

A Phase I, Multiple-Dose Study in Participants with Type 2 Diabetes Mellitus to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of XXX

Phase II-IV Studies

Addiction

A Phase IV, Open-label, Rapid Initiation Study for Extended-Release XXX Subcutaneous Injection

Attention-Deficit/Hyperactivity Disorder (ADHD)

A Phase III Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX in Adults with Attention Deficit/Hyperactivity Disorder

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Flexible-Dose Study of the Efficacy and Safety of XXX in Adults with Attention-Deficit/ Hyperactivity Disorder (ADHD)

CLINICAL TRIAL EXPERIENCE (*continued*):

Bipolar Disorder

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of Two Dose Levels of XXX in Bipolar I Disorder Patients with Acute Agitation

Depression

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX at 25 mg as Adjunctive Treatment of Major Depressive Disorder

A Phase III, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX with a Fixed, Repeated Treatment Regimen on Relapse Prevention in Adults with Major Depressive Disorder

A Phase III Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of XXX 20 mg as Adjunctive Therapy to Antidepressants in Adult and Elderly Patients with Major Depressive Disorder with Insomnia Symptoms Who Have Responded Inadequately to Antidepressant Therapy and an Open-labeled Long-term Safety Extension Treatment with XXX

A Phase II, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of the Safety and Efficacy of XXX in the Treatment of Adults with Major Depressive Disorder

A Phase III, Randomized, Double-Blind Study Comparing the Efficacy and Safety of XXX Plus Sertraline Versus Placebo Plus Sertraline in Adults With Major Depressive Disorder

A Phase III Randomized, Double-Blind, Placebo-controlled Study Evaluating the Efficacy and Safety of XXX in the Treatment of Adults with Severe Postpartum Depression

A Phase II, 6-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel group study with a Quetiapine XR arm to evaluate the efficacy, tolerability and safety of XXX in patients with Major Depressive Disorder

A Phase II, Two-Part Study of XXX as an Adjunct Therapy in Subjects with Major Depressive Disorder

Schizophrenia

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Acutely Psychotic Hospitalized Adults with DSM-5 Schizophrenia

CLINICAL TRIAL EXPERIENCE (*continued*):

A Phase I Randomized, Open-Label, Parallel, Single-Dose Study to Evaluate the Pharmacokinetic Characteristics of XXX of Two Formulations versus INVEGA SUSTENNA® after Intramuscular Injection in Schizophrenia Patients

A Phase III Multicenter, Randomized, Double-blind, Placebo-controlled Study to determine Efficacy and Safety of XXX in Agitation associated with Schizophrenia

A 56-week Open Label Extension to Assess Safety and Tolerability of XXX in Adult Subjects with Schizophrenia

A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dose, Multicenter Study to Evaluate the Efficacy and Safety of XXX in Acutely Psychotic Adult Subjects with Schizophrenia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX as an Adjunctive Treatment in Adult Patients with Schizophrenia

Other Indications

A Randomized, Single-blind, all Placebo, Pretest Posttest, Three-Part Investigation of the Efficacy of the Placebo-control Reminder Script (PCRS) Developed to Reduce the Placebo and Nocebo Effects

SCALE ADMINISTRATION EXPERIENCE:

Acceptance and Action Questionnaire (AAQ-22)
Adult ADHD Investigator Symptom Rating Scale (AISRS)
Abnormal Involuntary Movement Scale (AIMS)
Barnes Akathisia Rating Scale (BARS)
Beck Anxiety Inventory (BAI)
Beck Depression Inventory (BDI)
Beck Hopelessness Scale (BHS)
Beck Suicide Scale (BSS)
Benton Visuospatial Memory Test (BVMT)
Brief Assessment of Cognition in Schizophrenia (BACS)
Brief Mood Survey
Boston Diagnostic Aphasia Examination (BDAE)
Boston Naming Test (BNT)
Buschke Selective Reminding Test (SRT)
California Verbal Learning Test (CVLT)
Choice Reaction Time Test (CRT)
Clock Drawing Test
Columbia Suicide Severity Rating Scale (CSSRS)

SCALE ADMINISTRATION EXPERIENCE (*continued*):

Controlled Oral Word Association Test (COWAT)
Clinical Opiate Withdrawal Scale (COWS)
Delis Kaplan Executive Function System (D-KEFS)
Depression, Anxiety, and Stress Scale (DASS-21)
Difficulties in Emotion Regulation Scale (DERS)
Dissociative Experiences Scales (DES-II)
Extrapyramidal Symptom Revaluation (ESRS-A)
Finger Tapping Test
Flanker Test
Grooved Pegboard Test
House-Tree-Person (HTP)
Integrated Visual and Auditory Continuous Performance Test -(CPT)
Iowa Gambling Test
Karolinska Sleepiness Scale (KSS)
Montgomery – Åsberg Depression Rating (MADRS)
Mini Mental State Exam (MMSE)
Minnesota Multiphasic Inventory – Second Edition (MMPI-II)
Minnesota Multiphasic Inventory – Second Edition, Restructured Format (MMPI-2, RF)
Neuropsychological Assessment Battery (NAB)
Outcome Questionnaire (OQ-45)
Patient Health Questionnaire (PHQ-9)
Quality of Life Inventory (QOLI)
Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)
Rey Complex Figure Test (RCFT)
Reynolds Intellectual Assessment Scales (RIAS)
Rorschach Test
Simpson Angus Scale (SAS)
Structured Clinical Interview for DSM 5 (SCID-V)
Stroop Test
Test of Variables of Attention- (T.O.V.A.)
Texas Functional Living Scale (TFLS)
Thematic Apperception Test (TAT)
Trail Making Test (A& B)
UCSD Performance-based Skills Assessment (UPSA-B)
Wechsler Adult Intelligence Scale – Fourth Edition (WAIS-IV)
Wechsler Intelligence Test for Children (WISC-IV)
Wechsler Memory Scale – Fourth Edition (WMS-IV)
Wechsler Test of Adult Reading (WTAR)
Wide Range Achievement Test – Fourth Edition (WRAT-IV)
Wisconsin Card Sorting Test – (WCST)
Young Mania Rating Scale (YMRS)

ADVISORY BOARD/ENDPOINT ADJUDICATION COMMITTEE:

April 2020	Indivior Adjudication Committee
Aug 2020 – Present	Lyndra Scientific Advisory Board

PROFESSIONAL AFFILIATIONS:

2018 – Present	Member of the Addiction Society of Medicine
2016 – Present	Member of the National Academy of Neuropsychology
2014 – Present	Member of the Pennsylvania Psychological Association
2014 – Present	Member of the American Counseling Association
2012 – Present	Member of the American Psychological Association

PROFESSIONAL ACTIVITIES AND DEVELOPMENT:

07/ 2018 - Present	Naloxone Now: Narcan Certification Obtained
09/2018 - 06/2019	Cognitive Behavioral Therapy- Relapse Prevention Training Certification Obtained
07/2018 - 05/2019	Pennsylvania Department of Drug and Alcohol Programs (DDAP) Trainings
05/2017	Bancroft NeuroRehab, Grand Rounds Working in an Interdisciplinary Team for Persons Served with TBI
03/2017	National Academy of Neuropsychology Webinar: How to Conduct a Culturally- Informed Neuropsychological Evaluation with Asian Americans.
11/2016	Bancroft NeuroRehab, Grand Rounds Case Study on a Veteran with TBI and PTSD: Occupational Therapy's Role in Improving Community Reintegration
10/2016	National Academy of Neuropsychology Webinar: Memory Loss, Alzheimer's Disease & Dementia
04/2016	Trauma Focused: Cognitive Behavioral Therapy Web-based learning Course
01/2016	CITI GCP Training: Human Research Institute
09/2015	Relias Learning: Online Co-occurring Disorders Webinar Series: Integrating Combined Therapies

PROFESSIONAL ACTIVITIES AND DEVELOPMENT (*continued*):

03/2015	North Eastern Human Services (NHS): Mt. Airy, PA Child Abuse and Prevention Training
09/2011	New York State Psychiatric Institute, New York, NY HIPPA and Good Clinical Practice Training

POSTER PRESENTATIONS AND CONFERENCES:

Cohen, E. A., Hassman, H. H., Walling, D. P., Grindell, V. M., Wyka, K., Hough, D., Lobb, J. M., Joseph, A. V., Glass, S. J., Ball, R. R., and Ereshefsky, L. (November, 2020). Preferences of the Opioid Use Disorder patient: Clinical trial methodologies and COVID19 mitigations that motivate participation. Poster presented at the Annual International / Canadian Society of Addiction Medicine (I/CSAM) Conference, Virtual.

Rigney, N., Bessai, D., Paddock, B., Zugu, E., Haggerty, K. (2017). The intraclass correlation reliability of the Texas functional living scale. Poster Presentation at the National Academy of Neuropsychology conference in Boston, Massachusetts.

Jacob, C.J., Bessai, D., Ruggiero, S., & Theobald, A. (2016). Vicarious traumatization and the role of mindfulness among mental health counselors. Ninety-Minute presentation at the American Counseling Association conference in Montreal, Canada. **Acceptance rate for ACA 2016: 21%**

Jacob, C. J., Roth, G., Bessai, D., Ruggiero, S., & Theobald, A. (2015). Vicarious traumatization: Using mindfulness practice to increase awareness of internal processes. Ninety-minute presentation at the American Counseling Association conference in Orlando, Florida. **Acceptance rate for ACA 2015: 23%.**

BIOSKETCH:

Director of Addictions and Pain Management Research, Investigator, Hassman Research Institute

Dr. Hough joined HRI in 2019 with extensive experience in counseling and research in the areas of pain and addiction. She provides leadership of clinical services at both the Marlton and Berlin locations as well as expert support for study design. Dr. Hough oversees the dedicated pain and addictions unit and staff, regularly providing training sessions and workshops on topics such as the neurobiology of addiction, ways to effectively manage biases and implement sensitivity when interacting with SUD populations, and de-escalation strategies to employ if patients become uncooperative or agitated. Dr. Hough has additionally served on advisory boards for addictions studies. Dr. Hough's expertise has enabled HRI to expand its capabilities in pain and addictions, ensuring it can successfully execute highly demanding and complex trials.

BIOSKETCH (*continued*):

Work History:

Prior to HRI, Dr. Hough provided drug and alcohol counseling in inpatient and outpatient forensic settings at Pennsylvania Counseling Services, and addictions and pain management counseling at the University of Pennsylvania Outpatient Psychiatry Center. She has provided clinical services for the treatment of co-occurring SUDs, mood disorders, personality disorders, and psychoses in several community mental health settings. Earlier in her career she conducted research at the Columbia University addiction centers and New York State Psychiatric Institute.

Dr. Hough has written extensively on neuropsychological and cognitive function in SUD populations and delivered numerous poster presentations at major psychology conferences.

Dr. Hough is an advocate of Medication Assisted Treatment (MAT), which uses medications in combination with counseling and behavioral therapy, for patients with SUDs. She collaborates with MAT treatment providers to improve treatment outcomes and reduce incidence of relapse.