The ORARC Quality Improvement Program (QIP) Can Help!

- **QIP Services**
  - QIP Consultation
  - IRB/ESTR Submission Assistance
  - Study Management Tools (e.g., logs and Regulatory Binder)
  - Investigator/Study Staff Training
  - QIP Monthly Education Series (see website for details)
    - April: Creating a Safe Research Environment
    - Post-IRB Approval Basics

- **QIP Service Request Form**

*Contact QIP with any little (or big) question at all!*
IS YOUR CONSENT INFORMED?

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AGENDA

01 THE FORM
02 THE PROTOCOL
03 THE PROCESS
THE FORM
The Form: Basic Required Elements of Consent

☐ The study involves research.
☐ The purposes of the research.
☐ The expected duration of the subject's participation.
☐ The procedures to be followed.
☐ Identification of any procedures, which are experimental.
☐ Any reasonably foreseeable risks or discomforts to the subject.
☐ Any benefits to the subject or to others, which may reasonably be expected from the research.
☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.
☐ How to contact the research team for questions, concerns, or complaints about the research.
☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
☐ Whom to contact in the event of a research-related injury to the subject.
☐ Participation is voluntary.
☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Required for More than Minimal Risk Research
☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

OTHER ICF REQUIREMENTS

- Key Information Section (may not be waived)
- COC language requirements for NIH funded studies
- GDPR Requirements for data with EU
- FDA Regulated Research Requirements
- Prisoners requirements
- DOD, DOJ, etc.

- ORARC's Template has it all-only remove what doesn't apply to your study!
VARIOUS TEMPLATES

- Adult
- Parental Permission form
- Child Assent Form
- Consent for HIPAA covered entities
- Exemption Consent Script
- Short Form
- Adult Surrogate
MORE ACCESSIBLE FORM TIPS

- TABLES & IMAGES
- SIMPLE LANGUAGE
- WHITE SPACE
- CONVERSATIONAL TONE
- BULLET POINTS
COMMON MISTAKES
COMMON MISTAKES

- Signature lines are not correct, how many, who? (e.g., Witness line)
- Waiver of Doc of consent and the signature lines are still there
- COC language not in ICF for NIH funded protocol
- Missing basic required elements (e.g., element for identifiable specimens/data)
- Parental permission form written as a consent form
- Required Elements for greater than minimal risk research are left out
- Not understandable to the participant (reading level, native language, etc.)
- Non-US study listing HLC IRB information and contact for participants regarding participant rights, etc. (should be someone local they can feasibly contact to discuss in their own language)
THE PROTOCOL

DESCRIBE PROCESS
The protocol will describe the consenting process (i.e. who, what, when, where, & how)

DESCRIBE DOCUMENTATION
The protocol will also describe how the documentation of consent will be captured (i.e. signature, mark, etc...)

• No signature needed for Exemption
SPECIAL CIRCUMSTANCES

LAR
WITNESS
MINOR ASSENT
PARENTAL PERMISSION
**WAIVERS**

<table>
<thead>
<tr>
<th>Waiver of Documentation of Consent</th>
<th>Waiver or Alteration of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Waives the requirement to obtain a signature</td>
<td>• Waiving the entire or part of the consent process</td>
</tr>
<tr>
<td>• Consent still obtained via verbal yes/no, ticking a box, etc.</td>
<td>• Study must be:</td>
</tr>
<tr>
<td>• Waiver can be applied to all study participants or a particular cohort</td>
<td>• Minimal risk,</td>
</tr>
<tr>
<td>• Study team should track consent on their own end via a spreadsheet or other device</td>
<td>• Could not be carried out without the waiver, and</td>
</tr>
<tr>
<td>• May be requested for studies where obtaining a signature is not practicable, where the only link between the participant and the study is the consent, the study is minimal risk, or where a signature is not in alignment with cultural norms</td>
<td>• Does not adversely affect the rights and welfare of individuals</td>
</tr>
<tr>
<td>• Examples: Online survey, study that seeks to collect completely anonymous data, study with vulnerable populations, like prisoners, where the risk is the participants association with the study</td>
<td>• Where appropriate the study teams should provide additional information to subjects about their participant</td>
</tr>
<tr>
<td></td>
<td>• A waiver of consent is often seen in secondary data analysis studies, where there is not contact with the participant</td>
</tr>
<tr>
<td></td>
<td>• Depending on the type of data/data source, consent should have been obtained from the original study to conduct future research with the data</td>
</tr>
<tr>
<td></td>
<td>• The study should be able to provide/utilize a DUA, original consent or HIPAA waiver</td>
</tr>
</tbody>
</table>

https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/tips-and-tricks-for-a-successful-irb-submission-and-review-process/
THE PROCESS
THE PROCESS

FOLLOW PROTOCOL
The directions should be clearly outlined in the protocol. Update via a modification if needed.

DOCUMENT CONSENT
Make sure all signatures, checkboxes, etc. are complete from both participant and person obtaining consent.

USE APPROVED IC
Look for the most recent watermarked version.

IT’S A PROCESS
Consenting participants is a PROCESS, not just a form.
WHERE TO FIND THE APPROVED INFORMED CONSENT

To find the approved study documents of a project:

Log in to ESTR, find the submission, click the **Documents** tab on the main study workspace, click on the document link in the **Final** column to view the approved version. To save a document, right click and select ‘Save Link As.’
EXAMPLE CONSENT PROCESS

Office of Research Integrity, HHS

https://ori.hhs.gov/research-clinic
GRAB YOUR PHONES

—Quick (and painless) interactive activity
RESOURCES

- HRP-314 - Worksheet - Criteria for Approval and Additional Considerations
- ICF Templates
- IRB Tip sheets
- QIP Service Assistance