When is it necessary to "re-consent" a subject?

Re-consent follows the same standards, regulations and processes as initial consent. Re-consenting may be required in the following situations:

Study Changes	When a consent form is revised, the IRB reviews the requested changes with the Amendment Form. The IRB determines whether the requested changes merit requiring previously consented subjects to sign the revised consent form. For example, if the study protocol was revised to add an additional study visit or extend the duration of the study, the IRB might determine that previously consented subjects need to be informed and provide new consent. On the other hand, if the consent form was revised in such a way that the changes would not affect subjects who have already consented (e.g., screening visit procedures that all consented subjects have already completed), the IRB would likely determine that re-consenting was unnecessary. The IRB reviewer section of the amendment form will indicate whether current subjects need to be re-consented on the new consent form.
Fluctuating Capacity	For subjects with fluctuating capacity or decreasing capacity to give consent, a re-consenting process with a surrogate consent may be required. *See VHA Handbook 1200.05 (36.e and 49.c).*
Other scenarios	If a subject missed multiple visits for whatever reason but is eligible to resume the study, reconsenting may be appropriate.