

## Appendix H: BIOMEDICAL PROCEDURES

If the proposed research involves biomedical procedures (e.g., the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision) please provide the following information:

1. Describe, in detail, the biomedical **procedures** involved in this project. Please note that universal blood and body fluid precautions (also known as "universal precautions") recommended by the Centers for Disease Control and Prevention (CDC) must be used in all research protocols in which blood or other bodily fluid specimens are collected. Compliance with CDC guidelines should be addressed in the description of the study that is submitted to the IRB. Such activities may also require review and approval by the Institutional Biosafety Committee.
2. Identify anticipated and possible physiological **consequences** of this procedure for the subject(s) and steps to be taken to screen out subjects who may be at exceptional risk.
3. Identify the **site** where the procedure will occur.
4. Indicate the investigator's competence and identify his/her **qualification**, by training and experience, to conduct this procedure.
5. Describe what procedures will be in place should there be an adverse event, such as the provision of emergency medical services, who will incur the cost thereof, etc.