Guidance on Proper Eligibility Documentation

All eligibility determinations need to be documented and verifiable based on source documentation supporting each eligibility criterion. The purpose of this document is to provide investigators and their research teams best practices for creating the proper eligibility source documentation.

Method 1: Using the DF/HCC Eligibility Checklist

Note: This method can only be used if allowed by institutional policy. Please check with your institutional clinical trials office if you are unsure of the local policy regarding use of the eligibility checklist as source documentation.

Note: For criteria that do not involve judgement or interpretation (e.g., laboratory values, age) the checklist would not be considered the "source" since the original recording of the information elsewhere (e.g., in the medical record).

- Per REGIST-100, a physician investigator must complete the protocol-specific eligibility checklist (current version posted on OncPro) and sign as screening staff.
- When required by REGIST-100, and enrollment monitor must independently verify subject eligibility via source documentation review and sign the eligibility checklist.
- The completed and signed checklist must be filed in the subject's research chart.

Method 2: Eligibility Note

An appropriately delegated and qualified member of the study team captures the eligibility assessment, including all criteria as listed in the protocol, in narrative or list form.

Example:

In my opinion the patient has an estimated life expectancy of greater than 8 weeks. Her Karnofsky performance status is 80%. She has a diagnosis of XXXX as noted on her pathology report from her 8/22/2011 surgery. She has supratentorial disease without infratentorial involvement. She has unequivocal progression by MRI on 8/23/2012. She has not been on any steroids within the last 30 days. Based on the above, I have determined that this subject is eligible for participation in DF/HCC clinical trial Protocol # (protocol title).

(Signature and Date)

Example 2:

Assessing subject eligibility for participation in DF/HCC clinical trial Protocol # (protocol title):

- *Life expectancy is estimated to be greater than 8 weeks.*
- *Karnofsky performance status is 80%*
- *Diagnosis of XXXX. See pathology report from her 8/22/2011 surgery.*
- *Supratentorial disease without infratentorial involvement*
- *Unequivocal progression per MRI on 8/23/2012*
- *She has not been on any steroids within the last 30 days.*

I have determined that this subject is eligible and will proceed to receiving treatment under the above protocol. (Signature and Date)