Human Research COVID Risk Checklist

1. Locations			
A. Select any locations in which research procedures are planned		*B. Select any safety procedures employed by the study team*	
☐	Hospital or other health care facility	☐	Study procedures will be conducted by staff or others already in the facility, on behalf of researchers.
☐	Long-term care, senior living, or other assisted living facility		
2. Subjects			
*A. Select any criteria which are expected to apply to the subject population**		*B. Select any safety procedures employed by the study team*	
☐	Over 65 years of age Immunocompromised Serious heart conditions Chronic lung disease Severe obesity Diabetes Liver disease Chronic kidney disease (on dialysis) Under 2 years of age	☐	Subjects will be pre-screened based on the criteria selected, and those subjects identified at elevated risk will not be enrolled
3. Procedures			
A. Select any planned procedures		*B. Select any safety procedures employed by the study team*	
☐	Study personnel will approach subjects within six feet	☐	Subjects and study personnel will wear face coverings for duration of interaction
		☐	Approach within six feet will only occur as long as necessary to complete research task
☐	Study personnel will make physical contact with subjects	☐	Subjects and study personnel wear face coverings for duration of interaction
		☐	Pre-screening of subjects and study personnel for fever, symptoms, and exposure to individuals who have tested positive for COVID-19
		☐	Contact will only occur as long as necessary to complete research task
☐	Subjects will be asked to touch or hold surfaces or objects	☐	All surfaces and objects used will be disinfected prior to and after research intervention
☐	Study personnel will collect biospecimens from subjects by non-aerosolizing methods	☐	BSL 2+ precautions will be implemented, per approved IBC protocol
		☐	Pre-screening of subjects and study personnel for fever, symptoms, and exposure to individuals who have tested positive for COVID-19

* Select if research targets or expects subjects in these categories to be enrolled. Only when procedures selected under 3(A) are included should research that enrolls a broad subject population

	Presumed Standard Risk	Potentially Elevated Risk
Checklist	Items in 1(A), 2(A), or 3(A) are selected, as well as all corresponding safety procedures.	Items in 1(A), 2(A), or 3(A) are selected, but not all corresponding safety procedures.
Amendment*	No amendment is required to account for COVID-19 risk. Safety procedures may be integrated into study without amendment.	Submit an amendment with the completed worksheet attached, and provide justification for conducting study without those safety procedures.
Informed Consent	New language describing standard risk of COVID-19 should be added to informed consent document without amendment.	Language will need to be drafted by the study team to explain which study activities increase risk of COVID-19, and safety procedures that will be employed to prevent it.
Pre-study Communication	New template pre-study communication must be provided to potential subjects when recruited or during informed consent process.	New template pre-study communication must be provided to potential subjects when recruited or during informed consent process. Some language may need to be added to the document to identify specific activities that elevate risk to subjects. Include document in amendment submission.
Minimal Risk	Presumption that activities do not increase risk above probability and magnitude of that encountered in daily life.	Study activities have the potential to increase risk above probability and magnitude of that encountered in daily life.
Exempt/ Expedited*	Unlikely that re-evaluation of previous determination of minimal risk is necessary. You may contact ND Research Compliance if you believe your research has the potential for elevated risk even with safety procedures in place.	Potential that study may require Full Board review as a new study. Please contact ND Research Compliance if you believe your study is unlikely to meet the definition of “minimal risk.”
Full Board*	No need to submit new study or amendment.	No need to submit new study, amendment covers information needed for review.

* Applies to already-approved studies