Appendix N: Resumption of In-Person Human Participant Research Plan and PI Attestation

As human participant research activity resumes following a pandemic/public health crisis, consideration must be given to the procedures related to **in-person study visits** that will protect the participant, the PI and the research staff from exposure to the contagion. Please complete a Resumption of In-Person Research Plan, for IRB approval, describing the plan to mitigate risks of in-person study visits. Please submit the plan with new initial protocol submissions and as an amendment for currently active protocols.

*Whenever possible, research should **maintain remote study interventions/visits,** as per IRB approval. Consideration for limiting the number of in-person visits is important for the protection of the participants, the PI and the research staff.*

Informed consent is an ongoing, interactive exchange of information that begins with recruitment of the participant and continues through the completion of the study. For research that was paused during the public health crisis, the IRB recommends that the currently enrolled participant's willingness to continue in the research be documented. This can be done by reconsenting the participant with the approved consent or a consent addendum, or documenting participants' verbal assent in the research record.

COVID-19 Precautions Guidance:

For research conducted within the Standard medical care/hospital setting, please follow that site's COVID-19 standard operating procedures.

- For research conducted at a WSU research facility, refer to the university's guidance: Information on restarting WSU research operations: https://research.wayne.edu/coronavirus/restartguidance.
- Refer to the State of Michigan 's "MI Vacc to Normal" https://www.michigan.gov/whitmer/0,9309,7-387-90487-558091--,00.html
- Refer to the CDC Guidance, e.g. Get Your Clinic Ready for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinic-preparedness.html

Resumption of Research IRB Submission Instructions

For existing IRB approved studies, this appendix must be submitted along with the appropriate amendment form. The amendment submission should include any new or revised participant materials and communications (i.e. Consents, Consent Addendum, Research Information Sheet, Script, etc.).
For new study submissions, this appendix must be included in the initial IRB submission documents. The completed appendix should be attached to the Protocol Information- Attachments section of eProtocol.

- **Non eProtocol**: Paper-based amendment submissions should be saved in a zip file with the PI's name and IRB number and submitted to eIRBManager@wayne.edu. Please use either the Expedited Amendment Form or Full Board Amendment Form based on the instructions below.
- **eProtocol:** Select "Start an amendment" and complete this appendix and attach to the Protocol Information -Attachments sections. All other updated forms and documents should be attached to the appropriate sections: Consents and Research Information sheets attached to the Protocol Information-Consent Information section and all other documents attached to the Protocol Information-Attachment section
- **Full Board Amendment:** If the study was initially reviewed and approved by the Full Board, the Resumption of In Person Human Participant Research amendment will need to be a Full Board amendment. Please review the IRB Meeting Dates and Deadlines schedule for submission to the appropriate IRB committee. This schedule can be found athttps://research.wayne.edu/irb/meetings-deadlines
- **Expedited Amendment:** If the study was initially reviewed and approved as an expedited or exempt submission the Resumption of In Person Human Participant Research amendment will need to be submitted as an expedited amendment. *Please note that if upon review of the amendment it is determined that the study is no longer minimal risk, the IRB Administration Office will contact the PI with instructions to submit as a full board study.*

Section A: Administrative Information

1.	Current Study Title:			
2.	IRB #		Date:	
3.	Principal Investigator:		PI Email:	
	Department:		PI's Phone:	
	Campus Address		PI's Pager:	
4.	Form Completed By:		**Email:**	
	Research Role:		Phone:	

Section B: Study Site Details

Site Approval:

Before initiating research activities, contact the WSU site administrator to obtain approval to conduct the research at that site. The site's review of the research site utilization plan and the IRB review of Appendix N can take place concurrently.

- If available, please include the site's approval for the Site Utilization Plan with this submission.

5.	Will study visit(s) be conducted in a standard medical care/hospital setting? **Note:** This does not apply to sites designated to provide only clinical research interventions.	☐ Yes: Go to question 6 ☐ No: Skip to question 7
6.	The standard medical care/hospital institution's COVID-19 Standard Operating Procedures (SOPs) includes a plan to:	**Select all that apply:** ☐ Inform participants/patients, staff and visitors about COVID-19 risks; ☐ Screen participants/patients, staff and visitors for COVID-19 symptoms; ☐ Provide guidance for the conduct of person to person visits that includes social distancing, PPE, handwashing and disinfection? If all of the boxes above are checked then, **STOP you do not need complete this Appendix. Please follow the Clinical Care/Hospital Institutions COVID-19 SOPs.** ***At the next amendment and continuation indicate that the standard medical care /hospital institution's COVID-19 SOPs were followed, this appendix does not need to be submitted.**

7.	Will study visit(s) be conducted at a Wayne State site?	☐ Yes For research conducted at a WSU site, refer to the university guidance: https://research.wayne.edu/coronavirus/restartguidance ☐ No
8.	Will the study visit(s) be conducted at nonaffiliated WSU site(s)?	☐ Yes: *If yes, research that is of no direct benefit to participants conducted at a nonaffiliated WSU site(s) must submit with the study's mitigation plan the non-affiliated study sites' approval/letter of support to conduct in-person research activities. This approval/letter must address approval/support to resume research activities at their site effective July 1, 2021.* ☐ No: Skip to question 9
9.	Does this research provide a **direct benefit** to the participant?	☐ Yes: Provide justification for the potential direct benefit then go to question 10. **Note**: There needs to be scientific foundational justification to support the claim that the study involves direct benefit (i.e. literature, previous studies, etc.; literature and previous studies referenced cannot be from the PI's own studies)" ☐ No: Skip to #12

Section C: Benefit Assessment:

Direct Benefit:

A study involves direct benefit when the participant is expected to experience a positive outcome from an intervention related to their direct participation in the research.

- Direct benefit does not include research activities such as a free physical exam, financial compensation, or long-term benefits to society

10. Select all benefits that apply:

Note: If none of these benefits apply, then the study does not provide direct benefit.

Physical Benefits: Yes No

Select the type of physical benefits that apply:

- Therapeutic drug or device trial
- Behavioral interventions such as smoking cessation, drug addiction, diabetes with health improvement
- Will help to manage chronic conditions such as hypertension
- Potential to alleviate symptoms
- Potential to improve disease progression
- Other:

Psychological Benefits: Yes No

Select the type of psychological benefits that apply:

- ☐ Reduction of stress and anxiety
- ☐ Increased mental well-being
- ☐ Emotional benefit
- ☐ Other:

Social Benefits: ☐Yes ☐No

Select the type of social benefits that apply:

- Better interpersonal relationships
- Better quality of life
- Other:

11. Does the study require any in-person research interventions that are not standard of care?

- Yes- If yes, please describe in-person research interventions that are not standard of care
- No
- N/A- Non-clinical research

12.	Does the study require enrollment of a control group that is not expected to receive any direct benefit?	☐ Yes ☐ No
Non-Direct Benefit:		
13.	Is this a non-direct benefit study?	☐ Yes Non-direct benefit studies involving in-person interaction with research participants must include but are not limited to the following mitigation procedures; masking, social distancing, vaccination of study personnel that interacting with study participants, consideration of duration of in-person contact with participants, and an established scheduling structure for coordinated participant visits and cleaning procedures between participant visits. These mitigation procedures must be described for Section E of this form. ☐ No
14.	Will all in-person research activities take place at the same time and place as a regularly scheduled standard medical care visit?	☐ Yes: Answer question 14a. ☐ No
	14a. Do **ALL** of the following conditions apply? Check all conditions that apply	☐ All research personnel who will be in contact with research participants are currently regularly reporting to the site. ☐ The in-person research activity will not add a significant amount of time the participants would normally spend in the site at one time **Note:** Limiting the time spent in an indoor setting reduces the risks of exposure to COVID-19. ☐ The site where the in-person research activity will be conducted has COVID-19 precautions consistent with CDC guidance and precautions are strictly followed.

Section D: Sponsor Information

15.	Name of the current funding source or sponsor.	☐ ☐ N/A
16.	Has the **Sponsor** provided supporting documentation for the resumption of clinical/in-person research?	☐ Yes (*Please attach Sponsor documents)* ☐ No ☐ N/A

Section E: Safety Procedures & Participant Information

17.	**Procedures for Promoting Safety in the Physical Environment**	
	a. Identify all study visit location(s).	

	b. Describe the physical space in which the study visit will occur and how it will accommodate the COVID-19 precautionary measures, including **social distancing**	
	c. Describe the building access to the study visit location(s). • Are COVID-19 precautions in place from the point of entry to the study visit location?	
18.	**Procedures for Promoting Safety of Person to Person Interactions** **Vaccination of study personnel is encouraged, but not required.** **Vaccination does not eliminate the requirement for the mitigation procedures that must be described below.**	
	a. For currently approved protocols, describe any modifications that have been made to the protocol due to public health crisis. This includes modifications to the in-person study visit schedule, drug dispensing (including home delivery) and consent process.	☐ No changes made.
	b. The IRB recommends that, whenever possible, the in-person study visit **coincide with a standard of care visit**. Indicate whether the in-person study visits will coincide with standard of care visits.	☐ Yes, in-person study visit will coincide with standard of care visits. ☐ No, in-person study visits will not coincide with standard of care visits ☐ Some of the study visits will coincide with standard of care visits. ☐ N/A
	c. Describe the procedures to **pre-screen participants** for COVID-19 symptoms prior to the study visit.	
	d. Describe the procedures to **pre-screen research staff** for COVID-19 symptoms prior to the study visit.	

e. Indicate the **number of individuals** present during the study visit(s), this includes the Participant, the PI, and Research Staff. (Limit the research staff to only those necessary to perform the study visit interventions).	
f. Will study personnel interacting with research participants be vaccinated?	☐ Yes ☐ No
g. Describe the **social distancing plan**.	
h. Describe access to **personal protective equipment [PPE]** for participants and research staff.	
i. Describe the **handwashing/sanitizing** procedures for participants and research staff during and after the study visit.	
j. Describe the **disinfecting procedures** before and after each study visit.	
k. Describe the plan to assess and respond to the **participant's health concerns.**	

	l. Describe the plan to assess and respond to the **research staff's health concerns.** https://health.wayne.edu/coronavirus/	
19.	**Participant Information**	
	a. Are the participants at a high risk of severe illness if they become ill with COVID-19? https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html	Yes No If yes, describe how the benefit of the study exceeds the risks to participants vulnerable to severe illness if they become ill with COVID-19.
	b. Indicate the number of participants expected to complete in-person study visits following the resumption of research.	
	c. Indicate the number of in-person visits expected to occur per participant.	
	d. Describe any potential increased risks due to COVID-19 that may affect the participant population in this protocol.	

	e. Describe how participants will be informed about COVID-19 and the precautions in place to limit exposure. **Note:** The IRB has provided templates to help notify participants of COVID-19 precautions: • COVID-19 Phone Script template to be used when contacting a currently enrolled participant. • COVID-19 Participant Information Sheet to be provided to each participant. Templates are available on the IRB website: https://research.wayne.edu/irb/forms-requirements-categories)	
20.	**Procedural Checklist to Monitor Adherence to the Plan**	
	a. Create a checklist to document, at each visit, the steps taken to mitigate COVID-19 risks. b. Include the checklist with this submission	Is checklist included with this submission? ☐ Yes ☐ No

Section F: Principal Investigator's Attestation & Assurances

21.	**Principal Investigator Attestation** By checking the boxes and signing below, the PI attests to the adherence to the following COVID-19 precautionary measures:
	☐ Assurance that, whenever possible, **study visits will be managed remotely** to limit in-person study visits and potential COVID-19 exposure.

	☐ Assurance that for in-person study visits, the direct benefit of the in-person research intervention exceeds the risk of potential COVID-19 exposure/infection.
	☐ Assurance that the PI and research staff interacting with human research participants will: a. adhere to COVID-19 precautions as per CDC guidelines, university policy, clinic/hospital study site policy, and state/local laws; b. wear appropriate PPE during the study visits; c. adhere to appropriate handwashing/sanitizing procedures before and after each study visit; d. encourage the participant to wash/sanitize their hands before and after each study visit; e. wear gloves when in direct physical contact with the participants, and then follow with appropriate handwashing/sanitizing procedures; f. appropriately disinfect the study visit area, as per the site's standard operating procedures, before and after each participant study visit; g. maintain social distancing of at least 6-feet in all directions unless necessary to conduct a study intervention.
	☐ Assurance that appropriate PPE will be available at the study visit site for use by the participants, the PI and research staff.
	☐ Assurance that reporting of a participant who is symptomatic or tests positive for COVID-19 will be done in accordance with the University policy, clinic/hospital study site policy and state/local laws.
	☐ Assurance that reporting of an employee who is symptomatic or tests positive for COVID-19 will be done in accordance with the University policy, clinic/hospital study site policy and state/local laws.
	Principal Investigator Signature/Attestation: Name Signature Date