

# Clinical Trial/Gene Therapy Psychosocial Template

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## **Adult Psychosocial Assessment Template Research and/or Gene Therapy**

*This template is an outline of recommended psychosocial assessment considerations for clinical trial participation and/or evaluation of psychosocial impact of gene therapy trial participation. This document is subject to change at the clinical expertise of the clinical social worker administering the tool in compliance with the NASW Code of Ethics and the health care institutions policies and procedures.*

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## **Summary**

### **Clinical Trial and/or Gene Therapy Psychosocial Assessment Template**

**History & Need:** The engagement of clinical trials, and that of gene therapy has opened the blood disorder community to an expansion of care options through clinical trials. As part of the multidisciplinary care team in the federally funded hemophilia treatment centers, clinical social workers provide expertise to evaluate psychosocial barriers to care, supports, and socioeconomic impact.

**Purpose:** This Clinical Trial Psychosocial Template will provide standardized tools for clinical social workers to assist with evaluating psychosocial needs for patients considering Clinical Trials and/or Gene Therapy Clinical Trials.

**Use of tool:**

This template can be used in full or partial form at the discretion of the clinical social worker and their institution.

It is recommended fully licensed clinical social workers following the NASW Standards for Social Work Practice in Health Care assess patients considering clinical trails in the inheritable blood disorder community due to the complexity of psychosocial impact socially, emotionally, physically, mentally, and financially. Mental health clinicians of equal licenser and expertise are also appropriate pending the institution's composition of the multidisciplinary team.

National Association of Social Workers (NASW) Standards for Social Work Practice in Health Care Settings ensure fully licensed social workers follow the ethical standards of providing clinical care, and ensure competences for care spanning from clinical assessment and quality improvement through cultural and linguistic competencies.

## **Interview Specifics**

Date of interview: \_\_\_\_\_  Gene Therapy  Research Trial

Interviewer: \_\_\_\_\_ Interviewee: \_\_\_\_\_

Study Name: \_\_\_\_\_ Pharma Co: \_\_\_\_\_

Study Phase: \_\_\_\_\_ Duration of Study: \_\_\_\_\_

Has the patient been medically cleared to participate in this study/Gene Therapy?  
(Otherwise healthy; diabetes, history of cancer, heart disease, glaucoma, high blood pressure, etc.)

No  Yes  Document in record  Document pending

*This MSW Psychosocial assessment will assess for biopsychosocial barriers and resource needs.*

## **Demographic Information**

Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Medical Record #: \_\_\_\_\_ Age: \_\_\_\_\_

Race: \_\_\_\_\_ Gender: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ Diagnosis date: \_\_\_\_\_

Primary Physician: \_\_\_\_\_ PCP Location: \_\_\_\_\_

Hematologist: \_\_\_\_\_

HTC: \_\_\_\_\_

Patient Primary Language: Spoken: \_\_\_\_\_ Written: \_\_\_\_\_

Interpreter Needed: Yes  No  Language: \_\_\_\_\_

## **Household Composition**

Adult: Patient Married: \_\_\_\_\_ Partner/ Spouse: \_\_\_\_\_

Authorized consent to speak with spouse:  Yes  No Children: \_\_\_\_\_

Is there guardianship in place? \_\_\_\_\_

Advanced Directive on file:  Yes  No Healthcare Power of Attorney:  Yes  No

Follow up Needed? Explain: \_\_\_\_\_

## **Education & Development**

Highest level of education: \_\_\_\_\_ Occupation: \_\_\_\_\_

Currently enrolled in school: \_\_\_\_\_ Interested in further education: \_\_\_\_\_

Self identified learning: \_\_\_\_\_

Days missed from work and/or school: \_\_\_\_\_

Barriers to communication: \_\_\_\_\_

Other: \_\_\_\_\_

## **Medical History**

Other illnesses and diagnoses \_\_\_\_\_

Status: \_\_\_\_\_

Compliance with current treatment plan for BDO: (based on categories from SIPAT page 2-of 17):

\_\_\_\_\_

Good (mostly) \_\_\_\_\_ Moderate (partially) \_\_\_\_\_ Limited (no consistency with dosing)

Comments: \_\_\_\_\_

Compliance with treatment plan for other illnesses:

Good (mostly) \_\_\_\_\_ Moderate (partially) \_\_\_\_\_ Limited (no consistency with dosing)

Comments: \_\_\_\_\_

ADL/IADL/Mobility status/ use of DME: \_\_\_\_\_

\_\_\_\_\_

Potential impact of Gene Therapy/Research/Clinical trial on current compliance and developmental status: \_\_\_\_\_

## **Patient/Family Support/Resources**

Patient/Family identifies the following as their primary support: (List info after checked section, and level of engagement and support)

- Immediate Family \_\_\_\_\_
- Extended Family \_\_\_\_\_
- Partner \_\_\_\_\_
- Friends \_\_\_\_\_
- Mental Health Agency \_\_\_\_\_
- Disease Specific Agency \_\_\_\_\_
- Faith Community \_\_\_\_\_
- Social Organization \_\_\_\_\_
- Other (ex. Pain Specialist/etc.) \_\_\_\_\_
- Safety Assessment: (Evaluation of potential abuse, neglect, exploitation, sex trafficking). \_\_\_\_\_

## **Financial Resources**

- |   |  |
|---|--|
| <input type="checkbox"/> Full-time Employment               | <input type="checkbox"/> Food Assistance/WIC         |
| <input type="checkbox"/> Part-time Employment               | <input type="checkbox"/> Unemployment                |
| <input type="checkbox"/> Self Employed                      | <input type="checkbox"/> Veteran's Services/Military |
| <input type="checkbox"/> SSI/SSDI                           | <input type="checkbox"/> Pension                     |
| <input type="checkbox"/> Child Support                      |  |
| <input type="checkbox"/> Public Assistance                  |  |
| <input type="checkbox"/> Patient Assistance Programs: _____ |  |

Other Resources: (specify) \_\_\_\_\_

\_\_\_\_\_

**Social Security Disability Insurance (SSDI):** Is the patient on disability? \_\_Yes\_\_ No

Certified Disability Diagnosis: \_\_\_\_\_

Will Gene Therapy/Research process or outcomes impact disability status or requirements? \_\_Yes  
No

Explain: \_\_\_\_\_

**Financial Resources continued:**

Income:

- Meets usual expenses
- Exceeds usual expenses
- Doesn't cover expenses

Notes: \_\_\_\_\_

\_\_\_\_\_

Primary Health Insurance Provider: \_\_\_\_\_

Secondary Health Insurance Provider: \_\_\_\_\_

Dental Insurance: \_\_\_\_\_ Vision Insurance: \_\_\_\_\_

If unintended expenses occur that are not covered by the Gene Therapy/Research Trial, will financial assistance be needed?

- |   |  |
|---|--|
| <input type="checkbox"/> Depends on the amount                    | <input type="checkbox"/> No                                  |
| <input type="checkbox"/> Assistance is appreciated but not needed | <input type="checkbox"/> Specifically anticipated need _____ |
| <input type="checkbox"/> Yes                                      | <input type="checkbox"/> Notes/Concerns: _____               |

**Transportation**

Distance to treatment center from home: \_\_\_\_\_

Method of transportation:

- |   |  |
|---|--|
| <input type="checkbox"/> Public Transit   | <input type="checkbox"/> Non-profit organization |
| <input type="checkbox"/> Personal Vehicle | <input type="checkbox"/> Medicaid                |
| <input type="checkbox"/> Family/Friends   | <input type="checkbox"/> Other: _____            |

Barriers for reliable transportation to medical care: \_\_\_\_\_

**Lodging**

Review of facility rules and regulations with guests staying with patients in acute care.

If lodging arrangements are needed during Gene Therapy/Research, what type does the patient request:

- |  |  |
|--|--|
| <input type="checkbox"/> Local Residence       | <input type="checkbox"/> Hospitality House Program |
| <input type="checkbox"/> Ronald McDonald House | <input type="checkbox"/> Motel/Hotel               |

Other: \_\_\_\_\_

## Coping/Social

### Coping/Social: If confirmed factors, add expounding information

<i>Noted formal Clinical Mental Health diagnosis and treatment</i>	
<i>History of mental health issues/medications</i>	
<i>History of in-patient/out-patient treatment or hospitalization</i>	
<i>History of drug use</i>	
<i>History of alcohol use</i>	
<i>History of marijuana use (medical or recreational)</i>	
<i>History of domestic violence</i>	
<i>Abuse, neglect, or exploitation issues</i>	
<i>Legal Issues and/or history (probation/parole)</i>	
<i>Alternative medications/holistic medications</i>	
<i>History of opioid use</i>	
<i>Caregiving responsibilities</i>	
<i>Fear of medical care (needles, enclosed spaces, etc.)</i>	
<i>Other</i>	
<i>Notes:</i>	



## Coping/Social Risk Assessment

- no apparent risk factors
- have minimal issues but able to participate
- have issues that need to be resolved before successful participation

## Clinical Impressions

### CLINICAL IMPRESSIONS (*adaptation from The Valerie Fund Assessment Tool*)

<i>(Check all that apply)</i>	Patient	Parent	Parent	Other
<b>Usual Emotional Responses:</b>				
Appropriate & normal range of emotions				
Gets appropriately upset, yet reasonable				
Emotional but manageable, can calm				
Disruptive/extreme expression of emotions				
Withdraws/shuts down emotionally				
<b>Understanding of Research/Gene Therapy</b>				
Adequate understanding				
Seeks information appropriately				
Passive, asks few questions				
Poor or distorted comprehension				
Unrealistic expectations				
<b>Interactions with Treatment Team:</b>				
Cooperative, appreciative				
Appropriately assertive				
Guarded, quiet				
Has difficulty participating or asserting self				
Compliant; passive aggressive, not engaged				
Dissatisfied with team/process/care				
Other:				
<b>Ability to Cope/Function:</b>				
Capable of participating in plan				
Demonstrates ability to follow instructions				
Adequate functioning, though limited/slow				
Capable of participating with guidance				
Needs constant redirection & focus				
Has difficulty following instructions				
Other:				

### Clinical Impressions continued:

Is parent/child interaction appropriate? \_\_\_\_NA (adult patient) \_\_\_\_Yes \_\_\_\_NO \_\_\_\_Unknown  
*Explain (bond appropriate/caring or emotional inhibiting interactions/poor boundaries)*

---

Does mental, physical, emotional state appear to be appropriate for GT/research? \_\_\_\_Yes \_\_\_\_No *Explain, include potential barriers or concerns*

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## **Research Trial/Gene Therapy**

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li><input type="checkbox"/> Reasons <u>for</u> participating in trial/research<br/><i>(Check all that apply)</i></li> <li><input type="checkbox"/> I'm not sure why I signed up</li> <li><input type="checkbox"/> Take an active role in my healthcare</li> <li><input type="checkbox"/> To receive medical care without insurance</li> <li><input type="checkbox"/> Improved quality of life</li> <li><input type="checkbox"/> Financial compensation</li> <li><input type="checkbox"/> Access to new medications &amp; supplies</li> <li><input type="checkbox"/> Increased access to treatment team</li> <li><input type="checkbox"/> To help advance science in area of BDO</li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> To participate in building trust and decreasing fear about clinical trials</li> <li><input type="checkbox"/> Better outcomes for future generations</li> <li><input type="checkbox"/> Access without co-pays &amp; deductible</li> <li><input type="checkbox"/> Increased knowledge of my disorder</li> <li><input type="checkbox"/> Trial medications work better</li> <li><input type="checkbox"/> Ability to opt out, withdraw consent</li> <li><input type="checkbox"/> Other, <i>please explain</i></li> </ul> <hr/> <hr/> <hr/> |
|--|---|

Consider asking about goals for outcomes, anticipated expectations around outcomes, use teach back method to assess literacy

### **Level of comfort with existing? knowledge of this trial and participation**

- Very comfortable and able to move forward with the knowledge that I have
- Mostly comfortable with what I know but have a few more questions
- Slightly anxious about moving forward and have several questions for my treatment team
- Somewhat fearful and anxious and would like to temporarily postpone participation until I get more information and "feel better" about moving forward
- I realize that I do not want to move forward and would like to withdraw consent

### **Education on Gene Therapy Treatment (source [www.hemophilia.org](http://www.hemophilia.org)) Are you aware In addition to being a male over the age of 18 there are other important eligibility requirements that must be met:**

- Currently, women & children under 18 are not able to participate in Gene Therapy
- Responses to gene therapy varies from person to person
- Different gene therapy patients may have different factor level results
- At this time it is unknown how long the effects of gene therapy will last
- Your need for factor after gene therapy will be assessed & monitored by your medical team
- You may be required to be on steroid medications for an extended period to make sure you tolerate therapy
- Right now, if gene therapy doesn't work it can only be done once
- Gene therapy can't be reversed or stopped
- There are risks associated with gene therapy
- Once you have gene therapy you will need to be monitored for several years after the therapy.

## Educational Materials

**Note to Care Team:** NHF has extensive educational materials on clinical trials, gene therapy and more. Visit their website at [www.hemophilia.org](http://www.hemophilia.org) for more information or call NHF's Information Resource Center (HANDI) at 800-424-2634, extension 2 or via email at: [handi@hemophilia.org](mailto:handi@hemophilia.org)

## Plan of Intervention

Customary and supportive interventions will be provided throughout the research/gene therapy process for all participants based on the identified needs Consider language for formatting recommendations of written recommendation for both options

	Provided	Is needed
Targeted supportive counseling		
Educational materials on research/gene therapy		
Ongoing assessment(monitor progress in identified areas)		
Crisis intervention counseling		
Cognitive behavioral interventions		
Referral for psychiatric evaluation		
Assistance with practical/financial concerns		
Counseling/Interventions with/for family members		
Referral to community agencies, support groups		
Other ( <i>specify</i> )		

## Notes:

### Impression of Commitment to Care Plan: Level of understanding through teach back of required engagement and commitment to clinical trial participation

Knowledge & understanding of \_\_\_\_\_Gene Therapy \_\_\_\_\_Clinical Research Study

- Good Understanding:** Patient/support system have a reasonable and clear understanding of commitment, action steps, requirements and potential outcomes of participation
- Moderate Understanding:** Patient/support system need a minimal amount of education, information or literature for a reasonable and clear understanding of commitment, action steps, requirements and potential outcomes of participation
- Poor Understanding:** Patient/support system unable to retain, process or transfer learning necessary to follow through with the commitment, action steps or requirements of participation.

## **Psychosocial Recommendation**

- Recommend proceeding with Gene Therapy/Research
- Recommend proceeding with Gene Therapy/Research with concerns/interventions

*(Explain)* \_\_\_\_\_  
\_\_\_\_\_

- Do not recommend proceeding with Gene Therapy/Research *(Explain)*

*(Explain)* \_\_\_\_\_  
\_\_\_\_\_

## **Related Documents Tools:**

**(May vary with institutions and region)**

- Gene Therapy and/or Clinical Trial Educational Document
- Communication/Behavioral Agreement
- Unbiased/Unbranded Educational Materials
- DPOA/Advanced Directive/Power of Attorney
- Guardianship documents
- Electronic Communication Consent
- Employer Disclosure
- School Disclosure