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September 27, 2022

Christopher McGowan, MD, MSCR
True You Weight Loss
2001 Weston Parkway
Cary, North Carolina 27513

Dear Dr. McGowan:

SUBJECT: IRB EXEMPTION— HIPAA FULL WAIVER OF AUTHORIZATION AND
REGULATORY OPINION
Investigator: Christopher McGowan, MD, MSCR
Sponsor Protocol No.: RCR-002
Protocol Title: Transoral Outlet Reduction in the Non-Academic Setting:
Weight loss Outcomes, Safety, and Insights from a High-volume
Community Practice

On September 27, 2022, WCG IRB **approved** a request for a waiver of authorization for use and disclosure of protected health information (PHI) for the above-referenced research. This review was conducted through expedited review.

WAIVER OF HIPAA AUTHORIZATION

WCG IRB determined that documentation received from you satisfies the three requirements for a waiver of authorization. These requirements are:

1. The use or disclosure of the PHI involves no more than minimal risk to the individuals, based on the following elements:
 - a. An adequate plan to protect identifiers from improper use and disclosure;
 - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and,
 - c. Adequate written assurances that the PHI will not be reused or redisclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.

2. The research could not be practicably conducted without access to and use of the PHI; and,
3. The research could not practicably be conducted without the waiver.

The Board has determined that this waiver of authorization for the use and access of the protected health information as described in the above referenced protocol, and in the information provided in the submitted waiver of authorization form, is necessary for conduct of this research.

REVIEW OF EXEMPTION REQUEST

This is in response to your request for an exempt status determination for the above-referenced protocol. WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance.

We believe the study is exempt under 45 CFR § 46.104(d)(4), because the research involves the use of identifiable private information/biospecimens; and the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR §§160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR§164.501 or for "public health activities and purposes" as described under 45 CFR §164.512(b).

This exemption determination can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. You are responsible for ensuring that each site to which this exemption applies can and will accept WCG IRB's exemption decision.

WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Please discuss with the local IRB authorities in the country where this activity is taking place to determine if local IRB review is required.

Please note that any future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date on its IRB exemption determinations.

If you have any questions, or if we can be of further assistance, please contact Tanna M. MacReynold, C.I.P., at 360-269-5584, or e-mail RegulatoryAffairs@wirb.com.

Sincerely,

Kelly FitzGerald, PhD
IRB Executive Chair and
Vice President IBC Affairs

TMM:hp
D4-Exemption-McGowan (09-27-2022)
cc: Ashley Kucera, True You Weight Loss
WCG IRB Accounting
WCG IRB Work Order #1-1589010-1