Wits Cricket Research Hub for Science, Medicine and Rehabilitation: Data Management and Sharing Guide

Strategic & Optimum Use of Human Movement Data through the Development of a Human Movement Database

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Table of Contents

1 Contributions and Acknowledgements

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Medical Research Council (MRC) DMP Template as downloaded from https://mrc.ukri.org/research/policies-and-guidance-for-researchers/data-sharing/, also available on https://dmponline.dcc.ac.uk/

2 Version control

Version	Date	Description of changes	Person responsible for making changes
1.0	2020-09-21	Initial draft based on MRC DMPOnline tool	Benita Olivier
20201020	2020-10-29	Information from Alta Withers and Nina Lewin implemented	Benita Olivier
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20210811	2021-08-11	Additions of standard POPIA clauses to conditions of use agreement by Eleni Flack-Davison	Benita Olivier

3 Executive summary

Responsible data management is crucial to ensure that we optimise the use of our research data while we protect our precious intellectual property resources. According to the FAIR Data Principles data should be Findable, Accessible, Interoperable and Re-usable (https://www.force11.org/group/fairgroup/fairprinciples) for long term use. This document provides guidance to researchers who are doing research under the banner of Wits Cricket Research Hub for Science, Medicine and Rehabilitation (Wits CRH in short) on managing, sharing and re-using data in ways which are ethical, legal and responsible.

The re-use and sharing of research data will promote the dissemination of and improve the impact of our research as it will allow us to answer additional research questions using existing data. We may argue that because there are so much data available internationally on open access data sharing repositories, we don't need to invest time and energy on developing our own Human Movement Database. However, the data on international platforms are not specific to our context and don't necessarily contain the detail or constructs that we need to answer our specific research questions. Thus, in general this data will be provided on a preferential basis to researchers looking to solve specifically South African problems or do research which would be particularly to the benefit of the people of South Africa in light of the role that the country and its people have played in directly and indirectly funding this research.

Through the responsible management of data and through putting systems in place to allow for the re-use of data in future research projects, our capacity to generate research outputs will increase. Also, through the conversations and communication that happen around managing, curating and sharing our data, more insights will be gained into previous, current and ongoing research in this field. This knowledge will open doors for generating collaborative projects, formulating new research questions and avoiding unnecessary and unintentional duplication of studies. Furthermore, if we want to combine various datasets so that we can perform advanced data analysis (Big Data) in the future, then we need to be strategic in our approach to both data collection and data management.

Although this guide describes the overall processes and procedures related to the management of data, each specific study needs its own detailed data management plan (DMP). This plan can be created through using any of these online tools: https://www.dirisa.ac.za/dmp-tool/ or https://dmponline.dcc.ac.uk/ where possible, generic information from this guide can be copied and pasted into it. This video will show you two tools to help you develop a data management plan for your research project: https://youtu.be/q4gNa3xyLCQ. Funders may have their own Research Data Management policies and templates or might require an Outputs Management Plan (OMP) instead of a DMP so be on the lookout for those and ensure that your DMP/OMP is aligned with their requirements. This guide is dynamic and will be developed as we learn from the needs of new studies added to the Human Movement database. Please do inform the Wits CRH Data Manager of any modifications or adaptations needed to accommodate each specific case.

Implementation of the data management principles described in this guide will be done in phases:

- Phase 1: As a start, studies in which Benita Olivier is involved in as Principal Investigator (PI) will use the information in this guide and through these processes, information will be refined.
- Phase 2: Studies in which Benita Olivier is involved in as collaborator, can make use of this guide.
- Phase 3: Studies in which Benita Olivier is not directly involved but which takes place under the banner of the Wits CRH.

4 Definitions of terms

- Agreed Purpose – means the research purpose(s) approved by the Wits Cricket Research Hub for Science, Medicine and Rehabilitation Data Access Committee (DAC) in writing
- Agreed Time Period of Use – As defined above; it is the timeframe in which the Recipient, Recipient Institution and Data Users will have access to the Data and are allowed to make use of the Data for the Agreed Purpose; the maximum moratorium of two (2) years will be allowed whereafter the dataset will be made available for use in competing research projects or teaching and learning.
- DAC – Wits Cricket Research Hub for Science, Medicine and Rehabilitation Data Access Committee
- Data – the Data within the Human Movement Database
- Database – the Human Movement Database containing research Data on participants
- Data Manager – the individual responsible for managing data as per the DMP
- Data Participants – the individuals who have contributed their data which is housed in the Database
- Data Users – those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement
- Principal investigator: the researcher who collected the data which will be uploaded onto the Human Movement Database
- Publications – without limitation: articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research

- Recipient – the researcher who is applying to use the Data; also considered to be the applicant
- Recipient Institution – the organisation named above at which the Recipient is employed, affiliated or enrolled
- Responsible party – the individual or entity who has control over how and why personal information is processed
- University – University of the Witwatersrand, Johannesburg
- Wits CRH – Wits Cricket Research Hub for Science, Medicine and Rehabilitation

5 Policies and acts related to data management, sharing and security

The following documents were considered in the development of this guide:

- Wits Data Classification Policy
- Wits Data Cloud Policy
- Wits Research Data Policy draft 1 (8 July 2020)
- Protection of Personal Information Act (POPIA) https://popia.co.za/
- Intellectual Property Policy C2012/228
- POPIA Industry Code of Conduct: Public Universities (Universities South Africa, 24 June 2020 v4.2)

6 Research outputs summary

The following research outputs are intended to be flexible. We understand that research can change in the course of exploration and that output can change, be added or fall away. We also understand that publishing times are not necessary in the hand of a researcher. The original researchers will have a two year Agreed Time Period of Use. In case there is a patent pending, researchers can withhold data for four years.

The Data Management is governed by the specific Research Licences (where relevant) assigned to the data in consultation with the ethics and data access committees.

The expected outputs are data, research tools and intellectual property,

6.1 Data

This include both raw and derived data: surveys, clinical measurements, interviews, focus group discussions, observations using checklists, medical records, electronic health records, administrative records, genotypic data, images or tissue samples as detailed in section 7.2.

6.2 Research tools

These include all research instruments i.e. questionnaires, standard operating procedures, as well as any specific methodologies, knowhow or software.

6.3 Intellectual property

This refers to specific cases where commercialisation of research is implicated such as in the development of medical devices and sports performance improvement devices. This will be governed by separate agreements.

Papers, published and unpublished, will be made available on the library website in either print, preprint or draft forms. Embargoes can be placed. A library of documents can be held for the specific use of a group of researchers with controlled access to prevent issues in which publication will be affected.

7 Description of the data

7.1 Type of study

Each of the studies will develop their own data management plan within which the relevant type of study will be described.

A broad range of studies will be conducted as part of the collaborative efforts to create research outputs in Human Movement. Both qualitative and quantitative approaches will be used. The most common quantitative study designs include:

- Observational: descriptive studies are prevalence surveys, case series, surveillance data and analysis of routinely collected data, etc.
- Observational: analytical studies are cross sectional, case-control, cohort (retrospective and prospective)

- Experimental: controlled trials can be clinical trials (unit of randomization is an individual) or community trials (unit of randomization is a community or cluster).
- Interviews

As for qualitative research designs, studies will include a wide range of approaches including grounded theory, phenomenology and case studies.

7.2 Types of data

The type of data will be described in the DMP of a research protocol and this should be specific to a specified study, and should be described in detail. In our context, we often refer to quantitative and qualitative data, although note that there are disputes across disciplines with regards to how these are defined. It is therefore important to include enough information on the type of data i.e. tabular, audio, video, text, images. Also include the following as applicable (not an exhaustive list): generated from surveys, clinical measurements, interviews, focus group discussions, observations using checklists, medical records, electronic health records, administrative records, genotypic data, or tissue samples.

This guide applies to the management and sharing of the final, raw research data which in most cases, for quantitative data, is a computerised dataset captured in Excel as opposed to the clinical source documents or pathology reports, for example. In some cases, the computerised dataset will contain both raw and derived (calculated from the raw data) variables.

In case of data collected as part of qualitative study designs, the following will be stored (where relevant): voice recordings, video files, field notes and transcription. Note that to remove identifying information from the audio-visual files is costly and can damage the research potential of the data. In general, the removal of details from rich descriptive materials makes it less useable and potentially misleading. It is better to therefore get consent from the participant to use and share the data unaltered but with additional access control as appropriate.

7.3 Format and scale of the data

Depending on the type of data that will be collected, the data will be stored in the following formats:

- Tabular data will be stored in a comma-separated values (.csv) file.
- Audio files will be stored in Free Lossless Audio Codec (FLAC) (.flac) format.
- Video data in MPEG-4 (.mp4).
- Text files will be stored as a Rich Text Format (.rtf) or plain text (.txt) format.
- Images will be stored as either uncompressed (such as TIFF) or compressed (such as JPEG).

See: https://www.openaire.eu/data-formats-preservation-guide for more options.

8 Data collection / generation

8.1 Methodologies for data collection / generation

For each specific project a description of how the data will be collected or generated and which community data standards will be used, will be included in the study's DMP. Recommendations in the capturing of demographic data will be made so that all data can be captured in the same format.

Demographic data will be captured using international recommended standards that ensure inclusiveness. Demographic data includes data such as age, sex. occupation/occupation sector, gender, level of education, marital status, nationality, ethnicity and other socioeconomic data. The questions required to capture some of these data are sensitive. Therefore, it is very important to only request for the demographics that are important for each research study, keep the questions brief and without ambiguity and to always include among the options for each question, an option that say "prefer not to say." Furthermore, in order to ensure respect for the self-belief of the potential participants and also allow open-mindedness in research, the need to provide options such as "other," "please specify," "I prefer to describe" cannot be over emphasised.

For questions on sex, gender and ethnicity, the use of inclusive language is highly recommended. Also, it is preferable to use several check boxes in the options, and to provide opportunity for participants to check as many boxes that they believe applies to them. There are some published recommendations and tips on best practices for capturing demographic data, they include:

- https://cdn1.sph.harvard.edu/wp-content/uploads/sites/2102/2020/04/ORARC-Tip-Sheet-Inclusive-Demographic-Data-Collection.pdf
- https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status

It is important that all new data that are being collected are of high quality and that the processing thereof subscribe to good practice and standards to ensure future use of the data. Over time, data collection standards will be developed and recommended to ensure:

1. Variables are captured at international standards appropriate to our local context.
2. Data from different studies can be combined, with as little as possible transformation of data needed, to allow for a larger sample size, comparison of findings between studies, etc.

8.2 Data quality and standards

Each individual study's protocol and associated DMP will contain details on how data quality and standards will be ensured. The standards are governed by the (https://www.ncbi.nlm.nih.gov/pmc/pmcdoc/tagging-guidelines/article/genprac.html) and (https://www.dcc.ac.uk/about/digital-curation) guidelines. Further consultation with Wits Library Senior Data Librarian to ensure the schema is interoperable with the other schemas in the dataset. This can be achieved by documenting the details on how the validity of the instrument(s) for data collection will be ensured. Ways to ensure data quality and standards include: processes of calibration, repeat samples or measurements, pilot testing, systematic expert review of instruments, standardised data capture or recording, data entry validation, peer review of data or representation with controlled vocabularies (based on the examples provided in the UK MRC DMP template – see Appendix A).

9 Data management, documentation and curation

9.1 Managing, storing and curating data

9.1.1 Obtain consent from the potential participant

Prospective potential participants will be provided with an information sheet containing information on the conditions associated with re-using data in future research projects as well as a consent form asking for permission (see example in Appendix B). Similarly, consent can

be obtained retrospectively from participants who participated previously in a research project (see example in Appendix C). Explain that we would like to get the participant's permission to deposit his/her data into the Human Movement research database that will be used for future research by bona fide researchers. Also explain that at the moment, we do not know what the future research questions are, but if there is any specific topic that the participant would prefer his/her data not to be used for, then he/she can specify this in the consent form. Assure the participant that his/her data will not be sold for profit and you can indicate in the consent form if he/she prefers for his/her data not to be used in commercial projects (e.g. device development). Appendix B and Appendix C will provide more insight and have been approved by the ethics committee. In addition to the Microsoft Word version of the information sheet and consent form, each of these appendices contain an e-consent form which was developed in REDCap.

9.1.2 Transfer data onto REDCap

The principal investigator will provide the necessary data and associated documentation once the project ends to the Wits CRH Data Access Committee (DAC).

The following documentation should be provided at the end of a project employing a quantitative study design:

1. Consent forms in electronic format: either collected via e-consent or via hard copy (scanned in).
2. Data dictionary in .csv format. Before extraction of the data dictionary, the principal investigator should review the "Data Dictionary Codebook" in REDCap to ensure that each of the variables are clearly explained.
3. Raw de-identified data after it has been cleaned in .csv format. The raw data filed is downloaded from REDCap and then cleaned, however data should remain in the "raw" format e.g. where multiple choice options are used, the raw coded value (e.g. 0, 1, 2) should be added to the spreadsheet. Derived date i.e. the data calculated from the raw data such as the calculation of body mass index (BMI), need to remain in the dataset. Variable names should correspond to the variable names in the data dictionary.
4. Comprehensive protocol in .rtf format.
5. Outcome measures either as part of the protocol or as appendices. In the case where outcome measures are in PDF format, these need to be converted by the principal investigator into .tiff or .jpeg file formats.
6. Ethical clearance certificate.

The following documentation should be provided at the end of a project employing a qualitative study design:

1. Consent forms in electronic format: either collected via e-consent or via hard copy (scanned in).
2. Demographic and/or other background data need to be captured in REDCap. Data dictionary in .csv format. Before extraction of the data dictionary, the principal investigator should review the “Data Dictionary Codebook” in REDCap to ensure that each of the variables are clearly explained.
3. Raw de-identified demographic and/or other background data after it has been cleaned in .csv format. The raw data filed is downloaded from RecCap and then cleaned, however data should remain in the “raw” format e.g. where multiple choice options are used, the raw coded value (e.g. 0, 1, 2) should be added to the spreadsheet. of body mass index (BMI), need to remain in the dataset. Variable names should correspond to the variable names in the data dictionary.
4. Audio (in .flac format) and/or video (in .mp4 format), while image data need to be provided in .tiff or .jpeg file format.
5. Comprehensive protocol in .rtf format.
6. Outcome measures either as part of the protocol or as appendices. In the case where outcome measures are in PDF format, these need to be converted by the principal investigator into .tiff or .jpeg file formats.
7. Ethical clearance certificate.

The ideal is for the principal investigator to set the project up under his/her own REDCap account from the start of the project whether the project contains a self-administered questionnaire or data entered by the researcher. In this case, the project will be transferred to the central REDCap database by giving the Data Manager access to the project.

Researchers will send the data and associated documentation to the Data Manager via REDCap’s Send-It tool. The Data Manager will review the data and documentation and request for changes if needed. Once the Data Manager is satisfied that the data is the in the correct format and that all the associated documentation is complete, he/she will upload the data onto REDCap. The REDCap Data Import tool will be used to import data into REDCap. Each study will have a separate REDCap project which has been created.

9.1.3 Remove name, surname and contact details from the data

The participant's name, surname, and contact details, will be removed from the data and a study number will be allocated to each participant's data. The link between the study number and the above-mentioned identifying information will be kept in an access-controlled database which is only accessible by the Data Manager, access control committee and research hub director. If a participant would like to review the accuracy of the data, he/she can contact the Data Manager who will set up a meeting for him/her to verify information.

Both direct identifiers as well as information that could lead to "deductive disclosure" of participants identities, should be removed following the process described in: Hrynaszkiewicz, I., Norton, M. L., Vickers, A. J., & Altman, D. G. (2010). Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *British Medical Journal, 340*, c181. doi:10.1136/bmj.c181. Both direct (name, address, phone number, etc.) and indirect (place of treatment, sex, rare disease, etc) potential patient identifiers need to be considered. Furthermore, information about a person's race and ethnic origin, health and sex life, inherited characteristics, and biometric information must be necessary for the research activity in order to be included in the research project.

If a dataset cannot be sufficiently de-identified, a part of the data can be withheld.

9.1.4 Allocate a digital object identifier to the data

The dataset will be allocated a persistent identifier (PID)/ persistent object identifier (POID) through the Wits Library either via an internal system or though placing the data in an appropriate repository inside of the open access ecosystem. There will also be indexing of the data for online search and discovery. The aim would be to increase the access and visibility of the research data and ultimately the number of citations. These will be accomplished by librarians using professional library and archival approaches to dissemination and preservation of data.

The data and associated files will be stored on REDCap. The Data Manager will have access to REDCap. REDCap can be accessed via a password which will be known to the Data Manager and Research Hub Director only.

9.1.5 Store the data on REDCap

Data will be stored on a secure platform called REDCap (Research Electronic Data Capture) which is hosted by the University of the Witwatersrand. This platform is access-controlled, secured on two different servers with site encryption and only a Data Manager, DAC and the Research Hub Director will have access to the data.

The following information can be provided in each study's data management plan:

"REDCap (Research Electronic Data Capture) hosted at the University of the Witwatersrand is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (Harris et al 2009; Harris et al 2019)."

References:

PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81. http://www.sciencedirect.com/science/article/pii/S1532046408001226

PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, The REDCap consortium: Building an international community of software partners, J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]
https://www.sciencedirect.com/science/article/pii/S1532046419301261

9.1.6 Make data discoverable

Data will be made discoverable through a PID link to the metadata and/or publications on the Wits CRH website. The PID to the data will feature in the publication. There will be a link to the abstract, dataset metadata, sample or display data, protocol, data documentation and/or full text article which will be stored University of the Witwatersrand Library repository namely Wits Wired Space.

9.1.7 Give researchers access to the data

Researchers who would like to use the data on the Human Movement database in future research projects will apply for ethical clearance. In addition, these applications will be reviewed by a DAC in the light of the intension of the participant's original consent. If the committee is satisfied with the intentions of use, a Conditions of Use Agreement will be signed by all parties whereafter access will be granted to the specified REDCap project containing the data and associated documents. Upon completion of the project, the researcher will be required to upload the modified datasheet onto the REDCap system and remove the copies from his/her computer, whereafter the researcher's access to REDCap will be terminated.

9.2 Metadata standards and data documentation

Metadata will be requested from researchers through a REDCap link. The metadata will be posted on the website to help other researchers to interpret and re-use your data. It will make your data searchable in the database, easily located from a citation and easily understood by researchers who might want to re-use the data. A search function will be built into the website to improve the discoverability of studies.

Generally, metadata is made up of administrative, structural and descriptive data. All these make it easy for the data to be stored, managed, located and re-used without breeching the stipulated terms of use. Please click the link here to complete the data depositor's form https://redcap.link/datadepositorform. Any queries regarding the form can be directed to the Wits CRH data manger and the DAC.

The following information forms part of the metadata:

- Depositor details (address, contact number, email)
- Creator's (principle investigator's) details (affiliation, ORCID, email)
- Title of dataset
- Data collection timespan
- Date data was created (including versions)
- File format
- Kind of data
- Population
- Context/setting
- Outcome measures used

- Interventions (if applicable)
- Variable list
- Keywords
- MeSH terms
- ICD-10 codes (if applicable)
- Unique identifier
- Associated publications (Full citation for publications, datasets, and other materials associated with the data)
- Potential future research questions (optional)
- Grant/funding agency
- Grant/funding number
- Brief Abstract (Maximum of 100 words)

9.3 Data preservation strategy and standards

Data will be stored on the REDCap database hosted on the University of the Witwatersrand servers for an indefinite period, unless the participant stipulates otherwise when completing the consent form (Appendix B and Appendix C). Data will be stored in standard file formats as described earlier in this guide.

10 Data security and confidentiality of potentially disclosive information

10.1 Formal information/data security standards

The University of the Witwatersrand is a public university and is compliant with the International Organisation for Standardisation (ISO) ISO 27001 Information Security. Data will be stored in REDCap in an access-controlled project. REDCap uses encryption to protect traffic between the Web server and the End User as well as to protect REDCap authenticators. Only the Data Manager and Research Hub Director will have access to the passwords for the projects.

10.2 Data destruction

Data will not be destroyed unless required for ethical or legal reasons in which case the University of the Witwatersrand's Central Records Office will be consulted for advice on expertise. For destruction of physical data, the guidance on Biobanks is followed. For

destruction of data on the internet, the University of the Witwatersrand follows the guidance of the South African National Research Network: Computer Security Incident Response Team.

10.3 Main risks to data security

Where possible, no names, surnames or contact details will be captured for example in the case of cross-sectional data a study number can be allocated at the time of data collection and the participant's name do not need to be recorded. However, participants will complete their name, surname and contact details on the consent form. In case of longitudinal studies where participants need to be followed up over time, the name, surname and contact details of a participant is collected as part of the research data and this information features on the consent form as well. At the end of the study, study numbers will be assigned to each participant, and names, surnames and contact details will be removed from the data which are stored. The document containing the link between the study numbers and names, surnames and contact details, as well as the consent forms will be kept in a separate access-controlled project in REDCap and only the Data Manager, access control committee and Research Hub Director will have access to this information.

Where hard copy data is collected, it will be transformed into electronic data by entering the findings into REDCap. The hard copies will be shredded to Security Level P3 specifications which are:

- Particle Width: equal to or less than (4 millimeters)
- Particle Width: equal to or less than (80 millimeters)
- Total shred area not to exceed a total of 320 square millimeters

https://www.abe-online.com/paper-shredder-levels-of-security

11 Data sharing and access

11.1 Suitability for sharing

Suitability for sharing will be project specific. The majority of projects which fall under human movement analysis and intervention including physical activity, sport and health, are suitable for sharing because most information captured are not of a sensitive nature.

11.2 Discovery by potential users of the research data

Projects with their metadata will be shared on the Wits CRH website as well as on Wits Institutional Repository on the Wits Wired Space platform. Data can be located through the use of a search function. From here, interested researchers will follow a REDCap link where more information (project metadata) can be found. The process for requesting access to data will also be described on the Wits CRH website and this Data Management and Sharing Guide will be available via a download function on this same website.

The PID of the dataset on which the publication findings are based will feature in the associated publication.

11.3 Governance of access

Priority of access to data will be given to members of the Wits CRH, unless if funders or publishers of a specific study requires otherwise. This is in line with the overall intension of the establishment of the data, which is intended to primarily enable the advanced analysis of data collected in Africa and to encourage researchers to publish it and make it usable to the people of Africa.

The Recipient will complete an online data request form via the link https://redcap.link/datarequestform. The link for the data request form will also be made available on the data sharing webpage on the Wits CRH website. The REDCap form will request the following details: name, surname, contact number, email address, affiliation, detailed description of the objectives of the study, data needed and intended use of the data and a study protocol. A Recipient may be internal or external to Wits.

The request will be sent to the Data Manager who will review the request in relation to the following questions:

- Is the intended use of the data similar to what it has already been used for? If yes, the motivation for the request needs to be made clear.
- Is the scientific methods rigorous and ethical approaches sound as described in the protocol?
- If there are other data available which are more appropriate, these can be suggested.

Recipients are encouraged to submit their requests for data at least six weeks before the start of the intended period of use. The Data Manager, DAC, Research Hub Director and principal investigator who collected the data will review the request and inform the Recipient of the outcome via email within three weeks from the data on which the request was received. If the request is denied, reasons will be provided, and the Recipient can appeal through the University's Data Access Committee which will be convened by the Wits Data Protection officer on receiving an appeal via means the ethics hotline.

The Recipient will sign a Conditions of Use Agreement which can be found in Appendix D. Once the Recipient has obtained ethical clearance and the access agreement have been signed, the data will be released to the Recipient.

The Data Manager will keep a record of who the data is shared with as well as the intended use of the data. The Data Manager will share this report with the University or funders as required.

The application, review and approval processes are shown in Figure 1 (based on the MRC UK's suggested processes):

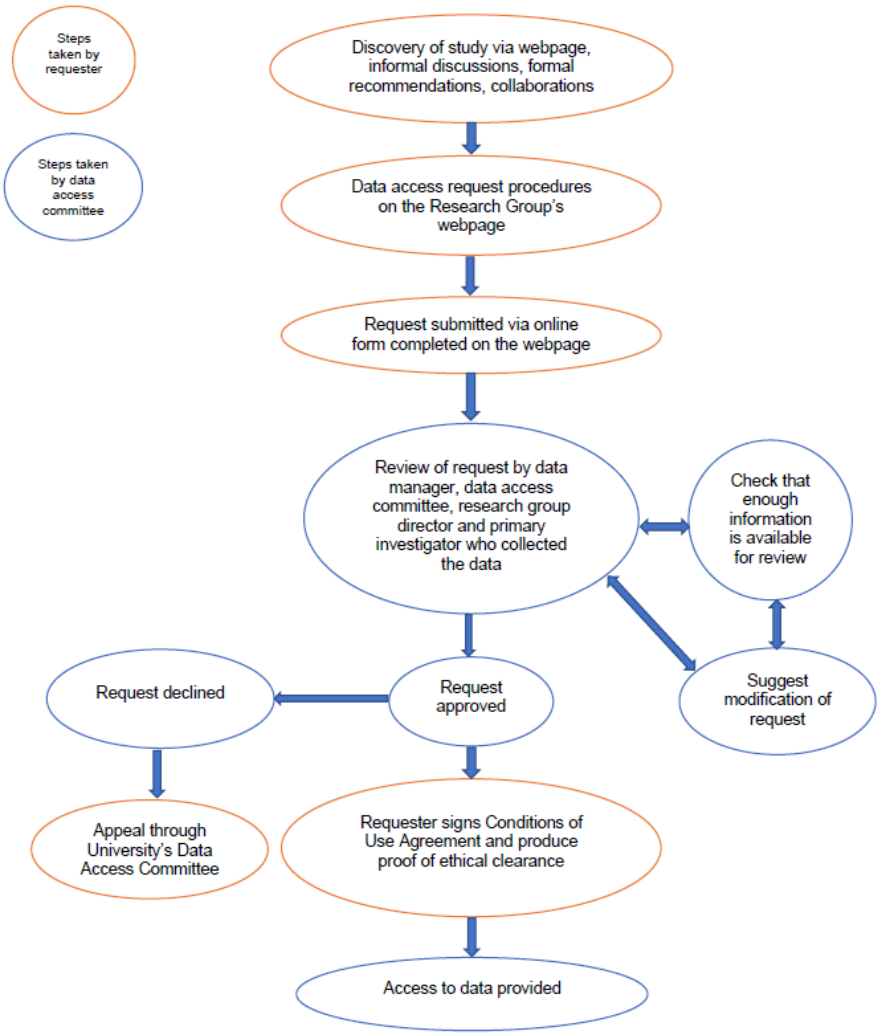

Figure 1. The application, review and approval processes

11.4 The study team's exclusive use of the data

The principal investigator can specify a time period in which the period will be for exclusive use which is to be specified in the protocol. This time period can be revised to account for unforeseen delays which impacted on the study's timelines. Requests for re-use of the data will be revised by the data management committee and will be referred to the principal investigator for agreement. There will be no sharing of data during the data collection phase and six months thereafter, where after the principal investigator should allow reasonable access to the data. The principal investigator can specify a specific period of exclusive use. This is especially if the dataset is needed for the proposes of training graduate researchers and increasing African specific research.

11.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Consent for data re-use and sharing should be obtained from participants at the time of data collection. Data should be submitted to the Human Movement Database and made available for sharing as soon as a paper is accepted for publication. Where data is not analysed and written up, or where there is no intention of publishing the data, these data should be shared within a reasonable period after publication. Wits respects the first and continuing use of the data that they collected but does not endorse prolonged exclusive use.

Researchers can withhold data for four years where there is a patent in place.

Data will be shared with the Recipient within six weeks from the time the request for data is submitted unless there are unforeseen delays due to a poorly completed data request form or additional information which need to be obtained in the approval process.

11.6 Regulation of responsibilities of users

Researchers who are not affiliated with the Wits CRH can request access to data on the Human Movement Database and will be held to the same conditions as researchers who are affiliated with the Wits CRH. All Recipients, Recipient Institutions and Data Users will be bound by the Conditions of Use Agreement (Appendix D).

12 Cost of data management

In line with the National Science Foundation (NSF)'s Dear Colleague Letter (DCL) on digital object identifiers (DOIs) in datasets it is encouraged to add the cost of data management and sharing to funding proposals. If you need unique data management and sharing resources (such as services or platforms), ask the Wits e-research office to review data management and sharing plans in order to assess the resources needed and confirm if those resources are available centrally.

Services provided centrally are under development and include: Wits Library (Nina Lewin) can assist with safe and secure data deposits to enable access-controlled sharing, but no metadata or data cleaning services (unless a special arrangement is made). Any costs which may arise such as shipping a disc to a researcher will recovered from the researcher who

wants to re-use the data. To reduce overheads, researchers should collaborate for easier transference of data. Data Management costs will be outlined in the individual DMP's.

13 Responsibilities

The responsibilities listed here specifically pertain to data management and does not exclude or replace any other responsibilities required from any other systems such as quality assurance through presentation of the protocol to the department in case of postgraduate research, for example. The principal investigator is responsible for familiarising him/herself with the necessary knowledge and processes related to data management and sharing as referred to in this guide. During the protocol development phase, the principal investigator is responsible for developing a DMP and applying the principles stated in this guide to the development of the DMP which will feature as part of the protocol and the ethics application including the information sheet and consent form.

The principal investigator is also responsible for the quality assurance during collection, capture, de-identification and cleaning of data during the data collection process as well as for the safe and secure storage and backup of data. Upon completion of the data collection, a copy of the data together with the additional information, including metadata, will be sent to the Data Manager. The principal investigator is responsible for putting the documentation together and for creating the metadata. The principal investigator will engage and participate where a revision of the submitted documents is needed in order for it to comply with data management standards. The principal investigator should ensure that the PID/DOI to the data should be referred to the article that is published.

The Data Manager will ensure that the data is complete and ready for storage. Where needed, issues will be referred back to the principal investigator for correction including but not limited to confirming if identifiers are allocated to relevant variables in REDCap, if all the required documents have been received and if the information is complete. The Data Manager is responsible for managing the data deposited to the Human Movement Database including but not limited to metadata creation, data security and quality assurance of data.

We expect all parties to comply in good faith according to the Code of Responsible Conduct of Research.

13.1 Consortium of researchers to determine and maintain standards

It is recommended that various research areas form a consortium or network of researchers sharing an interest in a specific area of research. The consortia can develop standards for the collection of data in a format which allows for data to easily be combined without having to undergo transformation processes. Guidance into the standardisation of variables collected will also assist researchers to use best practices when collecting data, for example in the collection of physical activity data or the assessment of the knee angle during the single leg squat.

14 Application of information to your own study

The list below can be used to guide you in the implementation of the contents of this Data Management and Sharing Guide into your own research:

1. Familiarise yourself with the contents of this guide
2. Add a DMP to your study protocol which will be submitted to the ethics committee
3. Add the relevant information to your information sheet and consent form
4. Capture your data throughout the data collection process according to the standards described in this guide
5. Store data securely
6. Back data up regularly
7. Clean data
8. Submit the cleaned data together with the relevant documentation to the Data Manager
9. Engage in the review process, if necessary, to ensure that your data is stored in the correct format with the correct associated documentation
10. Engage with the process when someone requests access to your study's data or give permission to the data management to manage requests on your behalf

15 Resources

Australian National Data Service: https://www.ands.org.au/
UK Medical Research Council Data Sharing https://mrc.ukri.org/research/policies-and-guidance-for-researchers/data-sharing/

Appendix A - Data Management Plan (DMP) template

This Data Management Plan (DMP) template was downloaded from the UK MRC website https://mrc.ukri.org/research/policies-and-guidance-for-researchers/data-sharing/ on the 27th of January 2021 and there is a Microsoft Word version available for easier completion. Do double check for the most recent version at the time of completion of your research proposal by clicking on the link above. You can also create your own DMP through this useful online tool: https://dmponline.dcc.ac.uk/. The DMP template below is needed when one applies for funding at the UK MRC, however, even if your aim is not to apply for funding at the UK MRC, this is a very comprehensive template and will cover you in terms of your ethics application. When you apply for funding from any institution, familiarise yourself with that institutions data sharing policies and templates. Although the policies are all fairly similar, it is important to be aware of any potential differences.

You can add the DMP as an appendix to your proposal. Most of the information which needs to be completed under the various sections, can be copied and pasted from this guide, but do note that a lot of the sections are specific to your study's design and methods. For PhD projects where lots of data will be collected, the DMP will be longer (2-3 pages) while for smaller studies it may be as short as a half a page.

TEMPLATE FOR A DATA MANAGEMENT PLAN

The following **template** should be used to develop a Data Management Plan (DMP) to accompany a research proposal. The notes (*in italics*) provide further context and guidance for its completion. Where substantial data is generated from the research, the DMP will be more in depth and therefore likely to be 2 or 3 pages long (3 pages maximum length - See MRC Je-S Help and Guidance for DMP) for low impact studies generating small amounts of data, DMPs will be short ie less than half a page. If you opt NOT to use the template the topics listed in the template MUST be addressed.

0. Proposal name

Exactly as in the proposal that the DMP accompanies

1. Description of the data

1.1 Type of study

Up to three lines of text that summarise the type of study (or studies) for which the data are being collected.

1.2 Types of data

Types of research data to be managed in the following terms: quantitative, qualitative; generated from surveys, clinical measurements, interviews, medical records, electronic health records, administrative records, genotypic data, images, tissue samples,...

1.3 Format and scale of the data

File formats, software used, number of records, databases, sweeps, repetitions,… (in terms that are meaningful in your field of research). Do formats and software enable sharing and long-term validity of data?

2. Data collection / generation

Make sure you justify why <u>new</u> data collection or long term management is needed in your Case for Support. Focus in this template on the good practice and standards for ensuring new data are of high quality and processing is well documented.

2.1 Methodologies for data collection / generation

How the data will be collected/generated and which community data standards (if any) will be used at this stage.

2.2 Data quality and standards

How consistency and quality of data collection / generation will be controlled and documented, through processes of calibration, repeat samples or measurements, standardised data capture or recording, data entry validation, peer review of data or representation with controlled vocabularies.

3. Data management, documentation and curation

Keep this section concise and accessible to readers who are not data-management experts. Focus on principles, systems and major standards. Focus on the main kind(s) of study data. Give brief examples and avoid long lists.

3.1 Managing, storing and curating data.

Briefly describe how data will be stored, backed-up, managed and curated in the short to medium term. Specify any community agreed or other formal data standards used (with URL references). [Enter data security *standards in Section 4].*

3.2 Metadata standards and data documentation

What metadata is produced about the data generated from the research? For example descriptions of data that enable research data to be used by others outside of your own team. This may include documenting the methods used to generate the data, analytical and procedural information, capturing instrument metadata alongside data, documenting provenance of data and their coding, detailed descriptions for variables, records, etc.

3.3 Data preservation strategy and standards

Plans and place for long-term storage, preservation and planned retention period for the research data. Formal preservation standards, if any. Indicate which data may not be retained (if any).

4. Data security and confidentiality of potentially disclosive information

*This section MUST be completed if your research data includes **personal data relating to human participants in research**. For other research, the safeguarding and security of data should also be considered. Information provided will be in line with you ethical review. Please note this section concerns protecting the data, not the patients.*

4.1 Formal information/data security standards

Identify formal information standards with which your study is or will be compliant. An example is ISO 27001.If your organisation is ISO compliant, please state the registration number.

4.2 Main risks to data security

All personal data has an element of risk. , Summarise the main risks to the confidentiality and security of information related to human participants*, the level of risk and how these risks will be managed. Cover the main processes or facilities for storage and processing of personal data, data access, with controls put in place and any auditing of user compliance with consent and security conditions. It is not sufficient to write not applicable under this heading.*

MRC guidance on the Confidentiality and data security is provided (please see page 24 of the PDF file generated by selecting the above or adjacent link).

5. Data sharing and access

Identify any data repository (-ies) that are, or will be, entrusted with storing, curating and/or sharing data from your study, where they exist for particular disciplinary domains or data types. Information on repositories is available here.

5.1 Suitability for sharing

Is the data you propose to collect (or existing data you propose to use) in the study suitable for sharing? If yes, briefly state why it is suitable.

If No, indicate why the data will not be suitable for sharing and then go to Section 6.

5.2 Discovery by potential users of the research data

Indicate how potential new users (outside of your organisation) can find out about your data and identify whether it could be suitable for their research purposes, e.g. through summary

information (metadata) being readily available on the study website, in the MRC gateway for population and patient research data, or in other databases or catalogues. How widely accessible is this depository?

Indicate whether your policy or approach to data sharing is (or will be) published on your study website (or by other means).

5.3 Governance of access

Identify who makes or will make the decision on whether to supply research data to a potential new user.

For population health and patient-based research, indicate how independent oversight of data access and sharing (please see page 10 of PDF file generated by selecting the above or adjacent link) works (or will work) in compliance with MRC policy.

Indicate whether the research data will be deposited in and available from an identified community database, repository, archive or other infrastructure established to curate and share data.

5.4 The study team's exclusive use of the data

MRC's requirement is for timely data sharing, with the understanding that a limited, defined period of exclusive use of data for primary research is reasonable according to the nature and value of the data, and that this restriction on sharing should be based on simple, clear principles. What are the timescale/dependencies for when data will be accessible to others outside of your team? Summarize the principles of your current/intended policy.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Restriction to data sharing may be due to participant confidentiality, consent agreements or IPR. Strategies to limit restrictions may include data being anonymised or aggregated; gaining participant consent for data sharing; gaining copyright permissions. For prospective studies, consent procedures should include provision for data sharing to maximise the value of the data for wider research use, while providing adequate safeguards for participants. As part of the consent process, proposed procedures for data sharing should be set out clearly and current and potential future risks associated with this explained to research participants.

5.6 Regulation of responsibilities of users

Indicate whether external users are (will be) bound by data sharing agreements, setting out their main responsibilities (please see page 13 section 7, titled Data-sharing agreements of the PDF file generated by selecting either of two links above).

6. Responsibilities

Apart from the PI, who is responsible at your organisation/within your consortia for:

- *study-wide data management*
- *metadata creation,*

- *data security*
- *quality assurance of data.*

7. Relevant institutional, departmental or study policies on data sharing and data security

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.
Add any others that are relevant

Policy	**URL or Reference**
Data Management Policy & Procedures	
Data Security Policy	
Data Sharing Policy	*e.g. a study policy of sharing research data*
Institutional Information Policy	
Other:	
Other	

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their **telephone & email contact details**

Appendix B - Example of an information sheet and consent form for prospective potential participants

An example of an information sheet and consent form to ask prospective participants for consent to re-use their data in future research projects.

This consent form will be made available to bowlers to sign via hard copy or e-consent (REDCap): https://redcap.link/FFB-prospective

11 November 2020

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

Dear Fast Bowler

I, Benita Olivier, am doing research on factors associated with injury in cricket players. Research is just the systematic process used to learn the answer to a question. In this study, we want to learn which factors increase a cricket player's risk to sustain an injury and which ones are protective against injury. This is a part of a research area which medical professionals, sport scientist and those interested in human movement have an ongoing interest in understanding.

I would be most grateful if you would allow for your data, which include your responses to the questionnaires and the results from the physical tests performed, to be used as part of this particular research project and also to contribute to the body of knowledge around ongoing research.

Information related to the Fearless Fast Bowling project:

The study is scheduled to commence in May 2020 and finish in April 2025.

Who is eligible to take part in this study?

Male and female cricket players aged 13 years and older, who are actively participating in high school, club, amateur and professional cricket teams.

What is involved in the study?

You will be invited to complete a demographic and lifestyle questionnaire that takes around 30minutes to complete. Should you prefer to complete any of the questionnaires via hard

copy, contact us in this case and we will make special arrangements. Once you agreed to participate, your bowling action will be captured. The entire process will take around an hour to complete. Testing will be done in the shoes that you usually wear when you bowl in the cricket nets. You will be required to wear a data collection suit. Movement sensors will be attached to specific sites on your body.

Are there any risks of taking part in this study?
You will not be exposed to any additional risks other than the risks that you are normally exposed to when you are performing the bowling action.

What are the benefits of taking part in this study?
Your bowling speed will be measured and given to you. Non-identifiable, generalised results will be made available to all participants at the end of the study. No monetary award will be given for taking part in this study.

Will access to information be controlled?
When you complete the questionnaires, identifying information will be captured such as name, surname and email address. If you are completing this questionnaire because your school or club has implemented this injury and workload surveillance system, the raw data will be submitted to your school or club's coaching and/or health care team as specified in your agreement with the school or club.

However, for research purposes the principal investigator, Benita Olivier and her research team which includes students, will have access to the raw data and at the time that data will be exported for research analysis. No information such as name, surname or contact details, will be exported and all participants will be allocated study numbers. You can request for your responses to be withdrawn from this research study by emailing the principal investigator, Benita Olivier (see email address below), on or before the last day of the last match of the cricket season in which you completed the questionnaire(s) without suffering any repercussions.

Information related to the use of your data in future research projects:
We would like to get your permission to deposit your data into a research database that will be used for future research by bona fide researchers. At the moment, we do not know what the future research questions are, but if there is any specific topic that you would prefer your data not to be used for, then you can specify this in the consent form. Your data will not be

sold for profit and you can indicate in the consent form if you prefer for your data not to be used in commercial projects (e.g. device development).

Will access to my data be controlled?
Identifying information, such as your name, surname, and contact details, will be removed from your data and a study number will be allocated to your data. The link between the study number and the identifying information will be kept in an access-controlled database which is only accessible by the Data Manager, access control committee and Research Hub Director. If you would like to review the accuracy of your data, feel free to contact the Data Manager (via Benita Olivier, email address below) who will set up a meeting for you to verify information.

Where will my data be stored?
Your data will be stored on a secure platform called REDCap (Research Electronic Data Capture) which is hosted by the University of the Witwatersrand. This platform is access-controlled, secured on two different servers and only a Data Manager, data access committee and the Research Hub Director will have access to the data.

How will researchers gain access to my data?
Researchers who would like to use your data in future research projects will apply for ethical clearance. In addition, these applications will be reviewed by a data access control committee in the light of the intension of your original consent. If the committee is satisfied with the intentions of use, access will be granted to your data. Your data might be linked to other datasets and merged with multiple sources of data. Upon completion of the project, the researcher will be required to upload the modified datasheet onto the REDCap system and remove the copies from his/her computer, whereafter the researcher's access to REDCap will be terminated.

Should you prefer not to allow for your data to be used in either the current or future research projects, or both, you will not lose out on any benefits that you are entitled to in the absence of this research project. If you would like to withdraw your consent for re-use of your data in future research projects you are free to do so by sending an email to the principal investigator, Benita Olivier (see email address below).

For further information, you are welcome to contact me, Benita Olivier, on 0823325776 or send an email to Benita.Olivier@wits.ac.za. This study has been approved by the Human

Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research. If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za.

Keep well,

Benita Olivier (PhD)
Researcher
Physiotherapy Department, University of the Witwatersrand

INFORMED CONSENT FORM: FAST BOWLER

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

I_____(e-mail address: _____ and cell phone number:_____) hereby agree to for my data to be used as stipulated below:.

I agree for my data to be used as part of the research project described in the information sheet and titled: "Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project".

☐ Yes

☐ No

I am aware that I can request for my data to be withdrawn from this particular research study, on or before the last day of the last match of the cricket season in which I completed the questionnaire(s), without suffering any repercussions.

☐ Yes

☐ No

I understand that there are no monetary rewards for allowing my data to be used as part of this research study and that participation is voluntary and I am not in any way obliged to take part.

☐ Yes

☐ No

I agree for my data, after my name, surname and contact details have been removed, be re-used in future research projects without my additional informed consent (tick all that apply).

☐ Yes, my data can be stored and re-used for an unlimited period of time.

☐ Yes, my data can be stored and re-used for a limited period of time with an end date specified here: _____(DD/MM/YYYY).

☐ Yes, my data can be re-used as part of a project of any type which has been approved by the data access control committee except for topics such as:
_____(leave blank if not applicable).

☐ Yes, my data can be used in commercial or device development projects.

☐ No, I do not agree for my data to be used in future research projects.

Signature of bowler _____ Date: _____

Signature of researcher _____

For office use only:
Study number:_____

INFORMED CONSENT FORM – GUARDIAN/PARENTS OF FAST BOWLERS

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

I_____(e-mail address: _____ and cell phone number:_____) hereby agree to for my child's data to be used as stipulated below:.

I agree for my child's data to be used as part of the research project described in the information sheet and titled: "Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project".

☐ Yes

☐ No

I am aware that I can request for my child's data to be withdrawn from this particular research study, on or before the last day of the last match of the cricket season in which I completed the questionnaire(s), without suffering any repercussions.

☐ Yes

☐ No

I understand that there are no monetary rewards for allowing my child's data to be used as part of this research study and that participation is voluntary and I am not in any way obliged to take part.

☐ Yes

☐ No

I agree for my child's data, after his/her name, surname and contact details have been removed, be re-used in future research projects without my additional informed consent (tick all that apply).

☐ Yes, my child's data can be stored and re-used for an unlimited period of time.

☐ Yes, my child's data can be stored and re-used for a limited period of time with an end date specified here: _____(DD/MM/YYYY).

☐ Yes, my child's data can be re-used as part of a project of any type which has been approved by the data access control committee except for topics such as: _____(leave blank if not applicable).

☐ Yes, my child's data can be used in commercial projects (e.g. device development).

☐ No, I do not agree for my data to be used in future research projects.

Signature of parent/guardian _____ Date: _____

Signature of researcher _____

For office use only:
Study number:_____

Appendix C - Example of an information sheet and consent form for retrospective participants

An example of information sheet and consent form to ask participants who have already been tested as part of this project for their consent to use their data in future research projects.

This consent form will be made available to bowlers to sign via hard copy or e-consent (REDCap): https://redcap.link/FFB-retrospective

11 November 2020

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

Dear Fast Bowler

You participated in a study titled “The Fearless Fast Bowling project” where we want to learn which factors increase a cricket player’s risk to sustain an injury and which ones are protective against injury. At the time, you agreed for your data to be used for this particular research project. However, I would be most grateful if you would allow for your data to be used as part of future research projects and in this way contribute to the body of knowledge around ongoing research.

Information related to the Fearless Fast Bowling project:

The following information was given to you at the time when you completed the questionnaires and underwent the physical testing. I am adding the information upon which you based your original consent for ease of reference, while information related to the use of your data in future research projects will follow below.

Who is eligible to take part in this study?

Male and female cricket players aged 13 years and older, who are actively participating in high school, club, amateur and professional cricket teams.

What is involved in the study?
You will be invited to complete a demographic and lifestyle questionnaire that takes around 30minutes to complete. Should you prefer to complete any of the questionnaires via hard copy, contact us in this case and we will make special arrangements.

Once you agreed to participate, your bowling action will be captured. The entire process will take around an hour to complete. Testing will be done in the shoes that you usually wear when you bowl in the cricket nets. You will be required to wear a data collection suit. Movement sensors will be attached to specific sites on your body.

Are there any risks of taking part in this study?
You will not be exposed to any additional risks other than the risks that you are normally exposed to when you are performing the bowling action.

What are the benefits of taking part in this study?
Your bowling speed will be measured and given to you. Non-identifiable, generalised results will be made available to all participants at the end of the study. No monetary award will be given for taking part in this study.

Will access to information be controlled?
When you complete the questionnaires, identifying information will be captured such as name, surname and email address. If you are completing this questionnaire because your school or club has implemented this injury and workload surveillance system, the raw data will be submitted to your school or club's coaching and/or health care team as specified in your agreement with the school or club.

However, for research purposes, the principal investigator, Benita Olivier and her research team which includes students, will have access to the raw data and at the time that data will be exported for research analysis. No information such as name, surname or contact details, will be exported and all participants will be allocated study numbers. You can request for your responses to be withdrawn from this research study by emailing the principal investigator, Benita Olivier (see email address below), on or before the last day of the last match of the cricket season in which you completed the questionnaire(s) without suffering any repercussions.

Information related to the use of your data in future research projects:

We would like to get your permission to deposit your data into a research database that will be used for future research by bona fide researchers. At the moment, we do not know what the future research questions are, but if there is any specific topic that you would prefer your data not to be used for, then you can specify this in the consent form. Your data will not be sold for profit and you can indicate in the consent form if you prefer for your data not to be used in commercial projects (e.g. device development).

Will access to my data be controlled?

Identifying information, such as your name, surname, and contact details, will be removed from your data and a study number will be allocated to your data. The link between the study number and the identifying information will be kept in an access-controlled database which is only accessible by the Data Manager, access control committee and Research Hub Director. If you would like to review the accuracy of your data, feel free to contact the Data Manager (via Benita Olivier, email address below) who will set up a meeting for you to verify information.

Where will my data be stored?

Your data will be stored on a secure platform called REDCap (Research Electronic Data Capture) which is hosted by the University of the Witwatersrand. This platform is access-controlled, secured on two different servers and only a Data Manager, data access committee and the Research Hub Director will have access to the data.

How will researchers gain access to my data?

Researchers who would like to use your data in future research projects will apply for ethical clearance. In addition, these applications will be reviewed by a data access control committee in the light of the intension of your original consent. If the committee is satisfied with the intentions of use, access will be granted to your data. Your data might be linked to other datasets and merged with multiple sources of data. Upon completion of the project, the researcher will be required to upload the modified datasheet onto the REDCap system and remove the copies from his/her computer, whereafter the researcher's access to REDCap will be terminated.

Should you prefer not to allow for your data to be used in future research projects, you will not lose out on any benefits that you are entitled to in the absence of this research project. If

you would like to withdraw your consent for re-use of your data in future research projects you are free to do so by sending an email to the principal investigator, Benita Olivier (see email address below).

For further information, you are welcome to contact me, Benita Olivier, on 0823325776 or send an email to Benita.Olivier@wits.ac.za.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research. If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za.

Keep well,

Benita Olivier (PhD)
Researcher
Physiotherapy Department, University of the Witwatersrand

INFORMED CONSENT FORM: FAST BOWLER

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

I_____(e-mail address: _____ and cell phone number:_____) hereby agree to for my data to be used as stipulated below:.

At the time when we collected data for the Fearless Fast Bowling project, you gave consent for the following:

I agree for my data to be used as part of the research project described in the information sheet and titled: “Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project”.

☒ Yes

I am aware that I can request for my data to be withdrawn from this particular research study, on or before the last day of the last match of the cricket season in which I completed the questionnaire(s), without suffering any repercussions.

☒ Yes

I understand that there are no monetary rewards for allowing my data to be used as part of this research study and that participation is voluntary and I am not in any way obliged to take part.

☒ Yes

We would now like to ask for your consent for the following:

I agree for my data, after my name, surname and contact details have been removed, be re-used in future research projects without my additional informed consent (tick all that apply).

☐ Yes, my data can be stored and re-used for an unlimited period of time.

☐ Yes, my data can be stored and re-used for a limited period of time with an end date specified here: _____(DD/MM/YYYY).

☐ Yes, my data can be re-used as part of a project of any type which has been approved by the data access control committee except for topics such as:
_____(leave blank if not applicable).

☐ Yes, my data can be used in commercial or device development projects.

☐ No, I do not agree for my data to be used in future research projects.

Signature of bowler _____ Date: _____

Signature of researcher _____

For office use only:
Study number:_____

INFORMED CONSENT FORM – GUARDIAN/PARENTS OF FAST BOWLERS

Study title: Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project

I_____(e-mail address: _____ and cell phone number:_____) hereby agree to for my child's data to be used as stipulated below:.

At the time when we collected data for the Fearless Fast Bowling project, you gave consent for the following:

I agree for my child's data to be used as part of the research project described in the information sheet and titled: "Injury prevention in cricket fast bowlers: The Fearless Fast Bowling project".

☒ Yes

I am aware that I can request for my child's data to be withdrawn from this particular research study, on or before the last day of the last match of the cricket season in which I completed the questionnaire(s), without suffering any repercussions.

☒ Yes

I understand that there are no monetary rewards for allowing my child's data to be used as part of this research study and that participation is voluntary and I am not in any way obliged to take part.

☒ Yes

We would now like to ask for your consent for the following:

I agree for my child's data, after his/her name, surname and contact details have been removed, be re-used in future research projects without my additional informed consent (tick all that apply).

☐ Yes, my child's data can be stored and re-used for an unlimited period of time.

☐ Yes, my child's data can be stored and re-used for a limited period of time with an end date specified here: _____(DD/MM/YYYY).

☐ Yes, my child's data can be re-used as part of a project of any type which has been approved by the data access control committee except for topics such as: _____(leave blank if not applicable).

☐ Yes, my child's data can be used in commercial projects (e.g. device development).

☐ No, I do not agree for my data to be used in future research projects.

Signature of parent/guardian _____ Date: _____

Signature of researcher _____

For office use only:
Study number:_____

Appendix D - Conditions of Use Agreement

Conditions of Use Agreement for the Human Movement Database

This Conditions of Use Agreement ("Agreement") governs the conditions of use of the Data generated and owned by the University of the Witwatersrand, Johannesburg, Faculty of Health Sciences, Wits Cricket Science, Medicine and Rehabilitation Research Hub (Wits CRH) which is curated in the Human Movement Database. The Human Movement Database include Data from studies conducted in the broad research area of human movement which encompasses the areas of physical activity, exercise, and sports.

In signing this Agreement, the Recipient Institution and the Recipient, as citied herein, agree to be bound by the terms and conditions of use of the Data as set out in this Agreement, and agrees to ensure that the Recipient Institution's Data Users comply with the terms and conditions of this Agreement.

For the sake of clarity, the terms and conditions of access set out in this Agreement apply both to the Recipient and the Recipient Institution (as defined below). The Recipient Institution and Recipient are referred to within the Agreement as "You", and "Your" shall be construed accordingly.

The Wits CRH Data Management and Sharing Guide can be accessed via the Wits CRH webpage (https://www.wits.ac.za/therapeuticsciences/physiotherapy/research/cricket-injury-prevention/cricket-research--wits/).

This Agreement is made on the_____day of_____20_____

BETWEEN:

1. The University of the Witwatersrand, Johannesburg acting through its Wits CRH is represented by: _____

2. The Recipient Institution _____whose registered office/principal address is_____

_____

The Recipient is _____

Agreed Time Period of Use: From_____ to _____

Agreed Purpose of the Data: _____

_____

Agreed Data: _____

Title of the Recipient Project where the Data will be used:_____

_____

Definitions:

- Agreed Purpose – means the research purpose(s) approved by the Wits Cricket Research Hub for Science, Medicine and Rehabilitation Data Access Committee (DAC) in writing
- Agreed Time Period of Use – As defined above; it is the timeframe in which the Recipient, Recipient Institution and Data Users will have access to the Data and are allowed to make use of the Data for the Agreed Purpose; the maximum moratorium of two (2) years will be allowed whereafter the dataset will be made available for use in competing research projects or teaching and learning.
- DAC – Wits Cricket Research Hub for Science, Medicine and Rehabilitation Data Access Committee
- Data – As defined above; the Data within the Human Movement Database
- Database – the Human Movement Database containing research Data on participants
- Data Participants – the individuals who have contributed their data which is housed in the Database
- Data Users – those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement
- Publications – without limitation: articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research
- Recipient – the researcher named above who is also considered to be the applicant
- Recipient Institution – the organisation named above at which the Recipient is employed, affiliated or enrolled
- University – University of the Witwatersrand, Johannesburg
- Wits CRH – Wits Cricket Research Hub for Science, Medicine and Rehabilitation

THE RECIPIENT INSITUTION AND THE RECIPIENT AGREE:

1. You confirm that you are affiliated with a tertiary institution or research entity for at least six (6) months prior to making this application. This affiliation, whether as a student or staff member of the institution, may require written verification if deemed necessary by the DAC.

2. You confirm that you will remain affiliated with a tertiary institution or research entity for the entire Agreed Time Period of Use. Should you no longer be affiliated with a tertiary institution, you will indicate this in writing to the DAC and cancel the Agreement, whereafter the dataset will be made available for use in competing research projects or teaching and learning.

3. You understand and acknowledge that the Data is experimental in nature, and that access to the Data is provided without any representations or warranties of any kind in relation to the Database or the Data. The Data is provided "as is", and Wits CRH assumes no responsibility for errors or omissions. Wits CRH members will NOT be liable in any way for any use made of the Data or the Database. You agree to hold the Wits CRH its members harmless from and to indemnify them against all and any losses, costs, fees, claims, demands and liabilities which may arise out of or in connection with Your use of the Data or the Database.

4. You will use the Data for the Agreed Purpose and shall not use the Data in such a way that damages or distress or is reasonably likely to cause damage or distress to any Data Participants.

5. The Data relates directly to individual Data Participants and is strictly confidential. You shall only disclose the Data to your Data Users. You shall take all reasonable measures to ensure that your Data Users shall not make copies of the whole or any part of the Data without your written consent, and shall keep a written record of any such copies sufficient to permit you to fulfil your obligations under clauses 4, 9 and 21 of this Agreement. You shall not transfer or disclose any part of the Data to any other person or body.

6. Except as reasonably required to carry out Your research with the Data for the Agreed Purpose You shall not duplicate or transfer or offer to transfer all or any part of the Data, on any media or any other platform.

7. You will not sell or offer for sale all or any part of the Data.

8. Should you wish to use the Data for commercial purposes such as, but not limited to, device development, You shall inform the Wits CRH DAC at the time of application.

9. You recognise the requirement to submit proof of ethical clearance to the DAC before release of the Data.

10. You agree at all times to keep strictly confidential and ensure that the Data Users keep confidential the information and Data pertaining to Data Participants. In particular, You undertake not to use, or attempt to use, or permit anyone other than the Data Users to use the Data on its own or in conjunction with other data, to seek to discover the identity of any Data Participants, to compromise or otherwise infringe the confidentiality of information on Data Participants and their right to privacy.

11. You accept that the Data is protected by and subject to national and international laws, and that You are responsible for ensuring compliance with any applicable laws. The DAC reserves the right to request and inspect data security and management documentation and procedures to ensure the adequacy of data protection measures in place. If the DAC makes any such written request, You agree to cooperate with it and to procure the cooperation of all your Data Users.

12. You may publish Your results arising from the use of the Data for the Agreed Purpose providing the Data itself is not disclosed. Aggregate or generic information generated from the Data may be published on the provisos that:
    - such aggregate or generic information does not allow Data Participants or groups of Data Participants to be identified with reasonable effort;
    - no damage or distress is or is reasonably likely to be caused to any Data Participants or groups of Data Participants;
    - the Data will not be used in any way that could reasonably be expected to lead to ethnic stigmatisation; and
    - no attempt will be made to identify the Data Participants.

13. You agree to acknowledge in any work based in whole or part on the Data, the published paper from which the Data derives, the version of the Data, and the role of the Wits CRH and the relevant principal collectors and their funders. You agree to refer to the source data via

the digital object identifier (DOI) or persistent identifier (PID), or other identifiable label, associated with the dataset.

Suggested wording in the Acknowledgement: *"[A part of] The Data used in this study was generated by the Wits Cricket Science, Medicine and Rehabilitation Research Hub, a research entity of the University of the Witwatersrand, Johannesburg, Faculty of Health Sciences."*

14. You are not permitted to give authorship to the researchers involved in the collection of the Data. However should the original research team be involved in this Project, you will give authorship according to each authors' individual contributions as described in the guide for authorship: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

15. You agree that you will submit any information reasonably requested to the DAC for the purposes of monitoring Data use.

16. You agree that if your application is approved by DAC, information about the proposed research use can be posted on Wits CRH's public website. The information may include Your name and institution, the title of the project, and a non-technical summary of the research question. If there are any changes / amendments to you're your Project, that you will notify the DAC as soon as is reasonably possible, especially if the Use of Agreed Purpose of the Data has changed.

17. You recognise that nothing in this Agreement shall operate to transfer to You any intellectual property rights and obligations relating to the Data. All Intellectual Property rights in the Human Movement Database are owned by the University of the Witwatersrand, Johannesburg. You have the right to develop intellectual property based on Your analysis of the Data.

18. If results arising from Your and/or Your Users use of the Data could provide health solutions for the benefit of people in the developing world, You agree to:
    - offer non-exclusive licenses to such results on a reasonable basis, should this be considered an appropriate request, for use in low income and low-middle income countries (as defined by the World Bank) by any party that requests such a license solely for uses within these territories;
    - provide preferential access to such results to South Africans.

19. You recognise that after the Agreed Time Period of Use has expired, the Data will be made available for use for competing research projects or teaching and learning. If You are not able to complete the Project within this time period, then You will submit a progress report stipulating all limiting challenges together with a completion plan, which will be considered by the DAC and which the DAC will have the sole discretion to provide an extension or not.

20. You commit to submit the modified dataset (if derivatives of the Data have been calculated or where new data has been added to the dataset), a data dictionary as well as other reasonably requested information which will allow for future use of the data, to the Data Manager on the date as agreed between Parties and conforming to the standard as set out in the Wits CRH Data Management and Sharing Guide.

21. The Wits CRH reserves the right to use any of these Data, which includes the original dataset made available to You as well as the modified dataset uploaded by You, in future research and teaching and learning projects.

22. You agree to carry all costs associated with cleaning, storing or preparation of data for upload of the modified dataset.

23. You commit and will confirm in writing to the DAC the removal of all copies of the Data from your computer or any other device on the date agreed to with the DAC, which is the same date on which access to the Data on REDCap will be terminated.

24. This Agreement is not transferable, and You may not assign under any circumstances (in whole or in part) without the written consent of the DAC.

25. If You commit a material breach of this Agreement or for any persistent breach of this Agreement, the DAC may terminate this Agreement immediately by notice in writing, without prejudice to its accrued rights and remedies.

26. You accept that it may be necessary for the DAC to alter the terms and conditions of this Agreement from time to time in order to address new concerns. In this event, the DAC will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the Parties entering into a written and signed variation of this Agreement.

27. The DAC may terminate this Agreement at any time by giving 30 (thirty) calendar days' notice in writing to You for whatever reason.

28. Your duty to protect the confidentiality of the Data received under this Agreement shall survive termination of this Agreement and shall continue in full force and effect indefinitely.

29. In performing their obligations under this Agreement, the Parties shall:
    a. comply with the provisions of the Data Protection Legislation insofar as it is applicable to this Agreement;
    b. not process Personal Information for any purpose other than to perform its obligations under this Agreement and ensure that such processing will not place Wits CRH in breach of any Data Protection Legislation;
    c. only act on the instructions of Wits CRH in collecting, processing and utilising the Personal Information and for avoidance of doubt, this Agreement will constitute such instructions;
    d. not disclose or otherwise make available the Personal Information to any third party other than authorised Personnel or sub-contractors who require access to such Personal Information strictly in order for You and Your Users to carry out its obligations pursuant to this Agreement, and ensure that such Personnel and any other persons that have access to the Personal Information are bound by appropriate and legally binding confidentiality and non-use obligations in relation to the Personal Information.

30. You and Your Users shall be responsible for establishing and maintaining an information security program that is designed to:
    a. ensure the security and confidentiality of the any Wits CRH information, including any back-ups, where applicable, by the use of encryption for such information at transit and rest;
    b. protect against any anticipated threats or hazards;
    c. protect against unauthorised access to, disclosure or use of any University information;
    d. ensure the proper separation of information belonging to Wits CRH from any third party information;
    e. where appropriate, ensure the proper disposal of information belonging to Wits CRH where appropriate;
    f. preserve the integrity of any information belonging to Wits CRH and prevent the corruption, destruction or loss of such information at all times; and
    g. ensure that all sub-contractors of You and Your Users, if any, comply with the provisions of clause 29 to 31.

31. You and Your Users will report orally and in writing any actual and/or suspected breaches such as security incidents, unauthorised access or disclosure of Confidential and/or Personal of Wits CRH immediately upon discovery of the unauthorised disclosure to Wits CRH Representative, but in no event more than 2 (two) calendar days after You and Your Users reasonably believes there has been such unauthorised use or disclosure.

32. Where the You and Your Users (including You and Your Users Personnel) is given access (whether direct or remote) to any Wits CRH Information Technology Systems under or in connection with the Agreement, You and Your Users will, and will ensure that You and Your Users Personnel):

    a. comply with any policies, requirements or other instructions of or, where applicable, Wits CRH's third party suppliers regarding use of such Wits CRH Information Technology Systems;
    b. only use Wits CRH Information Technology Systems in connection with the proper delivery of the Deliverables and/or Services;
    c. not permit any other individual or entity to access Wits CRH Information Technology Systems;
    d. upon Wits CRH's request, immediately cease access to and use of any Wits CRH Information Technology Systems and return all Wits CRH Information Technology Systems (and associated documentation) to Wits CRH; and
    e. not deactivate or disable any Information Technology Systems used by Wits CRH or introduce any viruses or other similar code to the same, or otherwise take action that would cause any damage or harm to any Information Technology Systems of the Wits CRH.

33. This Agreement shall be governed, interpreted and implemented by South African Law, and the Parties shall appoint an arbitrator for the resolution of any dispute which may arise out of this Agreement.

34. The Parties consent to the jurisdiction of the South Gauteng High Court, Johannesburg.

35. Neither Party shall be liable or deemed to be in default hereunder directly or indirectly, for any delay or failure in performance under this agreement or interruption of service resulting from any cause beyond the control of such party. Such causes may include, but shall not be restricted to, force majeure or acts of the Government civil or military, in either its sovereign or contractual capacity, acts of suppliers, wars, fires, floods, earthquakes. epidemics, quarantine restrictions, strikes, labour disputes, civil disturbances, shortage of suitable parts, freight embargoes or any other force majeure.

a. During any period of non-performance in terms of clause 31, the relevant terms and conditions of this Agreement will be suspended.
b. Should the duration of non-performance in terms of clause 31, go beyond a period of 6 (six) months, either party may cancel this agreement, without any right of recourse as against each other, save in respect of work already executed.

36. You and Your Users have insured yourselves against the acts and omissions of persons acting on its behalf and within the course and scope of its business. Your maximum liability will be limited, whether for a single or multiple events, to the extent of its insurance cover herein.

37. This Agreement contains all the express provisions agreed on by the Parties with regard to the subject matter of the Agreement and the Parties waive the right to rely on any alleged express provision not contained in the Agreement.
38. No Party may rely on any representation which allegedly induced that Party to enter into this Agreement, unless the representation is recorded in this Agreement.
39. No addition to or variation of any clause of this Agreement (including this clause 32.), consensual cancellation or novation of this Agreement and no waiver of any right arising from this Agreement or its breach or termination will be of any force or effect unless reduced to writing and signed by both Parties or their duly authorised representatives.
40. If either Party at any time breaches any of its obligations under this Agreement, the other Party ("the Aggrieved Party"):
    a. may at any time after that breach exercise any right that became exercisable directly or indirectly as a result of the breach, unless the Aggrieved Party has expressly elected in writing or by clear and unambiguous conduct, amounting to more than mere delay, not to exercise the right. In particular, acceptance of late performance will be provisional only, and the Aggrieved Party may still exercise that right during that period;
    b. will not be estopped (i.e. precluded) from exercising its rights arising out of that breach, despite the fact that it may have elected or agreed on one or more previous occasions not to exercise the rights arising out of any similar breach or breaches.

41. Without prejudice to any other provision of this Agreement, any successor-in-title, including any executor, heir, liquidator, judicial manager, curator or trustee, of a Party will be bound by this Agreement.
42. If any provision of this Agreement is invalid, unenforceable or illegal, the remaining provisions of this Agreement will be deemed to be severable therefrom and will continue in full force and effect unless such invalidity, unenforceability or illegality goes to the root of this Agreement.

43. This Agreement may be executed in any number of counterparts and by the Parties hereto on separate counterparts, each of which when executed and delivered will be an original and each of the counterparts will together constitute one and the same instrument.
44. Each Party will bear its own costs relating to the negotiation, preparation and signature of this Agreement.
45. Persons signing this Agreement on behalf of the Parties expressly warrants his/her authority to do so.
46. You and Your Users agree to be bound by the Wits CRH Data Management and Sharing Guide and You and Your Users agree to make yourselves familiar with this guide.

I acknowledge that I have read and understood the terms and conditions stipulated in this Agreement and I undertake to abide by the terms and conditions contained herein.

SIGNED by the Recipient:

Name: _____

Position and affiliation: _____

Signed at_____on this _____ day of _____20___

Signature:_____

SIGNED by the Recipient Institution:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20___

Signature:_____

SIGNED by the University of the Witwatersrand, Johannesburg

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20___

Signature:_____

SIGNED by the Data User:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20____

Signature:_____

SIGNED by the Data User:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20____

Signature: _____

SIGNED by the Data User:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20____

Signature: _____

SIGNED by the Data User:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20____

Signature:_____

SIGNED by the Data User:

Name: _____

Position and affiliation: _____

Signed at_____ on this _____ day of _____20____

Signature:_____

Acknowledgement: This Conditions of Use Agreement is based on SOUTHERN AFRICAN HUMAN GENOME PROGRAMME (SAHGP) Data Access Agreement.