

Modification of GCRC Guidelines Regarding Activity in Non-accredited Facilities – Effective April 1, 2003

As stated on the first page of the current (November 2001) GCRC Guidelines, “Inpatient and outpatient areas of the GCRC must be located in facilities either accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or certified to accept Medicare and/or Medicaid reimbursement.” Accordingly, any inpatient day or outpatient visit reported in the GCRC census must take place in such an accredited or certified facility.

The GCRC Guidelines are now modified (effective April 1, 2003) to allow low-risk research activity (e.g., administering a questionnaire, buccal swab) by GCRC-grant-supported personnel (e.g., nurses) to take place in facilities that are neither JCAHO-accredited nor Medicare- or Medicaid-certified (e.g., school, church, home, museum). Such activity is to be reported in the GCRC census, not as inpatient days or outpatient visits, but rather as a new category called “offsite research visits (ORVs).” The following caveats apply:

1. While all GCRC protocols continue to require approval of the Institutional Review Board and GCRC Advisory Committee (GAC) before they may be initiated, the GAC review of protocols involving ORVs must include (and document in the minutes) an assessment that the facility in which the ORV is to be conducted will not compromise research subject safety or data confidentiality, and that the medical coverage will be appropriate for the risk level of the proposed research activity.
2. As with all GCRC protocols, the protocol should not be coercive and investigators should exercise appropriate sensitivity regarding the populations to be studied.
3. Only category A and B ORVs will be allowed. GCRC personnel are not allowed to participate in category C or D activity in non-accredited facilities.
4. Initially, ORVs will only be allowed when they are part of a study receiving NIH or comparable peer-reviewed support other than the GCRC (M01) grant.