**PROTOCOL**

**<Protocol Title>**

Protocol Version: <Protocol Version>

Protocol Date: <dd Month yyyy>

*This Protocol contains information that is confidential and proprietary to < Client name > and YOUR COMPANY. YOUR COMPANY is not liable or in any way responsible for any written and/or verbal changes to the Protocol content as originally designed and presented hereinafter, without regard to origin.*

**<Protocol Title>**

**Client Contact submitted to:**

<Primary legal contact name>

<Title of primary contact name>

<Legal name of Client company>

<City>

<State, Zipcode> Phone: <Phone> E-mail: <E-mail>

**YOUR COMPANY Contact submitted by:**

<Primary contact name>

<Title of primary contact name>

YOUR COMPANY

<City>

<State, Zipcode> Phone: <Phone> E-mail: <E-mail>

YOUR COMPANCY project name: <name of project>

**PROTOCOL SIGNATORY APPROVAL**

**< Protocol Title >**

**< Protocol Version >**

The following people have reviewed the final Protocol and give their approval.



**Client Signatory**

< type name>

<type company title>

< type study role>

Signature Date

**YOUR COMPANY Signatory**

< type name>

<type HealthCore title>

< type study role>

Signature Date

**TABLE OF CONTENTS**

**Protocol Signatory Approval** .........................................................................................................3

**1. List of Abbreviations and Definition of Terms** ....................................................................5

**2. Study Investigators**................................................................................................................6

*2.1 Persons Involved in the Preparation of the Protocol*.....................................................6

*2.2 Persons Involved in the Review of the Protocol* ...........................................................6

**3. Amendments to the FINAL Protocol** ....................................................................................7



**4. Protocol Synopsis** .................................................................................................................8

**5. Introduction** ............................................................................................................................9

*5.1 Background* ...................................................................................................................9

*5.2 Study Rationale* .............................................................................................................9

**6. Study Objectives** ..................................................................................................................10

*6.1 Primary Objective ........................................................................................................*10

*6.2 Secondary Objective ...................................................................................................*10

*6.3 Exploratory Objective ..................................................................................................*10

**7. Study Design** ........................................................................................................................11

**8. Data Source** ..........................................................................................................................12

**9. Study Population** .................................................................................................................13

**10. Exposure Definition and Assessment** ...............................................................................14

**11. Outcome Definition and Assessment** ................................................................................15

**12. Covariate Definition and Assessment** ...............................................................................16

**13. Clinical Data** .........................................................................................................................17

**14. Statistical Methods and Sample Size**.................................................................................18

*14.1 Statistical Methodology* ...............................................................................................18

*14.2 Sample Size* ................................................................................................................18

**15. Limitations to the Study Design** .........................................................................................19

**16. Study Ethics** .........................................................................................................................20

**17. Adverse Event Reporting** ....................................................................................................21

**18. Study Details** ........................................................................................................................22

*18.1 Funding Source ...........................................................................................................22*

*18.2 Regulatory Requirement .............................................................................................22*

*18.3 Data Analytics Plan Requirement ...............................................................................22*

*18.4 Study Deliverables and Communication of Results ....................................................22*

**19. References**............................................................................................................................23

**20. Appendices**...........................................................................................................................24

*APPENDIX A. <Title> ...........................................................................................................*24

**1. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS**

< To add new terms insert a row into the table. Delete any abbreviations or special terms provided in the standard table that do not apply to the current project.>

The following abbreviations and special terms are used in this Protocol.

**Abbreviation or**

**Special Term**

**DAP** Data Analytics Plan

**Definition**

**HIPAA** Health Insurance Portability and Accountability Act

**IRB** Institutional Review Board

**2. STUDY INVESTIGATORS AND DEFINITION OF TERMS**

< All persons (e.g., YOU, Client, consultants, etc.) involved in the development and/or review of the Protocol must be acknowledged in this section, as appropriate. The Protocol lead author is the person responsible for writing the main content of the Protocol, and is the primary person responsible for the accuracy and completeness of the Protocol. >

**2.1 PERSONS INVOLVED IN THE PREPARATION OF THE PROTOCOL**

**Protocol Lead Author**

< Investigator name, degree(s) >

< Title >

< Company name >

**Protocol Co-author(s)**

< Investigator name, degree(s) >

< Title >

< Company name >

**2.2 PERSONS INVOLVED IN THE REVIEW OF THE PROTOCOL**

< Investigator name, degree(s) >

< Title >

< Company name >

< Investigator name, degree(s) >

< Title >

< Company name >

**3. AMENDMENTS TO THE FINAL PROTOCOL**

< List the original (v1) final Protocol in the table. For the original Protocol listing, the “Author” should be the name of the person referenced as the “Protocol lead author” in Section 2. Furthermore, state “Not applicable” in the “Protocol section” and “Detail of change(s)” columns. For each amendment to the Protocol, list in the table (by adding a new row) the updated version number (v2, v3, v4, etc.), date of amendment, person(s) responsible for making the amendment in the Protocol, and a brief description of the change, including a reference to the section number of the

Protocol indicating where the change was made. >



**Version Date**

dd/Mmm/yyyy

**Author**

First initial. Last name

**Protocol**

**Section**

**Detail of Change**

PROTOCOL

4. PROTOCOL SYNOPSIS

<Provide a high-level summary of the study similar to an executive summary, including the study background/rationale, objectives, study design, study population(s), exposure and outcomes measures, and statistical methodology.>

**5. INTRODUCTION**

**5.1 BACKGROUND**

< This section should describe the medical product history and/or therapeutic area of interest and any salient clinical and/or observational research studies related to the research question of interest. >

**5.2 STUDY RATIONALE**

< This section should describe why the study is being conducted. >

**6. STUDY OBJECTIVES**

**6.1 PRIMARY OBJECTIVE**

<Describe the primary objective(s) of the study.>

**6.2 SECONDARY OBJECTIVE**

<Describe the secondary objective(s) of the study, if applicable.>

**6.3 EXPLORATORY OBJECTIVE**

<Describe the exploratory objective(s) of the study, if applicable.>

PROTOCOL

7. STUDY DESIGN

<Describe the study design (e.g., observational, retrospective, cohort, case-control).>

**PROTOCOL**

**8. DATA SOURCE**

<Describe the database and data environment to be used for the study. >

**9. STUDY POPULATION**

< Describe the study population and cohort and/or cases and controls of interest, including the criteria for inclusion/exclusion. Any subgroup populations should also be described. >

**10. EXPOSURE DEFINITION AND ASSESSMENT**

< Describe the exposure(s) used in the study and how each exposure will be identified (e.g., National Drug Code) and characterized (e.g., dose, day supply, duration of use; naïve use, switcher). It is not necessary to include the codes for identification. >

11. OUTCOME DEFINITION AND ASSESSMENT

<Describe the outcome(s) to be used in the study and how each outcome will be identified. If applicable, indicate if an outcome is primary or secondary. It is not necessary to include the codes for identification. >

12. COVARIATE DEFINITION AND ASSESSMENT

<Describe the covariate(s) to be used in the study and how each covariate will be identified. It is not necessary to include the codes for identification. >

**13. CLINICAL DATA**

< If applicable, confirm if the clinical data (e.g., medical record data, survey data, National Death Index data, etc.) will be used and describe how the clinical data will be used in the study. >

**14. STATISTICAL METHODS AND SAMPLE SIZE**

**14.1 STATISTICAL METHODOLOGY**

< Provide a brief description of the primary, secondary, and/or exploratory analyses and statistical methods to be used in the study. If applicable, provide reference to the development of a Data Analytics Plan to accompany the Protocol, which will describe in detail the statistical methodology, codes, etc. >

**14.2 SAMPLE SIZE**

< Describe the sample size and/or power required to meet the study objectives. >

PROTOCOL

15. LIMITATIONS TO THE STUDY DESIGN

<Describe the limitations to the study design (e.g., exposure misclassification, outcome misclassification, generalizability, bias, etc.).>

**17. ADVERSE EVENT REPORTING**

< Describe how adverse event reporting will be conducted. The following is example language for this section.

*We will monitor for suspected adverse drug reactions, which for purposes of this study, are defined as adverse events for which the treating health professional indicates that a medical outcome could be related to Miraculon.*

**18. STUDY DETAILS**

**18.1 FUNDING SOURCE**

< Describe the funding source for the study. This information should be included in the Protocol. The following is example language for this section.

**18.2 REGULATORY REQUIREMENT**

< State if the study is required by a regulatory agency (e.g., United States Food and Drug Administration, European Medicines Agency, etc.). This information should be included in the Protocol. >

**18.3 DATA ANALYTICS PLAN REQUIREMENT**

< State if the study requires the development of a Data Analytics Plan. The development of a Data Analytics Plan is highly recommended for the conduct of a regulatory study, or may be specifically requested by the HealthCore Director, Client, or Sponsor. This information should be included in the Protocol. >

**18.4 STUDY DELIVERABLES AND COMMUNICATION OF RESULTS**

< Describe the study deliverables, as specified in study agreement between HealthCore and the Client and/or Sponsor. Include a description of the frequency of reporting, type of reporting (e.g., completed table results only or full report describing the background, methods, results, and discussion, transfer of survey data, etc.), and any planned publications. This information should be included in the Protocol. >

**PROTOCOL**

19. **REFERENCES**

< Use Reference Manager to insert references. >

**PROTOCOL**

**20. APPENDICES**

< Reference to appendices in the text of the Protocol must be in chronological order. Appendices should be labeled as Appendix A, Appendix B, etc. >

**APPENDIX A. < Title >**