Guidance on reporting UW-Madison purview enrollment

**Total number of subjects approved for enrollment in this study at sites under UW purview** (i.e. sites at which UW faculty, staff, students, or agents are responsible for the oversight of research activities)

*Section: Local Activities: Enrollment; Question 3.1 in the CR SmartForm:*

This is the total number of subjects currently approved by the IRB that may be enrolled on this study at sites under UW purview this site. If the UW IRB is serving as the IRB of record for other participating sites or is directly responsible for providing IRB oversight of collaborating investigators (who do not have IRB approval from their own institutions), these sites are considered to be under UW purview. In these cases, please include approved enrollment numbers for these other sites in the total number of subjects. This number must match the total number of local subjects, as listed in the approved ARROW application (*Section: Subjects General; Question 1.2*).

If the UW is the coordinating center for a multisite study, but the participating sites receive IRB approval from their own IRB, these sites would not be considered to be under UW purview. In these cases, approved enrollment numbers for these other sites should not be included in overall enrollment numbers.

*If the IRB did not approve a specific number for enrollment or for number of data/images/specimens to be collected, enter zero in this field.*

**Total number of subjects who have provided consent and were enrolled to date** (consented means that subjects have provided consent to participate in the study) at sites under UW purview

*Section: Local Activities: Enrollment; Question 3.2 in the CR SmartForm:*
List the total number of subjects who have provided informed consent to participate in this study and have begun study procedures (e.g., study treatment). Subjects who complete screening procedures and fail screening are not included in this number. Subjects who were consented and began study procedures/treatment, but were subsequently withdrawn by the investigator or voluntarily withdrew should be included in this number.

Additional subjects yet to be recruited and enrolled at sites under UW purview (Section: Local Activities: Enrollment; Question 3.3 in the CR SmartForm):

Indicate the number of future additional subjects that you plan to recruit to this study. If this number added to the number of subjects you’ve already enrolled (Section: Local Activities: Enrollment; Question 3.2 in the CR SmartForm) is lower than what was previously the total number of subjects approved for local (i.e., if your total enrollment, including subjects who have already enrolled in the study will be lower than what was previously approved), the reason for under-enrollment will need to be explained, in question 3.5.1.

In addition, you may not enroll more total subjects than have been IRB approved, but if you want to increase your approved enrollment total you must submit a Change of Protocol form to make such a request to the IRB after the continuing review is approved.

Note: If the IRB did not approve a specific number for enrollment or for number of data/images/specimens to be collected, enter zero in this field.

Total number of subjects who provided consent, but did not enroll in the study at sites under UW purview (Section: Local Activities: Enrollment; Question 3.4 in the CR SmartForm):

This number should include subjects who provide consent, but do not go on to enroll in the study (i.e., begin study procedures/treatment). This includes subjects who decline to participate after signing the consent form, subjects who were screened and found to be ineligible (screen failures), or subjects who did not return after the consenting visit to complete the remaining study visits, or subjects who are not deemed evaluable. Because these subjects did not enroll in the trial, the IRB understands that these subjects will likely need to be replaced to meet enrollment numbers. There are other cases, however, where subjects will not be replaced.