|  | **Closing** | **Reopening – Face to Face Clinical Research** | **Reopening – Face to Face non-Clinical Research** | **Additional Relevant Websites** |
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| **UVA** | [VPR Announcement – Requirements Specifically for Human Subject Research](https://secure-web.cisco.com/1nfgpIeMUWpZZ_tzeRw6oMcfpqwC-jenxPtw2HSiuIncsCbZVgUX7UjdX4-R_9RMqfpIrHBwr8duzaIJRxE8cNrNzGu-Mm0wtEpOjE3BJ9KHyCdnLW9aPOdOJpj9fKXk4h9yY5J3PiiAaxl_ZfRYXyutyCwjIJ0n7LazYK43Ji0OCchOMFgAZheGyUfhKInmIBMa_wfuEmjZBkdJkdexZPLm3ghfWIrXaLOvK0y9uY6yUXf_GoA8Fc-B07TsbGockRWMuTB_ClHKjeivJsTviQdIiYnXB1GrGwUN70tLKuEpPS-PF-EGTxmuFjnw4Jqjfg_2kd1g845ppPMobw3I_ncsFrDEmJbLCnJ40BGEKNlzdqG19AYeUtXWakzaAeCANMWXlyiPlmwKoSP8oYoidXUFQ6BATlh3RaChpnI9sR0edA5Yav9lWkW3y2bzdgm8L/https%3A%2F%2Fresearch.virginia.edu%2Firb-hsr%2FCOVID19)  **Paused March 16, 2020.**  Beginning Monday March 16th, the Vice President for Research office requires the following:  For all human subject research studies that involve direct subject contact, and that provide little or no potential benefit to subjects - human subject direct contact (face to face) must be paused until further notice in recognition of the COVID-19 pandemic. This directive is being made to decrease exposure for our staff, faculty and learners as well as research subjects. All other aspects of the research that do not involve direct human subject contact may be continued.  It is anticipated that certain types of human subject research will be allowed to continue. These include (but are not limited to):   1. FDA regulated clinical research that has the potential for direct health benefit to subjects. 2. Interventional/ treatment trials that have the potential for direct health benefit to subjects. 3. Studies that do not meet the criteria of # 1 and # 2 above and that have no physical or direct subject contact.  These are studies done via mail, phone, online, etc. or could be those involving things like review of medical records/ archival data/ public data sets or studies that are in the status of data analysis. | Earliest reopening for research not paused: **June 1, 2020**  <https://research.virginia.edu/sites/vpr/files/2020-06/ReturnToClinicalResearchJune30.2020.pdf>  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval required before projects may be (re)started.  Requires significant COVID-related safeguards  Tiered approach to re-opening human subject clinical research: June 1, 15, and July 1.  • Tier 1 – **(June 1, 2020)**: May continue those studies that were not previously paused, and may now start or restart those studies that do not have a potential for health benefit and require minimal face to face contact with subjects (e.g., a study requiring only a single blood draw within UVA Health or a study being conducted outside of UVA Health of a short time frame (e.g. less than an hour) provided the guidelines below are followed,  • Tier 2 – **(June 15, 2020)**: In addition to the studies in Tier 1, study personnel may now start or restart those studies that do not provide a potential for health benefit to the subject and that involves only a small number of face to face visits, with each visit lasting a moderate time frame (e.g., less than 4 hours /visit) and require a limited use of core or auxiliary services (e.g., CRU, BTRF).  • Tier 3 – **(July 1, 2020)**: All other human research studies, including those without a potential for health benefit, including biorepository specimen collections, observation studies, and other non-treatment clinical research may resume. At this time representatives from sponsors for site monitoring or site initiation visits will still not be allowed. | Earliest reopening for research not paused: **July 1, 2020**  <https://research.virginia.edu/sites/vpr/files/2020-06/ReturnToClinicalResearchJune30.2020.pdf>  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval required before projects may be (re)started.  Requires significant COVID-related safeguards  See Research Ramp-up Guidance  <https://research.virginia.edu/research-ramp-guidance>  Timeline for re-opening non-clinical research:   * Phase 1: Research off-grounds with human subjects which was not previously paused, may continue provided that face-to-face contact is not required. * Phase 2: (**July 1, 2020)** Off-grounds research with human subjects requiring face-to-face contact. * Phase 3: (**October 1, 2020)** Research with human subjects requiring face-to-face contact on grounds or under lease by UVA in support of UVA faculty and staff activities. | [COVID-19 FAQs Related to Human Subject Research](https://secure-web.cisco.com/1eY23KOJT0XWbSHhgXD76cNIPuCp1KfuEKovAkftHrstb9ELJCo5V8NUa6xvHrpSV9hqMCGMhrJdVTXXpC8D5vHkMR4XTA6reuOW02XPCmU_5vzKjfUGQP3c89Z8mEYna_sYDOkF2B5bk_BQ7En5DSYp6nVQnrTT_78BPUdfZ5Ob43QL7HOgie2Bb2P8_usI324Xxy88jiaL-zy8ALQ-1VZg5UP9tEq4ZZs4UZaROgmuC8PhZRjpHuhhmoKa_SiKbTk_DjW598mNn53SDjc0I5XpQV8w8D0QWsJlDh4YTVlnWinMjVV3qWXgtMy0qYkeQnONFPXRIiHOvNXVUE5zdUPcYQcNP13AmG1-X6kF7ZOX4k_Su-O_jhX67Y2PIo6loF8opEdguhUOMQoTRZJgP_7p3GgTDPCwhaiI3CRN1ZDImP62PQZJnqCNXH_fgFHYd/https%3A%2F%2Fresearch.virginia.edu%2Fhuman-research-protection-program%2FCOVID19FAQs)  [COVID 19 Research Prioritization Committee (CRPC)](https://secure-web.cisco.com/1_Krm2xKrNQdhzGQi77gd82WtiFPGAE8y0wjIJGcWCRfKQb1xTN4lx1Vwo3Irbqd61UMS6sYB9TP0UmGtUzGYJCgZVqKbxjPJT8y9dRIOvHF18hcSDuZNdwYbYTpyfzQeFgMIZNmbfZZg4RTJjqRn6-d8YoViwZ_ryuuWem896grHkl4vMKRCfIQIaB5tikoHbgobaV9feH-SWZhJpedN3sa9O-Z-7dBLNS6gJv7avkYtyvIJYg6qK_V102whzEFOl3isoJinpHiIZTuK1Cd02_Ovp1NynfHRFh-cXu9NJtECaW5u4aUE_T6ch1mATAU2c2LTn1PqdWIH40Vx3IGCLZH5YUJ2DJosWrkwaiunL5Uyeti3l9MEUKRT3qS_cEj8Xjv6si1J5prCTjBNYJaIBQIJy2hM0MFhcuiovmSrzig8SgdhcYS4z3kJSCqjX352/https%3A%2F%2Fresearch.med.virginia.edu%2Fclinicalresearch%2Fcovid-19-research-prioritization-committee%2F)  [VPR Research Continuity Guidance Website](https://secure-web.cisco.com/1T8C3uheC3WMJ845h27pjSu9JWkvGA4a7fr8lMuYk3RrNB16YZnB1iMYbmO_0HgAREuvPCaAzuPGIyNRXccYdKfGX_OWwJ76y86QFZxkVk-q2cpjLwSPX_1cImH0ICZMmhcs3axDg9fAPJYBXg5gNbRzNeo_DYMaOKHSYEWmK05yMHRTa3nCtMidXJK_i372c6SWD4mXMX0W_XKZC69Xo11J4V3WJIbQZ7cSMUdKmX3cBjusMmWzKGkZqa0veiIqtU6OCNlDrh9Vhz3t2dVxl7-XC3GnkRKEv7G3QvEGnP37v6UYsELmP3E7FXV2r7TSp3tCUVgX6jopcCukYtn6S7zOzI_Vs1oRgPdmOuVGM1g9J9m53JXYZj99jBG_SCnSPKz6GbuY05ZIo-Umix-h7V0kzSxSDrTlUCArNdkKhnMZ6uA_KD24olUZnWNnfuEGj/https%3A%2F%2Fresearch.virginia.edu%2FResearchContinuity) |
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| **ODU** | **Paused March 18, 2020.**  **Research Restart Plan disseminated on May 14, 2020**  “All human research activity involving in-person interaction with participants must pause immediately. This requirement applies regardless of the IRB of record approving the ODU human research activity.”  <https://www.odu.edu/emergency/news/2020/2/novel_coronavirus_co/faculty-resources/research-activities#tab21020202=0>  <https://odu.edu/news/2020/2/novel_coronavirus_od#.X3S3mWhKiUk> | Earliest reopening for research not paused: **June 10, 2020**  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval and IRB approval required before projects may be (re)started.  Requires significant COVID-related safeguards  **Phase 1: (June 10, 2020)** Human subjects work in re-opened clinics may begin if the research is part of standard of care, subject to IRB approval.  **Phase 2: (July 13, 2020)** Permissiblework in re-opened clinics expands beyond standard of care interventions to include projects that do not require additional travel to research site on the part of the participant (e.g. project takes advantage of participant being in the research setting naturally). | Earliest reopening for research not paused: **October 1, 2020**  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval and IRB approval required before projects may be (re)started.  Requires significant COVID-related safeguards  **Phase 3: (October 1, 2020)** In-person human subjects research may resume if social distancing can be maintained. Participants and researchers must wear masks. Higher risk studies (e.g. indoor strenuous exercise studies; close proximity work greater than 15 minutes) are prohibited. All new and restarted activity is subject to IRB approval. | [ODU Novel Coronavirus/COVID-19 Updates](https://www.odu.edu/emergency/news/2020/2/novel_coronavirus_co)  [Fall Semester 2020 Reopening Plan](https://www.odu.edu/content/dam/odu/admin/blueprint/fall-semester-2020-reopening.pdf) |
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| **Naval Medical Center Portsmouth** | **Paused early to Mid March 2020**:  Reduced Entrances, Screening begun, IRB Staff start telework  Late March, 2020:   * Limits on prospective Research Activities * Critical / essential research only * Research without oversight halted * Prioritize COVID research * Hierarchy for other research needs | **May 2020**  Requires significant COVID-related safeguards  Return to more routine clinic visits and surgeries  Most prospective research allowed to resume with safety measures  Prohibited research using procedures that are not standard of care  Recommend amending research to reduce exposure and take advantage of virtual options  No travel to extramural research sites  No focus groups or other research activities with greater than 10 people | **May 2020**  Requires significant COVID-related safeguards  Return to more routine clinic visits and surgeries  Most prospective research allowed to resume with safety measures  Prohibited research using procedures that are not standard of care  Recommend amending research to reduce exposure and take advantage of virtual options  No travel to extramural research sites  No focus groups or other research activities with greater than 10 people |  |
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| **George Mason** | **Paused March 21, 2020**  Research in Mason labs and facilities restricted only to critical activities.  No IRB approval required for temporary pause in research activity.  Researchers who wished to add team members to list of those permitted access to identifiable human subjects data (for COVID contingency purposes) encouraged to file protocol amendments with the IRB. | Earliest reopening for research not paused: **April, 2020**  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval and IRB approval required before projects may be (re)started.  Requires significant COVID-related safeguards  **Phase 1: (March 21, 2020)** – COVID-related research only, with a few narrow exceptions possible with University permission.  **Phase 2: (June 11, 2020)** – Clinical research not related to COVID permitted, if the research is part of standard of care.  **IRB approval letters noted university COVID approval required:**  “You are required to follow the George Mason University Covid-19 research continuity of operations guidance. You may not begin or resume any face-to-face interactions with human subjects until (i) Mason has generally authorized the types of activities you will conduct, or (ii) you have received advance written authorization to do so from Mason's Research Review Committee. In all cases, all required safeguards must be followed.” | Earliest reopening for research not paused: **July 1, 2020**  Coordinated with Governor Northam’s Phased Reopening Plans  University committee review and approval (Phases 1 & 2), department/Dean approval (Phases 3+) required before projects (re)started.  Requires significant COVID-related safeguards  **Phases 1-2: (March 21-June 30, 2020)** No human subjects research permitted that requires face to face interaction or researcher presence on campus. No field research involving human subjects.  **Phase 3: (July 1, 2020)**  Face-to-face interactions with human subjects in which there is no physical contact between the subject and researcher generally permitted to resume with prior written approval from the researcher’s department and college. (No research involving vulnerable populations permitted.)  **Phase 4: (August 1, 2020)**  Same as Phase 3.  **Phase 5: (August 24, 2020)**  IRB- approved human subjects research may resume with department/dean approval, and inclusion of COVID safeguards. Studies in which face coverings are removed for any length of time or physical distancing is not maintained are subject to heightened approval requirements. | [Mason Research Continuity Guidelines](https://www2.gmu.edu/safe-return-campus/research-continuity-guidelines)  [IRB and other research support COVID guidelines](https://oria.gmu.edu/topics/covid/)  [Safe Return to Campus](https://www2.gmu.edu/safe-return-campus-plan/repopulation-campus)  [Stage 5 Research Continuity and Safety Plan](https://www2.gmu.edu/sites/core/files/RESEARCH%20CONTINUITY%20AND%20SAFETY%20PLAN%20Stage%205%20Final%208-20-2020_0.pdf) |