**Wherever the form states “Choose an Item,” this is a drop down menu to make a selection; please be sure to make a selection. In the event that you are uncertain about how to answer any of the following questions, please refer to the Additional Detail section immediately following this form or refer back to the “**[**Temporary Guidelines for PIs**](https://und.edu/research/about/covid-19-research-updates.html#d29e84-2)**.” Completed forms should be submitted to Justin Berg at** [**justin.allen.berg@und.edu**](mailto:justin.allen.berg@und.edu)**.**

**Section 1: GENERAL INFORMATION**

1. Principal Investigator (PI) Information

Name:

Email address:

Department:

1. PI’s Department Chair, School Director, or Institute Director (or designee)

Name:

Email address:

Department:

1. Associate Dean for Research (or designee)

Name:

Email Address:

College:

1. If PI is a student, PI’s Advisor

Name:

Email address:

Department:

1. Identify the UND human research study you would like to resume or propose as a new study (if proposing a new study, skip 5A).

5A. UND IRB#(s):

Study title:

Restart request (select all that apply):

☐ Proceed with enrollment of new participants

☐ Resume in-person interactions with previously enrolled participant

5B. Study title:

Identify the potential direct benefit to participants. Choose an item.

Is the study externally sponsored? Choose an item.

If yes, check the box to acknowledge:

|  |  |
| --- | --- |
| ☐ | External sponsors may also have requirements or limitations that impact the restart, and such requirements or limitations may change. Any requirements or limitations placed on the restart by the sponsor will be followed. |

1. State your thesis and provide a detailed explanation of your methodology, including population being studied and all forms of data collection.
2. Briefly describe all of the in-person interactions with participants that will occur for this study, including the maximum number of individuals who will be present for the in-person interactions, the maximum length of time for the in-person interactions, and the number of interactions per participant (e.g. whether there will be multiple study visits).
3. Is collecting data via direct contact with participants the only way to meet the research objectives? Choose an item.
   1. If yes, provide an explanation why.
   2. If no, provide an explanation why alternative methods of data collection that do not involve direct contact with participants aren’t being pursued.
4. Provide a detailed description of all safety guidelines you will be implementing to ensure safety and well-being of research participants and research staff. Please reference guidance available on the Healthy Hawks website in developing your safety protocols: <https://und.edu/covid-19/healthy-hawks.html>
5. Explain how research team members will be trained to ensure proper implementation of safety protocols.
6. If this research is to be conducted off campus, please provide documentation of safety protocols in place at the site of the research. (Attach the outside institution’s safety protocol, if available).
7. Principal Investigator Attestation:

|  |  |
| --- | --- |
| ☐ | Human research or other work capable of being performed remotely must be performed remotely. |
| ☐ | Researchers will obtain any other university approvals needed to conduct the activity (e.g. domestic travel, biosafety). |
| ☐ | The PI (and advisor, if PI is a student) is responsible for implementing, monitoring, and reporting COVID-19 control strategies related to in-person interactions with human research participants (participants), including assuring that the research team has appropriate staffing, resources, and training to support the in-person participant interactions. If at any time those circumstances change and necessary COVID-19 safety precautions cannot be maintained, the in-person interaction must stop, and the IRB must be notified if there are risks to participants as a result of the stoppage. |
| ☐ | Concerns about COVID-19 safety precautions should be reported to the PI, who is then responsible for either addressing reported concerns or working with other UND individuals to address the concerns when needed, e.g. building contacts, UND Office of Safety. |
| ☐ | Safety precautions for COVID-19 may require IRB modification to approved research procedures. Any changes in research procedure or risk/benefit assessment that require IRB approval will be submitted to the IRB for review and approval. Approval of the Human Subjects Research Plan for a Safe Return should be obtained first, and then obtain approval from the IRB for any modifications that require review. |

**FORM ROUTING AND SUBMISSION**

**This form is to be submitted to HSR Restart Review Committee by the PI. A copy should be kept by the PI and shared with the research team, department chair, school director or institute director.**

**I certify that by typing my name below and submitting this form from my UND email, this is an accurate representation of my research and that this document, including its research and safety plans, will be explained to those that work in my research.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Principal Investigator Name** |  | **Date** |

**This form requires approval by:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **HSR Restart Review Committee designee Name** |  | **Date** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Interim Vice President for Research & Economic Development (or designee) Name** |  | **Date** |

**Please submit this form via email to: Justin Berg, Ph.D.,** [**justin.allen.berg@und.edu**](mailto:justin.allen.berg@und.edu)**.**

**ADDITIONAL DETAIL: INSTRUCTIONS FOR COMPLETION OF HUMAN RESEARCH PLAN FOR A SAFE RESTART CHECKLIST:**

* Reference the current Healthy Hawks guidance: <https://und.edu/covid-19/healthy-hawks.html>. **Note:** While Healthy Hawks Safety Levels 1-3 provide general guideposts, each level will itself encompass a range from more restrictive to less restrictive as conditions change. In general, at Safety Level 1, only remote research may be conducted; however, potentially approvable exceptions within Safety Level 1 might include, for example: clinical trials in which stopping the research protocol(s) would risk significant, direct harm to the participants; COVID-19 research; clinical trials for which ALL in-person interactions can occur in the context of a needed clinical care visit (at the specific clinical visit location) AND through interaction with only the clinical care providers the participant would see even if not participating in the research. At Safety Level 2, more HSR can be gradually phased in as risk levels and safety protocols evolve and allow additional approvals. At Safety Level 3, most HSR can begin, within the parameters of continuing UND and public health guidelines. Finally—and regardless of level--in the absence of effective therapeutics and/or vaccines, all research that can be conducted remotely without doing substantive harm to research protocols and outcomes should continue to be conducted remotely.
* Each PI and/or research group must submit a plan for ramping up research operations to the HSR Restart Review Committee for approval prior to submission to the IRB.
* The plan should provide the thesis of your research along with a detailed explanation of its methodology, the population(s) being studied, and all forms of data collection.
* A description of the number and kind of in-person interactions with participants that the research will require, as well as an explanation of why in-person contact is necessary, addressing the following:

Have you planned your research activities so that all work that can be done remotely will continue remotely?

• If yes, identify those activities

• If no, explain why not

If no, identify which of the following categories your research falls within:

A: HSR in-person, without touching. Such activities can be consistent with UND guidelines used for teaching activities, the face-to-face interaction can be physically distanced, and participants at high-risk can be excluded from participation.

B: HSR without direct contact but can’t be physically distanced. Such activities will require additional mitigation strategies, including additional PPE.

C: HSR that requires direct contact (e.g., to collect specimens). Such activities will include additional mitigation strategies and management plans (e.g., how to handle specimens). In addition, these activities will require IBC review.

D: Other. Please explain.

* A detailed description of all safety guidelines the research will implement—in accordance with Healthy Hawks—to ensure the safety of researchers and participants, including consideration of any modifications to the environment to achieve physical distancing, such as installation of new room dividers, respacing of cubicles or changing areas; specification of needed PPE (gloves, gowns, respiratory and eye protection); and availability of PPE in required quantities. If the research includes Aerosol-Generating Procedures (procedures likely to induce coughing), the plan should include justification of such procedures and subsequent safety protocols.
* The plan should explain include training, as necessary, for proper implementation of safety protocols, including the safe donning and doffing of PPE for all involved in the research protocols: explicit instructions can be found at <https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf>.
* The ramp-up document should include a detailed plan for transitions to additional contact or less, as those reflect UND and public health guidelines, and should be re-evaluated regularly and updated as needed. Approval of the plan sets the stage for implementation, which can *only* occur upon specific announcement of university leadership that research may transition.
* If the plan for transition involves changes to the research as currently approved by the IRB, a modification should be submitted and approved by the IRB prior to implementing the change.
* Will research personnel and/or participants need to go into non-UND facility areas to interact with research participants?

If yes, identify the locations where these interactions with research participants will occur; identify the plan for determining the health status of these research participants (healthy people, immunocompromised, seniors, etc.) and how PPE will be provisioned and social distancing measures be implemented at the off-site. If the off-site has adequate COVID-19 screening procedures and safety protocols—as or more stringent than UND safety protocols in place, researchers will not need to do additional screening, but must provide a copy of or link to the off-site’s screening procedures and safety protocols.

How you will prevent the transmission of COVID-19 back into campus spaces?