

## **HAC Policies and Procedures**

### **Protocol Deviations/Violations**

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Please refer to the section on reporting to the HAC.

#### **What Is A Protocol Deviation?**

Deviations generally do not have a major impact on subject's welfare or data integrity. Examples of deviations are scheduling a required procedure outside of the time frame specified in the protocol because the subject was on vacation when the procedure should have occurred or subject use of a prohibited concomitant medication.

#### **Is an Enrollment Exception to the Inclusion/Exclusion Criteria of an Approved Protocol a Protocol Deviation?**

Yes. The Principal Investigator should submit a written request for a one-time, one-patient enrollment exception as a modification request to the HAC to allow treatment of a single patient who does not meet the entry criteria of the HAC approved protocol.

These requests, which should be rare, must be justified in terms of serving the best interests of the one-time, one-patient only. The HAC Chairperson or his designee will evaluate the level of review required.

If the protocol receives external funding, the PI should attach a copy of the sponsor's written approval of this one-time event.

HAC approval is required before this type of exception to the inclusion/exclusion criteria of an approved protocol can be done. Contact the HAC Administrative Office at the numbers below to facilitate the request.

#### **What Is A Protocol Violation?**

Violations affect a subject's rights, safety or well-being or data integrity. It may also affect primary safety or efficacy endpoints of the study. Examples are:

- Enrolling subjects who did not meet entry criteria without prior permission of the sponsor/CRO
- Failing to obtain informed consent prior to any study-related procedures
- Failure to treat subjects according to protocol procedures that specifically relate to primary safety or efficacy endpoints

#### **Is There Any Other Additional Guidance Regarding Protocol Deviations/Violations?**

Elisabeth Clark, Research Ethics Officer/Human Protections Administrator of McGill University Health Center provides the following clarification:

"Protocol Violation - A term broadly used in clinical research to describe any study event whereby the current HAC approved research protocol was not followed, i.e. a change in a research activity. There is a general acceptance in the biopharmaceutical industry for two categories of protocol violation, protocol exception and protocol deviation."

## HAC Policies and Procedures for Investigators and Research Team Members

"Protocol Deviation - A divergence, or departure, from the expected conduct of an approved study that is inconsistent with the current research protocol, consent document or study addenda and that had not been anticipated".

Urgent action to eliminate an immediate hazard to a subject is the only acceptable protocol deviation, and the event must be explained in writing to the sponsor, and to the HAC, as soon as possible.

Protocol Exception - A divergence or departure from expected conduct of an approved study that is not consistent with the current research protocol, consent document or addenda, that had been anticipated by the investigator, and for which HAC grants acceptance.

### **Why Is a Prevention Plan Required?**

The prevention plan is necessary so that the HAC can determine what will be done to prevent future occurrences. They will review the plan to determine if it is appropriate. Additional information may be requested.

### **When Is The Reporting Deadline?**

All protocol deviations and violations must be reported to the Human Assurance Committee (HAC) within five (5) business days.

### **What Form Must Be Submitted?**

A completed HAC Form 120PDV, Protocol Deviation/Violation, must be submitted.

### **Who Do I Contact if I Have Any Questions About How to Complete the HAC Form 120PDV, Protocol Deviation/Violation?**

If there are any questions, please contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.