

NCI Activities: COVID-19 and Cancer Research

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No financial relationships to disclose.

The impact of the COVID-19 pandemic on NCI and the extramural community.

- Contributing to the COVID-19 crisis while ensuring progress in cancer research and cancer care continue

NCI's response to COVID-19

- Pivoting some cancer research activities to SARS-CoV-2 research
- Continuing progress in cancer research
- Special considerations for grantees and trainees

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Pivoting some cancer research activities to SARS-CoV-2 research

Compassionate Use Protocol for Tocilizumab

- **Goal:** Decrease time in ICU, time on ventilator, time in hospital
- NCI will use its **compassionate use** mechanism to distribute tocilizumab to cancer patients with incipient respiratory compromise based on potential role of IL-6 in etiology
- Accrue 200 patients (age >2 yrs) with broad eligibility criteria that include severe respiratory compromise from presumed or proven COVID-19 infection.

Cancer and COVID-19 Longitudinal Cohort

Goals:

- Cohort of cancer patients infected with COVID-19 of all age groups for collection a comprehensive dataset on cancers, treatments, medications, symptoms, course, and recovery, and co-morbidities with longitudinal follow-up
- Follow subset of pts for > 1 yr to assess impact of COVID-19 on survivorship and QOL
- Collect serial blood samples to estimate antibody response, genetic susceptibility, and for biomarker development; collect blood from family members
- Public database/biospecimens
- Enroll at least 2000 patients

Pivoting some cancer research activities to SARS-CoV-2 research

COVID-19 and Cancer Clinical Trials

- Therapeutic trials for cancer patients with COVID-19 developed by NCI-Designated Cancer Centers
- *COVID-19 Cancer Consortium* - Opened 3/30/2020
 - Vanderbilt Comprehensive Cancer Center initiated a grassroots effort to collect clinical data on cancer patients with COVID-19 infections based on a set of de-identified information;
 - Uses an open access, internet database that is now endorsed by >70 Cancer Centers, hospital systems, and large practices
- The Cellular Immunotherapy Data Resource (CIDR) collects patient metadata associated with cellular therapies and is now collecting data among cellular therapy recipients on COVID-19 infection and related death.

Pivoting some cancer research activities to SARS-CoV-2 research

- Identifying genetic determinants of SARS-CoV-2 susceptibility and outcomes
- Testing and validating serologic assays for SARS-CoV-2
- High throughput screening for small molecule inhibitors of SARS-CoV-2 proteins
- Analyzing COVID-19 patient tissues using the cyclic immunofluorescence platform within the Cancer Moonshot Human Tumor Atlas Network (HTAN)
- Identifying SARS-CoV2 protein interactions with cellular proteins using the cancer protein-protein interaction pipeline

Support for COVID-19 research

- **NCI NOSI – 20-042**

To better understand the impact of SARS-CoV-2 infection and its impact on cancer patients' disease progression, response to therapy, care delivery, or survivorship, the NCI encourages the submission of applications to:

PA18-935: Urgent Competitive revisions for research outside the scope of the parent award

PA18-591: Administrative supplements for research within the scope of the parent award

NOT-CA-20-043: Competitive revision for SBIR/STTR research

- **NCI NOSI – 20-054**

NCI will consider requests from its grantees to engage in limited COVID-19 related research using their existing NCI-funded resources

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Ongoing cancer clinical trials and COVID-19

- Some institutions have shut down accrual to most studies; volume of COVID-19 patients has overwhelmed ability to provide care (NYC)
- Several have not: UCSF, NIH clinical center, others: trial accrual continues where staff available to treat those patients:
 - ✓ who need curative therapy or who have no viable options beyond a clinical trial
 - ✓ with clear potential for therapeutic benefit
 - ✓ suggest limiting accrual for non-therapeutic studies

NCI adapting to COVID-19

- Patient care can be transferred to different participating study sites
- Local healthcare providers can provide study activities to provide continuity of care (oversight by responsible investigator)
- NCI can ship oral IND agents directly to patients. Injectable CTEP IND agents must be administered at a registered site (FDA)
- Alternative procedures that do not compromise safety or the integrity of the study will be considered *minor deviations*
- Major deviations may be unavoidable; must still be reported to CIRB
- On-site auditing visits are being re-scheduled; remote auditing has been adopted by NCTN groups
- NCI CIRB supports “remote” informed consent: telephone discussion in conjunction with patient signature on written document

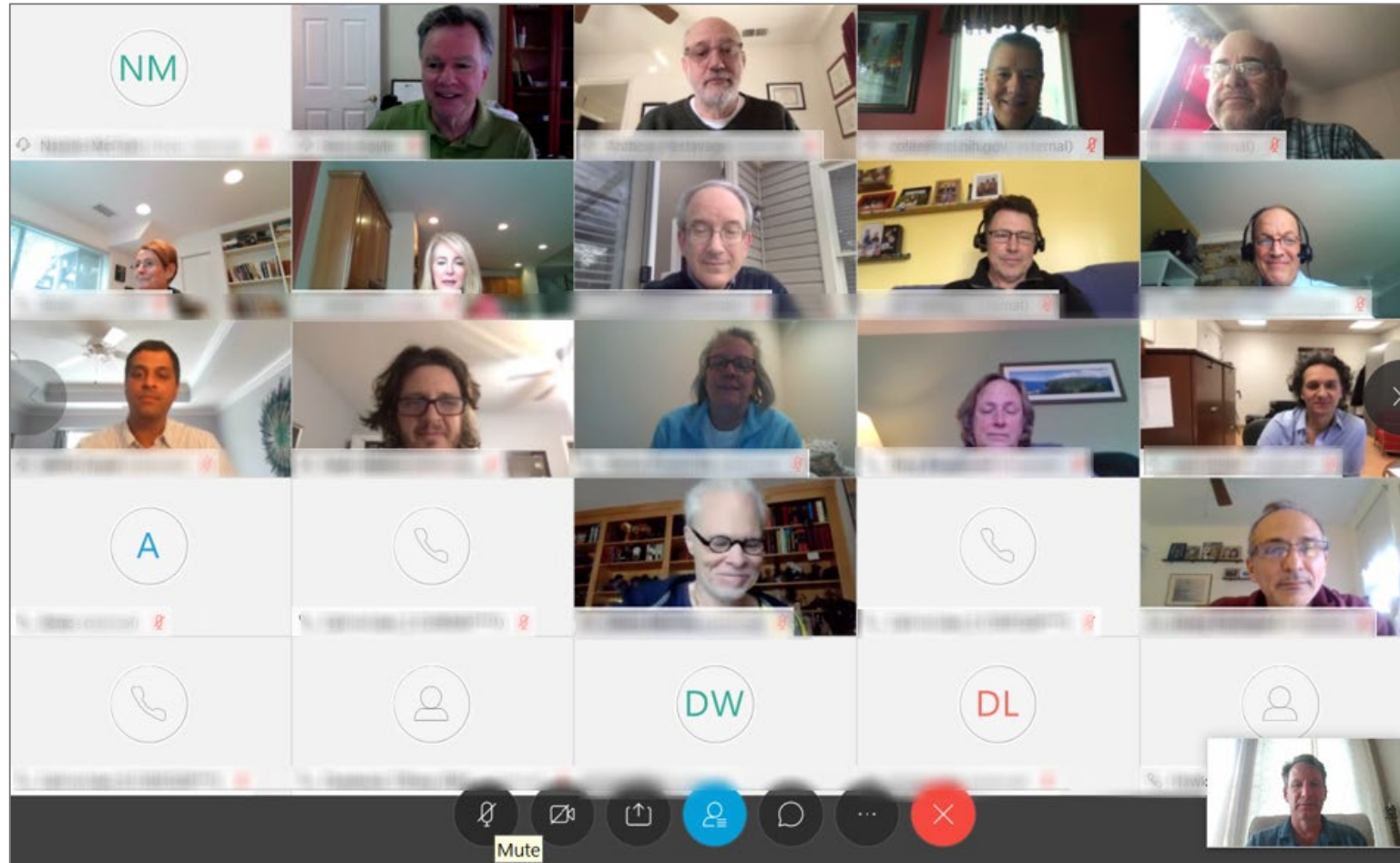
Progress in cancer research

- Study of Anti-CD33 Chimeric Antigen Receptor-Expressing T Cells (CD33CART) in Children and Young Adults With Relapsed/Refractory Acute Myeloid Leukemia.
 - First patient enrolled at CHOP, cells manufactured at FNLCR
- Selumetinib & NF1 – shrinks tumors and provides benefit to children with inoperable plexiform neurofibromas
 - Approved by FDA on April 10
- Natural Killer (NK) cells & metastasis – development of macrometastases from dormant tumor cells is suppressed by NK cell surveillance
- Serial Measurements of Molecular Responses to Treatment (SMMART) - elucidate mechanisms of response and resistance for the individual patient as they evolve during treatment by integrating clinical, -omic and multiscale imaging

NCI's response to COVID-19

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- Continuing progress in cancer research
- **Special considerations for grantees and trainees**

NCI is “Open for Business”: We are teleworking!



NCI is open for business



Extramural
staff are
working
remotely



Applications
are being
processed



Peer review
meetings are
occurring
virtually



Awards
are
being
made

NIH guidance for grantees

- Extended deadlines for applications; no justification required
- Use of NIH grant funds for salaries and stipends
- Flexibility regarding project extensions and accommodating unanticipated costs
- Extensions of post-award reporting requirements
- Numerous flexibilities regarding expenditures of funds
- Extensions for early stage investigator eligibility due to COVID-19-related disruptions will be considered
- NIH will be flexible with extending time constraints for fellowship, career development, and training awards, including phased awards

Adjusted application deadlines

- NIH will accept late applications
- No justification for the late submission is needed
- After May 1, late applications may not be reviewed until the January 2021 round
- FOAs expiring within this time period will be extended for 90 days

Grant flexibilities

- For grant recipients affected by COVID-19, NCI is allowing:
 - Pre-award costs to be incurred
 - Prior approval requirement waivers
 - Numerous flexibilities regarding expenditures of funds
 - NCI will exercise maximum flexibility in reviewing the carry forward requests
 - NCI will consider various options in awarding next year's Type 5's (e.g. awarding the full commitment level in addition to carryover if the needs are immediate).

Salaries & stipends

- If unable to work on grant or training activities, salaries and stipends may be charged to NCI grants
 - Ensure that your organization's policy allows such charges and then notify NCI
 - Prior approval is not required to divert faculty from research to clinical work related to COVID-19 until the end of the public health emergency period.
- Much can be accomplished working remotely – data analysis, manuscript writing, planning for future experiments, mentoring

Research Performance Progress Report (RPPR)

- NCI understands the potential effects of COVID-19 on the progress of NCI supported research.
- Grantees must contact NCI regarding any stoppage or disruptions to their research.
- NCI recognizes that there may be delays in submission of RPPRs and other reports. If so, contact the assigned grants management and/or program official to let them know the reports will be late.

Conference and travel costs

- **Non-refundable costs** associated with grant-related travel that has been cancelled due to COVID-19 may be charged to the grant if they would have otherwise been allowable.
- Where grant funds support a **specific in-person activity (e.g. conferences, steering committee meetings, training, etc.)**, recipients may use their existing resources to re-budget costs for allowable grant activities within the scope of the award.
 - This includes costs to support virtual meetings and events

Administrative supplements

- Administrative supplements for non-COVID-19 needs will be considered when absolutely necessary.
- In general, requests for administrative supplements should be delayed until:
 - The full impact of the pandemic on the research are clear,
 - The various options have been discussed with the relevant NCI staff

See [NOT-OD-20-086](#) for details.

Early stage investigator (ESI) eligibility



Extensions of ESI eligibility to accommodate loss of research time due to COVID-19-related disruptions will be considered.

NCI policies on training

Flexibility in...

- Management of existing awards to institutions
- Extending awards to allow trainees to complete their work, particularly for those in late phases of their programs.
- Extending time constraints for fellowships, career development, and training awards, including those with “career clocks” that can determine transitions (e.g. K22, K99/R00) or eligibility to apply
- Accepting late applications

More information

NIH

[COVID-19: Information for NIH Applicants and Recipients of NIH Funding](#)
[+ FAQs](#)
[NOT-OD-20-086](#)

NCI

- [Coronavirus: Guidance for Cancer Researchers](#)
- [NCI Bottom Line blog – April 8](#)
- [NOT-CA-20-042](#)
- [NOT-CA-20-048](#)



NIH NATIONAL CANCER INSTITUTE

CONTACT US FOR HELP

Emergency Resources

Coronavirus Information for Patients

Coronavirus Information

Coronavirus: Guidance for Cancer Researchers

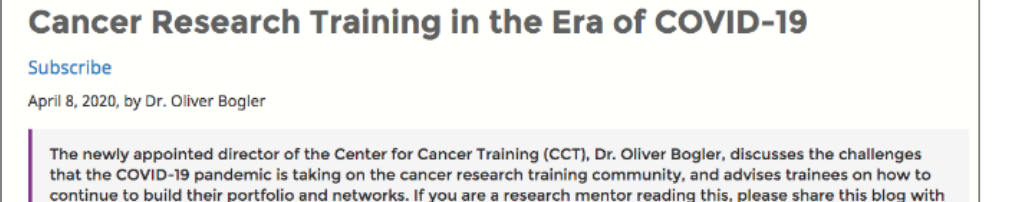
COVID-19 is affecting daily life around the globe, but the National Cancer Institute (NCI) remains committed to sustaining progress against cancer. NCI and the National Institutes of Health (NIH) are taking affirmative steps to help investigators deal with the challenges of conducting research during this time.

The following resources provide guidance that cancer researchers may find useful.



NIH GRANTS & FUNDING
NIH Central Resource for Grants and Funding Information

Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding



Cancer Research Training in the Era of COVID-19

Subscribe

April 8, 2020, by Dr. Oliver Bogler

The newly appointed director of the Center for Cancer Training (CCT), Dr. Oliver Bogler, discusses the challenges that the COVID-19 pandemic is taking on the cancer research training community, and advises trainees on how to continue to build their portfolio and networks. If you are a research mentor reading this, please share this blog with



CORONAVIRUS DISEASE 2019 (COVID-19)
Information for Applicants and Recipients

cancer.gov/coronavirus-researchers

COVID-19 is

What people with cancer should know: <https://www.cancer.gov/coronavirus>

Guidance for cancer researchers: <https://www.cancer.gov/coronavirus-researchers>

Get the latest public health information from CDC: <https://www.coronavirus.gov/>

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>



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