

# Consent Withdrawal – a True Story

Keisha Humphries, RN BSN MHCL  
Wichita NCORP

# The Rule

- SWOG Policy #30, Responsibility for Patient Follow-Up:
  - If a patient withdraws consent after registration, the institution must determine with the patient whether:
    1. they no longer wish to be treated per protocol;
    2. they no longer wish to be followed per protocol;
    3. or *both*.
  - **Withdrawing consent to participate in a study does not necessarily mean the patient also withdraws consent to being followed. This distinction must be clearly noted on the Off Treatment Notice or Follow-Up form.**

“Everyone has a plan until they get hit.”

-Joe Louis

# Wichita Situation

- Wichita CCOP → Wichita NCORP
  - Big Change
  - Staff Turnover
  - New Staff, New Ideas, Different Generations (We got hit!)
- Safety Huddle – News of the day
  - Where we discuss plans for day, new patient, new trials and issues
    - Frustration – unable to find patients in follow up, too many expectation reports, so many emails from Quality Assurance Specialist, patient is so frustrated with so many lab draws!
      - Solution – “I found a Withdrawal Consent on the Share Drive and can share it with you!”
        - This is so convenient

WHAT???

**Hello?**

**Did I hear that correctly?**

# The Evidence

- There had been 6 patients who had signed Consent Withdrawal forms
- Documentation was sparse
- Treating physician and research staff signature obtained

Two of the patients were truly a consent withdrawal

Step one: Educate

Step one b: Removed Withdrawal Consent from Share Drive

# The Principle of Balance

- “Life is about balance. The good and the bad. The highs and the lows. The pina and the colada.”  
- Ellen DeGeneres



# Purpose of long-term follow up

- Assure continued medical surveillance
- Allow meaningful end-results reporting
- Accurate survival data
- Disease recurrence
- Disease status
- Survival
- Monitor for long – term adverse events and treatment – related malignancies
- New Malignancies



# Consent Withdrawal Education

**Study Treatment:** Indicate your choice below

\_\_\_\_\_ I would like to stop treatment on this research study. I will continue as a study participant for follow-up visits and allow tests to be completed that will continue to be used for research purposes.

Asking to stop the treatment on trial

- Side Effects
- Life Plan
- Financial
- BUT this patient wants to continue follow up and will allow trial testing
- Notify Research Base of patient choice to stop treatment

# Consent Withdrawal Education

**Study Treatment:** Indicate your choice below

\_\_\_\_\_ I would like to stop treatment on this research study. I will continue as a study participant but will **not allow more tests** to be completed for research purposes. Information may be collected from my medical records.

Asking to stop the treatment on trial and does not want test for research purposes only. But you can follow this patient and report additional information, treatments, lab/path reports and medical testing (radiology etc.)

- BUT this patient wants to continue follow up
- Clarify if okay to see in clinic, and if phone calls are okay.
- Notify Research Base of patient choice to stop treatment and the decision to stop protocol testing.

# Consent Withdrawal Education

**Study Treatment:** Indicate your choice below

\_\_\_\_\_ I no longer want to participate in this study and I do not want any further medical information to be used for research. Information that has already been obtained will remain as part of the research record, but no additional information will be added to the research record.

- Patient does not want to be on trial and does not want additional information sent to the research base after this point.
  - Would consider this a Consent Withdrawal – no additional information or follow up information is to be sent.
    - Documentation of conversation – by physician and research staff
  - This patient wants NO additional information sent to research base.
  - Notify Research Base of patient consent withdrawal, but previous information/data is okay.

# Patient Case Study

- Female with stage II breast cancer
- Married, no children
- Registered to S1207 – Hormone Therapy + Everolimus/placebo

Then life happens:

- Marital issues → behavioral health issues → homeless →
- Fires physician → stops or runs out of study medication  
What do you do? How do you find her?
- Is this a withdrawal consent situation ?

# Next Steps

- Cool down period – (for all)
- Has she been on study medication? Supply?
- Contact possible?
- Discussion and possible transfer to a new physician? Or clinic in your area?

Patient has not asked to withdrawal from the trial, has only asked for a new physician. Would continue to follow up and send information as available. Not about convenience.

## Patient Situation Number Two

68 yo male with CML, married for 39 years

Married, 6 children and 10 great grandchildren

Has mentioned several times his fear of needles

Registered to a CML clinical trial – requires a kit q 6 months and a yearly bone marrow bx.

At year one, as you are prepping him for his bone marrow bx.....he says please don't make me do this. I hate needles!

# The Fear is Real!

This would be a time for a conversation with patient and his physician.

- Is this needed for disease process or a clinical trial requirement?
- What plan is worked out with the patient and physician?
- Can the patient stay on the study medication without a bm Bx? A call and follow up with research base would be necessary.
- IF the patient is off the medication – then discuss if the patient is still willing to be followed and information submitted.
  - Sometimes this is all in the approach --

# The tiny Writing at the bottom of the page....

2/7/10; 05/02/11am; 11/04/11 am; 06/02/2015 sp; 03/02/2017 at; 07/24/2017 srs;09/18/2018; srs 10/04/2018

---



# Notification Process

Please sign and date this form. Return the completed form to the research staff.

**Signature of Patient:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature of Physician:** \_\_\_\_\_ **Date:** \_\_\_\_\_

I have received and reviewed.

**Signature of Research Nurse:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature of NCORP Manager:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature of NCORP Administrator:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature of NCORP Principle Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Reason for form completion:** \_\_\_\_\_

929 N St Francis, Wichita, KS 67214 PH 316.268.5374 EX 316.291.7855 W [vlachristl.org/cancerresearch](http://vlachristl.org/cancerresearch)

Wichita NCI Community Oncology Research Program is a NCI grant-funded program since 1983. Administered by Via Christi Hospitals Wichita, Inc.

2/7/10; 05/02/11am; 11/04/11 am; 06/02/2015 sp; 03/02/2017 at; 07/24/2017 srs;09/18/2018; srs 10/04/2018

# Over KiLL?

- *Probably so*

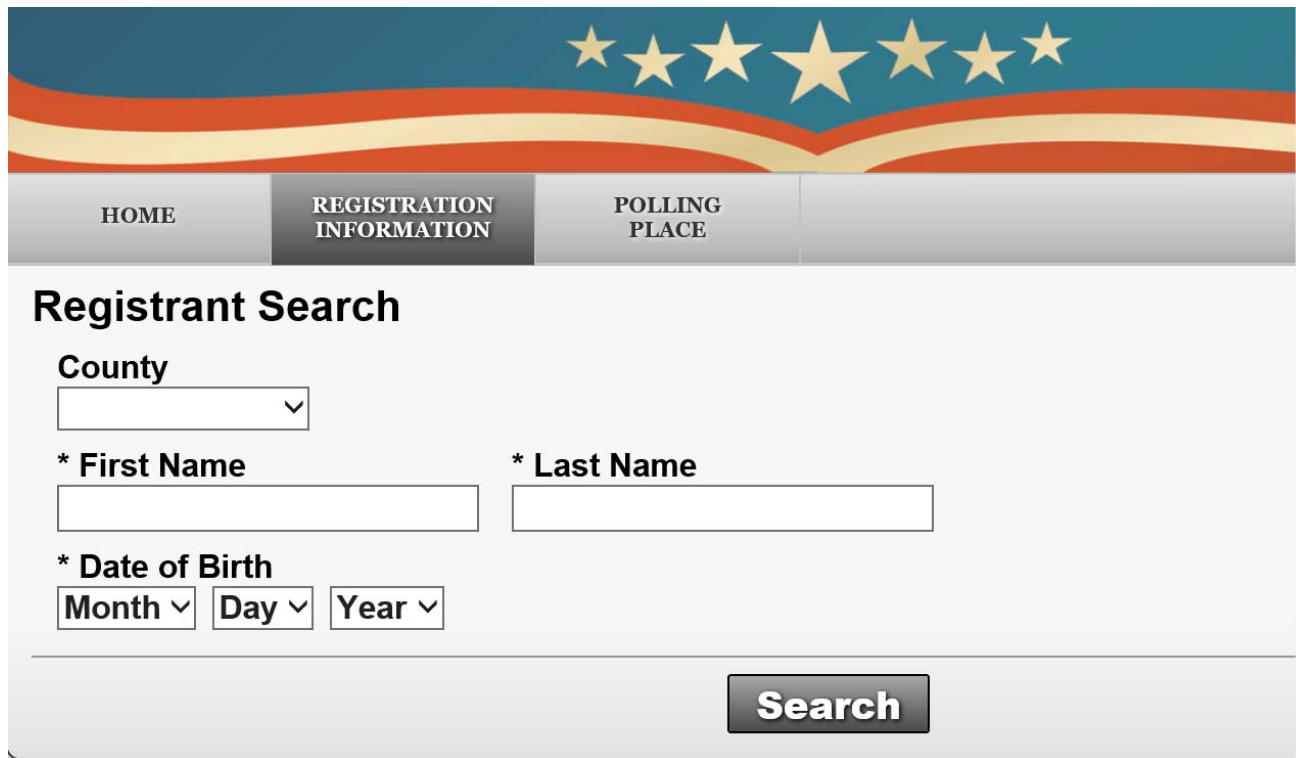
**But** the hope is that this form allows for patients to receive education on what options are available when life changes occur. It is important that patients know how important they are to clinical trials.....no patients would equal no cures or improvements.

By requiring all of those signature we are hoping that new staff and experience staff are having many conversations. These conversations may lead to changes in the processes of the clinic, communication regarding clinical trials and education for all that sign the form.

# If Patient is Difficult to Find - Tips

- Hospital EHR or computer system
- Voter registration – depend on State regulations.
- Hospital cancer registries
- Family members
- State EMR systems
- State cancer registries

# Example of Kansas Voter Registry Page



The screenshot shows the Kansas Voter Registry website. At the top is a decorative banner with a stylized American flag. Below the banner is a navigation menu with three tabs: 'HOME', 'REGISTRATION INFORMATION' (which is highlighted), and 'POLLING PLACE'. The main content area is titled 'Registrant Search'. It contains a 'County' dropdown menu, followed by two required text input fields for '\* First Name' and '\* Last Name'. Below these is a 'Date of Birth' section with three dropdown menus for 'Month', 'Day', and 'Year'. A large 'Search' button is positioned at the bottom right of the search form.

HOME    **REGISTRATION INFORMATION**    POLLING PLACE

## Registrant Search

County

\* First Name       \* Last Name

\* Date of Birth  
Month  Day  Year

**Search**

# Our Team



# Questions?

