

**N.B.** The form is to be submitted to the study office after completed patient appointment.

# CRF 1 - Research subject data

Study site  Göteborg  Linköping  Lund  Stockholm  Umeå  Uppsala  \_\_\_\_\_

A. Personal data		
Family number	Local identification number:	Cancer diagnosis or relapse in the last year Yes <input type="radio"/> No <input type="radio"/>
Name	First name/ Last name _____	
Social security no.	YYYYMMDD-XXXX <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Patient prefers Paper survey (record address) <input type="radio"/> E-survey online (record e-mail-address) <input type="radio"/>
Contact info.	Address / e-mail	

B. Consent	
Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

C. Inclusion criteria	
a) Referred to or contacted oncogenetic unit	Yes <input type="radio"/> No <input type="radio"/>
b) Returned signed consent form	Yes <input type="radio"/> No <input type="radio"/>
c) Is over 18 years of age	Yes <input type="radio"/> No <input type="radio"/>
d) Belongs to family with increased risk (to D)	Yes <input type="radio"/> No <input type="radio"/>
e) Has at least one at-risk relative to inform	Yes <input type="radio"/> No <input type="radio"/>

D. Family diagnosis	
1. Familial breast cancer (risk >20%)	Yes <input type="radio"/>
2. Familial colorectal cancer (>1 coloskopy)	Yes <input type="radio"/>
3. Pathogenic variant in BRCA1, BRCA2, PALB2	Yes <input type="radio"/>
4. Lynch syndrome (MLH1, MSH2, MSH6, PMS2, EPCAM)	Yes <input type="radio"/>

E. Randomization (if patient fulfills all criteria in C)		
<input type="radio"/> New patient	<input type="radio"/> Previously randomized	DIRECT-participant number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
<input type="checkbox"/> Control <input type="checkbox"/> Intervention		

Genetic screening  Predictive testing

F. Cancer genetic results discussed with patient		
Clinical relevance for at-risk relatives discussed with patient. (T=0).  <b>Note:</b> Also fill in the CRF2-form with listing of p at-risk relatives.	Staff in charge of appointment: _____	Date (T=0) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Date (YY/MM/DD)
	Comment / note: _____	

G. Transfer to research database (for study staff in Umeå)		
Date of registration (YYYY/MM/DD) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Other notes:	Adress to the study office: <b>Norrlands universitetssjukhus Regionalt cancercentrum Norr Cancerogenetisk mottagning "DIRECT-studien" / Carin Nylander 901 85 UMEÅ</b>
Signature		

**Questions?** Please contact the national study coordinator by phone **076-69 60 648** or by email **directstudien.rct@umu.se**.

**N.B.** The form should be stored together with patient records in local clinical archive.

# CRF 2 - Family follow-up data

## A. Patient under investigation

Family number	Local identification number:	Assigned to study group <input type="checkbox"/> Control <input type="checkbox"/> Intervention
Study-specific family number	DIRECT-study participant number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	
Name	First / Last name _____	Signature:
Social security no.	YYYY/MM/DD-XXXX <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Total number of at-risk relatives

Sex	<input type="text"/> <input type="text"/>	Women	<input type="text"/> <input type="text"/>	Men	<input type="text"/> <input type="text"/>
Relation	<input type="text"/> <input type="text"/>	1 <sup>st</sup> degree	<input type="text"/> <input type="text"/>	Other	<input type="text"/> <input type="text"/>

## B. At-risk relatives (complete the list for all study participants)

<b>1</b>	<input type="radio"/> Sister <input type="radio"/> Brother <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> _____	Is the at-risk relative already aware of the genetic investigation?	Yes <input type="radio"/> No <input type="radio"/> Unsure <input type="radio"/>
	First- & Last name _____	Has contacted oncogenetic clinic? Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>
	Street Address _____	Address details sufficient to send DIRECT-letter?	Yes <input type="radio"/> No <input type="radio"/>
	Zip code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> City _____	Proband consented to contact the at-risk relative by letter?	Yes <input type="radio"/> No <input type="radio"/>
	Date of birth (if known) + additional notes <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	DIRECT-letter sent to relative Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>
		Letter retrieved from postal office Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>

<b>2</b>	<input type="radio"/> Sister <input type="radio"/> Brother <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> _____	Is the at-risk relative already aware of the genetic investigation?	Yes <input type="radio"/> No <input type="radio"/> Unsure <input type="radio"/>
	First- & Last name _____	Has contacted oncogenetic clinic? Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>
	Street Address _____	Address details sufficient to send DIRECT-letter?	Yes <input type="radio"/> No <input type="radio"/>
	Zip code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> City _____	Proband consented to contact the at-risk relative by letter?	Yes <input type="radio"/> No <input type="radio"/>
	Date of birth (if known) + additional notes <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	DIRECT-letter sent to relative Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>
		Letter retrieved from postal office Date <input type="text"/>	Yes <input type="radio"/> No <input type="radio"/>

>>> Additional listing space on the next page

<b>3</b>	<input type="radio"/> Sister <input type="radio"/> Brother <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> _____	Is the at-risk relative already aware of the genetic investigation?	Yes <input type="radio"/> No <input type="radio"/> Unsure <input type="radio"/>
	First- & Last name _____	Has contacted oncogenetic clinic? Date _____	Yes <input type="radio"/> No <input type="radio"/>
Street Address _____		Address details sufficient to send DIRECT-letter?	Yes <input type="radio"/> No <input type="radio"/>
Zip code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> City _____		Proband consented to contact the at-risk relative by letter?	Yes <input type="radio"/> No <input type="radio"/>
Date of birth (if known) + additional notes <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		DIRECT-letter sent to relative Date _____	Yes <input type="radio"/> No <input type="radio"/>
		Letter retrieved from postal office Date _____	Yes <input type="radio"/> No <input type="radio"/>

<b>4</b>	<input type="radio"/> Sister <input type="radio"/> Brother <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> _____	Is the at-risk relative already aware of the genetic investigation?	Yes <input type="radio"/> No <input type="radio"/> Unsure <input type="radio"/>
	First- & Last name _____	Has contacted oncogenetic clinic? Date _____	Yes <input type="radio"/> No <input type="radio"/>
Street Address _____		Address details sufficient to send DIRECT-letter?	Yes <input type="radio"/> No <input type="radio"/>
Zip code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> City _____		Proband consented to contact the at-risk relative by letter?	Yes <input type="radio"/> No <input type="radio"/>
Date of birth (if known) + additional notes <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		DIRECT-letter sent to relative Date _____	Yes <input type="radio"/> No <input type="radio"/>
		Letter retrieved from postal office Date _____	Yes <input type="radio"/> No <input type="radio"/>

<b>5</b>	<input type="radio"/> Sister <input type="radio"/> Brother <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> _____	Is the at-risk relative already aware of the genetic investigation?	Yes <input type="radio"/> No <input type="radio"/> Unsure <input type="radio"/>
	First- & Last name _____	Has contacted oncogenetic clinic? Date _____	Yes <input type="radio"/> No <input type="radio"/>
Street Address _____		Address details sufficient to send DIRECT-letter?	Yes <input type="radio"/> No <input type="radio"/>
Zip code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> City _____		Proband consented to contact the at-risk relative by letter?	Yes <input type="radio"/> No <input type="radio"/>
Date of birth (if known) + additional notes <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		DIRECT-letter sent to relative Date _____	Yes <input type="radio"/> No <input type="radio"/>
		Letter retrieved from postal office Date _____	Yes <input type="radio"/> No <input type="radio"/>

Comment to the study secretariat:

# CRF 3 - Outcome data

Study site  Göteborg  Linköping  Lund  Stockholm  Umeå  Uppsala  \_\_\_\_\_

A. Patient who started the investigation		
Family number	Local unit/clinic number: _____	Assigned to study group
Study-specific family number	DIRECT-study participant number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	<input type="checkbox"/> Control <input type="checkbox"/> Intervention
Name	First / Last Name _____	Type of investigation
Social security no.	Date YYYY/MM/DD-XXXX <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Gen.screen. <input type="checkbox"/> Pred.testing

B. Evaluation of results	
Date when registers were checked	(First / Last name) _____
Relatives were followed-up (YYYY/MM/DD)	Comments /notes:
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

C. Summary of main outcome after 12 months	TOTAL					
I: Total number of relatives who could benefit from being informed	<input type="text"/> <input type="text"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">Women / Men</td></tr> <tr><td style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></td></tr> <tr><td style="text-align: center;">1<sup>st</sup> degree / Other</td></tr> <tr><td style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></td></tr> </table>	Women / Men	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	1 <sup>st</sup> degree / Other	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Women / Men						
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>						
1 <sup>st</sup> degree / Other						
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>						
II: Number of relatives who could not be identified / address unknown	<input type="text"/> <input type="text"/>					
III: Number of relatives who contacted a cancer genetics clinic within 1 year	<input type="text"/> <input type="text"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">Women / Men</td></tr> <tr><td style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></td></tr> <tr><td style="text-align: center;">1<sup>st</sup> degree / Other</td></tr> <tr><td style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></td></tr> </table>	Women / Men	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	1 <sup>st</sup> degree / Other	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Women / Men						
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>						
1 <sup>st</sup> degree / Other						
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>						

D. Intervention - secondary outcomes	
I: Relatives the proband consented to contact by DIRECT-letter (number)	<input type="text"/> <input type="text"/>
II: Relatives who had already contacted a clinic before letter (number)	<input type="text"/> <input type="text"/>
III: Number of registered letters which were actually sent	<input type="text"/> <input type="text"/>
IX: Number of registered letters which were retrieved from the post office	<input type="text"/> <input type="text"/>

G. Transfer to research databas		
Day of registration (YYYY/MM/DD)	Comments /notes for study administrator:	<p><b>Norrlands universitetssjukhus</b>                      Regionalt cancercentrum norr                      Att. Carin Nylander                      "DIRECT-studien"                      Byggnad 5B, plan 0,                      901 85 UMEÅ</p>
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Signature:		

**Questions?** Please contact the national study coordinator by phone **076-69 60 648** or by email **directstudien.rct@umu.se**.