1. **I just downloaded my watermarked consent documents and the formatting doesn’t look right. What should I do?**

First, check the original document that is uploaded in the RSRB application. If the formatting on this document is off, the only way to correct it is by submitting a revised document via amendment in ROSS. If the original document is correct and it appears that inserting the watermark changed the formatting, please contact our Data Manager at 275-3050.

2. **We would like to mail consents to subjects to review, sign and return. Is this allowed? What would be the best procedure for implementing this?**

Yes, obtaining written consent via mail is allowed; however, this process must be described in the protocol as appropriate for the study, the RSRB must approve this process, and there should be sufficient oral or in-person contact regarding the study prior to mailing the document (for example, if the consent discussion is conducted over the telephone). On the other hand, if you plan to obtain written consent in person and a situation arises where obtaining consent via mail is necessary, it would be best to contact your RSRB Specialist to discuss the situation and then document the process in the subject’s study file. In cases where subjects are being re-consented via mail (e.g., when study procedures have changed and re-consent is required), your process for re-consenting via mail should be described in the amendment making the changes to the consent document.

The process for obtaining consent via mail can be accomplished in 1 of 2 ways:

- Mail 2 consents forms to the subject. Instruct the subject to sign both, keep one for their records and mail back the second; or
- Mail 1 consent form to the subject. Instruct them to sign the document and mail it back to the study. Upon receipt of the consent, the person obtaining consent would then sign the document and mail a copy of the entire document (with both signatures) back to the subject.

Regardless of which procedure is followed, a letter should accompany the consent form in the mail providing subjects instructions for completing the form as well as providing contact information if additional questions arise (self-addressed stamped envelopes should also be included).
3. **Would the use of an “opt out” consent be permissible?**

No, the RSRB does not permit the use of “opt out” consents. All subjects should be provided the opportunity to actively consent for participation in a study and additional efforts should not be required on the part of a subject who does not want to participate in the study (e.g., asking subjects who do not want to participate to return a postcard/phone call to the study team indicating so).

4. **Who is allowed to obtain consent?**

While the federal regulations do not specify who should (or is allowed to) obtain consent, they do give the ultimate responsibility to the principal investigator, who may delegate to appropriately trained personnel. The RSRB requires that any investigator or other study personnel who may obtain consent complete human subjects training (based on the risk level of the study) and be listed on the RSRB application.

The training/background of the study team member(s) responsible for obtaining consent should be appropriate based on the nature and design of the study. For studies involving the use of an investigational drug or device, it may be necessary to involve a nurse or physician team member in order to ensure that questions are answered appropriately. If a study is particularly complex it may not be appropriate for a student team member to obtain consent.

In some cases a protocol or standard operating procedure may further delineate who can/cannot obtain consent (e.g., an industry-initiated study protocol that specifies that only the principal investigator obtain consent). Any additional conditions provided in a study protocol or standard operating procedure must also be adhered to in addition to RSRB requirements.

5. **The signature block for the person obtaining consent states “I have given the subject adequate opportunity to read the consent before signing.” What is considered “adequate opportunity” for the subject to read the consent and consider participation before signing the consent form?**

While there are no specific guidelines on how much time should be given to potential subjects to consider participation, it is good practice to estimate how much time a “reasonable person” would need to do so. The amount of time one might need to consider participation depends on multiple factors: the complexity of the study design & procedures, the study population, the setting in which the subject is approached for participation, and the readability of the consent document. For example, it may take a couple of meetings for a potential subject to not only understand the cancer they may have just been diagnosed with but also to understand the study as well as other treatment options.

The bottom line is, there should sufficient time for a “reasonable person” to read the form, ask questions and receive answers and consider their participation (potentially with the help of other friends/family). Generally speaking, unless it is a life-threatening situation, potential subjects should not feel rushed and should be given as much time as possible to consider their participation.