

# Protocol Development Resources

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## Useful Sites -

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

## Biostatistical Support -

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

## PROTOCOL TEMPLATES -

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



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