

Protocol Development Resources

Personnel -

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Useful Sites -

Scientific Review Committee	https://research.unc.edu/clinical-trials/scientific-review-committee/
ClinicalTrials.Gov	UNC Process: https://research.unc.edu/clinical-trials/clinical-trials-gov/ National Site: https://clinicaltrials.gov/
ReGARD.org	http://regard.org
UNC Health Science Library: guide for community engagement & recruitment resources, easy background & literature searches	https://guides.lib.unc.edu/c.php?g=787212&p=5636824
UNC Safety Reporting Requirements	https://ohresop.web.unc.edu/files/2018/04/1401-Reporting-New-Safety-Information.pdf

Biostatistical Support -

NC TraCS Biostatistics Consults (1 hour is free of charge)	https://tracs.unc.edu/index.php/consultation
LCCC Biostatistics Core Support	cancer@bios.unc.edu
UNC CFAR Biostatistics Support	CFARbios@bios.unc.edu
Center for Gastrointestinal Biology and Disease - Biostatistics	https://www.med.unc.edu/cgibd/cores/biostatistics/
Biometric Consulting Laboratory (School of Global Public Health)	https://sph.unc.edu/bios/bios-research-units/biometric-consulting-laboratory/ or email bcl@bios.unc.edu

PROTOCOL TEMPLATES -

NIH/FDA Phase II-III Template	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-064.html
Online NIH Protocol Tool	https://e-protocol.od.nih.gov/#/home
Social Behavioral Template	https://osp.od.nih.gov/2019/04/01/nih-releases-protocol-template-behavioral-social-sciences-research-involving-humans/
NIH Institute-Specific Templates	NCI-CTEP Phase I-II Dose Escalation: https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Generic_Protocol_Template_for_Cancer_Treatment_Trial.docx NIDCR Protocol Template: https://www.nidcr.nih.gov/sites/default/files/2017-12/nidcr-clinical-trial-interventional-protocol-template.dotx DMID – Minimal Risk Sample Collection https://www.dmidcroms.com/CRS/ProtocolDevelopment/ProtocolDevelopment/Minimal%20Risk%20Sample%20Collection%20Protocol%20Template.docx
SPIRIT Checklist - Serves as an outline	http://www.spirit-statement.org/
LCCC Protocol Templates	https://unclineberger.org/protocolreview/forms/