

Print on SHS IRRC/Research Letterhead

DATE:

TO:

RE:

DATE OF VISIT:

REVIEWER(S):

Thank you for your cooperation and please extend our appreciation to the members of your staff for their assistance during this site visit. If you have any questions about this report, please do not hesitate to call.

Review Criteria: The following criteria are evaluated during site visits:

- IRB Approval – ascertain whether or not the appropriate IRB approval had been obtained prior to initiation of the research project at Sparrow facilities.
- Subject selection – assure that subject selection is equitable; if applicable, assure that additional safeguards to protect vulnerable subjects are being met, as defined by the IRRC policies.
- Process of obtaining informed consent – assure that informed consent is obtained and documented as required by the Sparrow Health System Institutional Research Review Committee’s Policies and federal regulations (if applicable).
- Patient safety – document facilities available in the event of an emergency; assure appropriate reporting of adverse events as required in the IRB approval letter.
- Record keeping – assure protection of subject confidentiality; assure documentation of informed consent; assure documents are stored in a secure manner.

Your site was found to be

“Exemplary (no action indicated) – no objectionable conditions or practices were found during the audit of this study, or the following objectionable conditions do not justify further regulatory action, no further follow-up required.”

Or

“Acceptable (voluntary action indicated) – the following minor objectionable conditions or practices were found during the audit of this study, but the objections are to be corrected voluntarily by the study site, no further follow-up required.”

Or

“Non-acceptable (official action required) – the following objectionable conditions or practices that could impact subject safety and welfare or non-compliance with DHHS, FDA, or Sparrow Health System IRRC Policies and Procedures were found, mandatory corrections are required (a detailed plan of correction to be submitted and reviewed by the IRRC Office, corrections verified with a return site visit).

cc: IRRC Chair
BIRB Chair