MCW Guidance: Notifying Subjects of New Study Information

This document was created to provide guidance to investigators and research teams on notifying subjects of new study related information.

One of the required elements of informed consent states that when appropriate, significant new findings that develop during the course of the research and may relate to the subjects willingness to continue participation will be provided to the subject. As the regulations do not specify how this new information is to be provided to subjects, it can be given to subjects via various forms of either written or verbal correspondence.

The MCW FH IRB must review any new information that is to be provided to subjects before dissemination of the information unless the information must be provided to eliminate an immediate hazard to subjects or others.

Please note: This guidance does not constitute policy and is simply provided to give examples of how new study related information can be disseminated to subjects. These examples are meant to illustrate how information might be presented, but are subject to IRB and/or Sponsor approval.

What new findings should be provided to subjects?

New findings include, but are not limited to:

- new risks or changes to risks
- new or changes in study procedures or design
- changes in treatment plan or study groups/arms
- changes in costs or payments to a subject
- change in PI

Notification options:

- **Full re-consent with the informed consent document**
  - Appropriate when there are multiple or significant changes to a study.
  - Use can also depend on the status of the subjects enrolled in the study (often appropriate if subjects are still active in a study, but if all subjects are only in long-term follow-up, a full re-consent might not be necessary).
  - Might also be required by sponsor or funding agency when any change is made.
- **Creation of a new informed consent document**
  - May be used when a new group of subjects is added to the study or if adding a sub-study

- **Addendum to the ICF**
  - Appropriate for small or minor changes/additions.
  - The addendum must compliment and work in conjunction with the main ICF.
- **Letter**
  - Appropriate when subjects are no longer seen regularly by the study doctor and changes are not life threatening or time sensitive
- **Verbal notification**
  - Can be used in situations in which it is important to notify subjects as soon as possible regarding changes in the study.
  - Subjects might not be coming in for a study visit in the near future, so a phone call may be most appropriate.
  - Depending on the information, re-consenting of the subject may occur at their next study visit.
  -

Documenting the re-consent process:

- For situations which require a full re-consent, use of a newly created consent, and/or addendum, a signed copy of the document should be included in the research record.
- For notification of changes via letter, a copy of the letter that is sent to the study subject and the date that it is sent should be included in the research record.
- When verbal notification is used, the research record should document the conversation to indicate when & who provided the verbal notification.