0-☐ Completed and signed affidavit

**Part 1: Administration and Personnel**

**Question 1: Summary Statement.**

1-☐ Statement of Laboratory’s scope, purpose and mission is provided. Stated purpose indicates that the Laboratory is involved in clinical work.

**Question 2: Lab Personnel/Titles/Credentials/Licensure.**

2-☐ Completed Table of Laboratory personnel included in application.

3-☐ Appendix A is included – current CPR or BLS certificates of all staff with direct patient contact provided.

4-☐ Appendix B is included – current licensure verifications of all medical/clinical staff provided.

5-☐ Laboratory demonstrates that clinical assessments and evaluation are being conducted by or under the supervision of a clinician with credentials/licensure which includes assessment/evaluation within the scope of practice for the population being served.

6-☐ Laboratory demonstrates that any invasive procedures performed (including but not limited to fine wire placement) are being conducted by or under supervision of a clinician whose licensure/credentials include such procedures within the scope of their clinical practice.

7-☐ The Laboratory demonstrates that the data interpretation team includes at least one licensed clinician with demonstrated knowledge and expertise for treatment of conditions present in the population being served.

8-☐ The Laboratory demonstrates that the clinical recommendation team includes at least one licensed clinician with demonstrated knowledge and expertise for treatment of conditions present in the population being served.

**Question 3: Components of Clinical Evaluation**

9-☐ The application indicates that the Laboratory captures & reports 3-D kinematics

10-☐ The application indicates that the Laboratory captures & reports 3 orthogonal components of force (kinetics)
The application indicates that the Laboratory measures & reports electromyographic muscle activity (EMG).

The application indicates that the Laboratory captures all components (kinematics, kinetics, & EMG) simultaneously.

Documentation of volume of clinical cases provided.

Documentation of diagnosis categories & percentages of clinical cases provided.

Documentation of referral process for clinical cases provided.

Evidence provided that clinical motion studies are performed following physician referral.

Appendix C is included – Laboratory Referral Form.

**Question 4: Consumer Feedback**

Documentation of a mechanism for patient/family satisfaction

Documentation of a mechanism for referral source satisfaction

Appendix D included - Surveys

**Question 5: Laboratory Procedures**

Documentation of procedure manual, procedure protocols or operational definitions for physical examination or assessment as performed in the Motion Laboratory. Appendix E is included

Documentation of a procedure manual or procedure protocol for marker/target placement. Appendix F is included.

Documentation of a procedure manual or procedure protocol for EMG surface electrode placement as performed in the Motion Laboratory. Appendix G is included.

Documentation of a procedure manual or procedure protocol for EMG fine wire placement as performed in the Motion Laboratory. Appendix H is included.

Documentation of a procedure manual or procedure protocol for data collection. Appendix I included.

Documentation of a procedure manual or procedure protocol for data reduction which includes an established verification system for target tracking and event identification. Appendix J is included.
27-☐ Documentation of a process for data interpretation.

28-☐ Documentation of a process for clinical recommendations.

**Question 6: Competency**

29-☐ Documentation of methods to achieve initial competency of personnel for each of the following areas is provided:

- ☐ a. physical exam
- ☐ b. marker/target placement
- ☐ c. surface EMG placement
- ☐ d. fine wire EMG placement
- ☐ e. data collection
- ☐ f. data reduction
- ☐ g. data interpretation
- ☐ h. clinical recommendations

30-☐ Documentation of methods to maintain competency of personnel for each of the following areas is provided:

- ☐ a. physical exam
- ☐ b. marker/target placement
- ☐ c. surface EMG placement
- ☐ d. fine wire EMG placement
- ☐ e. data collection
- ☐ f. data reduction
- ☐ g. data interpretation
- ☐ h. clinical recommendations

**Question 7: Quality Assurance**

31-☐ Documentation of Quality Assurance Programs in at least two of the following areas within the past 3 years

- ☐ a. physical exam
- ☐ b. marker/target placement
- ☐ c. surface EMG placement
- ☐ d. fine wire EMG placement
- ☐ e. data collection
- ☐ f. data reduction
32-☐ Documentation of methods to maintain consistency within personnel for each of the following areas:

☐ a. physical exam
☐ b. marker/target placement
☐ c. surface EMG placement
☐ d. fine wire EMG placement
☐ e. data collection
☐ f. data reduction
☐ g. data interpretation
☐ h. clinical recommendations

33-☐ Documentation of methods to maintain consistency between personnel for each of the following areas:

☐ a. physical exam
☐ b. marker/target placement
☐ c. surface EMG placement
☐ d. fine wire EMG placement
☐ e. data collection
☐ f. data reduction
☐ g. data interpretation
☐ h. clinical recommendations

Question 8: Safety Policies and Personnel Competencies

34-☐ Documentation of Written Policies for adherence to:

☐ Local Building Safety Codes. Appendix K is included.
☐ Hazards Communication Program, including Material Safety Data Sheets available for potentially hazardous materials in work area. Appendix L included.
☐ Age-Specific Patient Care Services Program for all personnel with direct patient contact (technical and clinical). Appendix N included.
☐ Hospital and Departmental Infection Control Policies. Appendix O included.

35-☐ Evidence of maintained competency for all personnel by annual training in the following areas. Appendix P included:

☐ Local Building Safety Codes
☐ Environmental Safety Procedures
☐ Emergency Medical Provision & First Aid Procedures (demonstration of current CPR or BLS certification will suffice – see Appendix A)
☐ Age-Specific Patient Care Services
☐ Infection Control Procedures
Question 9: Other Accrediting Agencies

36-□ Documentation of current accreditation (including date of expiration) from agencies indicated. Appendix Q included.

Part 2: Equipment

Question 1: Physical Layout

37-□ Dimensions and description of current physical space or layout is provided. Appendix R is included.

Question 2: Hardware

38-□ Documentation of descriptions for all equipment in current use for routine data collection as described in Part 1 Question 3a.

39-□ Capability to capture & report 3-D kinematics

40-□ Capability to capture & report 3 orthogonal components of force (kinetics)

41-□ Capability to measure & report electromyographic muscle activity (EMG)

42-□ Evidence of system components for synchronization between kinematic, kinetic, and EMG measurement systems

Question 3: Calibration Procedures, Accuracy & Precision: Motion Capture System

43-□ Documentation of calibration procedures for the motion capture system.

44-□ Evidence that calibration occurs in accordance with manufacturer’s recommendations for the motion capture system being used.

45-□ Documentation of methods to ensure accuracy (validity) of the motion capture system.

46-□ Documentation of methods to ensure precision (repeatability) of the motion capture system

47-□ Appendix S is included.

48-□ Physical layout in Question 1 is consistent with the calibration volume described in Question 3.

Question 4: Calibration Procedures, Accuracy & Precision: Other Systems
49-□ Documentation that calibration procedures are in place for all additional measurement equipment used for clinical analysis.

□ 1. Force platform system
□ 2. EMG system
□ 3. All additional measurement systems as described in Part1 Question 3a.

50-□ Evidence that calibration occurs in accordance with manufacturer’s recommendations for each additional measurement system

□ 1. Force platform system
□ 2. EMG system
□ 3. All additional measurement systems as described in Part1 Question 3a.

51-□ Documentation of methods to ensure accuracy (validity) for each additional measurement system

□ 1. Force platform system
□ 2. EMG system
□ 3. All additional measurement systems as described in Part1 Question 3a.

52-□ Documentation of methods to ensure precision (repeatability) for each additional measurement system

□ 1. Force platform system
□ 2. EMG system
□ 3. All additional measurement systems as described in Part 1 Question 3a.

53-□ Appendix T is included.

**Question 5: Biomechanical Model/Marker Set.**

54-□ Evidence that marker set can characterize 3D kinematics of the lower limbs.

55-□ Evidence that the biomechanical model can utilize coordinate trajectories and ground reaction forces to calculate 3D kinetics of the lower limbs.

56-□ Description provided demonstrates that authors understand the strengths and weaknesses of the biomechanical model they are using

57-□ Description provided demonstrates that authors understand the potential sources of error in their calculations.
Part 3: Data Processing/Data Management/ Reporting

Question 1: Software/Data Processing/Data Reduction.

58-☐ Description of kinematic & kinetic data reduction software provided

59-☐ Description of EMG data reduction software provided.

60-☐ Description of how processing errors are identified and corrected is provided.

61-☐ Description of how gait events are identified is provided.

62-☐ Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction of kinematic and kinetic data.

63-☐ Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction of EMG data.

Question 2 & 3. Control Dataset.

64-☐ Description of control kinematic and kinetic dataset complete.

☐ Facility & Date(s) of data collection provided.
☐ Description of marker set provided.
☐ Type and Model of motion capture system provided
☐ Type and Model of force plate system provided

65-☐ Description of control EMG dataset complete (including facility & date of data collection)

66-☐ Suggested table provided and complete with data as requested.

67-☐ Description of data averaging, number of gait cycles per patient, and assignment of standard deviation provided.

68-☐ If control data taken from the literature or manufacturer, description of methodology for verification of consistency and validity of data with current clinical system is provided.

69-☐ Documentation of control kinematic and kinetic data provided. Appendix U included.

70-☐ Documentation of control EMG data provided. Appendix V included.

71-☐ Documentation of control temporal-distance parameters provided. Appendix W is included if necessary.
Question 4. Submission of Data Set and Descriptive Clinical Report.

72-☐ Data set includes a physical examination relevant to the condition being evaluated
   ☐ Passive Range of Motion Examination
   ☐ Lower Extremity Alignment (Transverse/Coronal Plane)
   ☐ Muscle Testing of Relevant Muscle Groups
   ☐ Assessment of Selective Motor Control

73-☐ Comprehensive kinematic data set provided
   ☐ Conditions of Testing Identified
     (e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.)
   ☐ Clear Identification of Right/Left sides
   ☐ Clear Identification of Gait Cycle
   ☐ Clear Identification of Y-axis label
   ☐ Anatomic/Planar Orientation of Plots
   ☐ Normative Data Included on Plots and Clearly Identified
   ☐ Temporal-Distance parameters included
   ☐ Type of Depicted data clearly identified
     (representative trial, multiple trials, mean of multiple trials, etc.)

74-☐ Comprehensive kinetic data set provided
   ☐ Conditions of Testing Identified
     (e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.)
   ☐ Clear Identification of Right/Left sides
   ☐ Clear Identification of Gait Cycle
   ☐ Clear Identification of Y-axis label
   ☐ Anatomic/Planar Orientation of Plots
   ☐ Normative Data Included on Plots and Clearly Identified

75-☐ Comprehensive EMG data set provided
   ☐ Clear Identification of Right/Left sides
   ☐ Clear Identification of Gait Cycle
   ☐ Normative Data Included on Plots and Clearly Identified
   ☐ Clear Identification of Type of processing, if appropriate
   ☐ Muscles or Muscle Abbreviations clearly identified

76-☐ Comprehensive Clinical History data set provided
   ☐ Identification of chief complaint or reason for study
77-☐ Comprehensive Clinical/Interpretive Report provided
  ☐ Anatomic and/or Problem List Organization of Report
  ☐ Identification of Clinically Important Deviations/Abnormalities
  ☐ Identification of Possible Specific Treatment Options Based on Deviations/Abnormalities
  ☐ Names, profession, signatures of interpreters included. At least one of interpreters has a medical practice license.

78-☐ The Laboratory demonstrates that treatment recommendations (including appropriate referrals) are made consistent with the clinician’s licensure guidelines.

**Question 5. Data Management/Confidentiality**

79-☐ Documentation of data management for raw data provided
  ☐ Location
  ☐ Back-Up
  ☐ Security
  ☐ Confidentiality
  ☐ Duration

80-☐ Documentation of data management for processed data provided
  ☐ Location
  ☐ Back-Up
  ☐ Security
  ☐ Confidentiality
  ☐ Duration

81-☐ Documentation of data management for video data provided
  ☐ Location
  ☐ Back-Up
  ☐ Security
  ☐ Confidentiality
  ☐ Duration

82-☐ Documentation of data management for clinical history/questionnaires provided
  ☐ Location
  ☐ Back-Up
  ☐ Security
  ☐ Confidentiality
  ☐ Duration
83-☐ Documentation of data management for physical examination provided
   ☐ Location
   ☐ Back-Up
   ☐ Security
   ☐ Confidentiality
   ☐ Duration

84-☐ Documentation of data management for clinical files provided
   ☐ Location
   ☐ Back-Up
   ☐ Security
   ☐ Confidentiality
   ☐ Duration

85-☐ Documentation of Written Policies regarding back-up procedures, security measures, and patient confidentiality in the following area. Appendix Y included and complete.

   ☐ Information Systems.
   ☐ Protected Health Information
   ☐ Medical Records or Health Information Systems

86-☐ Evidence of maintained competency for all personnel by annual training in the following areas. Appendix Z included:

   ☐ Information Systems.
   ☐ Protected Health Information
   ☐ Medical Records or Health Information Systems