



**Clinical Motion Laboratory Accreditation Application Form**

**Date:** \_\_\_\_\_

**Laboratory name:** \_\_\_\_\_

**Laboratory affiliation (Hospital, University, Medical School, etc.):**  
**If none, indicate free standing.**

\_\_\_\_\_

**Laboratory mailing address:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date laboratory opened:** \_\_\_\_\_

**Date 3-D kinematic studies initiated:** \_\_\_\_\_

**Contact person: (include telephone; FAX; e-mail contact information and mailing address if different from above):**

\_\_\_\_\_  
\_\_\_\_\_

**Responsible party and person submitting application:**

Affidavit to be completed by the responsible party of the application:

- I hereby affirm that I have completed all application documents accurately and truthfully.
- I hereby affirm that this application is to be HIPPA compliant.
- I further understand that any incorrect information or omission of information may result in the application materials not being reviewed.
- I further understand and agree that the application review fee is not refundable. (Even if a lab is not accredited.)
- I further understand and agree that if accreditation is not approved, I will have opportunity to offer more information, for up to one year, before a new application is required.
- I further understand that this accreditation is valid for a period of three (3) years.
- I understand that upon notification of receipt of accreditation, our name and identifying information will be included on the CMLA website ([www.cmlainc.org](http://www.cmlainc.org)) and a certificate of accreditation.

<b>Name (Printed or Typed)</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>

**Part 1: Administration and Personnel:**

1. Provide a summary statement of the scope, purpose, and mission of the Laboratory.
2. Submit a table, as structured below, summarizing staff experience and qualifications to include the following:
  - a. Name & credentials (professional degrees)
  - b. Job title or position. If an individual has only research responsibility, list separately from clinical commitment.
  - c. Evidence of current CPR/BLS certificates for Laboratory personnel who have direct patient contact. **Attach as Appendix A.**
  - d. Type of clinical job responsibility. Indicate if responsibility includes
    - i. physical examination
    - ii. marker placement
    - iii. electrode placement (surface EMG)
    - iv. invasive procedures (fine-wire EMG)
    - v. data collection
    - vi. data reduction (e.g. tracking, event identification)
    - vii. data interpretation
    - viii. clinical recommendation
  - e. Percent FTE in Laboratory (average time working in Lab per week). Designate percentage of time spent in clinical versus other responsibilities such as research.
  - f. Years of experience working in gait analysis
  - g. Specialty certifications (if any)

**For medical/clinical personnel also include:**

- h. Medical/Clinical specialty
- i. State of license(s) or registrations
- j. Licensure number(s)

If your state provides on-line verification of licensure, submit a copy of the on-line verification from the website of your state Board of Medicine or Board of Physical Therapy for each staff member who has licensure. If your state does not have online verification of licensure, or for other types of certifications, please include a copy of your current active licensure certificate or certification. Attach verifications as **Appendix B.**

Name & Credentials	Job Title	CPR or BLS	Clinical Job Responsibility	% FTE	Years Exp. in Gait Analysis	Certifications	Medical Specialty	State of License	License Number
Jim Bone, MD	Director	CPR	i-iv,vii,viii	.5 clinical .5 research	11	Fine Wire EMG	Ortho.	AL	0112

3. Components of clinical motion analysis
  - a. Define the components that comprise a “full diagnostic clinical motion study” in your Laboratory. Can the technical components of the evaluation (motion, forces, EMG) be collected simultaneously? Are data routinely collected in this fashion? Explain.
  - b. Submit a table, as structured below, that includes the total number of complete clinical patient studies\* performed in the last full calendar year which were not part of solicitation for

research. Provide a list of the diagnoses of the patients seen and the approximate percentage of patients in each category.

\*Minimum requirements to be categorized as a complete clinical patient study include: physician referral, physical examination, collection of 3-D kinematics and interpretation including physician recommendations.

Calendar Year	mmddyyyy - mmddyyyy	
Diagnosis	Number	Percentage
Diagnosis 1	Number	% of total
Diagnosis n	Number	% of total
<b>Total</b>	<b>Total</b>	<b>Total</b>

c. Describe the referral process for a clinical motion study in your Laboratory. Does evaluation in your Laboratory include a physician visit? **Include copy of referral form as Appendix C. (If your referral form is electronic, provide a screen shot image and submit as Appendix C).**

4. Describe mechanisms used to assess consumer satisfaction in the following areas of:

- a. patient/family
- b. referral sources

Include copies of surveys used for a and b above as **Appendix D**.

5. Laboratory Procedures

a. Provide evidence of documentation of technical and clinical procedures used at your facility. Include the appropriate sections from a document or manual as the following appendices:

- i. physical examination (**Appendix E**)
- ii. marker placement (**Appendix F**)
- iii. surface EMG electrode placement (**Appendix G**)
- iv. fine-wire EMG electrode placement (**Appendix H**)
- v. data collection (including a procedure for when a marker physically falls off the patient). (**Appendix I**)
- vi. data reduction (e.g. tracking, event identification) (**Appendix J**)

**Note: vendor manual descriptions are not sufficient for v and vi above. Description of how vendor protocols are adapted or customized to applicant's Laboratory process is required.**

b. Describe the process used for data interpretation.

c. Describe the process used for clinical recommendation.

6. Competency

**CMLA defines competency as a set of defined behaviors that provide a structured guide to proper performance of a task. The ability to execute a required task properly within a minimum level of proficiency.**

Describe methods of assessing competency for Laboratory personnel. List each area (i-viii) separately and include description of **initial competency** and **continued competency** in each area:

- i. physical examination

- ii. marker placement
- iii. surface EMG electrode placement
- iv. fine-wire EMG electrode placement
- v. data collection
- vi. data reduction
- vii. data interpretation
- viii. clinical recommendations

## 7. Quality Assurance

**CMLA defines a Quality Assurance Program as a set of procedures performed at routine intervals for systematic monitoring and evaluation of a process.**

- a. Provide an overview of the formal Quality Assurance Programs in place at your facility among the following areas. Please include information on frequency of assessment:
  - i. physical examination
  - ii. marker placement
  - iii. surface EMG electrode placement
  - iv. fine-wire EMG electrode placement
  - v. data collection
  - vi. data reduction
  - vii. data interpretation
  - viii. clinical recommendations
  
- b. Describe methods of maintaining consistency for Laboratory personnel. List each area (i-viii) separately and include description of both **within personnel consistency** and **between personnel consistency** in each area:
  - i. physical examination
  - ii. marker placement
  - iii. surface EMG electrode placement
  - iv. fine-wire EMG electrode placement
  - v. data collection
  - vi. data reduction
  - vii. data interpretation
  - viii. clinical recommendations

## 8. Safety policies & personnel competencies.

- a. Provide evidence of established policies (including date of approval) in the following areas. Attach as appendices as indicated.
  - i. local building safety codes/procedures (fire, chemical contamination, severe weather, evacuation plan, utility failure, community disaster) (**Appendix K**)
  - ii. environmental safety (including but not limited to hazards communication program) (**Appendix L**)
  - iii. emergency medical procedures & first aid (**Appendix M**)
  - iv. age-specific patient care services for all personnel involved in data collection (**Appendix N**)
  - v. infection control policies (**Appendix O**)
  
- b. How is personnel competency maintained in each of the above areas (i-v)? Provide evidence of completed competencies, with date of last completion (**Appendix P**).

9. Submit a table, as structured below, listing accrediting organizations that have assessed your facility in the past three years, where the Laboratory was directly involved in the accreditation process (JCAHO, CARF, etc.). (If none, write NONE under the organization column). In the table include status of accreditation and dates of accreditation approval and expiration. Attach evidence of all current accreditation(s) in **Appendix Q**.

Organization	Accreditation Status	Date of Approval	Date of Expiration
JCAHO	current	3/2007	2/2010

**Part 2 Equipment & Data Collection**

1. Provide a scaled diagram of the physical layout of your lab including perimeter dimensions & equipment placement. A photograph may be included, but does not substitute for the diagram requested. Attach as **Appendix R**.
2. Submit a table, as structured below, describing the equipment in current use for routine clinical data collection (as described in Part 1, Question 3a). Include any components used for synchronization between systems. Include the style of surface and fine wire electrodes used. System description must include, where applicable:
  - a. quantity of cameras, force plates, & channels of EMG
  - b. resolution
  - c. sample rate capability & the sample rate used for data collection
  - d. analog data sample rates
  - e. marker/electrode size
  - f. filters/cut-off frequencies
  - g. size of fine wire needles and composition of wire

Equipment Purpose	Manufacturer /Company	Product Version/ Name	Model Number	Webpage reference*	System Description	Date of Purchase
Kinematics						
Kinetics						
EMG						
Synchronization of Systems						
....						
Video System						
Energy Expenditure						
Plantar Pressures						
...						
All equipment for routine data collection						

\* if available

3. Describe the calibration procedure and volume for the motion capture system and how often this apparatus is calibrated (Please include manufacturer’s calibration recommendations). Describe the procedures used to assess accuracy (validity) and precision (repeatability) of the marker or target

identification and the frequency each procedure is performed. Attach example data from these procedures in **Appendix S**.

4. Describe the calibration procedures for all equipment used for routine clinical data collection as described in **Part 1, Question 3a**, other than the motion capture system (force plates, EMG, plantar pressures, O2 etc.). All equipment listed in **Part 1 Question 3a** must be included. Include how often each system is calibrated in the description. Please include manufacturer's calibration recommendations for comparison.

Describe the procedures used to assess accuracy (validity) and precision (repeatability) for each system, and the frequency each procedure is performed.

Attach example data (calibration, accuracy, and precision) for each system in **Appendix T**.

5. Describe the marker set and biomechanical model used for calculating kinematic and kinetic variables. Describe the relative strengths and weaknesses of the model used, including sources of error.

### ***Part 3: Data Processing/Data Management/Reporting***

1. Describe the software program used for data reduction in the following systems:

- i. kinematic and kinetics,
- ii. EMG

For each system include:

- a) manufacturer software version & purpose
- b) complete listing of any custom software & purpose
- c) assessment of strengths and weaknesses

For EMG system also include any software used for filtering, rectification, envelope, EMG quantification.

For kinematic system also include: 1) how errors are identified and resolved in initial processing (filling trajectory gaps, occluded markers, etc.), and 2) details of how gait events are identified.

2. Describe the control (normative) dataset used for:
  - a. kinematics (including temporal-distance parameters)
  - b. kinetics
  - c. EMG.

For each system indicate the facility where the data was collected and when it was collected. (Providing a reference only is not sufficient).

Address whether the equipment, marker set and testing protocol the same as is used currently for patient testing.

Describe how the data was averaged, the number of gait cycles used per patient and how the standard deviation was assigned.

For kinematic and kinetic data only also describe the marker set(s), type and model of the kinematic system, type and model of force plate system used for collection of this dataset. If you are using multiple marker sets for clinical movement analysis describe them all.

Attach control kinematic and kinetic data as **Appendix U**.

Attach control EMG data as **Appendix V**.

Attach control Temporal-distance Data as **Appendix W** if separate from kinematic and kinetic data.

3. Submit a table, as structured below, regarding specifics of the individuals in this data set.

If you are using control kinematic and kinetic data supplied by the manufacturer or collected at another facility, please describe how you have verified the consistency and validity of the data for use with the protocols and equipment you are currently using for collection of clinical data.

Age (in year increments)	Number of		
	Subjects	Male	Female
Age 1	#	#	#
Age n	#	#	#
<b>Total</b>	<b>Total</b>	<b>Total</b>	<b>Total</b>

4. Clinical Data & Reporting

a. Submit a de-identified (Health Insurance Portability and Accountability Act (HIPAA) compliant copy – US only) copy of a full data set (physical exam, kinematics, kinetics, and EMG) of a clinical patient. [Reference to this clinical patient should be maintained by the Laboratory in the case further information is requested.]

b. Submit the descriptive, clinical report of the patient for which the data set was submitted above (and the interpretive report if two documents are used). **Names and profession of interpreters must be included.**

Attach both components in **Appendix X**.

5. Data Management/Confidentiality

a. Submit a table, as structured below, to describe the procedures for data management (raw data, processed data, video, clinical data/reports, clinical history/questionnaires, physical examination) of all elements collected and produced as part of routine data collection (Part 1 Question 3a). For each type of data, include each area indicated. Include how patient confidentiality is maintained for both internal and external sources.

Data Element	Location	Back-Up Mechanisms	Security Measures	Patient Confidentiality Measures	Duration of Back-Up
<b>Kinematic/Kinetic/EMG Energy Expenditure Plantar Pressures</b>					
raw data	First stored on local hard drive of collecting computer; then to network file server	Network file server is backed up daily. Copied separately to an off-site location daily	Back-up occurs in non-browse able format. Password protected	Per Information System Policies; non-browseable format	indefinitely
processed data					
Video					
Clinical History/Questionnaire					
Physical Examination					
Clinical Files					

b. Provide evidence of established policies regarding data back-up procedures, security measures, and patient confidentiality, including date of approval, in the following areas. Attach as appendices as indicated:

- i. Information Systems (**Appendix Y**)
- ii. Protected Health Information (**Appendix Y**)
- iii. Medical Records or Health Information (**Appendix Y**)

c. How is personnel competency maintained in each of the above areas (i-iii)? Provide evidence of completed competencies with date of last completion. (**Appendix Z**).

**Note: Often, training modules at a specific institution are titled differently than above, but contain the appropriate content. Please provide evidence that annual training modules at your institution contain the above information.**

**END OF APPLICATION**