**Guidelines for Study Teams Outside UWHC Working with** [**Higher Risk Subject Populations**](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html)

The following guidelines should be used by researchers outside UWHC who may be working with subject populations or individuals in these populations (as defined by the CDC) at higher risk of contracting Covid-19 and/or experiencing severe illness if they contract Covid-19. These guidelines also should be used by associate deans for research (or their designees) when determining which studies can be approved for face-to-face interactions.

Please note the following:

* These guidelines do NOT apply to research activities occurring at UWHC facilities, where a range of precautionary measures are already in place.
* Study teams with questions about these guidelines should contact their associate dean for research (or designee) for assistance and NOT the IRB offices.

**Guidelines**

1. Study teams are responsible for reviewing [the CDC’s information on higher risk populations](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html) and to identify whether their subject population or any individual subject is at higher risk.
2. When considering whether to resume or initiate face-to-face interactions with higher risk subjects, study teams must:
	1. Be especially conservative in assessing whether **ANY** face to face interactions with these populations should resume at this time, particularly if subjects will be accompanied by a caregiver or others.
	2. Be prepared to strictly follow all [EHS guidance](https://facilities.fpm.wisc.edu/returning-to-campus-safely/) on minimizing COVID-19 risks for face to face research activities as well as [study team member screening](https://research.wisc.edu/employee-symptom-screening-guidance/) when interacting with these subjects.
	3. Ensure that all study activities that can be **conducted remotely** are done so, including any **informed consent process**.
		1. IRB review and approval of [remote study procedures and consent processes](https://kb.wisc.edu/hsirbs/page.php?id=102580) is required.
	4. Recognize that subjects at higher risk may be hesitant to agree to face-to-face interactions. If subjects are reluctant to agree to face-to-face interactions, study teams must respect this choice as they would for subjects who express dissent. Remuneration cannot be used to persuade subjects to agree to face-to-face study visits.
3. Study teams working with higher risk populations must send subjects a letter (mail or email) describing the protective measures the study team will have in place for their face-to-face interactions.
	1. Use Template: [Information sheets to study subject](https://research.wisc.edu/wp-content/uploads/sites/2/2020/07/template-for-information-sheet-to-study-teams-v7-2.docx)s and revise if needed to reflect the protective measures for that particular study.
	2. IRB review and approval of this communication is NOT required.
4. Pre-screen higher risk subjects for Covid-19 within 24 hours of face-to-face contact, regardless of the nature of those interactions.
	1. Use the [Template: Screening Script for Study Team](https://research.wisc.edu/wp-content/uploads/sites/2/2020/07/Template-script-for-study-teams-v7-2.docx)s
	2. IRB review and approval of this tool is NOT required.