

FORM NAME	CHANGES
C2 – Screening Form	Added first 2 sentences of second paragraph (including COVID-19) and added 2 questions to screening questions (1 - Do you think you have COVID-19 and 2 - Which symptoms are you experience - loss of taste/smell - nausea/vomiting
C3 – Consent/Assent Forms student	<p>4 - 6 Oral Assent – No change</p> <p>7 - 14 Assent – No change</p> <p>Parental Consent ages 4 - 14 – Removed completely per IRB request</p> <p>Subject Assent/Parental Consent ages 15-17/Consent ages 18 & older – changed to Subject Assent/Parental Consent ages 15-17/Consent ages 18 & older/Parent consent for minors ages 4 - 14 – this change was recommended by the IRB to simplify things.</p> <p>Added a note at the top for parents stating that in this consent form, “you” means the child who takes part in the study. Added “how long will my participation in this study last” paragraph. In “Are there any benefits to me” section added last sentence about being 18 or older. Changed age range of parent guardian signature from 15 - 17 to 4 - 17.</p>
C3a – Household Member Consent/Assent Forms	<p>4 - 6 Oral Assent – From first sentence in second paragraph removed “who goes to school in Oregon or Brooklyn”. Removed signatures at the bottom.</p> <p>7 - 14 Assent – removed “and they are in a different study called ORCHARDS” in last sentence of “What is this study about” section. In “How long does the study last” section added language stating that they can participate again between now and the end of the school year. Added language to “Can I stop being in the study” to clarify that if they get sick again later in the year they don’t have to participate if they don’t want to. Added 3rd and 4th bullet points to “Will anyone know I am in the study” to add language about flu and SARS-CoV-2 results being shared. Removed signatures at the bottom.</p> <p>Parental Consent Form ages 0 - 14 – Removed completely per IRB request</p> <p>Subject Assent/Parental Consent (ages 15 - 17)/consent (ages 18 & older) changed to Assent (ages 15 - 17)/consent (ages 18 &</p>

older)/Parent Consent (for minors 0 - 17) – this change was suggested by the IRB to simplify things. Added a note at the top for parents stating that in this consent form, “you” means the child who takes part in the study. In Invitation section, changed total number of samples from 720 to 1,700 and changed language saying “this research is being conducted in your home” instead of “in participant’s home”. In “What is the purpose of this study” section, changed from “to evaluate transmission of influenza in households from which a student (4k-12) has participated in ORCHARDS” to “the purpose of this study is to evaluate the spread of influenza and other respiratory illnesses in households”. In “what will my participation involve” section took out language that referenced ORCHARDS visit , added SARS-CoV-2 testing, added day 14 specimen collection and form completion, added language stating that specimens will be tested for influenza AND SARS-CoV-2 and that if positive for SARS-CoV-2 a parent/guardian will be notified immediately by phone. Also noted that results need to be reported to WI Dept. of Public Health and CDC. Added that ORCHARDS eligible participant’s day 0 swab will be additionally tested for 17 other viruses and results will be mailed. Added “How long will my participation in this study last” section. Added second paragraph in “Are there any side effects or risks to me” addressing that observed child abuse or neglect will be reported by employees. Added “Protected Health Information used in this study” section. Added first sentence to “How will my privacy be protected and who will use my health information” section about PHI. Removed sentence “All paper data sheets will be kept in locked filing cabinets in the UW Dept. of Family Medicine”. Added bold statement about being required to report all test results including PHI to CDC and WI DPH. Added language about publications and authorizing the research team to use you PHI. To “who at UW Madison can use my information” added “members of the research team” and “UW Madison regulatory and research oversight boards and offices” and WI State Lab of Hygiene. Removed WI State Lab of Hygiene from

	outside entity. Removed signature section and added language to Agreement to participate in this research study stating that by providing a sample and study forms, you are consenting to participate in this study.
C4 - ARI Surveillance Form	No change
C4a - Household Study Form	<p>Day 0 Form: Added Birth Date, Phone number, address, school ID and type of swab, added non-binary to gender, Added in person, Homeschool/virtual as an option for attending school, added "Have you been tested for COVID-19 question, changed # of days of flu-like symptoms from 7 to 14 days, added exposure to similar illness question and likely source questions. Removed symptoms: tiredness, poor appetite, nasal congestion and body aches and added symptoms of muscle pain, joint pain, no appetite, loss of smell, loss of taste, vomiting, diarrhea, wheezing, stuffy nose, ear pain, abdominal pain, conjunctivitis, and shortness of breath</p> <p>Day 7 Form: Added Household Member Name, Relationship to Student, Birthdate, phone number, address, participant ID, School ID, age nasal swab, race, ethnicity and gender to top portion. Added recent travel questions, Added question to clarify if these are new symptoms or continuing from day 0. Added end date if no symptoms. Added exposure to similar illness question and likely source questions. Removed symptoms: tiredness, poor appetite, nasal congestion and body aches and added symptoms of muscle pain, joint pain, no appetite, loss of smell, loss of taste, vomiting, diarrhea, wheezing, stuffy nose, ear pain, abdominal pain, conjunctivitis, and shortness of breath</p> <p>Day 14 Form - added entire form</p>
C7 - Biospecimen Collection Form	Added day 14
D1 - Student participant packet	No change