**FACULTY OF MEDICINE & HEALTH SCIENCES**

**HEALTH RESEARCH ETHICS COMMITTEE**

*(Adapted from University of Cape Town)*

**Health-Related Case Reports and Case Series**

(Kindly type in all the information and send to fhsrec@wsu.ac.za)

**Please Note:**

* This form is ONLY for applications for health-related case report research and case series involving three or less patients.
* Case reports and case series are descriptive studies that are prepared for illustrating novel, unusual, or atypical features identified in patients during routine clinical care or clinical settings.
* If the research involves more than three cases, a standard new protocol application will need to be completed.

|  |
| --- |
| 1. **Protocol Title**
 |
| Title of Case report/Case series |  |

|  |
| --- |
| **2. Principal Investigator (PI) / Researcher** |
| **2.1 Personal Details**  |
| Title, First name, Surname |  |
| Department/Division |  |
| Phone |  |
| Email address |  |

|  |
| --- |
| **2.2 Sub-investigators Note:** Staff and students involved in the case report must be listed as sub-investigators**.** For students, please also indicate level of study e.g., undergraduate, Masters, PhD etc |
| Title, First name, Surname | Department/Division | Email | Level of study (if applicable) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| **3. Synopsis/Summary of the Case Report/Case Series** |
| Please provide a synopsis / summary of the case report/series. The synopsis must include: * A short rationale for the case report/ case series
* The number of cases that will be included in the case report/case series.
* An outline of data/samples and information that will be collected from patients and reported on.
* Ethical considerations related to the case report/case series.
* Institutional permissions that are required to access patient data/samples/records.
 |
|  |

|  |
| --- |
| **4. Participants for the case report/series** |
| 🞏 Adults | 🞏 Minors (<18 years) |
| Number of participants: |  | Number of participants: |  |

|  |
| --- |
| **5. Please describe how participant privacy and confidentiality will be protected.****Note:** A case report/case series should be de-identified and must not contain personal identifying information including facial photographic images and any comparable images. It is required that patients/participants provide written consent to allow information on their case to be published if it is not de-identified. |
|   |

|  |
| --- |
| **6. Informed consent:** **Will informed consent/assent be obtained from participants for case report/case series purposes? (Please tick** ✓**)** |
| 🞏 Yes | 🞏 No  |
| **6.1 Please provide details about the consent process and attach informed consent /assent forms with this application.****Note:** * Written informed consent should be obtained from each participant before publishing or presenting a case report/ case series.
* The informed consent/assent form should preferably be submitted to the HREC for approval prior to completing the case report/ case series.
* If the patient is deceased or otherwise unable to consent/assent, permission should be obtained from a legally authorized representative or family member.
* Any waiver of informed consent will require an adequately motivated justification.
 |
|  |

|  |
| --- |
| **7. Declarations and signatures** |

|  |
| --- |
| **7.1 Principal Investigator**My signature confirms that:1. Information in this application is true and accurate.
2. I will begin the research only after written HREC approval is obtained.
3. I accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare.
4. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HREC’s Standard Operating Procedures; as well as national and international guidelines/regulations.
5. I will provide annual progress reports to the HREC as requested, including a final closing report at the end of the research.
6. I will notify the HREC in writing if any change to the research is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants’ safety.
7. I will notify the HREC in writing immediately if any adverse event or unanticipated problem occurs during the research.
8. I will allow an audit of my research if requested by the HREC.
9. I have the time, training, experience and resources to oversee this research.

I will endeavour to publish and disseminate the findings of the study. |
| Signature of Principal Investigator |  | Date |  |
| Print name |  |
| **7.2 Student supervisor (if research is for a degree)**My signature confirms that:1. The student researcher has adequate training and resources to complete the research in the allocated timeframe.
2. The research has scholarly merit.
3. The level of risk inherent in the study is commensurate with the student researcher’s experience and the extent of oversight that I will provide.
4. I have time, training, experience and resources to oversee this research.
5. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study.
6. I will ensure that the research undergoes continuing review as required by the HREC, including annual progress reports, protocol amendments and a final closing report at the end of the research.
7. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HREC.
8. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave.
 |
| Signature of Supervisor |  | Date |  |
| Print name |  |

|  |  |
| --- | --- |
| **Checklist of documents required for a case report/case series.** | **Tick** |
| 1. Completed HREC application form for case report/case series
 |  |
| 1. Informed consent/assent forms
 |  |
| 1. Motivation for waiver of informed consent for HREC consideration (if applicable)
 |  |

**Please Submit to** fhsrec@wsu.ac.za