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Neurobiological Research Institute 123 Wellness Avenue Metropolis, CA 90210

**Date:** October 15, 2023

**Clinical Research Study Cover Letter**

**Study Title:** Exploring the Gut-Microbiota and Mental Health Connection in Young Adults Study Protocol Number: GMHC-2023-001

**Signatures:**

**Principal Investigator:** [Signature] Dr. Elena Rodriguez, PhD Date: 10/15/2023

**Co-Investigator:** [Signature] Dr. Marcus Chen, MD Date: 10/15/2023

**Institutional Review Board Approval:** [Signature] Dr. Rebecca Hartman, IRB Chair Date: 10/20/2023

**Sponsor Representative:** [Signature] Michael Thompson NeuroGut Innovations, Inc. Date: 10/16/2023

**Study Title:** Exploring the Gut-Microbiota and Mental Health Connection in Young Adults Study Protocol Number: GMHC-2023-001

Dear Institutional Review Board,

I am submitting the comprehensive research protocol for our investigative study on gut microbiota and mental health among young adults.

**Project Description:** This is an observational, non-interventional research study designed to explore correlations between gut microbiota diversity and mental health metrics. The study will utilize a mixed-methods approach combining psychological assessments and microbiological analysis.

**Study Classification:**

* Type: Observational Cohort Study
* Phase: Not Applicable (Non-Interventional Research)

**Participating Research Sites:**

1. Metropolis Community Health Center (Primary Site) Address: 456 Health Boulevard, Metropolis, CA 90210 Principal Site Investigator: Dr. Marcus Chen, MD
2. Urban University Campus Research Facility Address: 789 Academic Way, Metropolis, CA 90211 Site Investigator: Dr. Sarah Johnson, PhD
3. Wellness Community Center, Downtown Location Address: 234 Wellness Street, Metropolis, CA 90212 Site Investigator: Dr. Robert Kim, PsyD

**Supporting Documentation:**

1. Research Protocol
   * Document: Comprehensive Research Protocol
   * Version: 1.2
   * Date: 15 September 2023
   * IRB Tracking Number: GMHC-IRB-2023-001
2. Informed Consent Document
   * Document: Participant Consent Form
   * Version: 1.1
   * Date: 1 September 2023
3. Assessment Instruments
   * Depression, Anxiety, and Stress Scale (DASS-21)
     + Version: Standard Clinical Version
     + Date of Use: 1 August 2023
4. Microbiota Analysis Procedures
   * Sampling and Sequencing Procedure Manual
   * Version: 1.0
   * Date: 1 August 2023
5. Data Management and Privacy Protocol
   * Version: 1.1
   * Date: 15 September 2023

**Sponsor Details:**

* Primary Sponsor: Neurobiological Research Institute
* Funding Source: Internal Institutional Grant
* Commercial Sponsor: NeuroGut Innovations, Inc.
  + Contract Number: NGI-2023-GMHC-001
  + Sponsorship Amount: $250,000

**Principal Investigator Details:**

* Name: Dr. Elena Rodriguez, PhD
* Credentials: Senior Research Scientist
* Institutional Affiliation: Neurobiological Research Institute
* Professional Qualifications:
  + PhD in Psychobiology
  + 15 years of research experience
  + Board Certified in Microbiome Research

**Study Parameters:**

* Total Participants: 150 young adults (18-30 years)
* Estimated Duration: 12-18 months
* Primary Methodology: Correlational research with microbiological and psychological assessments

**Ethical Considerations:**

* Full IRB Approval Pending
* Comprehensive participant protection protocols in place
* Adherence to NIH and FDA research guidelines

The research has been developed with rigorous ethical considerations and aims to contribute meaningful insights into gut-brain interactions.

Sincerely,

Dr. Elena Rodriguez, PhD Principal Investigator Neurobiological Research Institute

[Signature]