BRIDGEWATER STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD ADVERSE EVENT GUIDELINES

BSU is required by the Department of Health and Human Services and the Code of Federal Regulations to establish written procedures for ensuring "prompt reporting" to the IRB and appropriate officials "an unanticipated problem involving risks to subjects or others . . ." Any unanticipated problem involving "risk" that ultimately results in harm or potential harm to the subject or others, and is related or possibly related to research intervention, is a reportable adverse event.

An unexpected cardiac arrest in an exercise study is clearly reportable. It is important to note, however, that the possibility of harm is also reportable. For example, the loss of research records that contain identifiable private information would be a reportable event, as there is a risk of breach of confidentiality. Under the federal regulations an unanticipated risk to which a subject is exposed should be reported, regardless of whether actual harm has occurred.

In addition, the regulations also require that unanticipated problems involving risk to others must be reported. For example, if a researcher is harmed or may be harmed, or an event has the potential to influence the risk/benefit relationship for other subjects enrolled in the study, the event is reportable.

It is important that the IRB be able to perform a valid review of adverse events and determine their impact on continuation of the research, whether the informed consent form requires revision, and whether subjects already enrolled in the research should be re-consented. Prompt reporting and review of an adverse event could prevent others from risk or harm and help protect investigators and the institution against liability for breach of fiduciary duty (failure to disclose all known risks).

Important Adverse Event Terminology

- Unanticipated: the event, the specificity of the event, or the severity of the event is not consistent with the current investigator's risk information.
- Related or possibly related: there is a reasonable possibility that the adverse event may have been caused by the intervention, it is possible that the adverse event may have been caused by the intervention, or there is insufficient information to determine the likelihood of this possibility.
- Serious: 1) results in death, 2) is life threatening, 3) requires hospitalization or prolongation of hospitalization, 4) results in serious, persistent, or significant disability or incapacity, or 5) is any medical event which requires treatment.
- Internal event: an event that occurs at an institution served by BSUs IRB.
- External event: an event that occurs at an external, unaffiliated study site.