

# Phase 2 Intake Form

**FOR REVIEW AND PREP ONLY - DO NOT SUBMIT**

Please read all instructions before completing the form below.

## Instructions for Phase 2 of the 4-Phase Research Ramp-up Plan

**This form is intended for ramp-up to Phase 2 of the university's 4-Phase Research Ramp-up Plan. Using the COVID-19 Related Safety Guidelines for Research Ramp-up as a resource, please complete the requested information to the best of your ability with the goal of addressing Research Ramp-up Phase 2:**

**On-site research area occupancy increases to < 50% (compare to < 30% in Phase 1)  
Undergraduate involvement not permitted All gatherings, travel, and off-campus research activities must abide by VU guidelines If you have additional plans you can describe now that would apply to future phases of the ramp-up plan (Phases 3-4), please feel free to note them in your responses. You will be able to revise and expand any plans you describe in this form for future phases (Phases 3-4) of ramp-up.**

**For any questions that do not apply to you and your research, simply reply "N/A."**

**If additional information or documentation is required, you will be contacted separately. You will be notified of approval as soon as practicable, including the date on which you may resume on-campus research activities, as well as any special requirements or limitations.**

**Please note that you may not see/answer all possible items on this form. This is deliberate. In order to keep this form as short as possible for each respondent, built-in branching logic ensures you are asked only the items that are relevant to your Phase 2 research activities based on your answers to previous items. For this reason, you may notice that the items on this form do not proceed in normal numbered order. For example, you may answer items 1-9, but then skip to item 13. If this happens to you, do not be alarmed; unusual numbering is a normal side-effect of the built-in branching logic.**

- 1 During Phase 1 ramp-up of on-campus research activities, did you submit a completed Phase 1 intake form to your associate dean for research or other supervisory entity?
- Yes, I submitted a Phase 1 intake form and was approved to begin on-campus research activities in Phase 1.
  - Yes, I submitted a Phase 1 intake form, but I was NOT approved to begin on-campus research activities in Phase 1.
  - No, I did NOT submit a Phase 1 intake form.

**BASIC INFORMATION SECTION**

2 This Phase 2 intake form corresponds with the Phase 1 submitted project entitled

[phase1\_project\_name]

for which

[phase1\_pi1\_first\_name] [phase1\_pi1\_last\_name]

was listed as the lead researcher, with the following research personnel:

[phase1\_requested\_personnel]

This project was [phase1\_approval].

If this is not the project you are attempting to amend for Phase 2, DO NOT CONTINUE. Please stop now, and contact ovpr@vanderbilt.edu for assistance.

3 Select the appropriate supervisory entity for review and approval of this Phase 2 intake form.

In most cases, the appropriate supervisory entity is the school or college in which the lead researcher has their primary appointment (e.g., a faculty mentor/PI appointed in the College of Arts and Science would select College of Arts and Science).

If you're not sure which entity to select, see the Research Ramp-Up Review and Approval Process for further guidance.

If you applied in Phase 1, please select the same supervisory entity for review and approval in Phase 2.

- Blair School of Music
- College of Arts and Science
- Graduate School (select this option if you are a VUMC PI mentoring a VU grad student)
- Law School
- Owen School of Management
- Peabody College of Education and Human Development
- School of Engineering
- School of Medicine - Basic Sciences
- School of Nursing
- Other (e.g., trans-institutional research center or institute reporting to the Vice Provost for Research)

4 Please select your research center or institute from the drop-down list.

If you are affiliated with a different center or institute not listed among these options, please select "Other not listed."

- Advanced Computing Center for Research and Education (ACCRE)
- Center for Integrative Cognition and Cognitive Neuroscience (CICN)
- Center for Research on Men's Health (CRMH)
- Curb Center for Art, Enterprise, and Public Policy at Vanderbilt (Curb)
- Vanderbilt Brain Institute (VBI)
- Vanderbilt Data Science Institute (VDSI)
- Vanderbilt Institute for Energy and the Environment (VIEE)
- Vanderbilt Institute for Nanoscale Science and Engineering (VINSE)
- Vanderbilt Institute for Surgery and Engineering (VISE)
- The Wond'ry
- Other not listed

5 Department name (optional)

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6 Lead researcher (mentor/PI) given (first) name

In the case of a research center or institute, this would be the director's given name.

For lead researchers who already applied in Phase 1, re-entering your given (first) name here ensures that your Phase 1 and Phase 2 intake form data are matched in the RedCAP database.

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7 Lead researcher (mentor/PI) family (last) name

In the case of a research center or institute, this would be the director's family name.

For lead researchers who already applied in Phase 1, re-entering your family (last) name here ensures that your Phase 1 and Phase 2 intake form data are matched in the RedCAP database.

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8 Lead researcher (PI/mentor) Vanderbilt email address

For example:

john.doe@vanderbilt.edu

For lead researchers who already applied in Phase 1, re-entering your email name here ensures that your Phase 1 and Phase 2 intake form data are matched in the RedCAP database.

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9 Project name and general description of research activities during Phase 2 ramp up.

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## RESEARCH PARTICIPANTS SECTION

### 10 Research Activities with Research Participants in Phase 1 versus Phase 2

All research activities involving research participants (often referred to as "human subjects") require IRB approval and must abide by all relevant on-campus and Metro Nashville safety guidelines and protocols including but not limited to those related to COVID-19. Refer to the Vanderbilt Human Research Protections Program COVID-19 Updates for more information on protocol changes that require additional IRB approval.

GROUP 1 ACTIVITIES - With appropriate IRB approval and safety protocols, the following activities with research participants WERE PERMISSIBLE in Phase 1 and REMAIN PERMISSIBLE in Phase 2:

VU faculty, staff, and student researchers engaging in in-person research activities with research participants in VUMC spaces For example, treatment of clinical patients or observational research in healthcare service settings (e.g., operating rooms) VU faculty, staff, and student researchers engaging in remote research activities with research participants in VU or VUMC spaces, or from their own homes For example, telehealth or online polling VU faculty, staff, and student researchers conducting in-person self-assessment in VU or VUMC spaces, or from their own homes For example, a VU researcher testing an assistive mechanical device on themselves GROUP 2 ACTIVITIES - With appropriate IRB approval and safety protocols, the following activities with research participants were NOT PERMISSIBLE in Phase 1 but ARE NOW PERMISSIBLE in Phase 2:

ON-CAMPUS: VU faculty, staff, and student researchers engaging in in-person research activities with research participants in VU spaces For example, a research participant or group of participants comes to campus to meet with a VU researcher to complete an interaction protocol OFF-CAMPUS\*: VU faculty, staff, and student researchers engaging in in-person research activities with research participants in the field within the Metro Nashville area For example, a VU researcher goes to a research participant's home to complete an intervention protocol \*OFF-CAMPUS research activities with research participants in the field within the Metro Nashville area are being managed through a separate exceptions process not covered in this intake form. If you are seeking to begin research activities with research participants off-campus in Phase 2 either alone or in combination with other research activities with or without research participants on-campus, DO NOT continue this form. Instead, reach out to your dean and/or associate dean for research (if applicable) to request an exception. They will follow up with you to gather all further information necessary to proceed with project review and approval.

- 11 Referring to the definitions and examples above, select the item that best describes your research activities with research participants in Phase 2.
- If your research activities do not involve research participants/human subjects, please select "Neither GROUP 1 nor GROUP 2 research activities".
- Neither GROUP 1 nor GROUP 2 research activities.  
 GROUP 1 research activities only.  
 A combination of GROUP 1 and GROUP 2 research activities.  
 GROUP 2 research activities only.

- 12 WARNING: By continuing this form, you confirm that you will NOT engage in any research activities with research participants off-campus/in the field in Phase 2.

If you are seeking to begin research activities with research participants off-campus/in the field within the Metro Nashville area in Phase 2 either alone or in combination with other research activities with or without research participants on-campus, DO NOT continue this form.

Instead, reach out to your dean and/or associate dean for research (if applicable) to request an exception. They will follow up with you to gather all further information necessary to proceed with project review and approval.

- 13 Does the IRB need to be modified to address significant changes in the research protocol due to COVID-19 accommodations?
- Yes, the IRB requires modification related to COVID-19 accommodations.  
 No, the IRB does NOT require modification related to COVID-19 accommodations.

Refer to the IRB website for important updates and instructions regarding the need for IRB amendments (<https://www.vumc.org/irb/covid-19-updates-research>).

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- 14 Will visitors be accompanying research participants (e.g., parent or guardian of a research participant, aide, etc.)?
- Yes, research participants will be accompanied by visitor(s).
- No, research participants will NOT be accompanied by visitor(s).
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- 15 In Phase 2, how many total research participants do you estimate for this project per week on campus?
- \_\_\_\_\_
- 
- 16 During what general timeframes do you anticipate research participants to be on campus engaging in research activities for your project during Phase 2? Check all that apply.
- Weekdays (Mon.-Fri.) during business hours (8AM-5PM)
- Weekdays (Mon.-Fri.) outside business hours (before 8AM, after 5PM)
- Weekends (Sat.-Sun.) during business hours (8AM-5PM)
- Weekends (Sat.-Sun.) outside business hours (before 8AM, after 5PM)

**RESEARCH PERSONNEL SECTION**

- 17 The following personnel were requested for your Phase 1 on-campus research activities:

[phase1\_requested\_personnel]

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- 18 Of the Phase 1 research personnel listed above, were any personnel unable to complete and submit the Return to Campus acknowledgement?

For example, research personnel who work in the research space in an unpaid capacity (e.g., interns) and/or are employed by VUMC were often unable to complete and submit the Return to Campus acknowledgement in Phase 1.

If YES, please list all such personnel here. Please include all of the following information for each person listed:

Full name (Last, First) Role (Faculty Member, Staff Member, Graduate Student, etc.) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) Vanderbilt Hall, Rooms 200 and 201 Smith, Alice (Faculty Member) Barnard Hall, Room 130 If NO, please mark this item "N/A".

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- 19 List all research personnel (faculty, staff, postdoctoral fellows, and graduate students) who will be working in the research space during Phase 2.

Please include all of the following information for each person listed:

Full name (Last, First) Role (Faculty Member, Staff Member, Graduate Student, etc.) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) Vanderbilt Hall, Rooms 200 and 201 Smith, Alice (Faculty Member) Barnard Hall, Room 130 For lead researchers who already applied in Phase 1: You are welcome to copy and paste your list of Phase 1 research personnel to this item if they have not changed, or use this item to edit your previous list if research personnel have changed.

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- 20 Of all the Phase 2 research personnel listed above, which personnel will be interacting/engaging in research activities with research participants?

Please include all of the following information for each person listed:

Full name (Last, First) Role (Faculty Member, Staff Member, Graduate Student, etc.) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) Vanderbilt Hall, Rooms 200 and 201 Smith, Alice (Faculty Member) Barnard Hall, Room 130

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- 21 Of all the Phase 2 research personnel listed above, which personnel will be, which are POST-DOCTORAL FELLOWS and GRADUATE STUDENTS?

Please include all of the following information for each person listed:

Full name (Last, First) Role (Post-doctoral Fellow OR Graduate Student) Location (building, room) Please use the format of the following example in your answer, with one person per line:

Doe, John (Graduate Student) Vanderbilt Hall, Rooms 200 and 201 If your Phase 2 research personnel includes no post-doctoral fellows or graduate students, please mark this item "N/A".

- 
- 22 How many total research personnel will be engaged in research activities on-campus for this project in Phase 2?

**RESEARCH SPACE SECTION**

- 23 The following locations/research spaces were requested for your Phase 1 on-campus research activities:

[phase1\_requested\_location]

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- 24 Location of Phase 2 research space(s)

Include building name and room number of all research spaces you intend to use in Phase 2 as in the following example:

Vanderbilt Hall, Rooms 200 and 201 Barnard Hall, Room 130A Examples of applicable research spaces include but are not limited to lab space, research-related storage space, and office space used by researchers.

For lead researchers who already applied in Phase 1: You are welcome to copy and paste your list of Phase 1 research spaces to this item if they have not changed, or use this item to edit your previous list if research spaces have changed.

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- 25 Please list all on-campus locations/research spaces that will be used for research activities with research participants.

Include building name and room number of all lab/research spaces as in the following example:

Vanderbilt Hall, Rooms 200 and 201 Barnard Hall, Room 130A

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- 26 Description of research space.

Please include an analysis of the maximum intended occupancy and the closest proximity (in feet) of research personnel in a maximally occupied situation.

In other words, describe your research space as it would normally be used and occupied if COVID-19 safety regulations regarding social distancing and limited occupancy were not in effect.

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- 27 If desired, you may upload a map or diagram of your intended Phase 2 research space(s) here. (optional)



**PHASE 2 PROTOCOLS SECTION**

- 28 Describe plan for ensuring that all research spaces listed above are each never more than 50% occupied in Phase 2, and also for ensuring that research personnel and/or research participants (if applicable) maintain 6 ft of space between them under working conditions.
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Please be specific about how you will coordinate the activities of the members of your research group and/or research participants (if applicable), who is working which shifts and how the investigators are distributed in the lab space (provide diagram as needed; see COVID-19 Related Safety Guidelines for Research Ramp-up for examples).

If the number of members in your research group and/or number of research participants is 50% or fewer than the normal occupancy of your space then "shifts" may not be needed, but you still need to explain how you will distribute people in your space so that appropriate social distancing is maintained.

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- 29 If desired, you may upload a MAP OR DIAGRAM of your intended Phase 2 research space(s) here with annotations depicting social distancing and other safety measures. (optional)
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- 30 If desired, you may upload a SCHEDULE here showing when and where research personnel will perform research activities in Phase 2. (optional)
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- 31 Describe any research activities in your lab or research space that would require 2 or more research personnel and/or research participants (if applicable) to be in closer proximity than 6 ft and your plans for managing those interactions.
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For example, if research activities require close contact, like the measurement of blood pressure, ultrasound, etc., detail if additional personal protective equipment (PPE) will be used, protocol for disinfecting equipment and other important considerations.

If this issue is not applicable in your case, please answer "N/A".

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- 32 List other VU or VUMC location(s) needing to be accessed for Phase 2 research activities outside of the research spaces you listed earlier (e.g., research cores, library).
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If you do not need to access other spaces outside of those already listed elsewhere in this intake form, please answer "N/A".

- 33 Referring to the COVID-19 Related Safety Guidelines for Research Ramp-Up and Prescreening Checklist for Research Participants, describe any additional plans specifically made for the protection of research personnel and research participants.

Questions to address in your response:

Who will be responsible for sanitizing before, during, and/or after research participant interaction? How will research participants be greeted on campus and/or in the research space and what health precautions will be required as they enter the research space? If your research activities involve transport of research participants from one location to another on-campus (e.g., movement from one building to another), what are your plans for accomplishing this transport in a safe and socially distanced manner? How will research personnel and research participants confirm that they are not actively ill with COVID-19 and have not experienced any symptoms of COVID-19 over the past 14 days in advance of participation in research activities? How will this information be collected and stored? Who will be responsible for this step? How will research participants be consented to ensure safety? For example, consent forms can be converted to e-consent to reduce the need for paper and pens, limiting touch to a single cleaned keyboard or to the participant's personal smart phone. If visitors will accompany research participants, what procedures will be implemented to ensure safety and social distancing?

- 34 If needed because of a COVID-19 infection in the lab, in response to University orders (perhaps triggered by local/state/national developments), or for some other reason, it is possible that your lab/research activities need to be ramped down in a short time period.

Briefly describe your plans for a ramp-down and identify any research activities or specific considerations that would require more than one day to be shut down. You are welcome to use Research Continuity Planning as a guide.

- 35 Please refer to the COVID-19 Related Safety Guidelines for Research Ramp-up. Do you agree to implement these precautions?

- Yes, I agree to implement these precautions.  
 No, I do NOT agree to implement these precautions.

- 36 List any additional COVID-19 safety precautions you intend to implement that have not been addressed elsewhere in this form. (optional)

Please note that many precautions are outlined in the university-wide Return to Campus Plan. For ease of operations, please do not plan to implement precautions that conflict with or are in excess of existing university-wide precautions.

- 37 The COVID-19 Related Safety Guidelines for Research Ramp-up provides guidance on how to procure personal protective equipment (PPE) such as masks, gloves, and disinfectant.

Having followed this guidance, does your lab/research space now have at least 2 weeks' worth of PPE available?

Remember to account for research participants (if applicable) in your PPE preparations.

- Yes, my research space has at least 2 weeks' worth of PPE available.
- No, my research space does NOT have at least 2 weeks' worth of PPE available.

**MISCELLANEOUS RESEARCH DETAILS SECTION**

- 38 Do your Phase 2 plans DIFFER from your Phase 1 plans in any of the following areas? Select all areas that HAVE CHANGED from Phase 1 to Phase 2.

For example:

If your Phase 1 plans involved non-human vertebrate animals and your Phase 2 plans also involve vertebrate animals, you would NOT select "Non-human vertebrate animals". If your Phase 1 plans did NOT involve non-human vertebrate animals and your Phase 2 plans also do NOT involve vertebrate animals, you would NOT select "Non-human vertebrate animals". If your Phase 1 plans did NOT involve non-human vertebrate animals but your Phase 2 plans do involve vertebrate animals, you would select "Non-human vertebrate animals". If your Phase 2 plans do NOT differ from your Phase 1 plans in any of these areas, please select "None of the above (i.e., Phase 2 plans remain the same as Phase 1 plans in all of the above areas)".

- Use of additional resources (e.g., Environmental Health and Safety, core facilities)
- Use of non-human vertebrate animals
- Transporting non-human animal experimental subjects between facilities/buildings
- COVID-19/SARS-CoV-2 virus, infected cells/tissue, or infected patients
- VU-VUMC COVID-19 collaboration that involves live virus, infected cells or tissues, or patients
- None of the above (i.e., Phase 2 plans remain the same as Phase 1 plans in all of the above areas)

- 39 List any additional resources needed for research space ramp-up in Phase 2 (e.g., Environmental Health and Safety or Facilities services, supplies, etc.). (optional)

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- 40 Does/will your research activities in Phase 2 involve non-human vertebrate animals?

- Yes, my research activities in Phase 2 involve non-human vertebrate animals.
- No, my research activities in Phase 2 does NOT involve non-human vertebrate animals.

- 41 Does/will your research activities in Phase 2 necessitate transport of non-human animal experimental subjects between facilities/buildings?

- Yes, my research necessitates transport of non-human animal experimental subjects between facilities/buildings.
- No, my research does NOT necessitate transport of non-human animal experimental subjects between facilities/buildings.

- 42 Does/will your research activities in Phase 2 involve COVID-19/SARS-CoV-2 virus, infected cells/tissue, or infected patients?

- Yes, my research involves COVID-19/SARS-CoV-2 virus, infected cells/tissue, or infected patients.
- No, my research does NOT involve COVID-19/SARS-CoV-2 virus, infected cells/tissue, or infected patients.

- 43 You answered "YES", your Phase 2 research involves COVID-19, SARS-CoV-2 virus, infected cells/tissue, or infected patients. Please describe your plan for fulfilling the enhanced containment practices that are applicable to your research.

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See the Vanderbilt Environmental Health and Safety (VEHS) website for specific guidance on enhanced containment practices regarding research involving COVID-19/SARS-CoV-2 virus, infected cells/tissue, or infected patients.

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- 44 Is your research a VU-VUMC COVID-19 collaboration that involves live virus, infected cells or tissues, or patients?
- Yes, my research is a VU-VUMC COVID-19 collaboration that involves live virus, infected cells or tissues, or patients.
- No, my research is NOT a VU-VUMC COVID-19 collaboration that involves live virus, infected cells or tissues, or patients.
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- 45 Are you developing a prototype?
- Yes, a prototype is being developed.
- No, a prototype is NOT being developed.
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- 46 Is this to undertake iterative processes, to improve an existing prototype through testing?
- Yes, this is to undertake an iterative process.
- No, this is NOT to undertake an iterative process.
- 
- 47 How will you build/manufacture the device/product/test kit, etc.?
- \_\_\_\_\_
- 
- 48 Will built/manufactured products be donated or sold to VUMC?
- Yes, built or manufactured products will be donated or sold to VUMC.
- No, built or manufactured products will NOT be donated or sold to VUMC.
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- 49 Is there a potential for new intellectual property (IP) to be developed?
- Yes, there is potential for new IP to be developed.
- No, there is NOT potential for new IP to be developed.
- 
- 50 List VUMC location(s) needing to be accessed for the project.
- Include building name and room number of all VUMC locations as in the following example:
- Medical Center North, Rooms 500 and 501 Medical Research Building IV, Room 350A
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- 51 List VUMC personnel involved in the project and what they will be doing.
- Please include all of the following information for each VUMC personnel listed:
- Full name Role (Faculty Member, Staff Member, Graduate Student, etc.) Location (building, room) Activities Please use the format of the following example in your answer:
- Mary Jones (Staff Member), Medical Center North, Room 500, building prototypes
- 
- 52 Please upload a brief summary (< 1 page) of any other changes to your Phase 1 plans. (optional)

You have reached the end of the Phase 2 Intake Form.

To submit this completed form for review by your dean's office, click SUBMIT below. To save this form and return to it later, click SAVE & RETURN LATER. This will NOT send your form to your dean's office for review. By clicking either option:

You will have the opportunity to save a personalized return code and send a personalized survey link to your email address to enable you to return to this form to revise your responses and/or (re)submit your form to your dean's office. You will have the opportunity to download a PDF of your responses to this form.