Cancer Research Supported by Clinical Research Office

On January 1, 2013, the NCI reporting guidelines changed. The NCI clarified that hypothesis-driven studies that consent patients should be included on the Data Table 4, which is a compilation of clinical research. Clinical research does NOT include tumor banks or retrospective chart reviews.

The following table describes studies that we must track and report to the NCI, and the required committee approval required.

Type	Definition	Examples	Monitoring and Reporting Requirements					
Patient Oriented *Please Note: Investigator initiated therapeutic clinical trials require a two-step review: review of the concept, and if approved, review of the full protocol by PRMC.*	Conducted with human subjects or on matter of human origin for which an investigator (or colleague) directly interacts with human subjects. Matter of human origin includes: • tissues • specimens • cognitive phenomena	Includes studies of: • mechanisms of disease • therapies or interventions for disease • behavioral, health service, prevention interventions • clinical trials • development of new technology related to disease	Include on NCI Table 4	Clinical Research Office manages, including regulatory and IRB submissions (not mandatory for Cancer Control Program Members)	Protocol Review & Monitoring Committee Conducts a Full or Administrative Review & Prioritizes	PRMC determines SRC and HTR approval	Subjects entered into Velos	Department Chair approval not needed for HRRC submission
Epidemiological and Behavioral	Involves no intervention or alteration in the status of the participants	Studies can be among healthy and/or cancer populations. Includes: • surveillance • risk assessment • outcome • environmental • behavioral	Include on NCI Table 4	Clinical Research Office manages, including regulatory and IRB submissions (not mandatory for Cancer Control Program Members)	PRMC Expedited Review and determine community sites' interest	PRMC determines SRC and HTR approval	Subjects entered into Velos if they can be identified	Department Chair approval not needed for HRRC submission
Health Services	Evaluates the following attributes of Healthcare: • delivery • processes • management • organization • financing		Include on NCI Table 4	Clinical Research Office manages, including regulatory and IRB submissions (not mandatory for Cancer Control Program Members)	PRMC expedited review and will discuss to determine community sites' interest	PRMC determines SRC and HTR approval	Velos entry not applicable	Department Chair approval not needed for HRRC submission

Research Not Supported by Clinical Research Office

The Clinical Research Office does not support the studies listed in the table below, but will provide tools to manage them.

Type	Definition	Examples	Monitoring and Reporting Requirements					
In Vitro	Uses human tissues that cannot be linked to a living individual	Tissue banking	Not included on NCI Table 4	Clinical Research Office does not manage	PRMC does not review	Needs SRC and HTR Approval—see below	Subjects not entered into Velos	Department Chair approves for HRRC submission
Retrospective Chart Review	No plans to contact patients or subjects		Not included on NCI Table 4	Clinical Research Office does not manage	PRMC does not review	Needs IRB oversight—see below	Subjects not entered into Velos	Department Chair approves for HRRC submission

Contact Information

Clinical Research Office and New Mexico Cancer Care Alliance

Linda Losee, 505-272-5490, LinLosee@salud.unm.edu
Please note that you will need to login to the UNM Cancer Center intranet to reach the CRO website and forms.

Scientific Review Committee (SRC)

Angela Meisner, 505-272-2422, awmeisner@salud.unm.edu
*Please contact Angela **before** filling out any forms or applications; she will provide further instructions.*
Visit the SRC webpage to download forms and view meeting and submission dates.

Human Tissue Repository (HTR)

Call (505) 272-1127 or email: tissuebank@salud.unm.edu
The HTR is located in the Basic Medical Science Building (BMSB) rooms 306B, and 306C

Institutional Review Board (IRB)

Call 505-272-1129 or email HRPO@salud.unm.edu
The IRB is part of the Human Research Protections Office (HRPO)
The HRPO includes several Human Research Review Committees (HRRC)