### The University of Vermont Committees on Human Research

### Request to Waive the Requirement to Include the Full Study Title in PRISM

UVMMC requires that certain information (full protocol title, CHRMS/CHRBSS protocol number, Principal Investigator and Principal Investigator’s contact information) about research study participation be included in the Research Flag area of each participant’s electronic medical record. This requirement is for participant safety and billing compliance.

It is expected that full protocol titles are included in PRISM, however it is recognized that there may be rare circumstances in which inclusion of the full study title is inappropriate.

If the Principal Investigator feels that including the full protocol title in the PRISM record is not in the best interest of the participant, they may request a waiver of this requirement. The waiver request will either be that the protocol title is withheld completely (PRISM will indicate “*Protocol title withheld due to the confidential nature of the research”*), or that an alternate title, proposed by the Principal Investigator, is substituted.

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| --- | --- | --- | --- | --- | --- | --- |
| **CHRMS** |  | **CHRBS** | |  | **IRB Number** |  |
|  | | |  | | | | |
| **Current Protocol Title** | | | |  | | | |
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| **Principal Investigator** | | | |  | | | |

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| a. Are you requesting a waiver of inclusion of the title in PRISM? | |  | Yes |  | No |
| b. Are you requesting an alternate study title? | |  | Yes |  | No |
| If you feel that the study title as written may disclose too much confidential information, please provide an alternate study title that will be used in PRISM. | | | | |
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| c. If yes to either, provide justification below. See guidance for waiver. | | | | | |
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| **Investigator Signature** | |
| By signing below, the Principal Investigator assures the information contained on this form is true and accurate. | | | | |
|  | |  |
| **Signature** | | **Date** |

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**Examples of appropriate justification to waive the requirement to include the full protocol title or alter the title:**

* There is more than negligible risk of stigmatization or discrimination by health care providers, health insurance plans, employers, or others by placing the protocol title in the medical records of participants.
* There is an expected deterrent effect on research participation by including the protocol title in the medical records of the study population.
* There is misleading information (for example disease condition, drug names) that might lead to conclusions about the person’s condition or related treatment which may increase potential for risk to the participant.

**Example of inadequate justification to waive the requirement to include the full protocol title or alter the title:**

* Participant privacy by itself is not considered an appropriate justification as electronic medical records are considered private. All personnel with access to the Research Flag in PRISM have completed training in confidentiality and privacy matters and the appropriate access and use of patient medical information. In addition, UVM Medical Center tracks all PRISM access and audit trails are in place to monitor access.