

Institutional Approval Criteria/Assurance 300-010

Chair or Program Chief/Director

I have reviewed the proposed protocol. As Department Chair or Program Chair overseeing the conduct of the PI's scholarly activity at WMed and affiliates, I assure the following:

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|--------------------------|--|
| <input type="checkbox"/> | WMed investigative team are qualified and possess the necessary credentials to perform the activities described in the proposal/protocol. |
| <input type="checkbox"/> | The investigative team has access to adequate facilities, time, staff, and equipment to perform the activities described in the protocol. |
| <input type="checkbox"/> | The rationale for the study are clearly stated and the rationale is scientifically sound. |
| <input type="checkbox"/> | The aims and the corresponding hypothesis are clearly stated and the primary outcome (and secondary outcomes, as appropriate) are clearly defined. |
| <input type="checkbox"/> | The question or hypothesis being tested is providing important knowledge to the field and the design of the study is appropriate for the questions that are posed. |

Associate Deans

I have reviewed the proposed protocol. As Associate Dean for Educational Affairs overseeing the Medical Student scholarly activities, I assure the following:

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|--------------------------|--|
| <input type="checkbox"/> | I agree to allow the investigator access to WMed Student data for the QI or research activity. |
| <input type="checkbox"/> | I confirm the protected educational records being accessed or used for this study are allowable under the FERPA regulations. |
| <input type="checkbox"/> | I confirm the proposal/protocol outlines the appropriate notification to students, if appropriate, that their educational records will be used for research. |

I have reviewed the proposed protocol. As Associate Dean for Graduate Medical Education overseeing the Residents/Fellows scholarly activities, I assure the following:

| | |
|--------------------------|--|
| <input type="checkbox"/> | I agree to allow the investigator access to Resident/Fellow data for the QI or research activity. |
| <input type="checkbox"/> | I confirm the protected educational records being accessed or used for this study, as applicable, are allowable under the FERPA regulations. |
| <input type="checkbox"/> | I confirm the proposal/protocol outlines the appropriate notification to students, if appropriate, that their educational records will be used for research. |

I have reviewed the proposed protocol. As Associate Dean for Faculty Affairs overseeing faculty scholarly activities, I assure the following:

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|--------------------------|---|
| <input type="checkbox"/> | I agree to allow the investigator access to Faculty Data for the QI or research activity. |
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Appendix A., Cont'd

Associate Dean for Research

I have reviewed the proposed protocol. As Associate Dean for Research, I assure the following:

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|--------------------------|---|
| <input type="checkbox"/> | WMed investigative team are qualified and possess the necessary credentials to perform the activities described in the proposal/protocol. |
| <input type="checkbox"/> | The investigative team has access to adequate facilities, time, staff, and equipment to perform the activities described in the protocol. |

Hospital

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| <input type="checkbox"/> | I have reviewed the proposed protocol and support the QI activity or conduct of the research at my institution in accordance with the institutional agreement and the WMed HRPP policies. This includes but is not limited to access to patient records for research purposes, HIM report requests/release to WMed, interaction with patients for research purposes, or use of ancillary services/resources for my QI or research activity. |
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Ancillary Services/Research Support

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|--------------------------|---|
| <input type="checkbox"/> | I have reviewed the proposed protocol and agree to provide research support services for the QI or research activity as described in the proposal/protocol. |
| <input type="checkbox"/> | The statistical considerations, including sample size and justification, estimate accrual and duration, and statistical analysis clearly described and are adequate to meet the study objectives. |