FORCE-TJR Publications, Presentations, and Ancillary Study Proposals Guidelines

These guidelines are intended to provide a description of the role of the Publications, Presentations, & Ancillary study proposals Committee (PAC) and the policies involving the use of data from FORCE-TJR research in publications, presentations and ancillary study proposals.

PAC Purpose

- Promote scientific collaboration to ensure that a wide range of potential investigators are knowledgeable about current research and have the opportunity to participate in the development of new publications, presentations and/or ancillary study proposals.
- Coordinate research efforts in order to keep duplication to a minimum.
- Preserve the integrity and the high scientific standards of publications, presentations and ancillary study proposals.

PAC Composition

PAC membership includes:

- Chair
- FORCE-TJR PI
- UMass biostatistician
- Representatives of the high-volume contributing sites
- Representatives of community sites who may serve on a rotating basis.

PAC Meetings

The PAC meets monthly, or as needed.

PAC Role

For all publications, presentations, ancillary study proposals, "white papers," and summaries of data to be publically released that do not involve commercial interest, the PAC alone gives final approval.

All publications, presentations, ancillary study proposals, "white papers," and summaries of data to be publically released that involve commercial interest, follow a 3-step process:

1. The Public Private Partnership committee will review the ethical integrity of the project (publications, presentations or ancillary study proposals) and will provide recommendations to the Registry Oversight Team.
2. PAC will review the scientific approach and provides recommendations to Registry Oversight Team.
3. The Registry Oversight Team will make the final decision.

Overarching Principles

- Priority is given to papers with collaboration across core and community sites.
- Distribute leadership across all collaborators (UMass core team and site PIs).

Application Priority

Because of the need to efficiently use important resources, priority will be assigned to all proposals based on the following criteria:

- Scientific merit including, significance, innovation, and appropriate methodology
- Collaboration across core and community sites
- Appropriate resources identified to complete proposed scope of work
- Minimum degree of additional burden imposed on participating clinicians and patients

Formal Application Process

For all manuscripts, abstracts, presentations, and ancillary study proposals, a structured application form must be submitted to the PAC. This form includes a project abstract must be submitted with the following sections:

- Background
- Research hypotheses
- Data elements
- Statistical analysis

An ordered list of authors/investigators must be provided, including the designation of a corresponding author and lead investigator.

All investigators listed on any application should have appropriate NIH-certified training in protection of human subjects.

Manuscripts and Abstracts

Manuscript Process

- The formal approval process for a new manuscript begins with submission of a structured application to the PAC.
- The lead author is responsible for convening a writing group for their manuscript.
- The lead author has the responsibility of writing the paper according to the timeline outlined in this document. If the paper is delayed, the PAC chair has the option to re-assign lead authorship.
- The lead author will be responsible for obtaining the appropriate review by their local Institutional Review Board and assuring appropriate ethnics training for authors.
- Manuscripts must be submitted to the PAC for approval 30 days before anticipated submission to a peer-reviewed journal or public release.
- PAC will review progress on manuscripts quarterly.
- Manuscript should be completed within 9 months of PAC approval (except under special circumstances); after 9 months the manuscript will be considered ‘dormant’ and PAC will remove author and re-assign first authorship.
- The PAC should be regularly apprised of manuscript status, including editorial

decisions.

- The PAC should be provided with revised versions of the manuscript resulting from the peer-review process. Authors may assume that manuscript revisions in response to peer review have the implicit approval of the PAC, unless there is explicit communication to the contrary.
- A final copy of the manuscript accepted submitted should be sent to PAC.
- To "convert" an abstract into a manuscript, a separate proposal must be filed. The manuscript proposal should indicate the source abstracts to which it is linked.

Abstract Process

The PAC recognizes the important of both attaining national visibility at scientific meetings and moving abstracts presented at conferences to completed manuscripts.

- An approved proposal is required as a starting point for abstract presentations.
- After manuscript approval has been granted by the PAC, the UMass FORCE team will produce the analyses requested in the application.
- Abstract idea should be submitted at least 3 months prior to the abstract submission deadline.
- Authors should anticipate that FORCE-TJR analysts will have many competing demands, which may limit the total number of abstracts approved for data analysis.
- The final abstract must be approved by the PAC before submission.
- Recognizing the time urgency with which abstracts are often prepared, the PAC will review abstracts by e-mail so that decision are not delayed until the next formal meeting.

Authorship for Manuscripts and Abstracts

- All authors must meet criteria as established in the latest guidelines from the International Committee of Medical Journal Editors (www.icmje.org).
- Anyone with the appropriate scientific credentials may submit a manuscript proposal, but first priority will be given to FORCE-TJR investigators, including PI of core sites.
- Site PI should coordinate papers coming from investigators at their site.
- All paper proposals will be submitted on the FORCE-TJR proposal form that specifies the primary question, data required, suggested analyses/sample.
- Appropriate expertise from UMass should be represented on all manuscripts and abstracts.
- Approved manuscripts will be circulated among all collaborators (at UMass and core sites) to invite collaboration.
- There is a limit of 2 manuscripts per first author; as papers are submitted for publication, new papers can be proposed. This limit does not apply to abstracts or to manuscripts that are submitted as part of a doctoral dissertation package.
- There is a limit of 6 authors for manuscripts.
    - This limit may be exceeded on an exceptional basis if appropriate justification is made.
    - One approach to managing a large cadre of authors is to list a maximum of six authors and then designate that the listed authors are writing on behalf of the FORCE team. A foot note then lists the full authorship team. Using this approach does allow all authors listed on the writing team to linked

with the manuscript following a Medline search.

- Research described in the original grant proposal: Authorship on core papers proposed in Aim 2 and 3 of the research proposal (e.g., incidence of complications; risk factors for functional outcomes; disparities in use patterns) will include co-investigators at UMass and/or site PIs who participate in writing and analysis.

Ancillary Studies

- Anyone with the appropriate scientific credentials, appropriate access to required scientific and logistical expertise, and appropriate institutional support may submit an ancillary proposal. First priority will be given to FORCE-TJR investigators, including site PIs.
- Ancillary studies will include co-investigators from the core team at UMass who will collaborate on the development and analysis of the grant (see details in Budget section).
- All ancillary studies must be initially approved through the process described above.
- After approval, FORCE analysts will produce preliminary (de-identified) data for inclusion in the grant application.
- Study investigators are expected to communicate regularly with the PAC about changes to study design and to submit a final copy of the proposal.
- The final draft of all proposals should be submitted to the PAC for review prior to submission. If the timeline is tight, the UMass co-investigator can approve submission of final text.

Ancillary Study Types

- Studies using **existing** FORCE-TJR patients and data.
  - Select patient sample (e.g., years, locations)
  - Identify existing variables from FORCE-TJR data dictionary (appended to the end of this document)
  - Define secondary hypotheses and analyses
  - Example: Descriptive analyses examining outcome differences by age, surgical approach, or region of country
  - Budget- personnel for data management, statistical analyses, and interpretation; survey administration and infrastructure maintenance fees.

- Studies requiring **additional measures** on existing patients
  - Select patient sample
  - Identify existing variables from FORCE-TJR data dictionary
  - Define additional measures and time interval for assessment(s)
  - Example: Pain Survey at 3 weeks post-TJR on all patients; Rheumatoid Arthritis severity and activity scores on sub-sample of patients with RA.
  - Budget will include incremental research staff to manage additional data collection; plus cost of data management and analyses; survey administration and infrastructure maintenance fees
  - Proposals that involve additional measures will be reviewed by the Core site PI team for approval to assure that the additions are feasible.
  - Additional measures not proposed in the original application must be distributed to all site PIs prior to discussion at a regularly occurring Site PI conference call. All such measures will require approval from the site PIs before implementation as part of FORCE-TJR data collection.

- Studies requiring **additional patients/implant cohort**
  - Investigator/collaborating organization provides patient list
  - Identify existing variables from FORCE-TJR data dictionary to be collected from new cohort
  - Define additional measures and time interval for assessment(s)
  - Example: Assess current and longitudinal outcomes for a sample of metal on metal patients; include existing FORCE measures (e.g., SF36 AND HOOS/KOOS pain measures) as well as additional measures (e.g., x-ray)
  - Budget will include incremental research staff to manage new patient cohort plus additional data collection and measures; cost of data management and analyses; cost of incremental tests/studies (e.g., blood, x-ray); survey administration and infrastructure maintenance fees.

FORCE-TJR Budget and Personnel for Ancillary Studies

Ancillary studies are expected to provide the appropriate resources to the FORCE team to carry out the proposed data collection and analytic work. Budgets will include FORCE research staff and investigators.

- Research Support Staff
  The FORCE-TJR research coordinators, data coordinating center team, and analysts serve as the core resource for the parent project and for ancillary studies. Budgeting for ancillary studies will include:
  a. Data analysis- for studies using *existing* FORCE-TJR metrics includes effort for data base management, statistical analyses within the FORCE team
  b. Data collection- for studies proposing *additional* data collection/metrics.
     i. % effort for database management and statistical analyses within the FORCE team
     ii. % effort for research coordinator within the FORCE team to collect the incremental data
     iii. Budget for survey modification, deployment, and maintenance

- Co-Investigator participation
  a. Franklin or her designee for design and interpretation;
  b. W. Li and/or FORCE statistical team for data management and statistical analyses
  c. Others as appropriate to the topic proposed (e.g., activity, rheumatology, statistics, etc)

- Indirect funds and infrastructure fees for Ancillary Proposals
  a. Within UMMS: Division or Department indirects are shared with the FORCE team based upon the relative (%) contribution to the total personnel budget.
  b. External to UMMS: FORCE will be included as a sub-award to the Department of Orthopedics and include the UMMS indirects based upon the total budget.

- Data Monitoring Board and IRB Modifications
  a. Ancillary studies will maintain their own IRB approval at the initiating institution. UMMS staff effort will amend the existing FORCE-TJR IRB.

Data Usage

All statistical analyses of FORCE-TJR data will be performed by the FORCE-TJR analytic staff and supervised by a doctoral-level biostatistician affiliated with FORCE-TJR working in collaboration with the project or authorship team.

Original and patient-level data will remain "in-house," with summary statistics and statistical output presented to outside collaborators. Under special circumstances a limited de-identified data set may be released to external collaborators, in which case a data use agreement must be signed. All analyses will be subjected to independent verification.

Under exceptional circumstances, data may be shared with researchers outside of UMass. Under these circumstances certain restrictions will apply: (1) a data use agreement will be required; (2) individual participants will not be identifiable in any released data; (3) data will be released only for a particular project and must be destroyed after the specified project has been completed; (4) data may not be transferred to other researchers; and (5) only the minimum amount of data necessary to accomplish the project will be released.

Database

The PAC will maintain a list of current publications, presentations and ancillary studies that will be available to general public through the FORCE-TJR website. Authors/investigators are responsible for updating PAC on status of their publications, presentations and ancillary studies. PAC is responsible for circulating updates regularly.

Patient Pain and Function Survey
Self-Report--Takes 15-20 min to complete

Patient

Contact Information/ Demographic data

Education Level
Employment status
Race or Ethnicity
Gender
Marital status
Age
Body Mass Index
Smoking status

SF36
(36 items)

General health status

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
1. Accomplished less than you would like	◯	◯	◯	◯	◯
2. Had difficulty performing work	◯	◯	◯	◯	◯

Activity limitations due to current health

Does your health now limit you in these activities? Is so, how much?

	Limited a lot	Limited a little	Not limited at all
1. Climbing several flights of stairs	◯	◯	◯

Co-morbidity Index
(14 items)

Co-Occurring Medical Conditions

Indicate if you have been diagnosed with any of the following conditions:
COPD, Connective Tissue Disease, Diabetes, Cancer, PVD, etc.

Back Pain
(1 item)

Severity of Back Pain

My back pain at the moment is:
No back pain--Very mild--Moderate--Fairly severe--Very severe--Worst imaginable

HOOS/ KOOS
(68 items/ 71 items)

Symptoms, stiffness, and pain associated with the surgical joint

What amount of pain have you experienced in the last week in your **surgical (hip/knee)** during the following activity?

	None	Mild	Moderate	Severe	Extreme
1. Sitting or lying down	◯	◯	◯	◯	◯
2. Going up or down stairs	◯	◯	◯	◯	◯

Physical function (Surgical Joint)

For each of the following activities, please indicate the degree of difficulty you have experienced in the last week due to your **surgical (hip/ knee)**:

	None	Mild	Moderate	Severe	Extreme
1.Getting in/out of car	◯	◯	◯	◯	◯
2. Rising from sitting	◯	◯	◯	◯	◯

Surgical joint specific

Please rate your symptoms and difficulties in your **surgical (hip/ knee)** during the last week when doing these activities:

	Never	Rarely	Sometimes	Often	Always
1.Do you have swelling in your surgical knee	◯	◯	◯	◯	◯
2.Difficulties to stride out when walking	◯	◯	◯	◯	◯

FORCE-TJR QI Data Dictionary

OR Data	**Implant Data**	**Data elements**
		Manufacturer of Implant Model of Implant Catalogue Number of Implant Product Lot Number
	Surgical Data	**Data regarding surgical procedure**
		ICD9 procedure code ICD9 primary diagnosis code Hip/Knee surgical approach data Discharge Summary
Chart Data	**Surveillance and Adverse Events**	**Surgery/Post-Surgery treatment**
		Patient reported Pain and Function post-operatively Patient Reported Post-surgery events/complications, including: Death Deep Joint Infection Deep Vein Thrombosis Emergency Department Visit Dislocation Fracture Hardware Failure Hematoma Pulmonary Embolism Other Other Return to the OR for Total Readmission No 90 Day Post-operative Events