NEW MEXICO CANCER CARE ALLIANCE and
UNIVERSITY OF NEW MEXICO COMPREHENSIVE CANCER CENTER

Concept / Protocol Routing Form
INSTRUCTIONS

The **Principal Investigator** is responsible for filling out **Pages 1-3** on this form and sending it to Karen Gaines (kgaines@salud.unm.edu) before the Clinical Working Group (CWG) meeting at which their concept or full protocol will be discussed.

The **CWG Leader** completes **Page 4** on behalf of their CWG after they discuss the concept or protocol and decide whether to recommend the study to the PRMC.

Page 1 (PI): Basic information about the study. Fill out every space for which you have information.

- **UNMCCC Study Number** will be assigned by the CRO, so please leave that space blank.
- **Funding**: Please provide the name of the sponsor or funding agency if you have already secured funding or plan to apply for funding from that sponsor / agency.
  - If this is an Investigator Initiated Trial and you have not yet developed a budget for your study, you will have to do so after the PRMC approves the concept. Please contact Jennifer Castro at 925-0388 or JCastro@salud.unm.edu.
- **Length of accrual period** ("Y"): For how many years do you plan to recruit participants?
- **Total UNM/NMCCA study accrual goal** ("G"): How many patients do you plan to enroll over the entire lifetime of the study, including those patients at participating NMCCA sites?
- **Projected annual accrual per year** (= "G" divided by "Y"): Divide your "Total UNM/NMCCA study accrual goal" by the number of years that you will recruit patients.
- **Estimated number of eligible patients seen per year**: How many patients do you typically see at UNM/NMCCA sites each year that *potentially* could be enrolled in your study, based on their medical condition?
- **Clinical Research Type**: If this study involves health services research or epidemiologic and/or behavioral research with cancer patients and/or healthy populations (e.g., surveillance, risk assessment, outcomes, environmental studies) and does NOT involve any interventions or alterations in the status of participants, you DO NOT need to complete Pages 2-3 of this form.
- **Does this study require inpatient admission or services**? If inpatient admission, services, or resources are required, please indicate "Yes." The PI will need to complete a Clinical & Translational Science Center (CTSC) Request for Resources form. The Protocol and Outreach Coordinator (Kathy Anderson) will supply this form to you if necessary.
- Stop here and send the form to Kathy Anderson.

Page 2 (PI): Prioritization scoring sheet. Assign scores for each criterion to calculate a total score out of a possible 15 points. Also, at the bottom of this sheet, please indicate whether the study involves a "Rare Cancer" as defined by the NCI.

Page 3 (PI): Justification for opening the study. The PI should make a convincing argument for opening the study, especially if the Prioritization Score calculated on Page 2 is eight or lower.
Sign and date where indicated at page bottom, scan the signed page, and e-mail the scan to Karen Gaines.

Page 4 (CWG Leader): CWG's decision. The CWG Leader indicates the CWG's decision (recommend, decline, or table) and the CWG's reason(s) for declining or tabling the study, as appropriate.
Sign and date where indicated at the bottom, scan the signed page, and e-mail the scan to Karen Gaines.

QUESTIONS? Please contact Karen Gaines at 925-0353 or kgaines@salud.unm.edu. Thank you.

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Concept / Protocol Routing Form

Pages 1-3: To Be Completed by the Principal Investigator

UNMCCC Study Number:	
Sponsor and Study Number:	
Full Study Title:	
Version and Date of protocol:	
Principal Investigator:	
Has external funding been identified for this study? Please provide sponsor / grant program name.	☐ Yes; Source: _____ ☐ No; Funding application will be / has been submitted to: _____
Will Internal Funding be needed to complete this study?	☐ Yes (After PRMC approval of concept, Investigator is required to submit concept and draft budget for consideration of funding) ☐ No
Length of accrual period in years ("Y"):	
Total UNM/NMCCA study accrual goal ("G"):	
Projected annual accrual per year (= G ÷ Y): (A single number, not a range or ">")	UNMCCC: # _____ per year (annual accrual) Annual accruals at NMCCA network sites: NMOHC: _____ ; CSV: _____ ; Pres: _____ ; SW Gyn: _____; MMC: _____ ; LovelaceCC: _____;
Estimated # of eligible patients seen per year at UNM/NMCCA sites:	
IND Status (if applicable):	Holder: Applicant:
Clinical Research Type: NOTE: If study is a retrospective chart review or tissue study, DO NOT complete this form. Obtain approval from your department chair for submission to the HRRC.	☐ Patient Oriented Research ☐ Epidemiologic / Behavioral Research * ☐ Health Services Research *
Does this study require inpatient admission or services?	☐ Yes (A CTSC Request for Resources form must be completed) ☐ No

Send this completed form to Kathy Anderson, Protocol & Outreach Coordinator at: kanderson@nmcca.org.

*** Note to PI:** If this study involves **health services research** or **epidemiologic and/or behavioral research** with cancer patients and/or healthy populations (e.g., surveillance, risk assessment, outcomes, environmental studies) and **does not involve any interventions or alterations in the status** of participants, **only complete Page 1 and sign/date Page 3.**

To Be Completed by the Principal Investigator

Criteria	Scoring Rubrics	Scores
The study includes Institutional Translational Research.	Yes = **1** or No = **0**	__ / 1
The study provides care that does not currently exist at the Institution.	Yes = **1** or No = **0**	__ / 1
The study enhances referrals to NMCCA sites.	Yes = **1** or No = **0**	__ / 1
The study is a therapeutic intervention.	Yes = **2** or No = **0**	__ / 2
Patient Accrual: = Total number of patients expected to be enrolled during the course of the study	• Less than 5 patients in Phase II or III trial = **1** • 5 to 19 patients in Phase II or III trial = **2** • More than 20 patients in *any* Phase trial = **3** • At least 2 patients in Phase 0 or I trial = **3** • Non-therapeutic feasibility or pilot study, more than 20 patients = **3**, fewer than 20 **= 1**	__ / 3
Cancer Center Scientific Programs: . Cancer Control (CC) . Cancer Genetics, Epigenetics, and Genomics (CGEG) . Translational Cancer Biology and Signaling (TCBS) . Cancer Therapeutics, Technology, Discovery, and Targeted Delivery (CT)	• The study involves at least 1 of these areas = **1** **AND** • There is potential for collaboration or development of additional research studies from the trial = **2** **AND** • The study specifically uses a product or strategy that is an existing strength at our institution, **OR** • There is a defined collaboration or additional research from the trial already included in the proposal = **3**	__ / 3
The study enhances the reputation of the UNM Cancer Center/NMCCA and/or the PI.	• Institution: Yes = **1** or No = **0** • PI: Grant proposal: Yes = **1** or No = **0** • PI: Authorship: Yes = **1** or No = **0**	__ / 3
The study develops a specific strategy to support minorities and/or underserved populations.	Yes = **1** or No = **0**	__ / 1
TOTAL SCORE	Low Priority: ≤ 8 points High priority: > 8 points	**__ / 15**

Rare Cancer: The NCI has defined a "Rare Cancer" to be one that has an incidence of < 6 newly diagnosed persons out of a population of 100,000. The link for the list of Rare Cancers is: http://www.rarecare.eu/rarecancers/Rare_Cancers_list_March2011.xls

Is this a study for a "Rare Cancer"? ☐ Yes ☐ No

To Be Completed by the Principal Investigator

Please provide a justification to open the study at UNMCCC / NMCCA (e.g., reason to open, programmatic strategy, good use of available time and monetary resources, etc.):

_____ _____

Principal Investigator's Signature Date

To Be Completed by the Clinical Working Group (CWG) Leader

UNMCCC Study #:	
Sponsor Study #:	
Decision (check one ↓)	
☐	The _____ CWG voted to **RECOMMEND** this trial to the Protocol Review and Monitoring Committee.
☐	The CWG and/or its Leader voted to **DECLINE** this trial for the following reason(s): ☐ Scientific rationale is weak or poorly explained. ☐ Competing open protocol for the same patient population without adequate enrollment plan. ☐ Eligibility criteria are too restrictive for robust accrual. ☐ Significant feasibility barriers exist based on the supporting information from the CWG. ☐ The supporting CWG does not provide sufficient justification for opening this trial. ☐ Other (specify):
☐	The CWG voted to **TABLE** this trial and requests resubmission after the following revision(s) are made and/or question(s) are answered: 1. 2. 3.

_____ _____

CWG Leader's Signature Date of Decision

CWG: _____