



## Help Sheet for Exemption Umbrella Protocol Applications

When completing your IRB application for an [Exemption Umbrella Protocol](#), you must include the following information as indicated below, replacing any instruction text in red with project-specific information.

### General Application Guidance

You must answer all question in the application broadly enough to cover all possible activities that may be conducted under the umbrella protocol as part of individual project. See the examples of an [Exemption Umbrella Protocol](#) for additional help.

Although this is important for all questions in the application, key sections to focus on for a clear description are as follows.

### Contacts and Title Page, Question 8

The title of the application must be clear that it represents an exemption umbrella; include “Exemption Umbrella” in the title. Additionally, the title should be specific about the activities that will be conducted under the umbrella application. For example:

- Exemption Umbrella: Secondary Analyses of Data and Tissues for Pediatric Neurological Disorders
- Exemption Umbrella: Assessment of College Student Perceptions Toward Issues Regarding Public Transportation using Survey and Interview Procedures

### Contacts and Title Page, Question 9

After you describe your overall aims for the project, include the following text as justification for the umbrella protocol:

*This is a submission for an umbrella protocol that will cover all procedures and analyses conducted by the investigators on this application according to the aims above. This umbrella protocol meets the criteria for University of Utah IRB Exemption Category [INSERT CATEGORY NUMBER]:*

*[INSERT CATEGORY TEXT – Categories can be found here: [http://irb.utah.edu/\\_pdf/IGS-ExemptResearch.pdf](http://irb.utah.edu/_pdf/IGS-ExemptResearch.pdf)]*

### Study Location and Sponsors page, Question 4

List all possible external locations that may participate in any study procedures for which the PI is responsible. If additional locations may be determined later, an amendment to update this list of external locations is required.

### Participants page, Question 1-6

Ensure that the description of the participant population is broad enough to include all possible participants, including all age groups and vulnerable populations. If additional vulnerable populations are to be included later, an amendment to update this page is required.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



### **Study Information page, Questions 4 and 6**

Describe all possible recruitment methods, participant identification methods, and types of procedures that you may use and perform as part of this project. Give examples of each method and procedure if that is helpful for the description. If you are accessing existing datasets or tissue sets as part of the project, list any data or tissue sources that may possibly be used.

### **Consent Process page, Question 3**

If you will obtain verbal or written consent from participants, describe the possible consent situations that will occur.

Because the IRB will not be approving individual consent documents and consent processes for each specific project, the PI is required to ensure that any consent documents or verbal consent discussions used include at a minimum the following elements:

1. A description that the project is for research purposes.
2. A description of the procedures that will be conducted.
3. A statement that participation is voluntary.
4. The name and contact information for the investigator.

Remember, you must still be able to account for consent for all participants in the study. The IRB requires this documentation to be maintained in the study records.

After describing the consent process, include the following text on question 3:

The PI will ensure that any consent documents or verbal consent discussions used for the projects include at a minimum the following elements:

1. A description that the project is for research purposes.
2. A description of the procedures that will be conducted.
3. A statement that participation is voluntary.
4. The name and contact information for the investigator.

### **Data Monitoring Plan page, Question 4**

After you select the appropriate monitoring plan elements for the project, also select the “Other” options and include the following text in the text box:

*The study team will maintain a record of all specific projects and analyses that are conducted under this protocol, including documentation that each is conducted in accordance with the procedures and provisions described in this umbrella application. A report of the specific, individual projects/analyses will be submitted annually to the IRB via the ERICA Report Form for acknowledgement. This report will include the name of the investigators who conducted the specific project, the date the project began and ended (if ended), the actual or estimated number of patients whose data/tissue were/will be analyzed, and a short description of the specific aims and procedures for the projects.*

*The PI will ensure that any substantial amendments to the umbrella protocol, including changes in co-investigators, will be submitted to the IRB via an amendment application.*

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*The PI will also ensure that all possible unanticipated problems or instances of non-compliance related to any individual projects under this umbrella will be reported to the IRB according to standard IRB reporting policies.*

**Risks and Benefits page, Questions 1 and 2**

Describe all possible risks and benefits to participants that may occur for all individual projects performed under the umbrella. If new risks are identified while the application is open, an amendment to update this page is required, in addition to regular IRB reporting requirements (described on the IRB website).