

# EFIC HRP Reviewer Worksheet

The purpose of this worksheet is to provide the University of Utah IRB with insight into your local community and to provide recommendations to help the University of Utah IRB make an informed decision regarding the community consultation plan for your local site.

You should have received a copy of your site investigator's proposed community consultation plan for a study that would like an Exception from Informed Consent (EFIC) for emergency research. In preparation for this review, we recommend you read the FDA's guidance on this topic at: <https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf>.

If you have any questions, please let us know:

University of Utah IRB  
[irb@hsc.utah.edu](mailto:irb@hsc.utah.edu)  
(801) 581-3655

\* Required

## EFIC HRP Reviewer and Site Information

1. First Name \*

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2. Last Name \*

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3. Title \*

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4. Institutional Affiliation \*

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5. Email Address \*

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6. Telephone Number

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7. May the University of Utah IRB (UU IRB) contact you to follow up if additional information is needed relating to your review of this Community Consultation Plan?

*Mark only one oval.*

Yes

No

# EFIC HRP Reviewer Statement of Assurance

## STATEMENT OF ASSURANCE

I understand that my role is to provide the University of Utah IRB with insight into my local community and to provide recommendations to help the University of Utah IRB make an informed decision regarding the community consultation plan for my local site.

I understand that all final determinations relevant to the approval of this study will be made by the University of Utah IRB, and that I am serving as a consultant to provide site-specific recommendations for the community consultation period of this study.

I do not have a conflict of interest (personal, financial, academic or other interest) in reviewing this community consultation plan that would prevent me from providing fair and objective recommendations.

If you agree with the above statement, please select "Yes" below and continue ->

**8. If you agree with the above statement, please continue. \***

*Mark only one oval.*

Yes, I agree.

No. *Stop filling out this form.*

## Cultural, Demographic, Geographic, and Economic Considerations

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

**9. What is the anticipated geographic area that participants may be recruited from at your site?**

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**10. What is the ratio of rural to suburban to urban populations in this geographic area?**

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**11. Do you have any minority populations that should be considered?**

*Mark only one oval.*

Yes

No

**12. 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?**

*Mark only one oval.*

Yes

No

13. How would you describe your community's access to healthcare and awareness of existing clinical research efforts in the area?

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14. Please provide more information about your responses above, if needed.

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### Languages and Local Educational and/or Literacy Concerns

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

15. Does your site have a significant non-English speaking population?

*Mark only one oval.*

- Yes
- No

16. If yes, what languages?

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### Religious, Social, and Political Considerations

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

17. 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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18. 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?

*Mark only one oval.*

- Yes
- No

19. **What are the dominant political inclinations of your community?**

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20. **Please provide more information about your responses above, if needed.**

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## Subject Selection

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

21. **Are there populations being targeted by this study that may be more likely to be enrolled than others?**

*Mark only one oval.*

Yes

No

22. **Are recruitment procedures designed to ensure a representative sample of participants?**

*Mark only one oval.*

Yes

No

23. **Will certain disadvantaged or vulnerable groups be over or under represented?**

*Mark only one oval.*

Yes

No

24. **Will potential risks and benefits be reasonably distributed across the community as a whole?**

*Mark only one oval.*

Yes

No

25. **Please provide more information about your responses above, if needed.**

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## Community Consultation Plan Criteria

Please answer each question with respect to the proposed Community Consultation and Public Disclosure activities proposed at your local site.

26. 1) Please provide a brief description of your site's community consultation plan, as well as any thoughts, questions, or concerns you may have relating to the proposed plan. \*

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27. 2) Are the proposed community consultation methods based on appropriate factors such as the size of the communities, the languages spoken within those communities, and the targeted research population and the heterogeneity of the population? \*

*Mark only one oval.*

- Yes  
 No  
 N/A

28. 3) Do the type and frequency of consultation activities facilitate broad community discussion with representative samples of the community? \*

*Mark only one oval.*

- Yes  
 No  
 N/A

29. 4) Do the proposed Community Consultation materials include an accurate representation of the risks and benefits of the project, as well as a clear indication that study procedures will take place without informed consent from individual participants and/or Legally Authorized Representatives? \*

*Mark only one oval.*

- Yes  
 No  
 N/A

30. 5) Does the proposed Community Consultation Plan include adequate methods for participants to exclude themselves from participation? \*

*Mark only one oval.*

- Yes  
 No  
 N/A

31. **6) Does the proposed Community Consultation Plan include methods for receiving and incorporating feedback from the community into the research protocol? \***

*Mark only one oval.*

- Yes
- No
- N/A

32. **7) Does the proposed Public Disclosure plan include adequate methods for dissemination of information after the investigation is completed so that communities and scientific researchers are aware of the study's results? \***

*Mark only one oval.*

- Yes
- No
- N/A

33. **8) Overall, is this research appropriate for your community?**

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

34. **9) Do you have any additional information to provide the IRB?**

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