Developing a Standardized Library of Informed Consent Language to Ensure Consistency and Quality across Clinical Studies at a Large Academic Medical Center

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BACKGROUND

As the volume of clinical studies at our institution continues to increase, and in view of recent changes to the Common Rule, it has become necessary to develop institutional guidelines for consent writers to ensure consistency, clarity, and quality of informed consent forms across all clinical studies. This situation has presented an opportunity to develop new consent templates, consent writing guidelines, and other resources to ensure quality and consistency as new consent forms are written and older consent forms are updated and revised.

METHODS

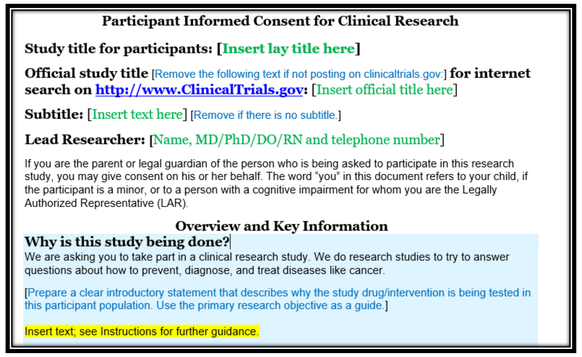
- In January 2018, MSK launched a centralized Protocol Activation Core (PAC) composed of 6 Protocol Activation Managers (PAMs), 3 Managers, and 1 Editor
- Over the last 15 months, this team has grown to 13 staff members who are involved with activating trials, which includes writing and editing consent forms for all newly-opened clinical studies
- As a result, the team has gained experience with the nuances of different studies and their effect on consent elements and structure
- This experience has lead to the revision and development of new consent writing tools that will be shared with the Center

GOALS

- Continue to develop and expand PAC Consent Library Excel tool to share with primary disease management teams (DMTs) for consent amendments
- Pilot the tool with 3-5 high-volume DMTs to train the team members and elicit feedback
- Present findings to IRB members
- Roll out PAC Consent Library to all DMTs and track efficiency metrics for DMTs, PAMs, and IRB members
  - Time required to write (PAM), review (IRB), amend (DMT/PAM) consents
  - Number of amendments returned or not approved for consent-related reasons

SOLUTIONS

Revised Consent Templates



Participant Informed Consent for Clinical Research

Study title for participants: [Insert lay title here]

Official study title [Remove the following text if not posting on clinicaltrials.gov.] **for internet search on http://www.ClinicalTrials.gov:** [Insert official title here]

Subtitle: [Insert text here] [Remove if there is no subtitle.]

Lead Researcher: [Name, MD/PhD/DO/RN and telephone number]

If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

Why is this study being done?

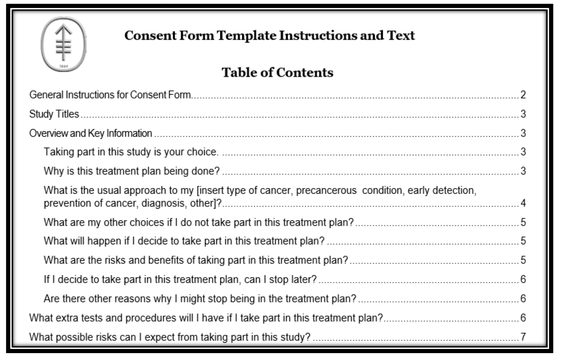
We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

[Prepare a clear introductory statement that describes why the study drug/intervention is being tested in this participant population. Use the primary research objective as a guide.]

Insert text; see Instructions for further guidance.

- Redesigned MSK templates for treatment and verbal consents; developed templates for other consent situations (e.g., pre-screening, treatment past-progression, and specialized templates for industry partners)
- Based on NCI Model, incorporating Common Rule changes, and institutional requirements

Revised Template Instructions and Text Guide

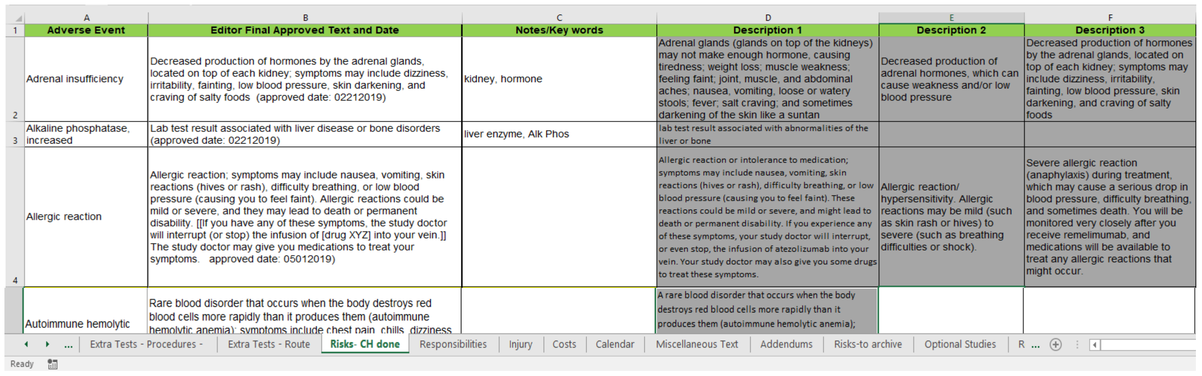


Consent Form Template Instructions and Text

Table of Contents

- Language examples organized by section of consent form
- Detailed examples provided for various types of studies (e.g., Phase 1 First-in-Human, Phase 2/3 in Previously Untreated Patients, Diagnostic Imaging)
- Approved conflict of interest text, Research-related injury language (by sponsor), and required genetic testing text

NEW – PAC Consent Library



	A	B	C	D	E	F
1	**Adverse Event**	**Editor Final Approved Text and Date**	**Notes/Key words**	**Description 1**	**Description 2**	**Description 3**
2	Adrenal insufficiency	Decreased production of hormones by the adrenal glands, located on top of each kidney; symptoms may include dizziness, irritability, fainting, low blood pressure, skin darkening, and craving of salty foods (approved date: 02212019)	kidney, hormone	Adrenal glands (glands on top of the kidneys) may not make enough hormone, causing tiredness; weight loss; muscle weakness; feeling faint; joint, muscle, and abdominal aches; nausea, vomiting, loose or watery stools; fever, salt craving; and sometimes darkening of the skin like a suntan	Decreased production of adrenal hormones, which can cause weakness and/or low blood pressure	Decreased production of hormones by the adrenal glands, located on top of each kidney; symptoms may include dizziness, irritability, fainting, low blood pressure, skin darkening, and craving of salty foods
3	Alkaline phosphatase, increased	Lab test result associated with liver disease or bone disorders (approved date: 02212019)	liver enzyme, Alk Phos	lab test result associated with abnormalities of the liver or bone		
4	Allergic reaction	Allergic reaction; symptoms may include nausea, vomiting, skin reactions (hives or rash), difficulty breathing, or low blood pressure (causing you to feel faint). Allergic reactions could be mild or severe, and they may lead to death or permanent disability. [[If you have any of these symptoms, the study doctor will interrupt (or stop) the infusion of [drug XYZ] into your vein.]] The study doctor may give you medications to treat your symptoms. approved date: 05012019)		Allergic reaction or intolerance to medication; symptoms may include nausea, vomiting, skin reactions (hives or rash), difficulty breathing, or low blood pressure (causing you to feel faint). These reactions could be mild or severe, and might lead to death or permanent disability. If you experience any of these symptoms, your study doctor will interrupt, or even stop, the infusion of atezolizumab into your vein. Your study doctor may also give you some drugs to treat these symptoms.	Allergic reaction/ hypersensitivity. Allergic reactions may be mild (such as skin rash or hives) to severe (such as breathing difficulties or shock).	Severe allergic reaction (anaphylaxis) during treatment, which may cause a serious drop in blood pressure, difficulty breathing, and sometimes death. You will be monitored very closely after you receive remelimumab, and medications will be available to treat any allergic reactions that might occur.
	Autoimmune hemolytic	Rare blood disorder that occurs when the body destroys red blood cells more rapidly than it produces them (autoimmune hemolytic anemia); symptoms include chest pain, chills, dizziness		A rare blood disorder that occurs when the body destroys red blood cells more rapidly than it produces them (autoimmune hemolytic anemia);		

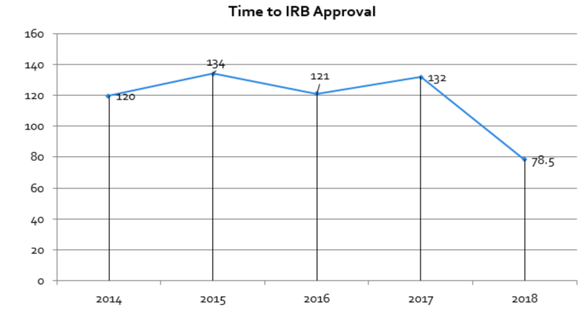
Extra Tests - Procedures - | Extra Tests - Route | Risks- CH done | Responsibilities | Injury | Costs | Calendar | Miscellaneous Text | Addendums | Risks-to archive | Optional Studies

Ready

- Text collected from IRB-approved consents since the launch of the PAC unit
- Vetted by PAC Editors, with final approved version for quick addition to new consent forms
- Separated into tabs for quick access to section-specific standardized language
- Notes/keywords column helps user find terms and definitions easily (e.g., Electrocardiogram procedure key words: ECG, EKG, electrocardiogram, heart)
- Living document! Text changes with feedback from IRB reviewers, PIs, and sponsors

OUTCOMES

- As we have continued to expand the use of these tools, we have seen a marked decrease in time to IRB approval:135 days in 2017 to 78.5 days in 2018



- Consent writing has been standardized across the institution, decreasing the time it takes to write (PAM), review (IRB), and/or amend (DMT/PAM) these forms
- The PAC Library and Template instructions have been revised and updated as we receive feedback or establish new consent best practices/SOPs

FUTURE DIRECTIONS

- Continue to develop and negotiate master consent templates for industry partners
- Post consent resources for DMTs outside of PAC to access as needed for amendments
- Train DMTs to use the consent resources
- Establish a structured feedback system for the IRB to review and update these resources
- Develop “smart” eConsent authoring tool that uses keywords to collect approved text from the PAC Consent Library. Other features of this tool will include:
  - Locked sections of required language
  - Audit trail for consent edits
  - More accurate version control