Ethical & Independent Review Services
A Shared Commitment to Ethical Research

IRB APPROVAL CERTIFICATION
Modification - Study

E&I IRB #2 - IRB00007807
Roster dated January 24, 2022

IRB Signature

Signature Jean Taylor-Woodbury By TM 3/10/2022
Jean Taylor-Woodbury, RN, MS, ANP-BC, Chair Teresa Majors Date

Review and Approval Information

E&I Study Number 18053 - 04A
Review Process Expedited
Approval Date Wednesday, March 9, 2022
Expiration Date Saturday, May 21, 2022 at 11:59 PM

This document certifies the IRB's approval of the bolded items identified under "Documents Approved" to be conducted by the named Principal Investigator.

A waiver of the requirement for documentation of informed consent is granted according to 45 CFR 46.117(c)(2).

In accordance with §46.109(f), the requirement for continuing review does not apply to this study. IRB approval will not expire on the stated expiration date, however a continuing review check-in process must be completed on or before the stated expiration date. Any changes to research activity continue to require IRB approval prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject.

NOTE: Subjects must be asked for their consent using the most recently approved, stamped version(s). All IRB approved consent documents are version controlled and may not be modified in any way without prior IRB approval. Use of an unapproved document may constitute non-compliance.

Study

Managing Metabolic Disease and Related Co-morbidities Through A Precision Digital Care Program

Client Digbi Health (formally 3TandAi)
Sponsor Digbi Health (formally 3TandAi)

Principal Investigator

Ranjan Sinha, BTech, MBA

E&I PI Number 17182 - 001

Address

Digbi Health
13105 Delson Court
Los Altos Hills, CA 94022

Performance Sites

Digbi Health, 13105 Delson Court, Los Altos Hills, CA 94022

Documents Approved	Document #	Version	Date
Protocol			**21-Jan-22**
Web-Consent Form	**E&I 03/10/2022**	**4**	**16-Feb-2022**
Brochure and Recruitment Material			5/7/2018
Online Intake & Lifestyle Questionnaire	Appendix A		Rec'd 04/23/2020
Digbi Health Program Website Screenshots	**Appendix B**		**Rec'd 03/04/2022**
Sample Wellness Plan	Appendix C		Rec'd 04/23/2020

Stipulations of Approval

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date, unless otherwise stated in this letter. Investigators and sponsors are responsible for initiating Continuing Review proceedings.
2. All protocol modifications must be IRB approved prior to implementation. This includes any addition or change of recruitment materials, change of investigator, or performance site address. (Exception: If

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necessary to eliminate apparent immediate hazard to subjects.)

3. Report to E&I within five working days of learning if any of the following occur:
   - Unanticipated problems involving risk to human subjects or others;
   - Unanticipated Serious Adverse Events and Safety Reports;
   - Protocol deviations, violations, and exceptions that impact subject welfare or safety or study integrity including changes intended to reduce immediate risk to subjects;
   - Use of an investigational product in an emergency situation; and
   - Claims for compensation or for medical care for research-related injury.
4. Advertising and recruitment materials must be approved by E&I prior to use or publication.

END