



Application Review Criteria

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)

- 11- The application indicates that the Laboratory measures & reports electromyographic muscle activity (EMG)
- 12- The application indicates that the Laboratory captures all components (kinematics, kinetics, & EMG) simultaneously.
- 13- Documentation of volume of clinical cases provided.
- 14- Documentation of diagnosis categories & percentages of clinical cases provided.
- 15- Documentation of referral process for clinical cases provided.
- 16- Evidence provided that clinical motion studies are performed following physician referral.
- 17- Appendix C is included – Laboratory Referral Form.

Question 4: Consumer Feedback

- 18- Documentation of a mechanism for patient/family satisfaction
- 19- Documentation of a mechanism for referral source satisfaction
- 20- Appendix D included - Surveys

Question 5: Laboratory Procedures

- 21- Documentation of procedure manual, procedure protocols or operational definitions for physical examination or assessment as performed in the Motion Laboratory. Appendix E is included
- 22- Documentation of a procedure manual or procedure protocol for marker/target placement. Appendix F is included.
- 23- Documentation of a procedure manual or procedure protocol for EMG surface electrode placement as performed in the Motion Laboratory. Appendix G is included.
- 24- Documentation of a procedure manual or procedure protocol for EMG fine wire placement as performed in the Motion Laboratory. Appendix H is included.
- 25- Documentation of a procedure manual or procedure protocol for data collection. Appendix I included.
- 26- 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.
- Emergency Medical Provision & First Aid Procedures. Appendix M 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



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- Documentation of pertinent past medical history
- Documentation of pertinent past surgical history
- Documentation of current orthotic, prosthetic, assistive device use

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