# CONSENTS
## *THE GOOD, THE HARD, THE BEAUTIFUL*

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## AGENDA AND EXPECTATIONS

*One of the most important aspects of research can be appropriate, respectful, and compliant consenting. This seminar will start with an overview of recommendations for the consent form, discussion, and necessary documentation. A primary focus of this seminar will be on Licensed Independent Practitioners and best practices and requirements for enrolling participants with Limited English Proficiencies including working with BMC Interpreter Services.*

- ✓ Learn general best practices for consent forms, discussions, and documentation
- ✓ Understand when to involve a Licensed Independent Practitioner and how to document
- ✓ Identify recommended and required steps for enrolling participants with Limited English Proficiencies

## BASIC GOAL OF INFORMED CONSENT

That participants:

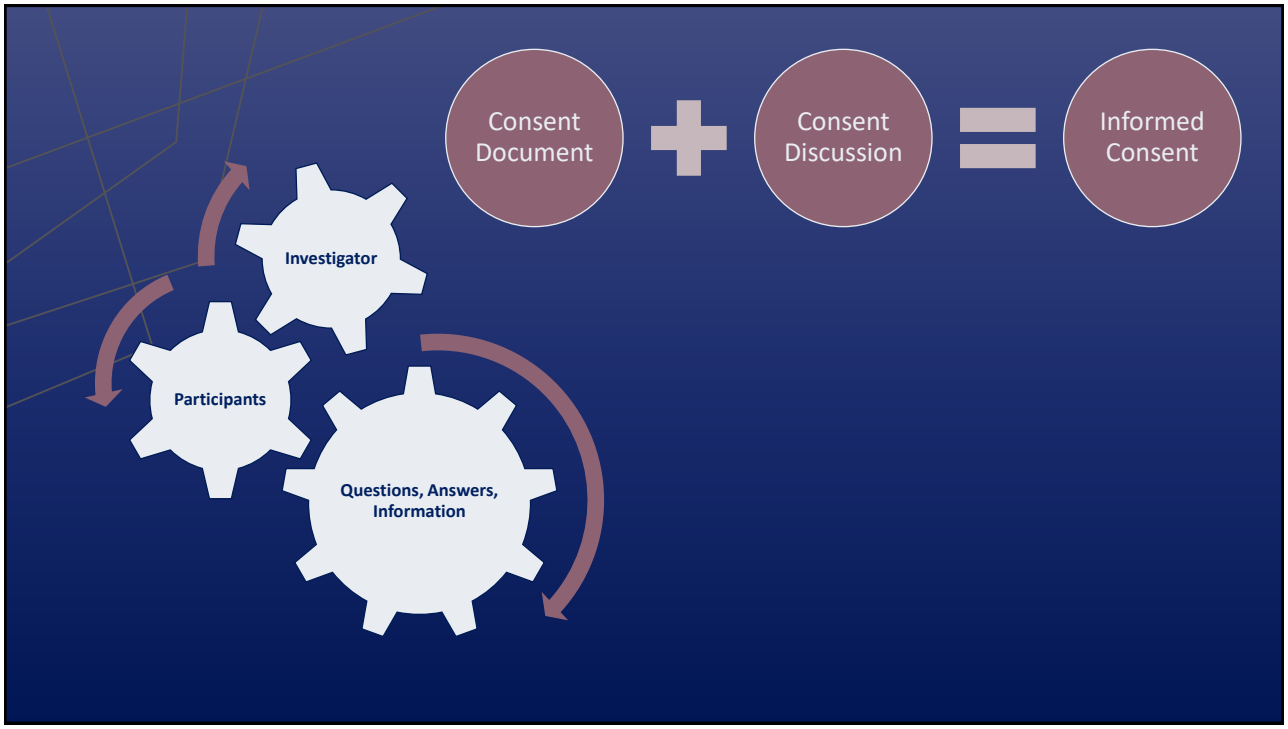
| | |
|---|---|
| Have the necessary and complete information | Understand the necessary and complete information |

To be able to make an informed decision regarding participation.

**One of the basic ethical principles underlying our work.**

**Respect For Persons – Belmont Report**

## GENERAL BEST PRACTICES




# CONSENT BEST PRACTICES: THE FORM

- Short sentences – if tempted to use comma or semi-colon – don't! Split into individual sentences for clarity.
- Short paragraphs – if tempted to have a paragraph that is long (4 or more sentences), think about splitting it.
- 8th grade reading level – think about how you would explain something to a person on the street. This isn't just word length but sentence length and structure. Remember your audience – not a grant and not a manuscript.
- Use bullets and tables when appropriate instead of explaining in text – or do both! Just make sure that both text and table match!
  - What happens at each visit
  - If multiple and different reimbursement amounts at different visits

# CONSENT BEST PRACTICES: THE FORM

- **Don't use "buried verbs" – also called "nominalizations"**
  - **Definition: expressing a verb or an adjective as a noun**
- **Don't use a verb where a noun can be used**

| Not Terrible | Could Be Better |
|---|---|
| We are doing the research to gain an understanding of how diabetes can have an impact on high blood pressure. | We are doing the research to understand how diabetes impacts high blood pressure. |
| The second visit will include a discussion on the risks of the intervention and a review of your medical history. | ➢ Visit 2<br>• Discuss intervention risks<br>• Medical history review<br>➢ At the second visit, we will discuss with you the risks of taking the drug. We will also review your medical history with you. |

# CONSENT BEST PRACTICES: THE FORM

- Use the IRB consent templates
- But be careful with templates –
  - Actually include all required sections and information for your specific study
  - Read the instructions carefully
  - Do not modify the templates other than adding your study-specific info
- Common missed sections dropped/deleted
  - ✓ Clinicaltrials.gov statement
  - ✓All required/relevant sub-sections in Confidentiality
  - ✓All required/relevant sub-sections in Use and Sharing of Your Health Information
- Common problems or IRB stipulations
  - Incorrect signature page or missing pieces of signature section

# WAIVERS AND ALTERATIONS

When requesting these from the IRB – be specific and careful!

- ✓Waiver of Documentation – not obtaining signatures on the consent
- ✓Waiver of Consent – the entire consent is waived, participants are not made aware that they or their data are being used for research
- ✓Alteration of Consent – one ore more of the required elements will not be included in the consent form/discussion, IRB may require that those elements be provided as information after research is complete

*Neither of these situations are the same as a Waiver of HIPAA Authorization*

- HRPP Policy Section 8.4.2 Waiver of Documentation of Consent
- HRPP Policy Section 8.4.3 Waiver or Alteration of Consent

# CONSENT BEST PRACTICES: THE PROCESS

- However you do consent – must be approved and the approved process must be followed
- Standard vs Non-Standard
  - When you go to enroll a Non-English Speaking Participant or a Non/Limited Reader, go back to your INSPIR application and review the process

# CONSENT BEST PRACTICES: THE PROCESS

- ✓ **Keep the entire original consent** form in your research records
- ✓ Signed and/or dated is per HRPP Policy, federal regulation, or GCP – whichever you are supposed to be following and are approved for
- ✓ Best practice is original signed and dated

- ✓ Provide a **copy of the consent to the participant**
- ✓ Signed and/or dated is per HRPP Policy, federal regulation, or GCP – whichever you are supposed to be following and are approved for
- ✓ Best practice is copy of signed and dated

**Consents are retained after the end of the study for a minimum of seven years**

- All consents, including reconsents
- Best practice, not just a scanned PDF but the actual consent
- Include all pages, not just signature page

# CONSENT BEST PRACTICES: THE PROCESS

**Copy of consent provided to participant**

- HRPP Policy 8.4.1 *The subject must be given a copy of the consent form, unless this requirement is specifically waived or modified by the IRB.*
- OHRP 45 CFR 46.117(a) *A written copy shall be given to the person signing the form.*
- FDA 21 CFR 50.27 *A copy shall be given to the person signing the form.*
- ICH GCP 4.8.11 *The subject…should receive a copy of the signed and dated written informed consent form.*
- *What does your IRB-approved application say?*

# CONSENT BEST PRACTICES: THE PROCESS

**Practice and Practice Some More**

- With peers, other team members
- Teach-back: how to ask questions and assess understanding
- Answering questions
  - OK to say: I don't know the answer, but I'll find out and get back to you…
- How to engage subjects
- If using, Zoom and phone consenting – both the tech and the process
- *Regardless of experience or knowledge*

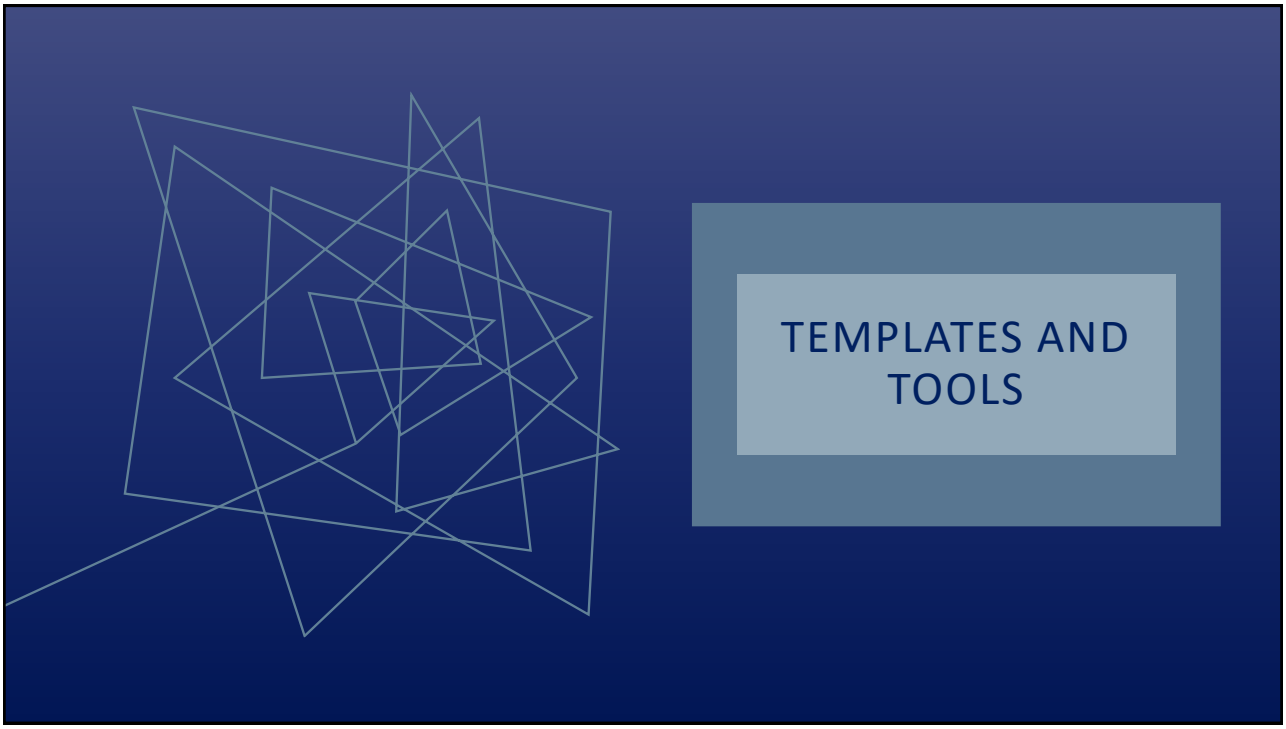
# CONSENT BEST PRACTICES: DOCUMENTATION

- While signatures on a consent are considered "documentation" – best practice is that separate "documentation" is done to confirm specific things
- If study has Waiver of Documentation – very important that a separate note is written to document consent

| | | | |
|---|---|---|---|
| Consent done before any research procedure has taken place | Questions asked ad answers provided | Copy of consent provided – signed and/or dated specifically | Licensed Independent Practitioner involved |

| | | |
|---|---|---|
| How a Limited or Non-Reader was consented | How a Non-English speaking participant was consented | Others – See CRRO Template! |

- OHRP Common Rule 45 CFR 46.117 (a) – signature as documentation

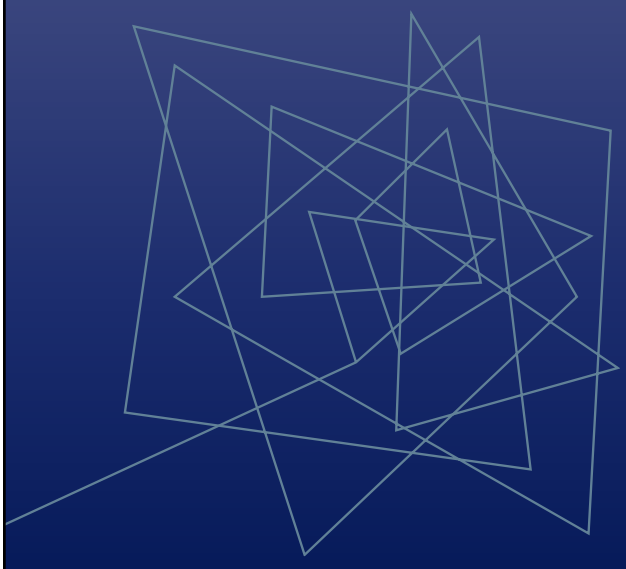



# CRRO INFORMED CONSENT DOCUMENTATION TEMPLATE

- Not meant to be static
- Designed so that study teams *should and must* update for their specific study design and procedures
  - Delete sections that are not applicable
  - Add sections that you want to document
  - Should align with IRB-approved consenting procedures (protocol or INSPIR application)
- Use consistently with all participants

# IRB CONSENT TEMPLATES

| ***Template Name*** | **When (generally!) To Use** |
|---|---|
| Adult Consent Form | Research on adults |
| Brief Screening Agreement | Screening consent ONLY – direct contact but NO clinical procedure needed for screening OR NO retention of PHI from screening – *example: asking a few questions directly to candidate* |
| Screening Questions Full Consent | Screening consent ONLY – direct contact AND has clinical procedure needed for screening OR retention of PHI from screening – *example: finger poke to check current glucose level* |
| Exempt Information Sheet | Exempt adult research only – approved for no signature for consent, still might need signature for HIPAA authorization |
| Parent Permission Form | Parents are providing permission for their child for non-exempt research |
| Parent Consent and Permission Form | Parents are providing permission for their child *and* are also considered participants for non-exempt research |
| Parent Permission Exempt Information Sheet | Parents are providing permission for exempt research<br>***This is rarely used. If you think this applies, contact your IRB analyst.*** |
| Adult Consent Form | When enrolling older children and expect them to "age out", must reconsent using Adult Form |
| *Other templates are available –*<br>*"Adult Authorization Form", "Single Patient Expanded Access Consent", "Consent to Collect Data After Withdrawal"* | |



# LICENSED INDEPENDENT PRACTITIONER

# LICENSED INDEPENDENT PRACTITIONER (LIP)

**HRPP Policy 8.1.3.7 Individuals Who Must be Involved in the Informed Consent Process**

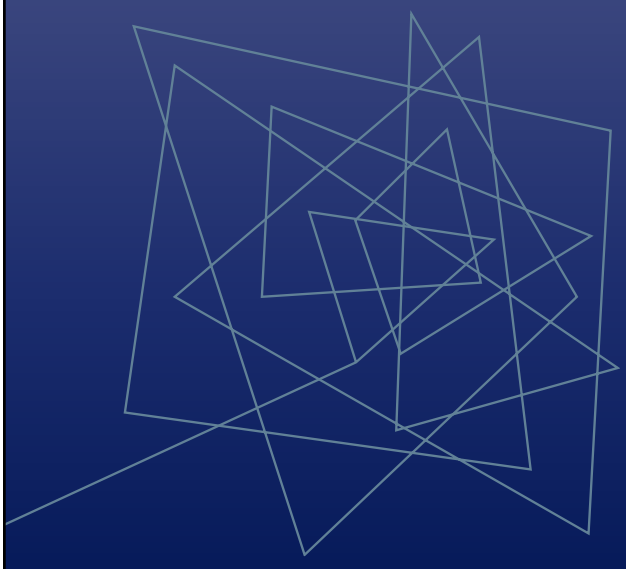
- LIP must complete the discussion of purpose, risks, benefits, and alternatives
- All studies involving drugs, devices, or surgical procedures
- Independent:
  - Individual permitted by Massachusetts law and by Boston Medical Center to provide care, treatment, and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges
  - **Residents and fellows do not qualify as LIPs** unless they have been issued a full license that allows them to practice medicine independently and they are members of the Medical-Dental Staff

**Required Documentation – Either is valid**

- ✓ LIP signs the consent document as the person who conducted the entire consent discussion
- ✓ LIP writes and signs a brief summary of the consent process as a "progress note"
  - ✓ Location of this documentation is at study team discretion – medical record or participant study binder

**Exception Possibility**

- Submit to the IRB:
  - Alternate consenting process with no LIP involvement, must include justification →
    - Why an LIP cannot be involved in consenting
    - How an alternate consenting process will protect the rights, safety and welfare of potential research subjects



# ENROLLING PARTICIPANTS WITH LIMITED ENGLISH PROFICIENCY

# LIMITED ENGLISH PROFICIENCY - LEP

- IRB Guidance on Enrolling
- HRPP Policy Section 8.4.5 Informed Consent for Non-English Speaking Subjects
  - Presented in language understandable to participant (with interpreter)
  - Written in a language understandable to the participant (translated)

  - Targeted (expected to enroll): full translation of entire consent
  - Incidental (unanticipated to enroll): short form

# LIMITED ENGLISH PROFICIENCY - LEP

**Targeted (expected to enroll) – Fully Translated Consent**

- Translation of IRB-approved English consent – submitted to IRB as amendment
- Translator qualification form submitted to IRB with translated full consent
- Conversation should take place in language understandable to participant - Interpreter
  - BMC services
  - Minors cannot serve as interpreter
- Translated consent form signed by participant and investigator

**Incidental (unanticipated to enroll) – Short Form**

- IRB will provide Short Form and Short Form Signature Page as part of approval process
- Short form + Short Form Signature Page + English narrative (can be English consent, per IRB submission/approval)
  - Stapled together – Originals kept by investigator
  - Stapled together – Copies given to participant
- Witness must be present
  - If verbal translation is done by study team member – need an impartial witness
  - If impartial interpreter used – that person can serve as witness too
- Conversation should take place in language understandable to participant - Interpreter
  - BMC services
  - Minors cannot serve as interpreter
- Short form signed by participant, witness, investigator
- Short Form Signature Page signed by witness and investigator

# TRANSLATION SERVICES
## *WHO CAN HELP AND HOW MUCH WILL IT COST?*

### ICF & RECRUITMENT MATERIAL TRANSLATION

CONTACT BMC's Clinical Trial Office for Quotes: CTO@bmc.org

Translation & Localization Vendor:

CYRACOM INTERNATIONAL, INC.

www.cyracom.com

- 300+ languages
- ISO-certified translation process
- Clear, concise, culturally relevant messaging (*localization*)

### COST (PER WORD)

| Language | New Word | 100% Match | Repeat Text | Fuzzy Match |
|---|---|---|---|---|
| Spanish | $0.13 | $0.03 | $0.04 | $0.09 |
| Haitian Creole | $0.22 | $0.06 | $0.07 | $0.15 |
| Portuguese | $0.17 | $0.04 | $0.06 | $0.11 |
| Vietnamese | $0.18 | $0.05 | $0.06 | $0.12 |

### OTHER SERVICES

| | |
|---|---|
| $65 | Translation Hourly Rate (Review, Glossary Translation) |
| $65 | Initial Source Language Glossary & Style Guide Creation |
| $60 | Post Translation DTP Format & QA Hourly Rate |
| $65 | Transcription and Voiceover Hourly Rate |
| $60 | Complex Multilingual DTP Hourly Rate |
| $70 | Graphics Localization |
| $80 | Multimedia Translation Integration |
| $100 | Project Minimum – All languages |

# SAMPLE TRANSLATION QUOTE

English to Haitian Creole

- Assent Script
- ICF
- Baseline Questionnaire
- Eligibility Screening Script – In Clinic Setting
- Eligibility Script – Response to Flyer
- Study Brochure
- Study Flyer

**Total Cost: $1,795**

**Task ID**
133307/EN » HT_HT/1

**Language pair**
English [EN] » Haitian Creole [HT_HT]

**Files**
Assent Script.docx, H-[redacted] Baseline Questionnaire (4).docx, H-[redacted] Eligibility Screening Script - in-clinic setting (5).docx, H-[redacted] Eligibility Screening Script - Response to flyer (4).docx, H-[redacted] Informed Consent.docx, revised brochure.pdf, revised flyer 2 (1).pdf

**Service**
translation

| | source word | Price | Amount |
|---|---|---|---|
| Non-translatable | 22 | $ 0.0000 | $ 0.00 |
| ICE match | 63 | $ 0.0550 | $ 3.47 |
| Leveraged match | 629 | $ 0.0550 | $ 34.60 |
| 95-99% | 535 | $ 0.1452 | $ 77.68 |
| 85-94% | 523 | $ 0.1452 | $ 75.94 |
| 75-84% | 401 | $ 0.2200 | $ 88.22 |
| Machine Translation | 0 | $ 0.2200 | $ 0.00 |
| Repetitions | 576 | $ 0.0726 | $ 41.82 |
| Internal 95-99% | 177 | $ 0.0726 | $ 12.85 |
| Internal 85-94% | 189 | $ 0.1452 | $ 27.44 |
| Internal 75-84% | 292 | $ 0.2200 | $ 64.24 |
| No match | 5,132 | $ 0.2200 | $ 1,129.04 |
| | | **Subtotal** | **$ 1,555.30** |

| Service | Quantity | Price | Amount |
|---|---|---|---|
| DTP | 4 hour(s) | 60.0000 | $ 240.00 |
| | | **Subtotal** | **$ 240.00** |
| | | **133307/EN » HT_HT/1 — Total** | **$ 1,795.30** |

# INTERPRETER SERVICES

## *STUDY SET-UP & PROCESS*

### STUDY SET-UP

1. Research teams are responsible for the interpreter costs and must build these costs into the funding/grant budget during study start-up.
2. Please complete the **Research Interpreter Service Form** so we can set your team up with **Propio®**, our phone vendor (form also found on CTO website).

   https://bmc.tfaforms.net/137
3. Study Teams will have their own direct access to interpreters and will be billed directly by the vendor. This will allow your research team to receive your own call data reports.

### HOW TO INITIATE SERVICES

1. After completing the **Research Interpreter Service Form**, study teams will be issued a **study code**.
2. To request Interpreter Support, call **(617) 414-5549 (option #3)** or **75757** from a BMC phone.
3. Enter your **study code** when prompted for a "*dept code*"
4. Request appropriate language

### 10 Tips on Working with Multicultural Patient

https://hub.bmc.org/sites/default/files/docs/2020-12/10%20AND%2010_DEC2020.pdf

# PROPIO INFORMATION CARD & COST

**Boston Medical Center**

**1. To access interpreter, dial: 75757 or (617) 414-5549 (option #4)**

**2. Enter department code /study code**

**2. Select target language**

**3. Provide required information:**

Patient MRN

**Complete language list at:**
LanguageCodes.info

| Top Language Auto Attendant | |
|---|---|
| Spanish | 1 |
| Haitian Creole | 2 |
| Cape Verde Creole | 3 |
| All Other Languages | 8 |

propio

**Telephonic Interpreting Services**

| BMC/Propio Fee Schedule | |
|---|---|
| Phone Interpretation | $0.55/min |
| Video Interpretation | $0.65/min |

# SUMMARY AND QUESTIONS

**General Resources and Guidance**

- HRPP Policy Section 8 Consent and Authorization
- HRPP Policy Section 8.1.3.7 Licensed Independent Practitioners
- IRB Consent Templates
- IRB Guidance Non-English Speaking Subjects
- Institutional SOP on Consent
- CRRO Templated Tool for Informed Consent Documentation
- OHRP Webinar "Respecting Persons – From Basic Requirements to Embracing Participant-Centered Informed Consent"


**BMC Interpreter Services Resources**

- Clinical Trial Office
- Research Interpreter Services Form
- 10 Tips on Working with Multicultural Patient