IRB Essentials:

Permissions, Recruitment and Consent

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Agenda

IRB Process Discussion:

- Permissions
- Recruitment
- Informed Consent
- Guidance Documents / IRBNet
- Q&A

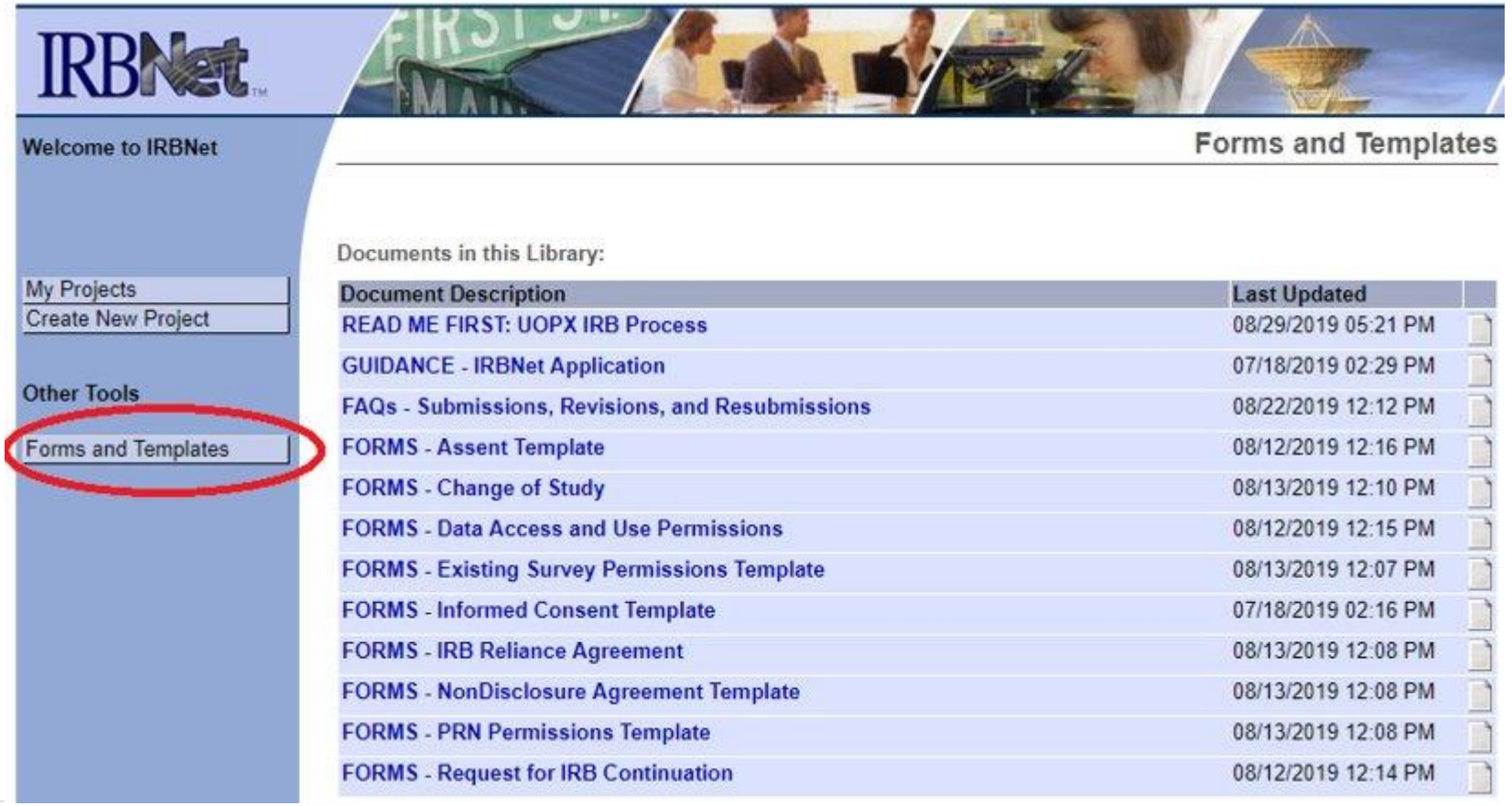
Objectives

IRB Process

- Understand the differences between Permission, Consent and Recruitment in a research context
- Gain a practical understanding of the IRB review process and how Permissions, Consent and Recruitment plans fit within the process
- Identify where Guidance Documents can be found in IRBNet

Forms and Templates Library

Everything you could ever want to know about the UOPX IRB is in the IRBNet Forms and Templates Library



Permissions

- Getting access to people or data for research usually requires cooperation from associations, organizations, schools, etc.
- Permissions should be obtained **before** submission to the IRB, but the actual *recruiting* cannot happen until **after** IRB approval is obtained.
- Permissions forms are used to verify this cooperation.
    - Signed Data Access form
    - Signed Premises, Recruitment, and Naming (PRN) form
- Researchers attach signed permissions to their IRBNet package as supplemental documents.

IRBNet forms and templates library: **GUIDANCE – Permissions**

Recruitment

- Recruitment is the identification and selection of human subjects for research.
- Recruitment is *not* “Informed Consent”. Informed Consent comes *after* recruitment.
- Recruitment materials such as announcements, flyers, letters, emails and/or scripts should include the following at minimum:
- Description of the research purpose
    - Name of the researcher,
    - university affiliation,
    - contact information
    - Eligibility criteria
    - Time commitment required
    - Location of the research

IRBNet forms and templates library: **GUIDANCE – Recruitment**

Informed Consent

- “Informed Consent” is the process for obtaining *individual* study participants.
- Informed Consent is usually a form (Paper or electronic) that participants sign prior to participating in the research.
- It provides comprehensive information regarding the study’s purpose, any possible risks and/or benefits, time required, process for withdrawing, tasks required, etc.
- In some cases, the informed consent process can be altered and/or waived depending on the risks and study design.

IRBNet forms and templates library:

– **GUIDANCE – Informed Consent**

– **GUIDANCE – Online Surveys and IRB Review**

Practical Example

- Researchers first get permissions to recruit their participants.
    - Then they must be approved by the IRB
- Researchers then recruit their participants via letters, announcements, etc.
- Once enough people have agreed to participate, each must be individually “Consented” via an informed consent process.

For example:

1. Permission to recruit teachers at a local school is obtained from the school’s Principal – and possibly from the superintendent as well
2. Researcher submits to the IRB and is approved.
3. Researcher invites all the teachers at that school to participate in the study via email.
4. Ten teachers agree to participate. The researcher collects individual informed consents from each of the ten teachers.

IRBNet forms and templates library:

– **GUIDANCE – Permissions**
– **GUIDANCE – Recruitment**
– **GUIDANCE – Informed Consent**

Forms and Templates Library

Once again:

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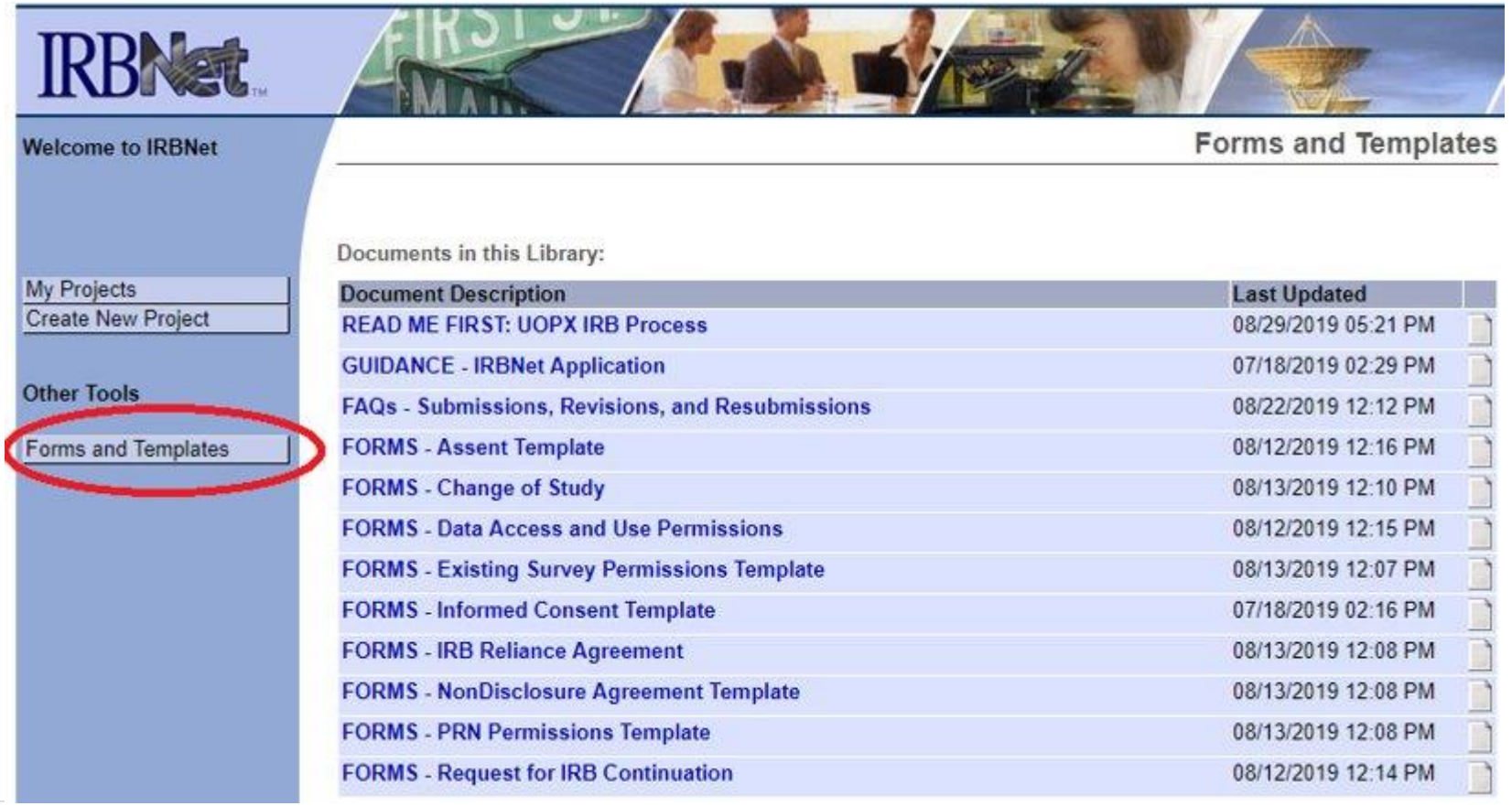

Q & A