

User-Friendly Glossary to the Pediatric GCRC

(12-1-04 revision)

Ancillary services – Services routinely available from various hospital departments to all patients in the hospital, i.e., routine laboratory tests, radiology procedures

Annual Report – Once a year the GCRC is required to submit a report of scientific progress to the NCCR. At this time, investigators are asked to provide information regarding their GCRC protocols to the GCRC Administration Office.

Assent Form – modified consent form for signature by children old enough to understand, and decide for themselves whether they want to participate in research study. A parent or guardian is also required to sign the Consent Form.

Authorization Form – HIPAA authorization form must be signed by individuals to allow use of their protected health information for purposes other than treatment, payment and healthcare operation.

Bionutrition – the bionutrition core works closely with physicians and nurses regarding the nutrition component of GCRC protocols

Bioinformatics – As used in the GCRC Informatics Cores, and as listed in the 2004 revised GCRC Program Guidelines, this term generally refers to the traditional Informatics Core, with responsibility for computer and information systems within the Center and as used in research studies that receive Informatics support. In the broader sense however the term “bioinformatics” means the application of computer systems and computational methods as applied to systems biology, typically used to identify genes, gene sequences, coding and non-coding regions on DNA, gene networks, the presence of gene-products (RNA) in larger or smaller amounts than expected (i.e., up-regulation and down-regulation), proteins including amino acid sequences and 3D structures, etc.

Biomedical Informatics – The application of computer systems and technology to manage health information, for example in Electronic Medical Records (EMR) or Electronic Health Records (HER) used to track patient clinical-care information, or to track and analyze health outcomes data.

Biostatistician – Assists investigators in planning, analysis, and publication of study data. Researchers are encouraged to meet with the Biostatistician, Joe Coll, prior to submitting their protocol for review.

COMIRB – Colorado Multiple Institutional Review Board. All GCRC protocols have COMIRB approval prior to being initiated.

Consent Form – Informed consent must be obtained by the researcher (or designee) from each study participant (or parent/guardian). This form explains the study, what tests or procedures the subject will be asked to participate in, potential risks and benefits, and is signed by the participant and the PI or designee after the study is explained to him/her,

and all his/her questions have been answered by the investigator. Consent forms are approved by COMIRB prior to study initiation.

Core Laboratory – The Pediatric GCRC Core Laboratory offers approximately 80 specialized laboratory assays to investigators of GCRC-approved research protocols, supporting sophisticated clinical research. The Core Lab can develop and validate new assays if requested by 2-3 investigators.

CRC – Clinical Research Center, short for GCRC or General Clinical Research Center

CTO – The Children’s Hospital Clinical Trials Organization

Data Coordinating Center – the center which coordinates the storage and analysis of data collected in multi-center protocols

GAC – GCRC Advisory Committee, meets quarterly and oversees general operations of the GCRC

GCRC – General Clinical Research Center. Why General? The word “general” implies that GCRC support is available to investigators from across The Children’s Hospital, UCHSC and affiliates, regardless of their department.

HIPAA – Health Insurance Portability and Accountability Act – Legislation effective in April 2003 which protects individuals’ personal health information

Informatics –the Informatics Core provides GCRC investigators information regarding data safety, storage options, assists with database design and presentation of results. Maintains GCRC file server, which is available to GCRC researchers. Ensures that current technologies are employed to meet the GCRC’s goals. Researchers are encouraged to discuss their data storage plans with the Bioinformatics Manager, Bob DiLaura, prior to submitting their protocol for review.

Informed Consent - see Consent Form

Inpatient Day – A patient admitted to the GCRC inpatient unit, who is here at 12:00 midnight constitutes an “inpatient day”.

Inpatient Unit – 10-bed unit located within The Children’s Hospital, on 4 Northwest.

IRB – Institutional Review Board, reviews protocols for human subject safety concerns (see COMIRB)

MSSC – Medical Surgical Specialties Clinic – location of the GCRC Outpatient Clinic

NCRR – National Center for Research Resources, the division of NIH which funds the General Clinical Research Center (GCRC) Program

NIH – National Institutes of Health

Neonatal - Pertaining to the first four weeks after birth

NM – GCRC Nurse Manager

Outpatient Visit – a patient who is registered as an outpatient, and is not at the hospital at 12:00 midnight. Some long outpatient visits are conducted on the GCRC inpatient unit.

Outpatient Clinic – GCRC Outpatient Clinic located in the MSSC, 3rd floor of the Health Center at TCH

Patient Categories – NIH designations which assign financial responsibility of costs for patients receiving GCRC support:

A – Subjects are admitted solely for research purposes.

B – Subjects may participate in a research protocol during an admission or visit for routine clinical care.

C – Patients are admitted to the GCRC as regular hospital patients.

These patients do not participate in research. They are also referred to as “boarders”.

D – Subjects who are enrolled in industry-initiated protocols. All charges are paid by industry through the responsible GCRC investigator.

PD – GCRC Program Director

Perinatal – Pertaining to or occurring in the period shortly before and after birth

PI – Principal Investigator – The principal investigator of the GCRC grant is the Dean of the School of Medicine at UCHSC, Richard D. Krugman, MD.

*Also, each protocol approved by the GCRC is written and conducted by a principal investigator who is a specialist in the field of investigation.

Protocol – a research study written to investigate a specific hypothesis

Publications – the results of research protocols are usually published in scientific journals at the conclusion of the protocol, and acknowledge that the study was supported by Grant #MO1 RR00069, NCR, NIH. This acknowledgement of GCRC support is critical to continued funding of the GCRC. The GCRC maintains a bibliography of publications resulting from GCRC-supported protocols.

Research Institute (RI) – The Children’s Hospital Research Institute

Research Nurses – nurses who are highly skilled in conducting patient oriented research, collecting timed specimens

Research Subject Advocate (RSA) –assists investigators in writing Data Safety Monitoring Plans for their research protocols, ensures research conducted in the GCRC is in compliance with the COMIRB-approved protocol, and that serious adverse events are reported in a timely fashion to the COMIRB and appropriate Federal agencies. Serves as a resource for patients or volunteers participating in GCRC studies, may participate in obtaining informed consent and educating research subjects. Researchers are encouraged to discuss their protocol with the RSA, Terri O'Lonegan, prior to submitting their protocol for review.

RSR – Research Service Request, a request for ancillary services, specific to the protocol and to the providing department (i.e., TCH Laboratory, Radiology)

Research Subject vs. Patient - A research subject is someone who willingly participates in a research protocol. A patient is someone who is being clinically treated by a physician.

RSA – See Research Subject Advocate

SAC – GCRC Scientific Advisory Committee members are appointed by the PI of the GCRC grant, the Dean of the School of Medicine. The committee meets monthly, reviews new protocols submitted which request support of the GCRC resources. Protocols are reviewed and given a priority score for scientific merit and need of GCRC resources.

Scatterbed – a research protocol may require that the subject be located on a unit of the hospital other than the GCRC inpatient unit, i.e., ICU, Oncology, Emergency Dept.

Scatterbed Nurse – also called Clinical Coordinator, a critical care-trained GCRC nurse who travels to the patients in scatterbeds, for the purpose of conducting the research protocol, collecting research data and samples, etc.

Scientific Advisory Committee – see SAC

Study Coordinator – the person who works with the Principal Investigator of the protocol, to coordinate enrollment and scheduling of subjects, conduct of the protocol, data collection, etc.

TCH – The Children's Hospital

UCDHSC – University of Colorado at Denver and Health Sciences Center (this is the newly merged University of Colorado institutional entity as of August 2004 between CU-Denver and the University of Colorado Health Sciences Center).

UCH – University of Colorado Hospital

UCHSC – University of Colorado Health Sciences Center