IRB Approval- Integreview/Salus: 27/Apr/2020 Advarra: 28/Apr/2020

PPD Clinical Research Unit (CRU) SUBJECT RULES AND REGULATIONS-

COVID-19 Precautions

The information in this document explains precautions that have been put into place at the PPD CRUs in Austin, Las Vegas and Orlando in response to COVID-19.

Please note: Financial penalty could occur if you do not follow these precautions. Also, due to the precautions added, all appointments may take longer than expected.

I. SCREENING, REPEATS, PHYSICAL EXAM APPOINTMENTS, CHECK-IN

A. If you have experienced or have been in close contact with any person that has experienced any fever, upper respiratory, or cold/flu-like symptoms or tested positive for COVID-19 within 14 days of your appointment, please call the 24-hour telephone number below based on your location:

Austin 24-hour telephone number: (512) 447-2985 Las Vegas 24-hour telephone number: (702) 219-4979 Orlando 24-hour telephone number: (407) 955-5400

Note: You may also be screened over-the-phone for the signs and symptoms mentioned above, on the day prior to any appointment

- B. Please do not come in for your appointment until 15 minutes prior to the scheduled time or you may be asked to leave until 15 minutes prior to your appointment
- C. Only study participants will be allowed in the building. Please do not bring anyone with you

Note: Exceptions can be made for special populations where a caregiver or study partner are necessary

- D. You must wear a mask/face covering upon entry into the building. A mask can be provided to you if you do not have one, if available. Without a mask or face covering you may be turned away
- E. Upon entry, staff will take your temperature and ask you a series of health questions
- F. To maintain social distancing:
 - Staff will direct you where to sit while you wait for your appointment
 - At the time of your appointment you will be escorted to a room and directed where to sit
- G. During your procedures:
 - Cleaning measures (ex. wiping down areas, changing gloves between subjects, etc.) will be performed
 - You will be asked to maintain social distancing between other subjects during your procedures

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II. IN HOUSE STAY

- A. Once you have been searched, you will be escorted to your unit
- B. Once you are in your unit, you must maintain social distancing by:
 - Wearing a mask/ face coverage at all times while outside of your dorm or respective sleeping area and also while in contact with staff
 - Not loitering in the bathroom or common areas. Certain common areas may be limited/closed down for your safety
 - Maintaining at least 6 feet of distance between yourself and other subjects
 - The number of subjects will be limited in common areas (such as the shower room and entertainment rooms)
 - You may be housed in the same housing/dorm as another subject, however social distancing will be maintained
 - If allowed per study requirements, meals might be delivered to your bed/dorm room
 - If allowed per study requirements, procedures will be performed at bedside
- C. You should wash your hands with soap and water for at least 20 seconds each time
- D. Sanitation stations are available to you throughout the unit
- E. Each day, your temperature will be collected by staff along with a question regarding how you feel
- F. Walks/"Fresh-air breaks" may be limited and will be determined on a case-by-case basis, to limit the risk of outside-exposure, for yours and the staff's safety
- G. If you need to speak with a staff member regarding non-medical needs, you should contact the appropriate phone number below based on your location:

Austin: A Research Technician Coordinator at (512)-748-2855

Las Vegas: Front desk at (702)-963-1600 Orlando: Front desk at (689) 216-3100

H. If you need to speak with a medical professional regarding a non-emergency need, you should contact the appropriate phone number below based on your location:

Austin: A Paramedic at 512-748-2874

Las Vegas: A Research Nurse at (702) 219-4979 Orlando: A Research Nurse at (321) 594-8936

If you are experiencing a serious medical event, you should activate the Emergency Medical Alert (EMA)
device closest to you by either pushing the button, pull string or sliding the switch to alert a Research
Nurse or Paramedic

III. CHECK OUT

- A. You will be expected to stay in your bed/dorm room until staff directs you otherwise
- B. Once you have been checked out, you must exit the building, no loitering

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C. You will receive a phone call approximately one day prior to your next appointment, if applicable, to remind you of your appointment and to ask you a series of health questions

IV. OUTPATIENT VISITS

- A. If you have experienced or have been in close contact with any person that has experienced any fever, upper respiratory, or cold/flu-like symptoms or tested positive for COVID-19 within 14 days of your appointment, please call the 24-hour telephone number
- B. Please do not come in for your appointment until 15 minutes prior to the scheduled time or you may be asked to leave until 15 minutes prior to your appointment
- C. Only study participants will be allowed in the building. Please do not bring anyone with you

Note: Exceptions can be made for special populations where a caregiver or study partner are necessary

- D. You must wear a mask/face covering upon entry into the building. A mask can be provided to you if you do not have one, if available. Without a mask or face covering you may be turned away
- E. Upon entry, staff will take your temperature and ask you a series of health questions
- F. To maintain social distancing:
 - Staff will direct you where to sit while you wait for your appointment
 - At the time of your appointment you will be escorted to a room and directed where to sit
- G. During your procedures:
 - Cleaning measures (ex. wiping down areas, changing gloves between subjects, etc.) will be performed
 - You will be asked to maintain social distancing between other subjects during your procedures
- H. You will receive a phone call approximately one day prior to your next appointment, if applicable, to remind you of your appointment and to ask you a series of health questions

SUBJECT SIGNATURE

I understand and agree to abide by the precautions outlined in this document. I have been given the opportunity to ask questions and have received answered to those questions. I understand that I will be given a copy of this document to keep.

| Subject Signature | Date |
|------------------------|------|
| | |
| Subject Name (Printed) | |

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