**The University of Vermont Committees on Human Research**

**21 CFR 50.24 Exception from Informed Consent Requirements for Emergency Research**

To be submitted as supplemental information to a new protocol submission.

**Note: If the study involves a drug, device or biologic, you (or the sponsor company) are required to submit a *separate* IND or IDE to the FDA specifically for conduct of a study with waiver of informed consent--even if the intervention is currently under IND/IDE without a waiver of consent.**

**General**

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| 1. Describe life-threatening situation requiring emergent intervention. |
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| 2. Describe available treatments and why those treatments are unproven or unsatisfactory. |
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| 3. Define the length of time of the potential therapeutic window based on scientific evidence.  |
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| 4. Explain how an independent data safety monitoring board who will exercise oversight of the research will be appointed and function. |
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**Feasibility of Obtaining Initial Consent from the Individual**

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| 5. Explain why subjects will not be able to provide informed consent as a result of their medical condition. |
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| 6. Explain why investigational intervention must be administered prior to obtaining informed consent from the subjects' legally authorized representatives. |
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| 7. Explain why there is no reasonable way to prospectively identify the individuals who are likely to become eligible for participation in the study. |
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| 8. Explain why the clinical investigation could not practicably be carried out without a waiver of consent. |
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**Assessment of Potential for Direct Benefit**

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| 9. Cite animal and pre-clinical studies that have been conducted, and the information derived from those studies and related evidence that support the potential for the intervention to provide a direct benefit to the individual subjects.  |
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| 10. Explain why the risks are reasonable in relation to:  |
| a) what is known about the medical condition of the potential class of individuals,  |
| b) the risks and benefits of standard therapy, if any, and |
| c) what is known about the risks and benefits of the proposed intervention or activity.  |
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**Proposed Initial Consent Procedures**

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| 11. Describe consent procedures for the subject, when appropriate. |
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| 12. Describe consent procedures when using a legally authorized representative. |
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| *Explain your attempts to contact a legally authorized representative within the therapeutic window and, where possible, obtain consent from such legally authorized representative rather than proceeding without consent. A summary of these efforts will be required at time of continuing review.* |
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| 14. If obtaining consent is not feasible and a legally authorized representative is not reasonably available, attempts to contact a family member to object to participation must be made and documented. Describe the process for contacting a family member and the information that will be made available to them to make a decision about their family member’s participation. *Note: You will be asked to summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.* |
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**Proposed Community Consultation**

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| 15. Describe plans for consulting with representatives of the communities in which the clinical investigation will be conducted and from which the subjects are likely to be drawn. |
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| 16. Describe plans, **both interactive and passive**, for disclosing to those communities your plans for the clinical investigation along with the risks and expected benefits.  |
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| 17. Describe plans for informing the community of sufficient information following completion of the investigation, including the demographic characteristics of the research population and the study results.  |
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| 18. Describe procedures offered to community members to proactively choose not to participate in the research intervention. |
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**Procedures for Obtaining Consent After Waiver of Consent was Employed**

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| 19. In each of the boxes below, describe procedures to inform the subject, the subject's legally authorized representative, or if none is available, a family member that:a. the subject was included in the clinical investigation along with the details of the investigation and other information contained in the informed consent;  |
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| b. he/she may discontinue the subject’s participation at any time without penalty of loss of benefits to which the subject is otherwise entitled; |
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| c. the subject was included in the clinical investigation and the subject’s condition improves (subjects should be informed as soon as feasible).  |
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| d. the subject was included in the clinical investigation under a waiver of consent and dies prior to contact with the subject’s legally authorized representative or family member. Information about the clinical investigation is to be provided to the subject’s legally authorized representative or family member, if feasible.  |
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**Participating Community Profile Worksheet**

Provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) waiver for emergency research would be used.

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| **Cultural, demographic, geographic, and economic considerations:** |
| What is the anticipated geographic area that participants may be recruited from your site? |
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| What is the ratio of rural to suburban to urban populations in this geographic area? |
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| Do you have any minority populations that should be considered? |
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| Do you have any particular populations of affluence or poverty that may require special methods of outreach in order to inform them about the research? |
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| How would you describe your community’s access to healthcare and awareness of existing clinical research efforts in the area? |
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| **Languages and local educational and/or literacy concerns:** |
| Does your site have a large non-English speaking population? |
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| If yes, what languages? |
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| **Religious, social, and political considerations:** |
| What are the predominant religions in your area? Do they have any beliefs that may affect their willingness to participate in research or to accept an EFIC model? |
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| Has your community experienced any major events (i.e. local/national tragedies, heated social or political issues, etc.) that may require added sensitivity when considering an appropriate community consultation plan for this study? |
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| What are the dominant political inclinations of your community? |
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| **Are there populations being targeted by this study that may be more likely to be enrolled than others?** |
| Are there specific patient populations affected by this research that should be specifically consulted? |
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| Are recruitment procedures designed to ensure a representative sample of participants? |
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| Will certain disadvantaged or vulnerable groups be over or under represented? |
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| Will potential risks and benefits be reasonably distributed across the community as a whole? |
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| **Other considerations:** |
| Overall, is this research appropriate for your community? |
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| Do you have any additional information to provide to the IRB? |
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