

ACRIN 6673

Multicenter Feasibility Study of Percutaneous
Radiofrequency Ablation of Hepatocellular
Carcinoma in Cirrhotic Patients

CRF Set



ACRIN Adverse Event Form

ACRIN Study

Case #

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

All questions regarding Adverse Events should be directed to ACRIN. All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI and ACRIN within 24 hours of knowledge, (b) AdEERS report completed and submitted as specified in the protocol, and (c) completed AE case report form with investigator's signature submitted to ACRIN via web and filed in the participant chart.

AE Description	AE Short Name CTCAE v3.0	CTCAE Grade	Attribution	1 = Expected 2 = Unexpected	AdEERS Submitted for SAEs	Action Taken	Outcome	Date of AE Onset and Resolution
		1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening or disabling 5 = Fatal	1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite		1 = No 2 = Yes	1 = None 2 = Medication Therapy 3 = Procedure 4 = Hospitalization 5 = Other	1 = Recovered 2 = Improved 3 = Ongoing 4 = Death 5 = Unknown	(mm-dd-yyyy); check box "on-going" if the AE is on-going at the time of report <input type="checkbox"/> On-going
1								Start date: ____ - ____ - ____ Resolution date: ____ - ____ - ____ <input type="checkbox"/> On-going
2								Start date: ____ - ____ - ____ Resolution date: ____ - ____ - ____ <input type="checkbox"/> On-going
3								Start date: ____ - ____ - ____ Resolution date: ____ - ____ - ____ <input type="checkbox"/> On-going

Comments - for each comment, identify the AE number from above (#1-3):

If there are more than 3 AEs for a visit, check this box and use another form.
 <<Page ____ of ____>>

Investigator Signature _____

Date Form Completed (mm-dd-yyyy) _____



**ACRIN 6673
Treatment Labs**

If this is a revised or corrected form, indicate by checking box.

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

Instructions: To be completed at each ablation session by the Study Interventional Radiologist. Report all dates mm-dd-yyyy. Pages 1 and 2 must be completed "prior" to ablation session. Pages 3 and 4 are completed "post" ablation session.

1. Date of RFA session: ① - ___ - ___ Date 10
(mm-dd-yyyy)

② 2. Aspirin and nonsteroidal anti-inflammatory multiple medications, antiplatelet medications, or warfarin discontinued prior to the procedure, per Sec 5.3.8?

- No, specify reason: ③ _____ (STOP, SIGN and DATE form. RFA treatment may not commence)
- Yes Character 40
- Participant not taking these medications

④ 3. Low molecular heparin discontinued 12 hours prior multiple to RFA session, per Sec. 5.3.9

- No, specify reason: ⑤ _____ (STOP, SIGN and DATE form. RFA treatment may not commence)
- Yes Character 40
- Participant not taking heparin

⑥ 4. Pregnancy test performed, per Sec. 5.3.7.7 Multiple

- No, specify reason: ⑦ _____ (STOP, SIGN and DATE form. RFA treatment may not commence)
- Yes, results negative Character 40
- Yes, results positive (STOP, SIGN and DATE form. RFA treatment may not commence)
- Not applicable



ACRIN 6673 Treatment Labs

Revision

ACRIN Study 6673 PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

5. PRE-RFA SESSION LABORATORY EVALUATIONS:

[Performed within 14 days prior to RFA]

- 1 done, within normal limits
- 2 done, abnormal elevated
- 3 done, abnormal depressed
- 98 not done
- 99 unknown

Instructions: If lab units are other than that prompted within the Lab Value Column, record unit of measure in field provided. If unit reports are the same as those prompted, then Column III (Other Unit of Measure) is to be left blank.

Labs Evaluation	Lab Value	Other Unit of Measure Character ID	Date of test (mm-dd-yyyy)	Normal Range LOW	Normal Range HIGH
	(Number of length 4)		(date is required for all labs)	(required for all abnormal results)	(required for all abnormal results)
			Date 10 mm-dd-yyyy	(Number of length 4-)	
8 Platelets	9 K/uL	10	11 - - -	12	13
14 PT	15 seconds	16	17 - - -	18	19
20 PTT	21 seconds	22	23 - - -	24	25
26 INR	27 %	28	29 - - -	30	31
32 Serum Creatinine	33 mg/dL	34	35 - - -	36	37
38 GGT	39 U/L	40	41 - - -	42	43
44 LDH	45 IuL	46	47 - - -	48	49
50 AFP	51 ng/mL	52	53 - - -	54	55
56 SGOT	57 U/L	58	59 - - -	60	61
62 SGPT	63 U/L	64	65 - - -	66	67
68 Total bilirubin	69 mg/dL	70	71 - - -	72	73
74 Sodium	75 mmol/L	76	77 - - -	78	79
80 Potassium	81 mmol/L	82	83 - - -	84	85
86 Chloride	87 mmol/L	88	89 - - -	90	91
92 Glucose	93 mg/dL	94	95 - - -	96	97
98 BUN	99 mg/dL	100	101 - - -	102	103
104 Calcium	105 mg/dL	106	107 - - -	108	109
110 Phosphorus	111 mg/dL	112	113 - - -	114	115
116 Total Protein	117 gm/dL	118	119 - - -	120	121
122 Albumin	123 g/dL	124	125 - - -	126	127
128 Ammonia	129 μmol/L	130	131 - - -	132	133
134 Hgb	135 g/dL	136	137 - - -	138	139
140 Hct	141 %	142	143 - - -	144	145
146 Wbc	147 K/uL	148	149 - - -	150	151



ACRIN 6673
Treatment Labs

Revision

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

6. POST-RFA SESSION LABORATORY EVALUATIONS:

[Performed within two hours after ablation procedure.]

- 1 done, within normal limits
- 2 done, abnormal elevated
- 3 done, abnormal depressed
- 98 not done
- 99 unknown

Instructions: If lab units are other than that prompted within the Lab Value Column, record unit of measure in field provided. If unit reports are the same as those prompted, then Column III (Other Unit of Measure) is to be left blank.

Labs Evaluation	Lab Value	Other Unit of Measure	Date of test (mm-dd-yyyy) <small>(date is required for all labs)</small>	Normal Range	
				LOW <small>(required for all abnormal results)</small>	HIGH <small>(required for all abnormal results)</small>
152 Platelets	153 Ku/L	154	155 - - -	156	157
158 PT	159 seconds	160	161 - - -	162	163
164 PTT	165 seconds	166	167 - - -	168	169
170 INR	171 %	172	173 - - -	174	175
176 Serum Creatinine	177 mg/dL	178	179 - - -	180	181
182 GGT	183 u/L	184	185 - - -	186	187
188 LDH	189 lu/L	190	191 - - -	192	193
194 AFP	195 ng/mL	196	197 - - -	198	199
200 SGOT	201 u/L	202	203 - - -	204	205
206 SGPT	207 u/L	208	209 - - -	210	211
212 Total bilirubin	213 mg/dL	214	215 - - -	216	217
218 Sodium	219 mmol/L	220	221 - - -	222	223
224 Potassium	225 mmol/L	226	227 - - -	228	229
230 Chloride	231 mmol/L	232	233 - - -	234	235
236 Glucose	237 mg/dL	238	239 - - -	240	241
242 BUN	243 mg/dL	244	245 - - -	246	247
248 Calcium	249 mg/dL	250	251 - - -	252	253
254 Phosphorus	255 mg/dL	256	257 - - -	258	259
260 Total Protein	261 gm/dL	262	263 - - -	264	265
266 Albumin	267 g/dL	268	269 - - -	270	271
272 Ammonia	273 μmol/L	274	275 - - -	276	277
278 Hgb	279 g/dL	280	281 - - -	282	283
284 Hct	285 %	286	287 - - -	288	289
290 Wbc	291 Ku/L	292	293 - - -	294	295



ACRIN 6673
Treatment Labs

Revision

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Comments: 296 - Character 60

297 - character 25
Signature of Person Responsible for the date ¹

298 Date 10
Date form completed ³ _____
(mm-dd-yyyy)

299 - character 25
Signature of person entering data onto the web ²



ACRIN 6673 Telephone Contact

If this is a revised or corrected form, indicate by checking box.

ACRIN Study 6673 PLACE LABEL HERE

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

This form is to be completed by the Research Associate at 1 Day, 1 Week, and 1 Month after the initial Ablation Session.
This form is to be completed at 1 Day, 1 Week, 1 Month and 3 Months after additional ablation sessions.

- ① 1. Date of evaluation: _____ - _____ - Date 10
(mm-dd-yyyy)
- 2. Reason for contact: multiple
 - ② 1 day post ablation
 - 21 week post ablation
 - 31 month post ablation
 - 43 months post ablation
- 2a. Date of last RFA session: _____ - _____ - Date 10
③ (mm-dd-yyyy)
- 3. Participant status: multiple
 - ④ 1 Alive (Proceed to Q4)
 - 2 Transplanted (Complete 3a)
 - 3 Dead (Complete 3b, 3c, and 3d)
 - 4 Lost to follow-up; unable to contact (complete 3c)
- ⑤ 3a. Date of transplant: _____ - _____ - Date 10
(mm-dd-yyyy)
- ⑥ 3b. Date of death: Date 10
(mm-dd-yyyy)
(If date of death unknown, code 12-12-2100)
- ⑦ 3c. Date of last contact: Date 10
(mm-dd-yyyy)

- 3d. Cause of death: multiple
 - ⑧ 1 Progressive/persistent cancer
 - 2 Complications of protocol treatment
 - 3 Progressive cirrhosis
 - 4 Other, specify: (9) character
 - 9 Unknown (40)
- 4. Performance status (Zubrod Scale) multiple
 - ⑩ 1 Fully active
 - 2 Ambulatory, capable of light work
 - 3 In bed less than 50% of the time, capable of self-care, but not of work activities
 - 4 In bed greater than 50% of the time, capable of only limited self care
 - 5 Bedridden
 - 6 Not evaluated
 - 9 Unknown
- 5. Are there any reportable complications/adverse events per Sec 15.7.1 of the protocol?
 - ⑪ 1 No multiple
 - 2 Yes (If yes, an AE form must be completed)

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Comments: ⑫ character - 60

⑬ character 25
Signature of Site Principal Investigator

⑭ Date 10
Date form completed ³ _____ - _____ - _____
(mm-dd-yyyy)

⑬ character 25
Signature of person entering data onto the web²

PO

**ACRIN 6673
RFA-HCC
ACRIN Consensus Pathology Read**

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, indicate by checking box.

Instructions: This form is completed by the Alternate ACRIN Pathologist.

1. Interpretation Date

1 - ____ - ____ (mm-dd-yyyy)

2. Specimen type (select one)

- 2 FNA
- 2 Core Needle Biopsy
- 3 Resected Hepatic Tissue

2a. Specimen ID#:

_____ 3

3. Findings

3a. Presence of hepatocellular carcinoma (HCC)

- 4 Not present (Stop, sign, and date form)
- 2 Present
- 3 Equivocal

3b. Nuclear grade

- 3 I
- 2 II
- 3 III
- 4 IV

3c. Growth pattern (check all that apply)

- 6 Trabecular
- 7 Pseudoglandular
- 8 Compact
- 9 Fibrolamellar
- 10 Scirrhous
- 11 Mixed

Comments:

_____ 12

Signature of person entering data onto the web¹

13

Date form completed³ _____ - _____ - _____
(mm-dd-yyyy)

14

Printed name of pathologist²

15

PL **ACRIN 6673**
RFA-HCC
Local Pathology Interpretation

ACRIN Study 6673
PLACE LABEL HERE
 Institution _____ Institution No. _____
 Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: Part A is to be completed by the Research Associate. 'Date form completed' under Part A is the date that questions 1 - 6 under Part A were completed. After completion of Part A, the form and pathologic material are sent to the local pathologist. Part B is to be completed by the local pathologist. 'Date form completed' under Part B is the date that questions 1 - 5a under Part B were completed. The completed form is submitted to ACRIN. A separate form is submitted for each tumor.

Part A (completed by site Research Associate)

Part B (completed by the local Pathologist)

1. Procedure Date:
 (mm-dd-yyyy)
2. Type of Procedure (select one)
 1 FNA
 2 Core Needle Biopsy
 3 Resected Hepatic Tissue
3. Couinaud Segment Location
 (check all that apply for this tumor)
- 3 Segment I
 4 Segment II
 5 Segment III
 6 Segment IV
 7 Segment V
 8 Segment VI
 9 Segment VII
 10 Segment VIII
4. Specimen ID # 12
5. Slide ID # 13
6. Tumor # 14

- Interpretation Date:
 (mm-dd-yyyy)
2. Specimen type (select one)
 1 FNA
 2 Core Needle Biopsy
 3 Resected Hepatic Tissue
3. Specimen ID # 21
4. Findings
- 4a. Presence of hepatocellular carcinoma (HCC)
 1 Not present (skip 4b and 4c)
 2 Present
 3 Equivocal
- 4b. Nuclear grade
 1 I
 2 II
 3 III
 4 IV
 5 Unable to determine
- 4c. Growth pattern (check all that apply)
- 24 Trabecular
 25 Pseudoglandular
 26 Compact
 27 Fibrolamellar
 28 Scirrhous
 29 Mixed
 33 Unable to determine

Comments: 15

Comments: 30

16
 Signature of person responsible for the data ¹

Date form completed ³ 31 - _____ - _____
 (mm-dd-yyyy)

Date form completed ³ 17 - _____ - _____
 (mm-dd-yyyy)

32a
 Printed name of pathologist

18
 Signature of person entering data on to the web ²

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P4

**ACRIN 6673
RFA-HCC
ACRIN Central Pathology Interpretation**

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: Part A is to be completed by the Research Associate. After completion of Part A, the form is sent to the Core Pathologist for completion of Part B. Part B will be completed by the Core Pathologist based on the pathologic material available. At the time of slide submission a copy of the PC form, the P4 form and the P1 (pathology report) should be mailed to ACRIN 6664 Data Management, 1818 Market Street, Suite 16, Philadelphia, PA 19103. A separate form is submitted for each tumor.

Part A (completed by site Research Associate)

1. Procedure Date: 1 - ____ - ____
(mm-dd-yyyy)

2. Date Specimen sent to Core Lab:
2 - ____ - ____
(mm-dd-yyyy)

3. Couinaud Segment Location
(check all that apply for this tumor)

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

4. Specimen ID # 12

5. Number of Slides
13 Submitted on this Specimen

6. Tumor # 14

Comments: 15

Completed by (Site RA): 16

Part B (completed by the ACRIN Pathologist)

1. Interpretation Date:
17 - ____ - ____
(mm-dd-yyyy)

2. Specimen type
 FNA
 Core Needle Biopsy
 Resected Hepatic Tissue

3. Specimen ID # 19

4. Findings
4a. Presence of hepatocellular carcinoma (HCC)
 Not present (skip to Q5)
 Present
 Equivocal

4b. Nuclear grade
21
 I
 II
 III
 IV
 Unable to determine

4c. Growth pattern
22 Trabecular
23 Pseudoglandular
24 Compact
25 Fibrolamellar
26 Scirrhous
27 Mixed
33 Unable to determine

5. Agree with local diagnosis
 No (complete 5A)
 Yes (skip to end)

5a. Date specimen(s) forwarded to alternate
ACRIN pathologist
29 - ____ - ____ (mm-dd-yyyy)

Comments: 30

Date form completed 31 - ____ - ____ (mm-dd-yyyy)

32
Printed name of ACRIN pathologist

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**ACRIN 6673
RFA Hepatocellular Carcinoma
Initial RFA Treatment Form**

ACRIN Study **6673**

PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

If this is a revised or corrected form, indicate by checking box.

Instructions: This form collects information related to the RFA Treatment. Use code table when provided and report dates mm/dd/yyyy. If a response is unknown, record (99).

1 Did the RFA treatment commence?

- 1 No (complete 1a)
- 2 Yes
 - Lesion 1
 - Lesion 2
 - Lesion 3
- 3 Not applicable

1a If RFA treatment did not commence, specify reason why:

- 1 Patient refused to start treatment
- 2 Technical problems
- 3 Adverse event or toxicity, specify:

- 4 Other reason, specify:

1b Were any adverse events reported during this time period:

- 1 Yes
 - 2 No
- If yes, specify date:**
____ - ____ - _____ (mm-dd-yyyy)

2 Has the tumor been biopsied?

- No (skip to Q3)
- Yes

2a Date of biopsy ____ - ____ - _____
(mm-dd-yyyy)

2b Type of procedure:

- 1 FNA
- 2 Core Needle Biopsy

3 Date of RFA treatment ____ - ____ - _____ (mm-dd-yyyy)

3a Was the RFA treatment completed for each tumor?

- 1 No (complete 3a)
- 2 Yes
 - Lesion 1
 - Lesion 2
 - Lesion 3
- 3 Not applicable

3b If RFA did not commence or was not completed, specify reason:

- 1 Patient refused to start treatment
- 2 Technical problems during procedure
- 3 RFA treatment initiated but not completed
- 4 RFA treatment not initiated
- 5 Adverse event or toxicity, specify:

- 6 Other reason, specify:

4 **Number of tumors treated:

- 1 2 3

***[Complete an Ablation Treatment Form per tumor treated - see pages 3-5.]*

5 Radiologist ID performing procedure:

--	--	--	--	--	--	--	--

6 Imaging modality utilized for RFA

- 1 Ultrasound
- 2 CT Scan
- 3 MRI

7 Was a pregnancy test performed (BetahCG blood test) within 24 hours prior to RFA procedure?

- 1 No (complete 7a)
- 2 Yes (complete 7b)
- 3 Not applicable

7a If no specify:

7b Test results:

- 1 Negative
- 2 Positive

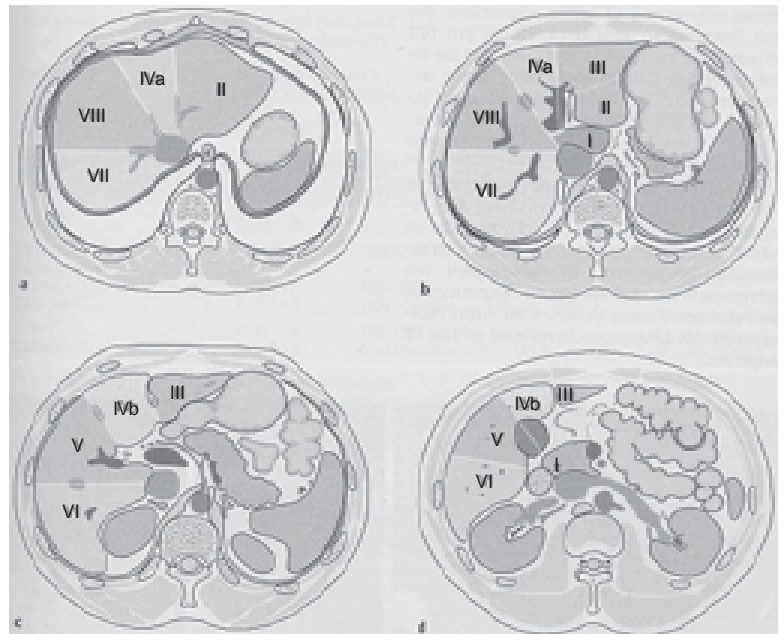
8 Complete description of each tumor ablated and indicate location using the diagram, (Appendix VI). Numbering must be consistent throughout the study.

Assigned Tumor #	Liver Segment *	Size (mm) Trans (M-L) x CC (S-1) x AP (A-P)	Subcapsular		Contiguous to major (< 1 cm) vessels	
			1 No	2 Yes	1 No	2 Yes
<input type="text"/>	<input type="text"/>	<input type="text"/> x <input type="text"/> x <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> x <input type="text"/> x <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> x <input type="text"/> x <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII



Ablation Treatment Form

9. Tumor (Record tumor number per diagram)

9a. Number of ablations this session within this tumor

9b. Number of cauterizations for this tumor:
 1 2 3 4 5 6

9d. Indicate Valley Lab Cooled Tip Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

9e. Were any complications encountered?

- No Yes
- If yes, check all that apply:*
- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

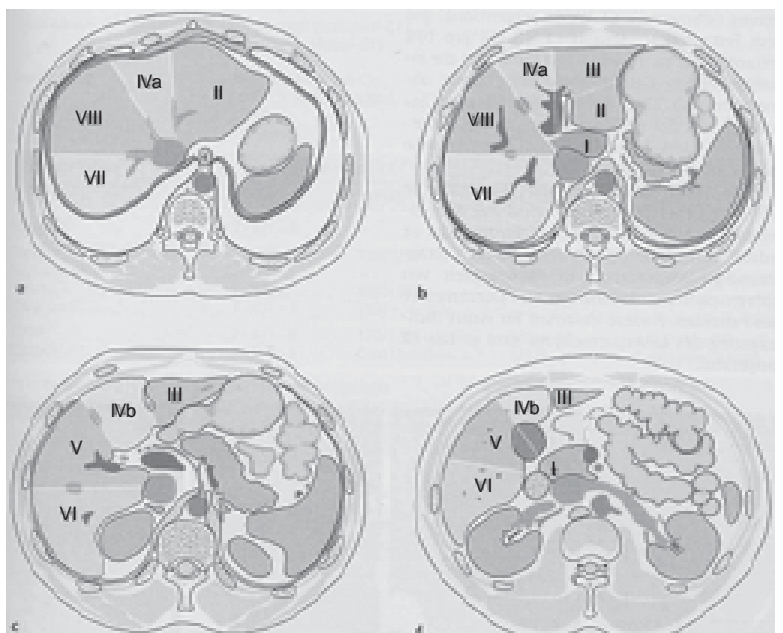
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
2		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
3		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
5		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
6		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
7		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
8		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
9		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
10		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

9f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

10. Tumor (Record tumor number per diagram)

10a. Number of ablations this session within this tumor

Not applicable

10b. Number of cauterizations for this tumor:

1 2 3 4 5 6

10d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

10e. Were any complications encountered?

No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

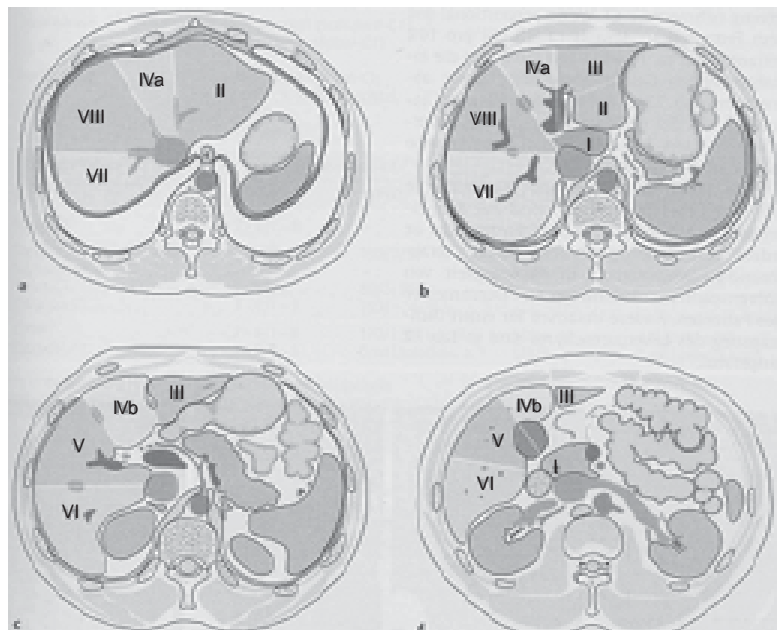
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10f. Mark location cauterizations on diagram with a "c".

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

11. Tumor (Record tumor number per diagram)

11a. Number of ablations this session within this tumor

Not applicable

11b. Number of cauterizations for this tumor:

1 2 3 4 5 6

11d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

11e. Were any complications encountered?

No Yes

If yes, check all that apply:

- abscess
- pneumothorax
- hemorrhage
- tumor seeding
- other, specify: _____

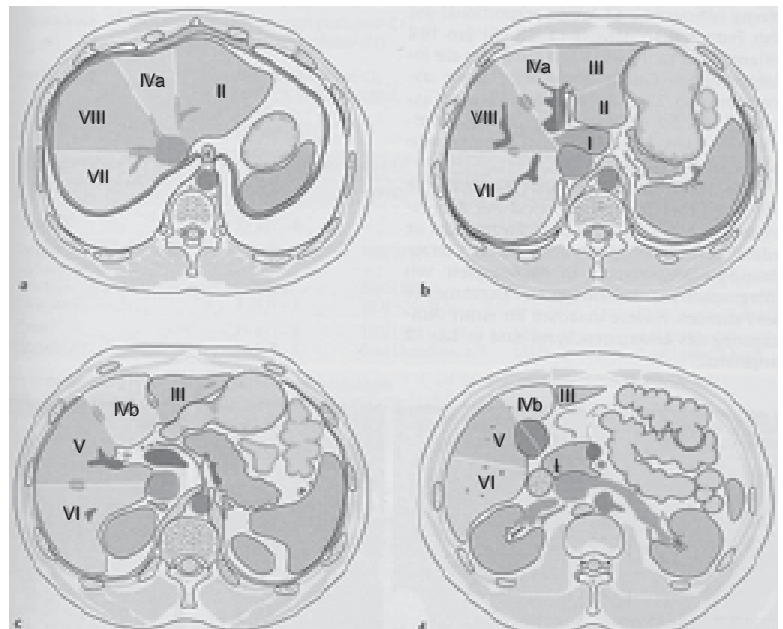
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
7	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
9	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

11f. Mark location cauterizations on diagram with a "c".



TF

Study 6673

Case # _____

Revision

Comments: _____

Signature of person responsible for the data ¹

Date form completed ³ ____ - ____ - ____
(mm-dd-yyyy)

Signature of person entering data onto the web ²



**RFA-HCC
Additional RFA Session Form**

ACRIN Study **6673**
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The **Additional RFA Session Form (RA)** is to be completed by the Study Radiologist (the radiologist performing the RFA), for tumors ablated after the initial ablation session. A **RA Form** is completed for **each tumor ablated**. The ablated tumor and cauterization locations are marked within the diagrams (page 2, question 6b) with a "t" and "c" within the appropriate segment. Once the form data has been entered into the ACRIN website www.acrin.org a copy of page 2 of the RA form must be mailed to the Data Management Center. A case specific label should be affixed to the form in the designated area.

1. Did RFA session commence for this tumor? [110]
(Complete one RA form per tumor)

- No (Complete Q1a - 2d, then sign and date form)
- Yes (Proceed to Q2)

1a. If no give reason: [111]

- Participant refused
- Technical problems during procedure
- RFA deferred
- Adverse Event
- Claustrophobia
- Complications, specify: _____ [112]
- Medical reason
- Equipment failure
- Injection site complications
- Unable to visualize lesion
- Other reason, specify: _____ [113]

1b. How many tumors were scheduled to be treated? [114]

1c. This form represents tumor number: [115]

1d. Was the participant rescheduled? [116]
 No
 Yes

2. Type of recurrence (select one) [1]

- Local (failure of primary ablation)
- Remote intrahepatic
- Both

2a. Proof of recurrence (select one) [2]

- CT (complete Q2b)
- Biopsy (complete Q2c and Q2d)

2b. Date of CT scan: _____ - _____ - _____ (mm-dd-yyyy) [3]

2c. Date of biopsy: _____ - _____ - _____ (mm-dd-yyyy) [4]

2d. Type of procedure [5]

- FNA
- Core needle biopsy

3. Date of RFA session: _____ - _____ - _____ (mm-dd-yyyy) [6]

3a. Reader ID #: [7]

4. Total number of tumors treated this session: [8]
(Complete one RA form per tumor)

4a. This form represents tumor number: [9]

4b. Imaging modality used for RFA: [10]

- Ultrasound
- CT scan
- MRI

5. Are there any reportable complications / adverse events per Sec. 15.0 of the protocol? [11]

- No
- Yes (AE form must be completed)



If this is a revised or corrected form, please box.

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

ABLATION SESSION FORM

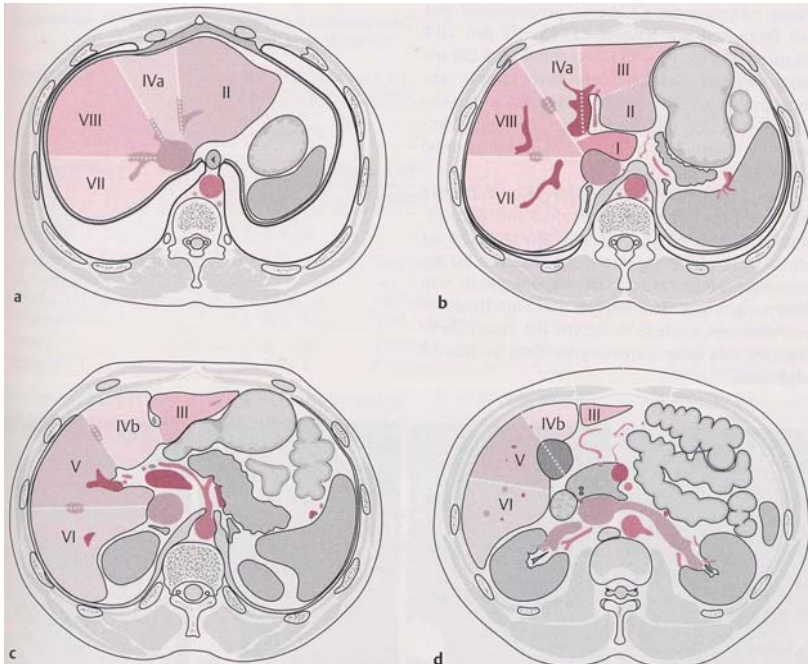
Tumor location and numbering must remain consistent throughout study.

6. This form represents Tumor Number [12]

6a. Date of Session: _____ - _____ - _____ (mm-dd-yyyy) [13]

6b. Mark location of this tumor number and cauterization with a "t" and "c" respectively on the diagram below.

Diagram of the Liver (Appendix VI)



6c. Was the RFA session completed or attempted for this tumor? [14]

- No, RFA not completed, no RFA treatment to record (Complete 6d, sign and date form)
- Yes, RFA complete (Proceed to Q7)
- Yes, RFA attempted and incomplete (Complete 6d and proceed to Q7)

6d. If RFA was not completed, specify reason: [15]

- Participant refused
- Technical problems during procedure
- RFA deferred
- Adverse Event
- Claustrophobia
- Complications, specify: _____ [117]
- Medical reason
- Equipment failure
- Injection site complications
- Unable to visualize lesion
- Other reason, specify: _____ [16]

Couinaud Segments:

Segment I	Segment II	Segment III
Segment IVa	Segment IVb	Segment V
Segment VI	Segment VII	Segment VIII



**RFA-HCC
Additional RFA Session Form**

ACRIN Study **6673**
PLACE LABEL HERE

If this is a revised or corrected form, please box.

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Ablation Session Form

7. Complete description of this tumor

Assigned Tumor Number	Record Session Date	Couinaud Liver Segment <i>(Check all that apply for this tumor)</i>	Size (cm) Largest Size in Diameter	Subcapsular	Contiguous to Major Vessels? <i>(vessels > 5mm)</i>	Number of ablations this session within this tumor	Number of percutaneous punctures during this session
[17] <input type="text"/>	[18] ____ - ____ - 20 <i>(mm-dd-yyyy)</i>	<input type="checkbox"/> Segment I [19] <input type="checkbox"/> Segment II [20] <input type="checkbox"/> Segment III [21] <input type="checkbox"/> Segment IVA [22] <input type="checkbox"/> Segment IVB [23] <input type="checkbox"/> Segment V [24] <input type="checkbox"/> Segment VI [25] <input type="checkbox"/> Segment VII [26] <input type="checkbox"/> Segment VIII [27]	[28] Note: Lesion size recorded on C2 or NT form(s) must remain consistent throughout the study on RA forms. _____ . _____	[29] <input type="radio"/> No <input type="radio"/> Yes	[30] <input type="radio"/> No <input type="radio"/> Yes	[31] <input type="text"/>	[32] <input type="text"/>



**RFA-HCC
Additional RFA Session Form**

**ACRIN Study 6673
PLACE LABEL HERE**

If this is a revised or corrected form, please box.

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Note: Required ablations (as per Section 9 of the protocol) less than 12 minutes (16 minutes if using switchbox) will be considered non-compliant according to Section 20.6 of the protocol.

Ablation Number	Baseline Impedance (R)	Treatment Duration (min)	One minute Post Treatment Temperature (C)	Switch box used?	Switch box cycle number	Indicate Valley Lab Cooled Tip RF ablation needles utilized	Cauterization of needle track performed? If yes indicate location on diagram with a "c"	Number of tumors ablated utilizing switch box	Assigned tumor number of tumors ablated utilizing Switch box (check all that apply)	Are there additional ablations to describe for this tumor?
1.	[35] 	[36] 	[37] 	[38] <input type="radio"/> No <input type="radio"/> Yes	[39] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[34] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[33] <input type="radio"/> No <input type="radio"/> Yes	[118] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[119] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[40] <input type="radio"/> No <input type="radio"/> Yes
2.	[41] 	[42] 	[43] 	[44] <input type="radio"/> No <input type="radio"/> Yes	[45] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[120] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[121] <input type="radio"/> No <input type="radio"/> Yes	[122] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[123] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[46] <input type="radio"/> No <input type="radio"/> Yes
3.	[47] 	[48] 	[49] 	[50] <input type="radio"/> No <input type="radio"/> Yes	[51] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[124] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[125] <input type="radio"/> No <input type="radio"/> Yes	[126] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[127] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[52] <input type="radio"/> No <input type="radio"/> Yes
4.	[53] 	[54] 	[55] 	[56] <input type="radio"/> No <input type="radio"/> Yes	[57] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[128] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[129] <input type="radio"/> No <input type="radio"/> Yes	[130] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[131] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[58] <input type="radio"/> No <input type="radio"/> Yes
5.	[59] 	[60] 	[61] 	[62] <input type="radio"/> No <input type="radio"/> Yes	[63] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[132] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[133] <input type="radio"/> No <input type="radio"/> Yes	[134] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[135] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[64] <input type="radio"/> No <input type="radio"/> Yes
6.	[65] 	[66] 	[67] 	[68] <input type="radio"/> No <input type="radio"/> Yes	[69] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[136] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[137] <input type="radio"/> No <input type="radio"/> Yes	[138] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[139] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[70] <input type="radio"/> No <input type="radio"/> Yes



**RFA-HCC
Additional RFA Session Form**

**ACRIN Study 6673
PLACE LABEL HERE**

If this is a revised or corrected form, please box.

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Note: Required ablations (as per Section 9 of the protocol) less than 12 minutes (16 minutes if using switchbox) will be considered non-compliant according to Section 20.6 of the protocol.

Ablation Number	Baseline Impedance (R)	Treatment Duration (min)	One minute Post Treatment Temperature (C)	Switch box used?	Switch box cycle number	Indicate Valley Lab Cooled Tip RF ablation needles utilized	Cauterization of needle track performed? If yes indicate location on diagram with a "c"	Number of tumors ablated utilizing switch box	Assigned tumor number of tumors ablated utilizing Switch box (check all that apply)	Are there additional ablations to describe for this tumor?
7.	[71] 	[72] 	[73] 	[74] <input type="radio"/> No <input type="radio"/> Yes	[75] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[140] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[141] <input type="radio"/> No <input type="radio"/> Yes	[142] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[143] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[76] <input type="radio"/> No <input type="radio"/> Yes
8.	[77] 	[78] 	[79] 	[80] <input type="radio"/> No <input type="radio"/> Yes	[81] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[144] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[144] <input type="radio"/> No <input type="radio"/> Yes	[146] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[147] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[82] <input type="radio"/> No <input type="radio"/> Yes
9.	[83] 	[84] 	[85] 	[86] <input type="radio"/> No <input type="radio"/> Yes	[87] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[148] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[148] <input type="radio"/> No <input type="radio"/> Yes	[150] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[151] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[88] <input type="radio"/> No <input type="radio"/> Yes
10.	[89] 	[90] 	[91] 	[92] <input type="radio"/> No <input type="radio"/> Yes	[93] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[152] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[152] <input type="radio"/> No <input type="radio"/> Yes	[154] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[155] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[94] <input type="radio"/> No <input type="radio"/> Yes
11.	[95] 	[96] 	[97] 	[98] <input type="radio"/> No <input type="radio"/> Yes	[99] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[156] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[156] <input type="radio"/> No <input type="radio"/> Yes	[158] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[159] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	[100] <input type="radio"/> No <input type="radio"/> Yes
12.	[101] 	[102] 	[103] 	[104] <input type="radio"/> No <input type="radio"/> Yes	[105] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3	[160] <input type="radio"/> Single, 2cm tip <input type="radio"/> Single, 3cm tip <input type="radio"/> Cluster 3-prong 2.5 cm tip	[160] <input type="radio"/> No <input type="radio"/> Yes	[162] <input type="radio"/> 1 <input type="radio"/> 4 <input type="radio"/> 2 <input type="radio"/> 5 <input type="radio"/> 3 <input type="radio"/> 6	[163] <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	



**RFA-HCC
Additional RFA Session Form**

**ACRIN Study 6673
PLACE LABEL HERE**

If this is a revised or corrected form, please box.

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

 _____ [106]

 Signature of Person Responsible for the data [107]

Date form completed _____ - _____ - _____ [108]
 (mm-dd-yyyy)

 Signature of person entering data onto the web [109]



**ACRIN 6673
CT Imaging Follow-up Form**

ACRIN Study 6673

PLACE LABEL HERE

If this is a revised or corrected form, indicate by checking box.

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

Instructions: This form is completed by the Study Radiologist.

1. RFA Follow-up Time Period

- Within 7 days of initial RFA Treatment
- 0-3 month
- 3-6 month
- 6-9 month
- 9-12 month
- 12-15 month
- 15-18 month
- Other, specify: _____

1a. Reason for CT Imaging Follow-up:

- Every 3 month visit
- Post ablation/re-ablation treatment
- Repeat CT Scan

2. Date of last RFA procedure: _____ - _____ - _____
(mm-dd-yyyy)

2a. Total number of tumors treated since enrollment:

- | | | | |
|-------------------------|-------------------------|-------------------------|-------------------------|
| <input type="radio"/> 1 | <input type="radio"/> 3 | <input type="radio"/> 5 | <input type="radio"/> 7 |
| <input type="radio"/> 2 | <input type="radio"/> 4 | <input type="radio"/> 6 | <input type="radio"/> 8 |

3. Date of imaging study: _____ - _____ - _____
(mm-dd-yyyy)

4. AFP drawn on same day as CT Scan?

- No
- Yes (complete 4a)
- Not applicable

4a. AFP lab value _____ ng/ml

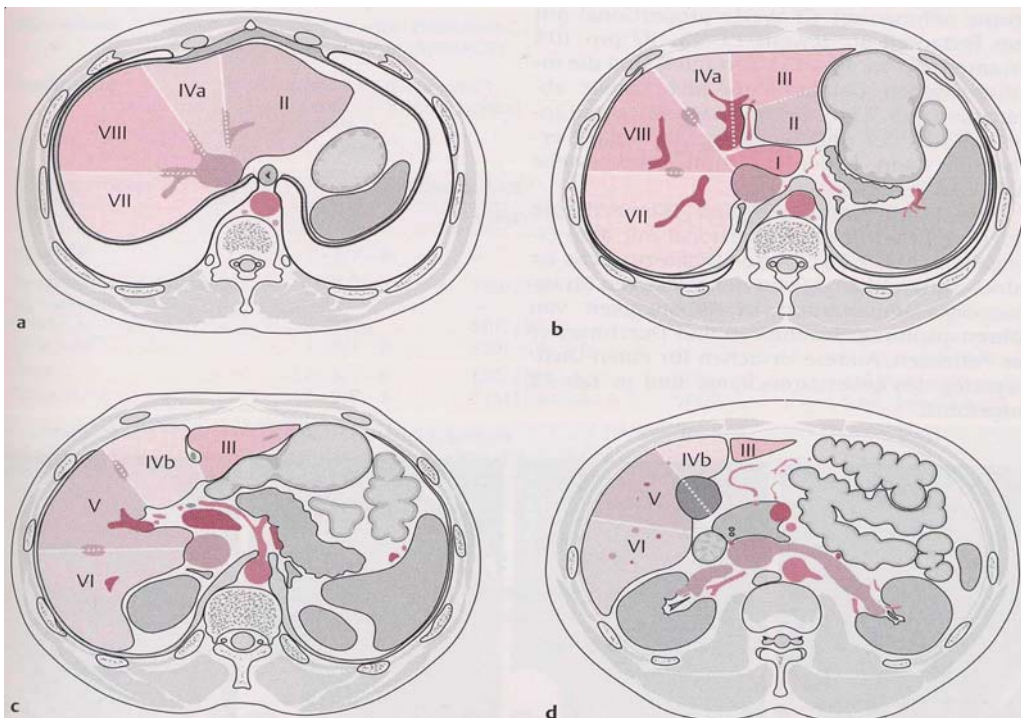
5. Does the CT Scan meet the imaging criteria as outlined in the protocol, section 13.2.1?

- No (Answer 5a, stop and sign form)
- Yes

5a. If NO, scheduled date of repeat CT:

_____ - _____ - _____
(mm-dd-yyyy)

Diagram of the Liver



***Couinaud Segments:**

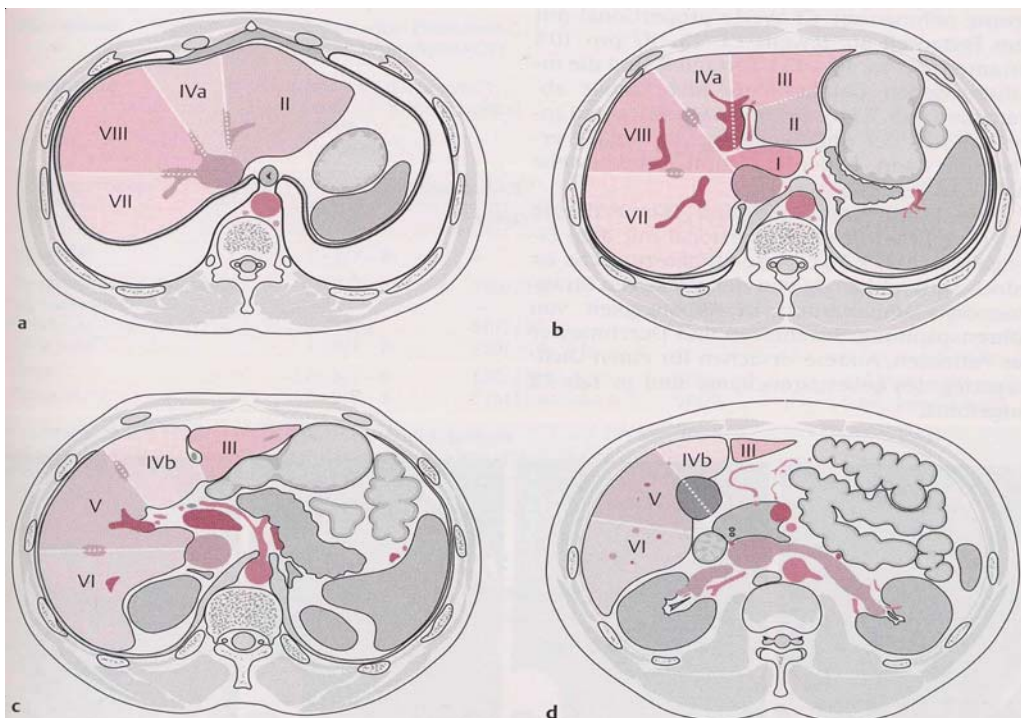
Segment	I
Segment	II
Segment	III
Segment	IVA
Segment	IVB
Segment	V
Segment	VI
Segment	VII
Segment	VIII

6. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the protocol, section 9.5.3	If Not re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

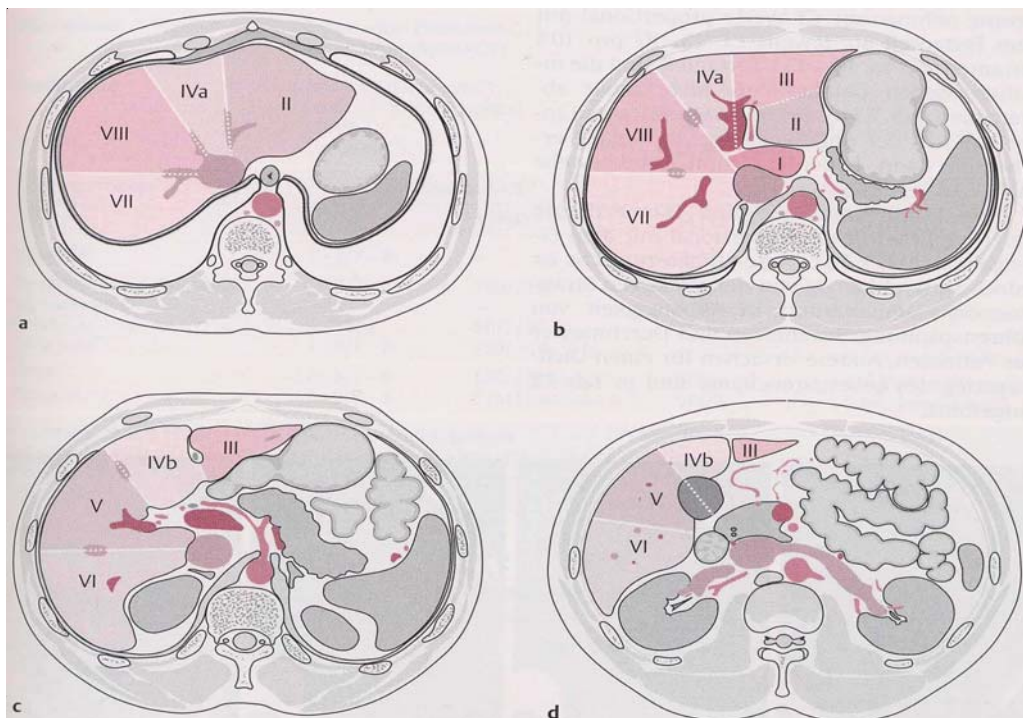
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

7. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	<u>If YES to Re-ablation</u> does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	<u>If No to re-ablation</u> provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

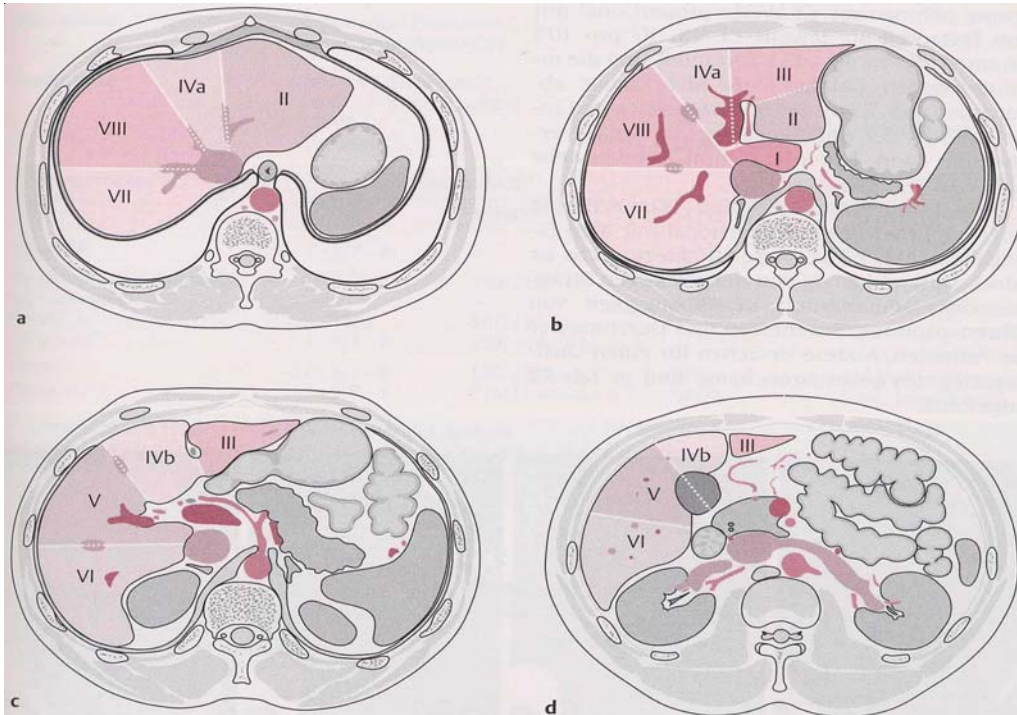
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

8. Ablated Tumor Status

TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	<u>If YES to Re-ablation</u> does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	<u>If No to re-ablation</u> provide reason: (Check all that apply for this tumor)	<u>Are there additional ablated tumors to describe?</u>
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

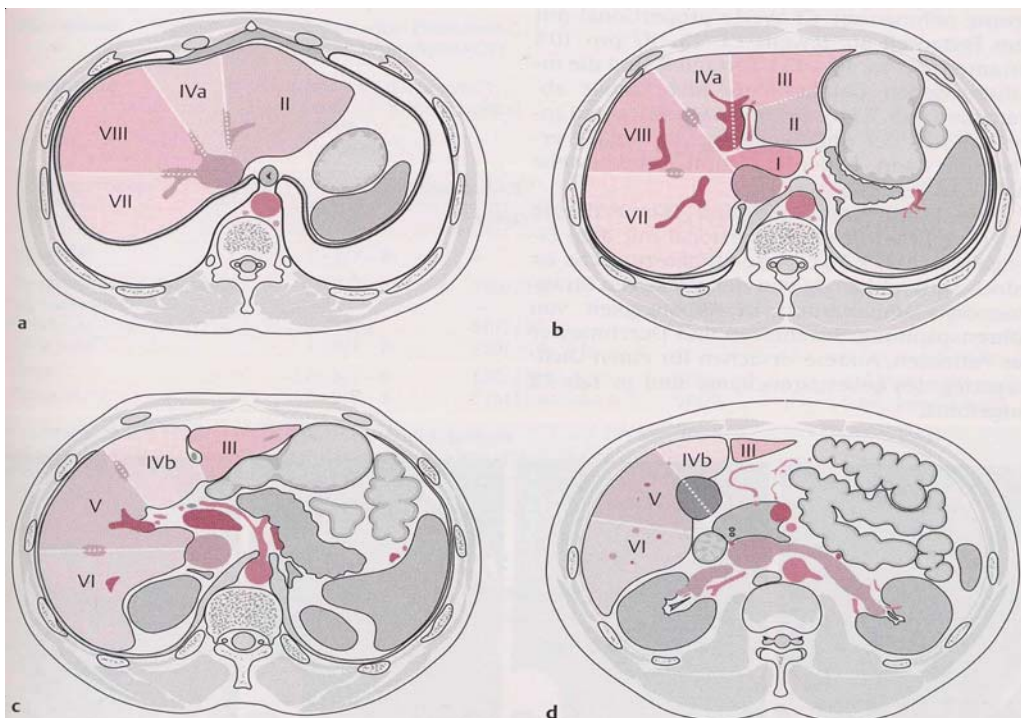
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

9. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	If No to re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

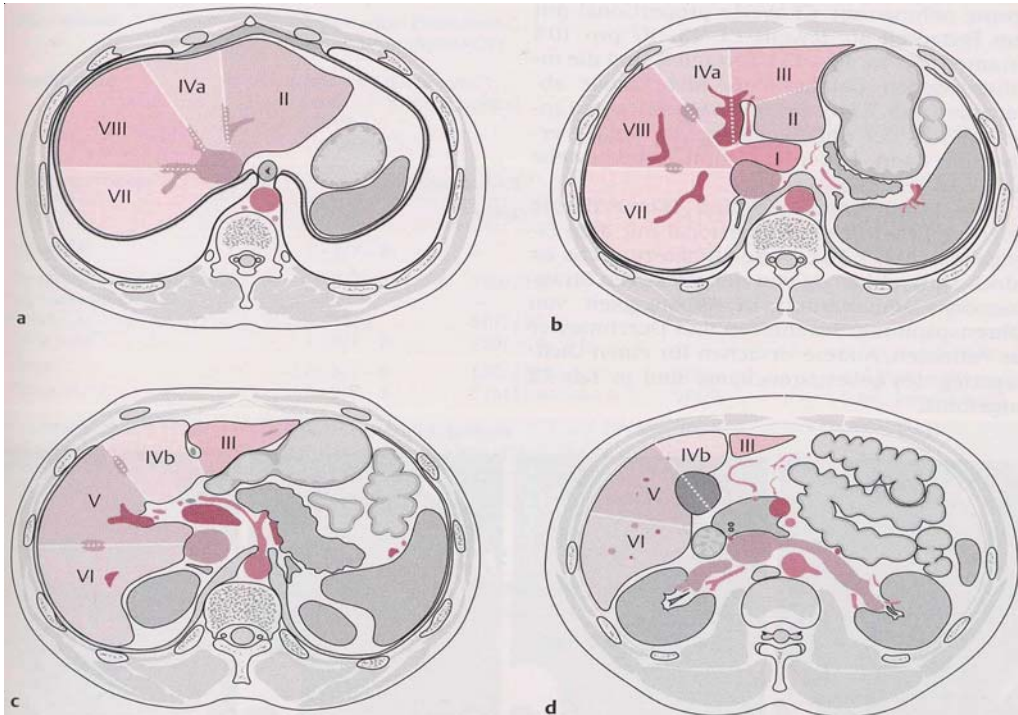
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

10. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	If No to re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> No technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

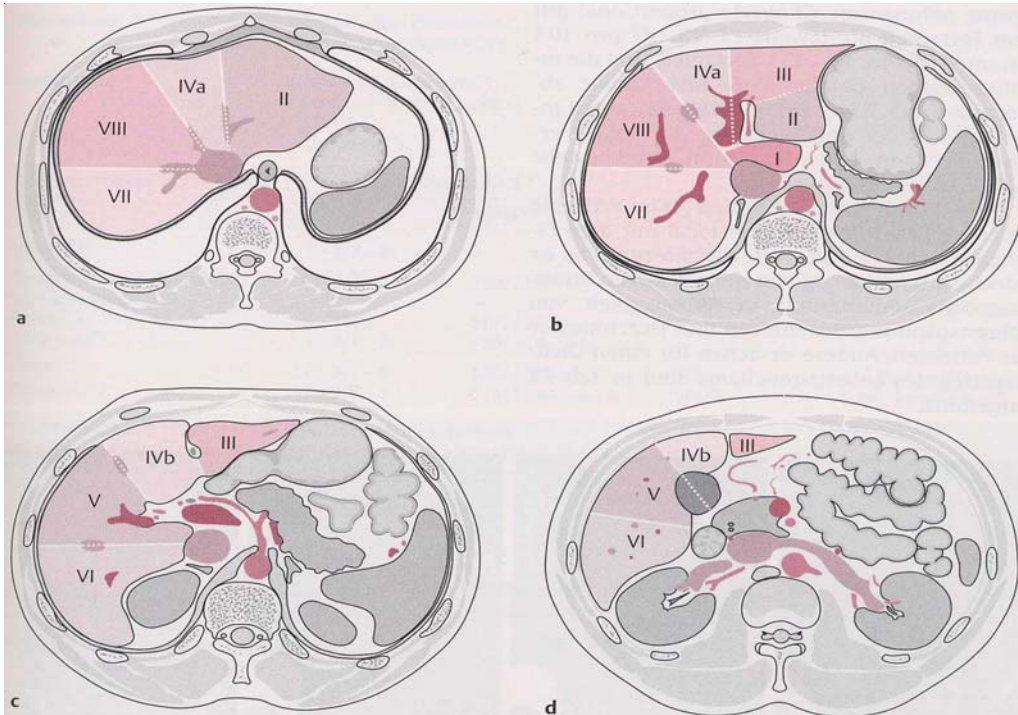
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

11. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	If No to re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> No technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

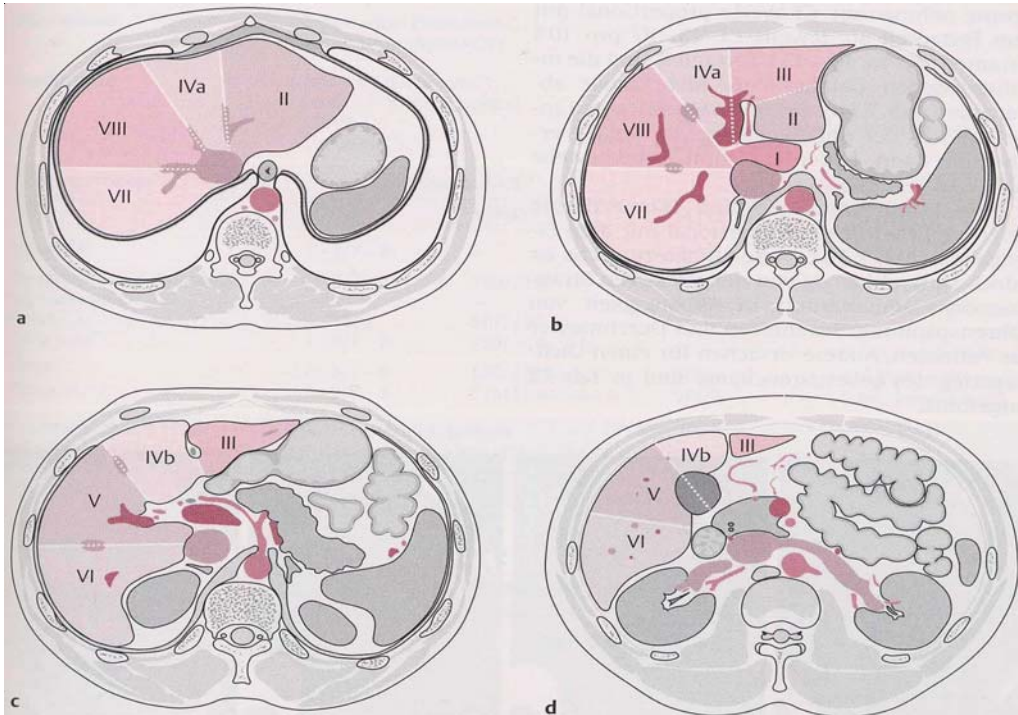
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

12. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	If No to re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> No technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

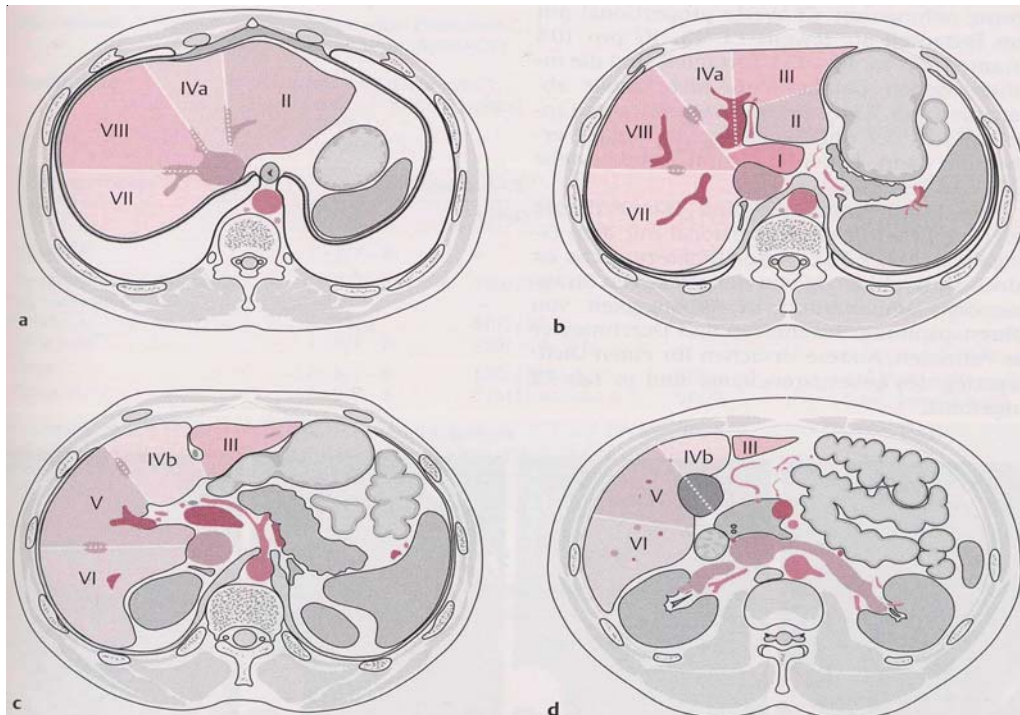
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

13. Ablated Tumor Status

[TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY]

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3	If No to re-ablation provide reason: (Check all that apply for this tumor)	Are there additional ablated tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 Tumor Absent 2 Tumor Present 88 Indeterminate <input type="checkbox"/> <input type="checkbox"/>	1 Enlargement 2 Halo 3 Nodule <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> No technically feasible <input type="checkbox"/> Not clinically indicated	1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

14. Ablated Tumor Status

TUMOR NUMBERING MUST REMAIN CONSISTENT THROUGHOUT THE STUDY

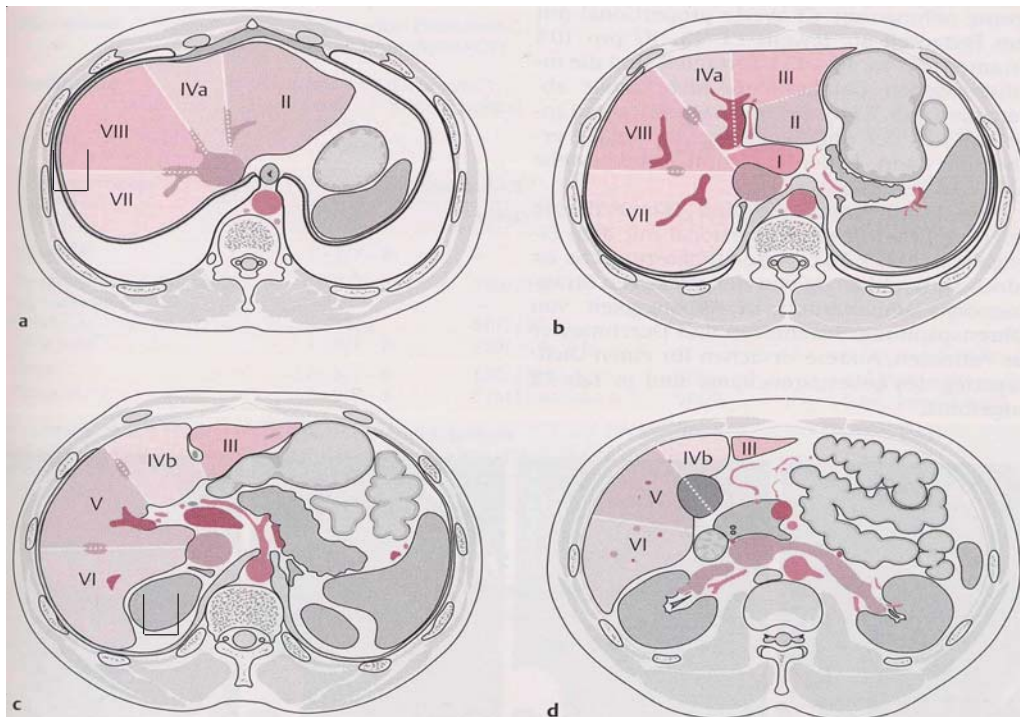
Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Local intra-hepatic tumor status:	Patterns of recurrence:	Re-ablation indicated:	<i>If YES to Re-ablation does this meet the follow-up criteria as outlined in the rotocol, section 9.5.3</i>	<u>If No to re-ablation provide reason:</u> (Check all that apply for this tumor)
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	1 <i>Tumor Absent</i> 2 <i>Tumor Present</i> 88 <i>Indeterminate</i> <input type="checkbox"/> <input type="checkbox"/>	1 <i>Enlargement</i> 2 <i>Halo</i> 3 <i>Nodule</i> <input type="checkbox"/>	1 <i>No</i> 2 <i>Yes</i> 88 <i>Indeterminate</i> <input type="checkbox"/>	1 <i>No</i> 2 <i>Yes</i> <input type="checkbox"/>	<input type="checkbox"/> Size of recurrence exceeds 5cm <input type="checkbox"/> Recurrence adjacent to vital structures <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> No technically feasible <input type="checkbox"/> Not clinically indicated

15. Is there evidence of Remote Intrahepatic Tumor?

- No (STOP and sign form)
- Yes (Complete 5a)
- Indeterminate

15a. **Number of Remote Intrahepatic Tumor(s)**

Diagram of the Liver



***Couinaud Segments:**

Segment	I
Segment	II
Segment	III
Segment	IVA
Segment	IVB
Segment	V
Segment	VI
Segment	VII
Segment	VIII

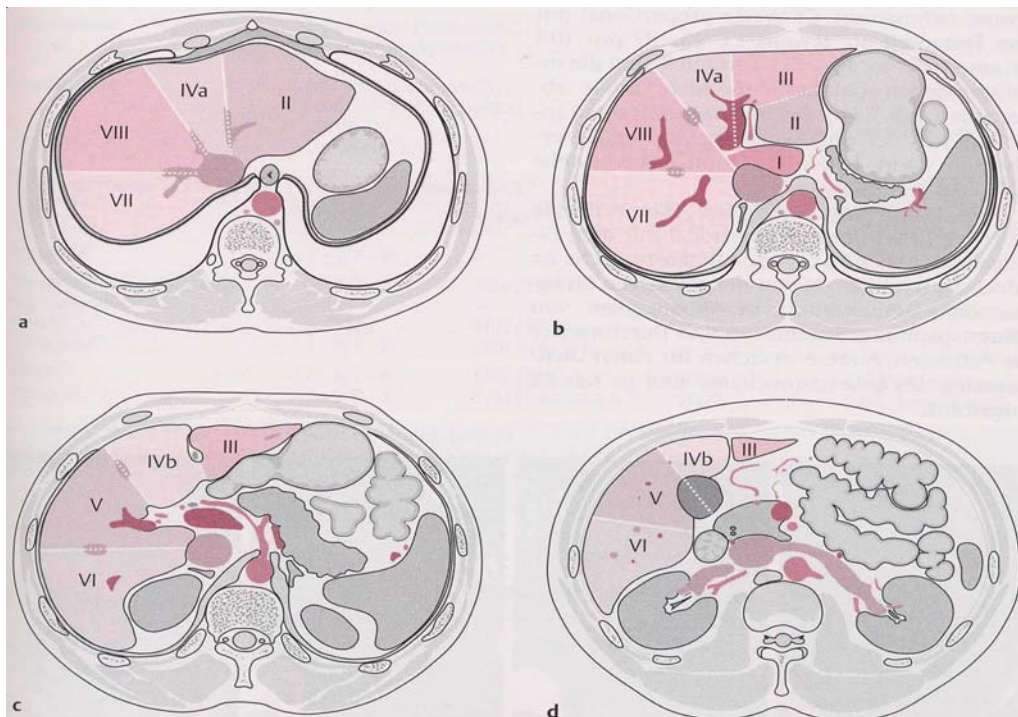
Remote Intrahepatic Tumor

16. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Largest size in diameter (cm)	Biopsy Indicated? 1 No 2 Yes	Does tumor meet the criteria for RFA treatment as outlined in the Protocol? 1 No 2 Yes 88 Indeterminate	<u>If No to RFA, provide reason</u> <small>(Check all that apply for this tumor)</small>	Are there additional tumors to describe? 1 No (Stop and sign form) 2 Yes
<input type="text"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	<input type="text"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

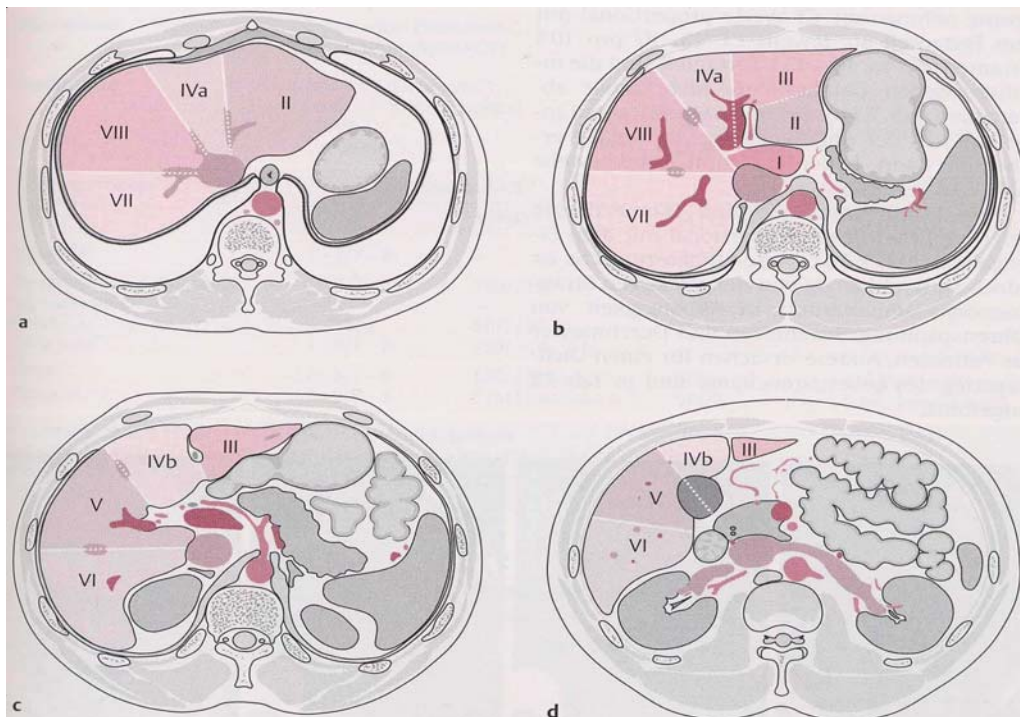
Remote Intrahepatic Tumor

17. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u><i>If No to RFA, provide reason</i></u> <small>(Check all that apply for this tumor)</small>	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

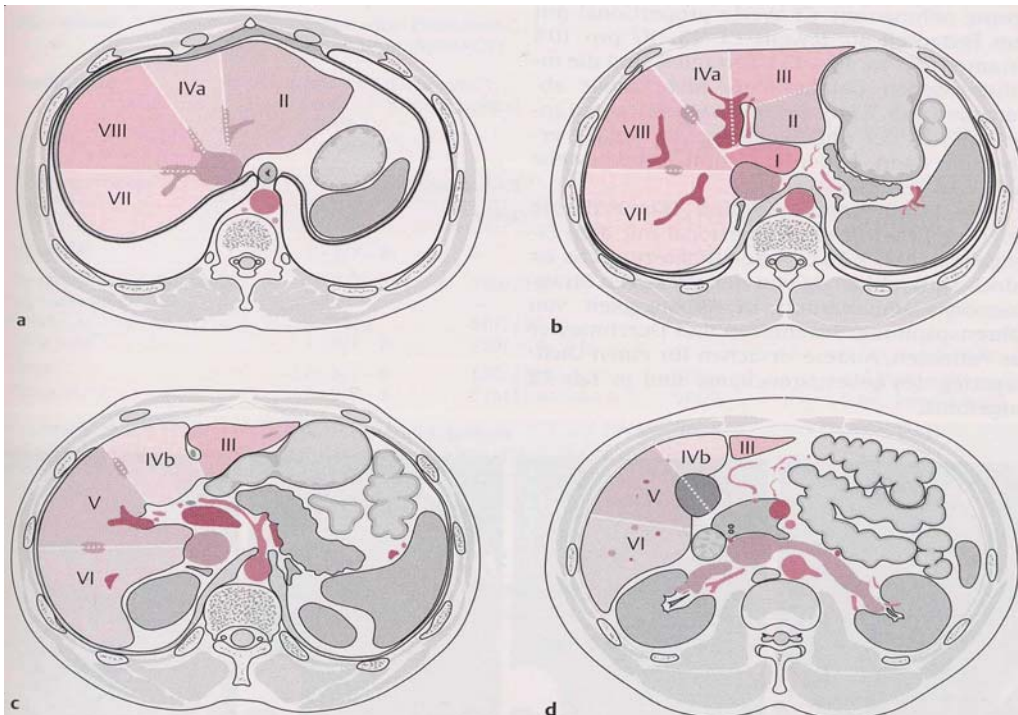
Remote Intrahepatic Tumor

18. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> <small>(Check all that apply for this tumor)</small>	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

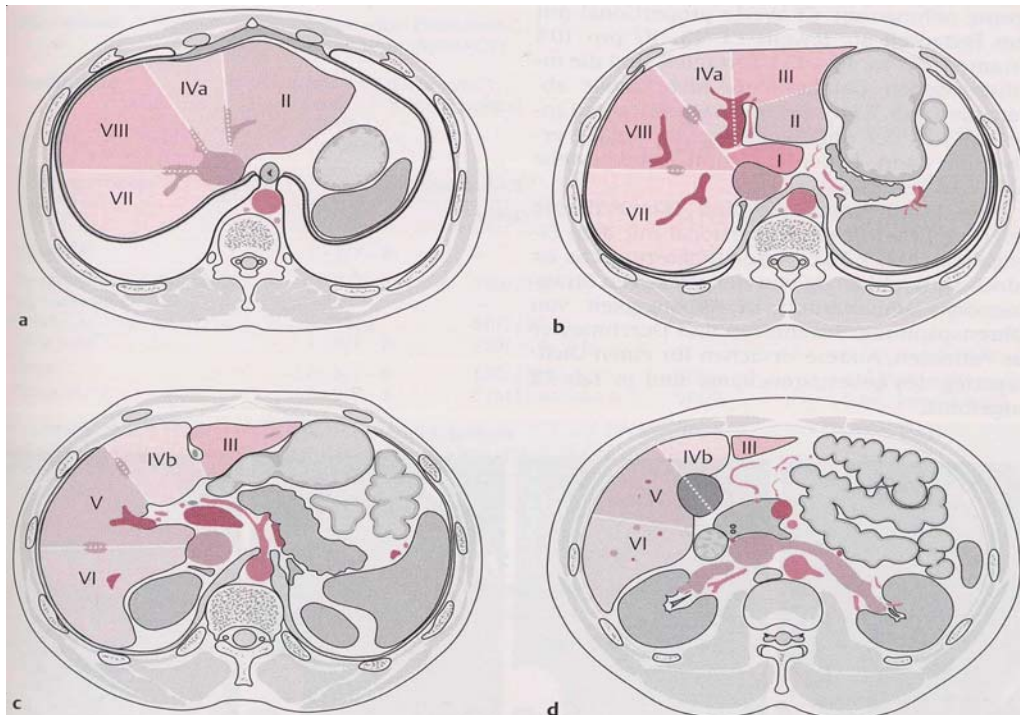
Remote Intrahepatic Tumor

18. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> <small>(Check all that apply for this tumor)</small>	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

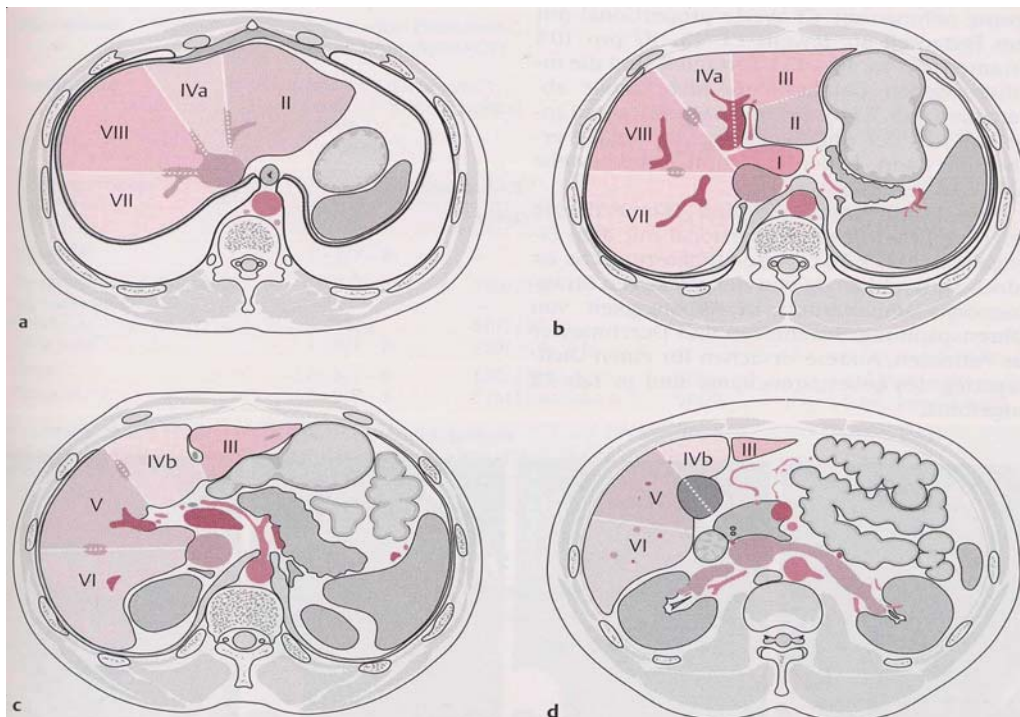
Remote Intrahepatic Tumor

19. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> (Check all that apply for this tumor)	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

Segment	I
Segment	II
Segment	III
Segment	IVA
Segment	IVB
Segment	V
Segment	VI
Segment	VII
Segment	VIII

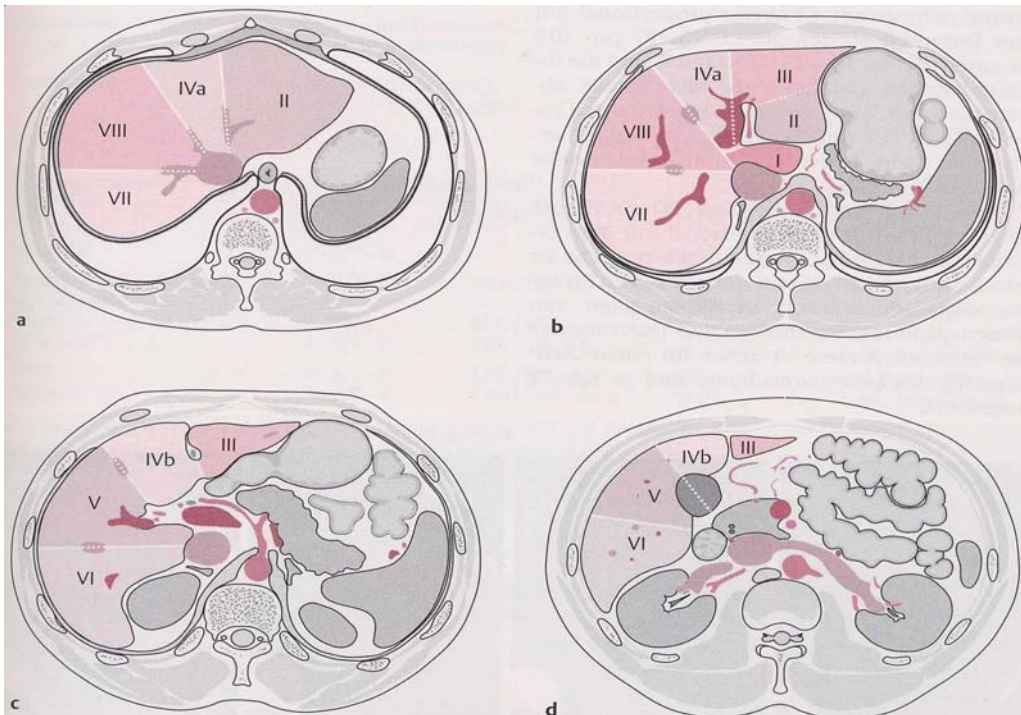
Remote Intrahepatic Tumor

20. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> <small>(Check all that apply for this tumor)</small>	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

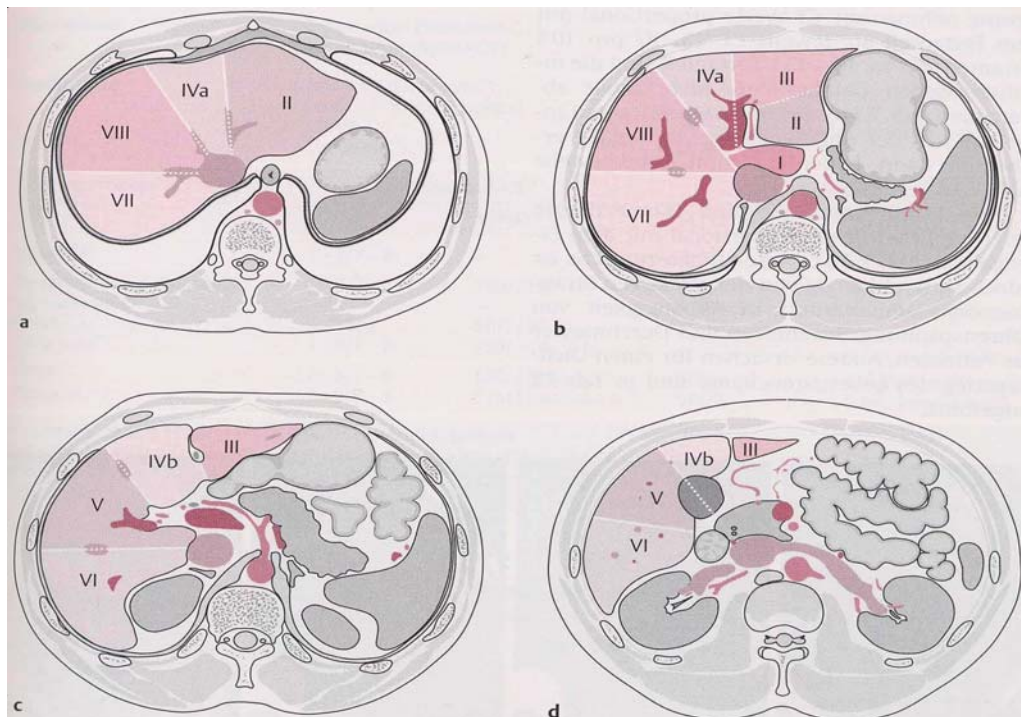
Remote Intrahepatic Tumor

21. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> (Check all that apply for this tumor)	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



*Couinaud Segments:

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

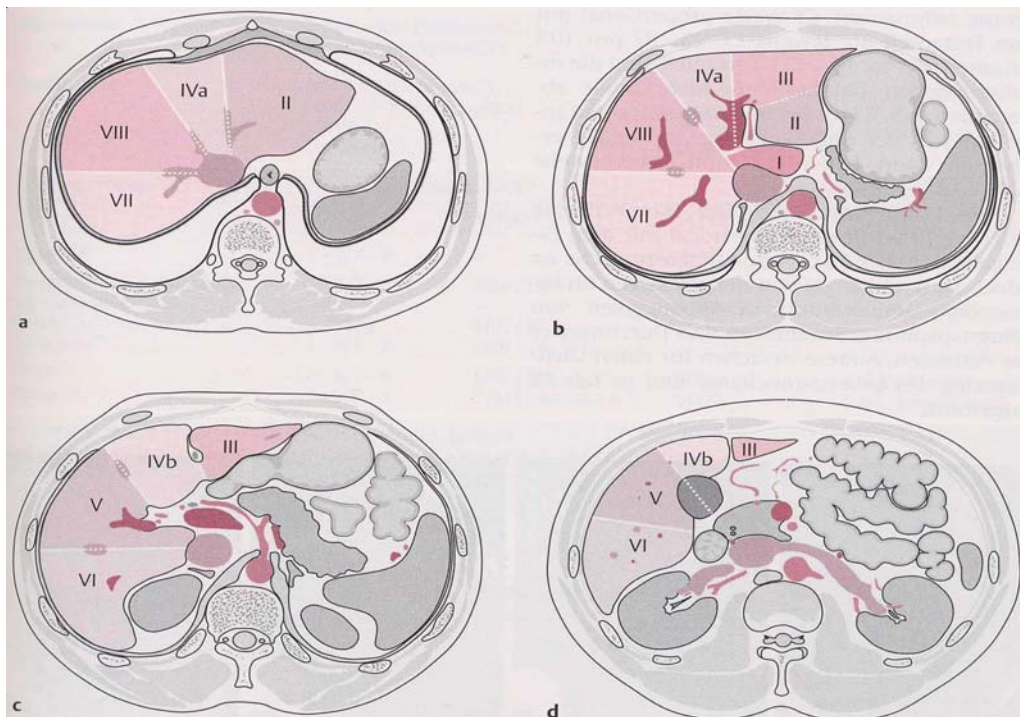
Remote Intrahepatic Tumor

22. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Largest size in diameter (cm)	Biopsy Indicated? 1 No 2 Yes	Does tumor meet the criteria for RFA treatment as outlined in the Protocol? 1 No 2 Yes 88 Indeterminate	<u>If No to RFA, provide reason</u> (Check all that apply for this tumor)	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

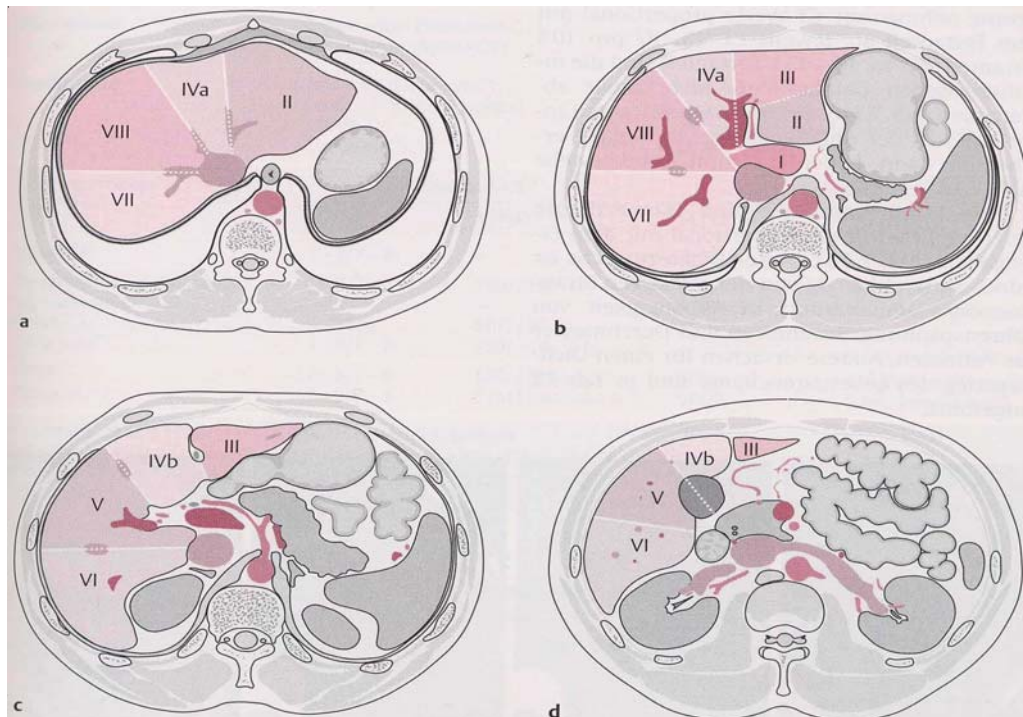
Remote Intrahepatic Tumor

23. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<u>If No to RFA, provide reason</u> (Check all that apply for this tumor)	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated	1 No (Stop and sign form) 2 Yes <input type="checkbox"/>

Diagram of the Liver



- *Couinaud Segments:**
- Segment I
 - Segment II
 - Segment III
 - Segment IVA
 - Segment IVB
 - Segment V
 - Segment VI
 - Segment VII
 - Segment VIII

Remote Intrahepatic Tumor

24. Number of New Tumor

Complete description of each tumor, and indicate location using diagram.

Tumor Number	Couinaud Liver Segment* (Check all that apply for this tumor)	Largest size in diameter (cm)	Biopsy Indicated?	Does tumor meet the criteria for RFA treatment as outlined in the Protocol?	<i>If No to RFA, provide reason</i> (Check all that apply for this tumor)
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	1 No 2 Yes <input type="checkbox"/>	1 No 2 Yes 88 Indeterminate	<input type="checkbox"/> Tumor Size exceeds 5 cm. <input type="checkbox"/> Tumor adjacent to vital structures. <input type="checkbox"/> Evidence of extrahepatic tumor <input type="checkbox"/> Not technically feasible <input type="checkbox"/> Not clinically indicated

Comments: _____

Signature of person responsible for the data ¹ _____

Date form completed ³ _____ - _____ - _____
(mm-dd-yyyy)

Signature of person entering data onto the web ² _____



ACRIN 6673
RFA Hepatocellular Cancer
Initial Evaluation Form

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

If this is a revised or corrected form, indicate by checking box.

Instructions: Complete and submit this information at the time of the patient's entry to the study. Information reported is for observations and findings prior to the start of protocol RFA. All dates are mm/dd/yyyy unless specified otherwise.

1. Performance status (Zubrod Scale)

- Fully active, able to carry on all predisease activities without restriction.
- Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.
- Ambulatory and capable of all self-care but unable to carry out any work activities.
- Capable of only limited self-care, confined to bed or chair 50% or more of waking hours.
- Completely disabled
- Unknown

2. Diagnosis of Cirrhosis (Check all that apply)

- Biopsy proof
Date of biopsy: ____ - ____ - ____ (mm-dd-yyyy)
- Type of procedure
 - FNA
 - Core Needle Biopsy
- Clinical and imaging confirmation

3. Confirmation of Hepatocellular carcinoma (HCC)

- Biopsy proof
Date of biopsy: ____ - ____ - ____ (mm-dd-yyyy)
- Type of procedure
 - FNA
 - Core Needle Biopsy
- Barcelona imaging criteria:
 - Radiologic criteria [two coincidental imaging techniques (CT, MRI, US, angio) showing > 2 cm arterial enhancing tumor nodule]
 - Combined criteria [single imaging technique (CT, MRI, US, angio) showing > 2 cm arterial enhancing tumor nodule with AFP > 400 ng/mL]
- Tumor growth criteria

4. Pre-enrollment imaging

- (performed within 60 days of RFA treatment)
- Not done
 - Done
 - Unknown

<u>Imaging</u>	<u>Date</u>
Abdominal CT	____ - ____ - ____ (mm-dd-yyyy)
Hepatic Ultrasound (If performed)	____ - ____ - ____ (mm-dd-yyyy)
Chest CT	____ - ____ - ____ (mm-dd-yyyy)
	<input type="radio"/> Negative for metastatic disease
	<input type="radio"/> Positive for metastatic disease
Other, specify _____	____ - ____ - ____ (mm-dd-yyyy)

5. Prior treatment for HCC:

- No
- Yes (Answer 5a)

5a. If yes, specify treatment: _____

6. Patient a surgical candidate?

(see Surgical Assessment Form, Appendix IX)

- No
- Yes

7. Baseline Laboratory Evaluations:

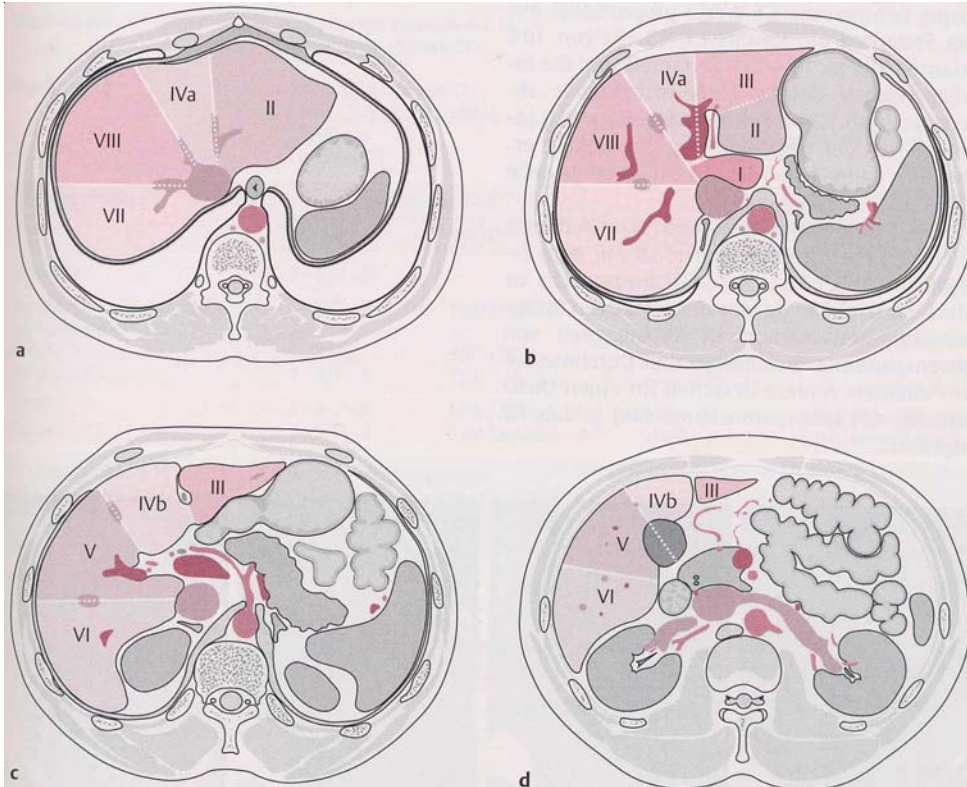
[Performed within 14 days prior to RFA]

- 1 done, within normal limits
- 2 done, abnormal elevated
- 3 done, abnormal depressed
- 98 not done
- 99 unknown

Pre-Registration Baseline

<u>Labs</u>	<u>Lab Value</u>	<u>Date of test (mm-dd-yyyy)</u> <i>(date is required for all labs)</i>	<u>Normal Range</u> LOW <i>(required for all abnormal results)</i>	<u>Normal Range</u> HIGH <i>(required for all abnormal results)</i>
<input type="checkbox"/> Platelets	<input type="checkbox"/> ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> PT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> PTT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> INR	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Serum Creatinine	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> GGT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> LDH	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> AFP	<input type="checkbox"/> ng/ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGOT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGPT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total bilirubin	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Sodium	<input type="checkbox"/> meq/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Potassium	<input type="checkbox"/> . <input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Chloride	<input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Glucose	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> BUN	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Calcium	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Phosphorus	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total Protein	<input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Albumin	<input type="checkbox"/> . <input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Ammonia	<input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hgb	<input type="checkbox"/> . <input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hct	<input type="checkbox"/> ml/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Wbc	<input type="checkbox"/> . <input type="checkbox"/> k/mm ³	____ - ____ - ____	_____	_____

Diagram of the Liver (Appendix VI)



*Couinaud Segments:

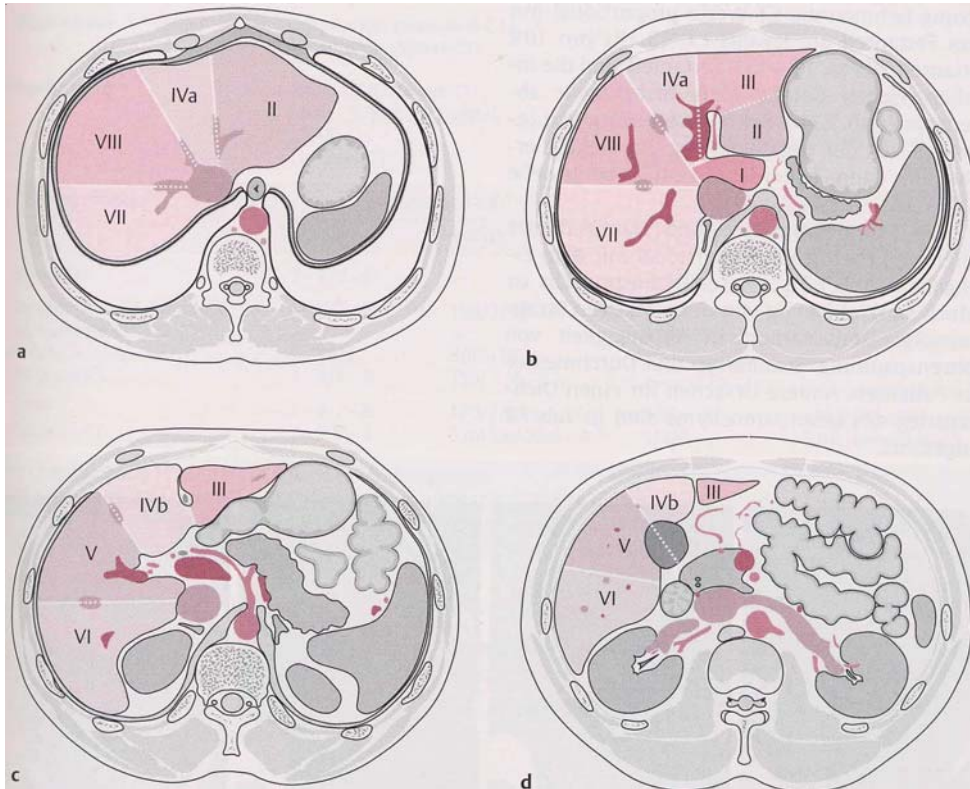
- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

8. NUMBER OF TUMORS PRESENT:

Complete description of each tumor and indicate location using the diagrams, (Appendix VI).
Numbering must be consistent throughout the study.

Assigend Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Size (cm) Largest Size in Diameter	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	.1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver (Appendix VI)

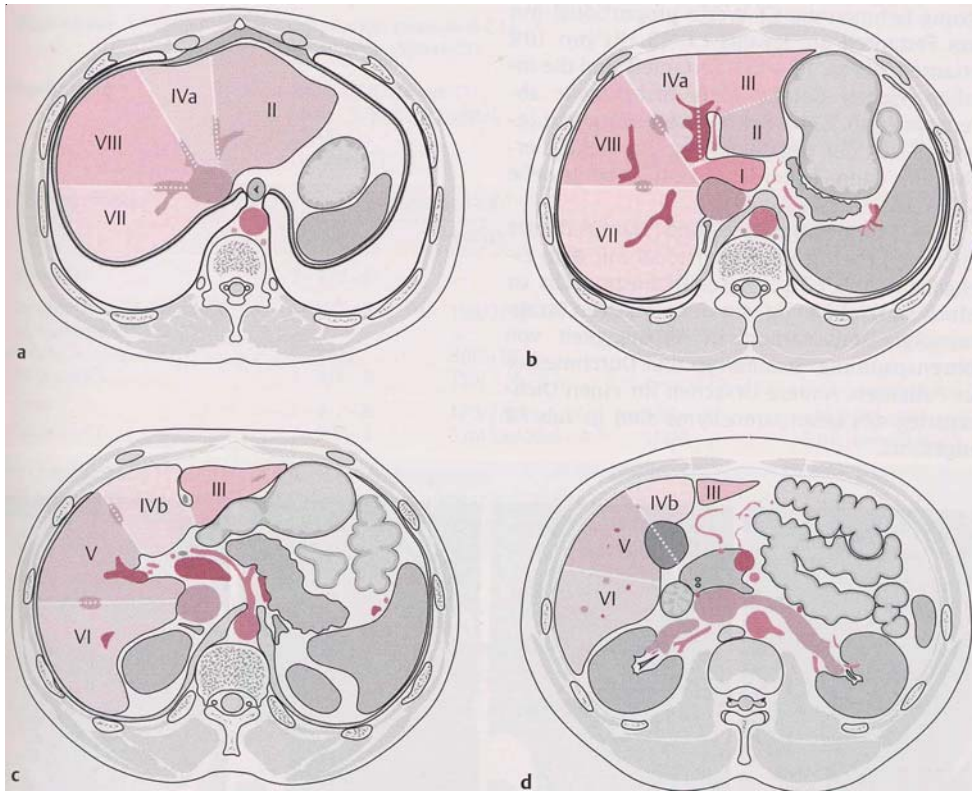


- *Couinaud Segments:**
- Segment I
 - Segment II
 - Segment III
 - Segment IVA
 - Segment IVB
 - Segment V
 - Segment VI
 - Segment VII
 - Segment VIII

9. Complete description of each tumor and indicate location using the diagrams, (*Appendix VI*).
Numbering must be consistent throughout the study.

Assigend Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Size (cm) Largest Size in Diameter	Are there additional tumors to describe?
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>	.1 No 2 Yes <input type="checkbox"/>

Diagram of the Liver (Appendix VI)



- *Couinaud Segments:**
- Segment I
 - Segment II
 - Segment III
 - Segment IVA
 - Segment IVB
 - Segment V
 - Segment VI
 - Segment VII
 - Segment VIII

10. Complete description of each tumor and indicate location using the diagrams, (Appendix VI).
Numbering must be consistent throughout the study.

Assignid Tumor Number	Couinaud Liver Segment* <small>(Check all that apply for this tumor)</small>	Size (cm) Largest Size in Diameter
<input type="checkbox"/>	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="checkbox"/> . <input type="checkbox"/>

Comments: _____

Signature of person responsible for the data ¹

Date form completed ³ ____ - ____ - **20**____
(mm-dd-yyyy)

Signature of person entering data onto the web ²



**ACRIN 6673
RFA-HCC
Additional RFA Treatment Form**

ACRIN Study **6673**

PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

If this is a revised or corrected form, indicate by checking box.

Instructions: This form collects information related to the RFA Treatment. Use code table when provided and report dates mm/dd/yyyy.

1. Tumor recurrence

- No (skip to Q2)
- Yes

1a. Proof of recurrence

- CT
- Biopsy

1b. Type of recurrence

- Local (failure of primary ablation)
- Remote
- Both

2. Date of RFA treatment: - - **20**
(mm-dd-20yy)

3. Did the Re-ablation treatment commence?

- No* (complete 3b)
- Yes

3a. Was the Re-ablation treatment completed?

- No* (complete 3b)
- Yes

3b. *If RFA did not commence or was not completed, specify reason:

- Patient refused to start treatment
- Technical problems during procedure
- Adverse event
- Other reason, specify:

3c. Were any adverse events reported during this time period:

- 1 Yes
- 2 No

If yes, specify date:

____ - ____ - _____ (mm-dd-yyyy)

4. Radiologist ID performing procedure:

5. Imaging modality utilized for RFA

- Ultrasound
- CT Scan
- MRI

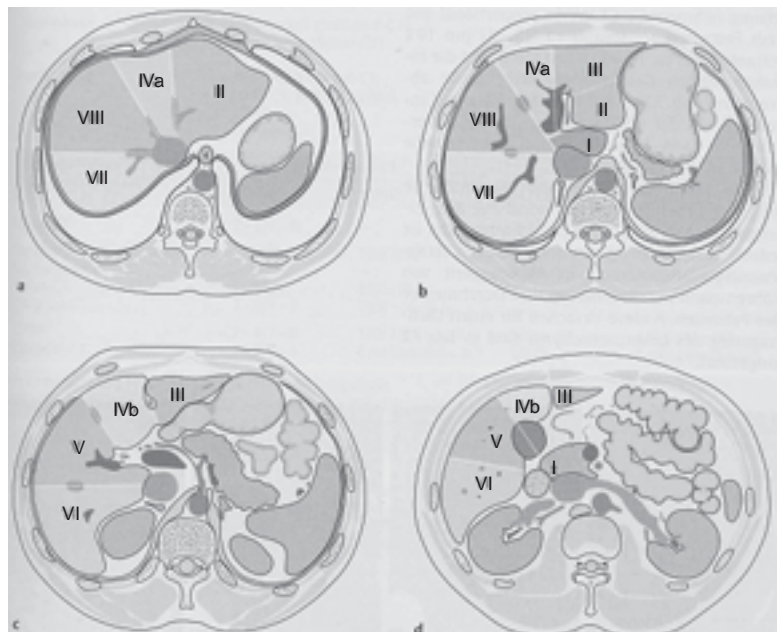
7 Complete description of each tumor ablated and indicate location using the diagram (appendix VI). Numbering must be consistent throughout the study.

Assigned Tumor #	Liver Segment *	Type of recurrence** 1 Local 2 Remote	Size (mm) Trans (M-L) x CC (S-I) x AP (A-P)	Subcapsular 1 No 2 Yes	Contiguous to major (< 1 cm) vessels		Number of previous RFA sessions
					1 No	2 Yes	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <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"/> x <input type="text"/> x <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Diagram of the Liver
Appendix VI**

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII



Ablation Treatment Form

8. Tumor (Record tumor number per diagram)

8a. Number of ablations this session within this tumor

8b. Number of prior RFA sessions for this tumor

8c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

8d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

8e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

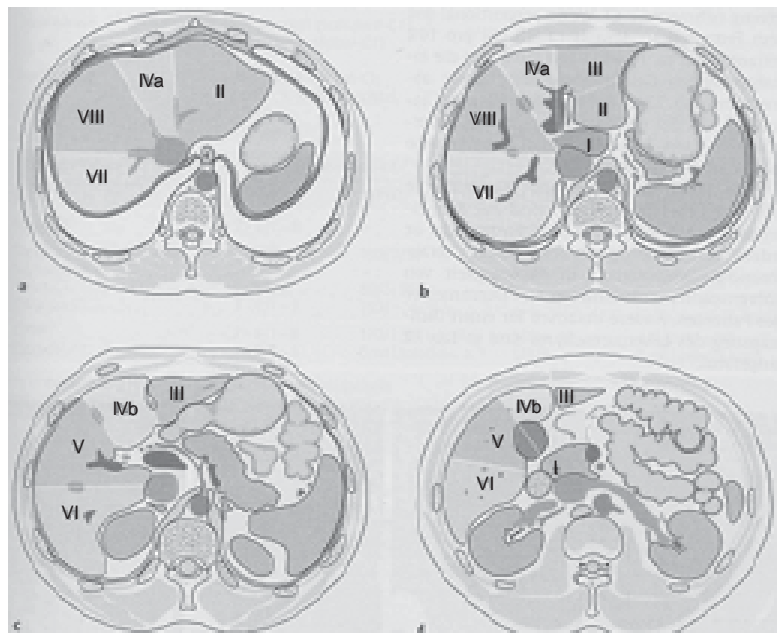
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

8f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

9. Tumor (Record tumor number per diagram)

9a. Number of ablations this session within this tumor

9b. Number of prior RFA sessions for this tumor

9c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

9d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

9e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

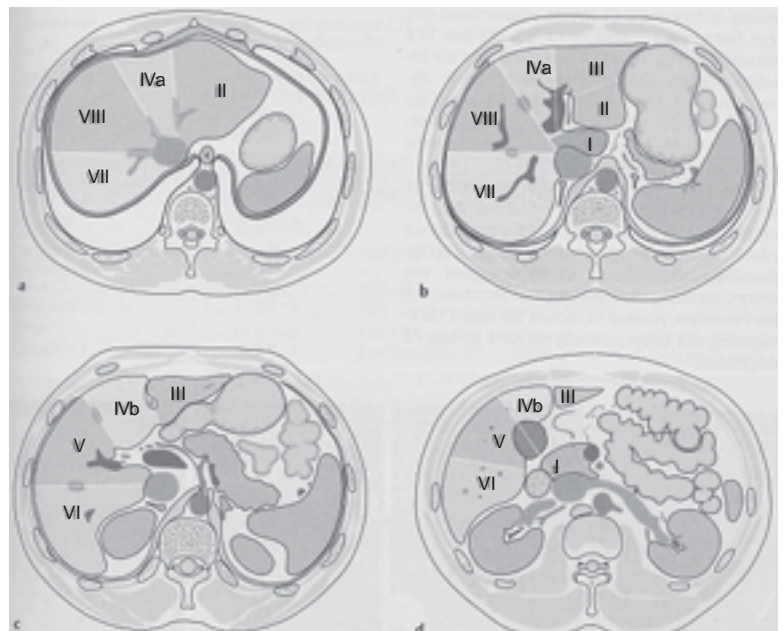
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

9f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

10. Tumor (Record tumor number per diagram)

10a. Number of ablations this session within this tumor

10b. Number of prior RFA sessions for this tumor

10c. Number of cauterizations for this tumor:

- 1
- 2
- 3
- 4
- 5
- 6

10d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

10e. Were any complications encountered?

- No
- Yes

If yes, check all that apply:

- abscess
- pneumothorax
- hemorrhage
- tumor seeding
- other, specify: _____

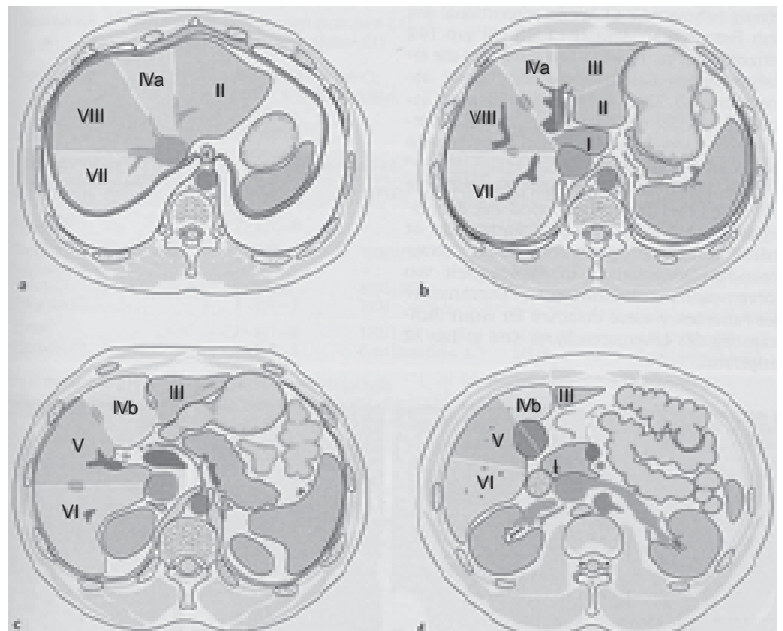
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

10f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

11. Tumor (Record tumor number per diagram)

11a. Number of ablations this session within this tumor

11b. Number of prior RFA sessions for this tumor

11c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

11d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

11e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

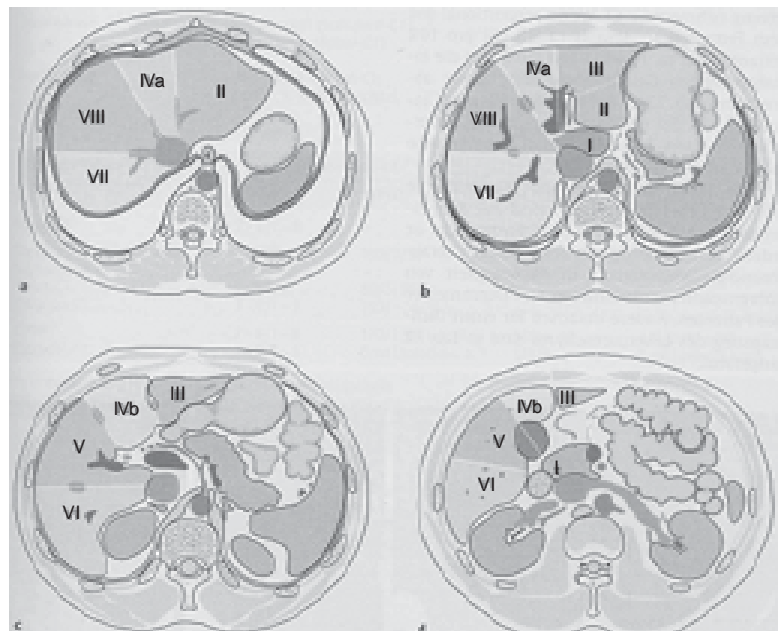
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

11f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

12. Tumor (Record tumor number per diagram)

12a. Number of ablations this session within this tumor

12b. Number of prior RFA sessions for this tumor

12c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

12d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

12e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

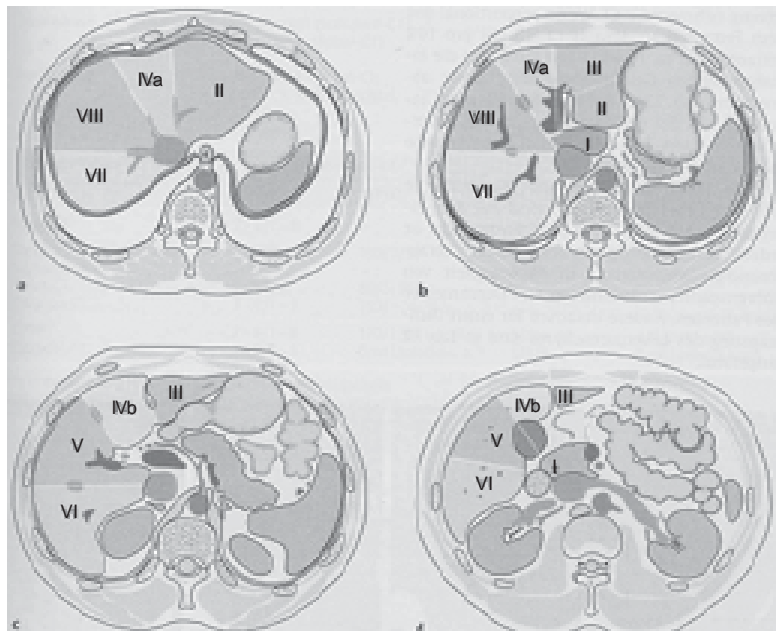
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

12f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

13. Tumor (Record tumor number per diagram)

13a. Number of ablations this session within this tumor

13b. Number of prior RFA sessions for this tumor

13c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

13d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

13e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

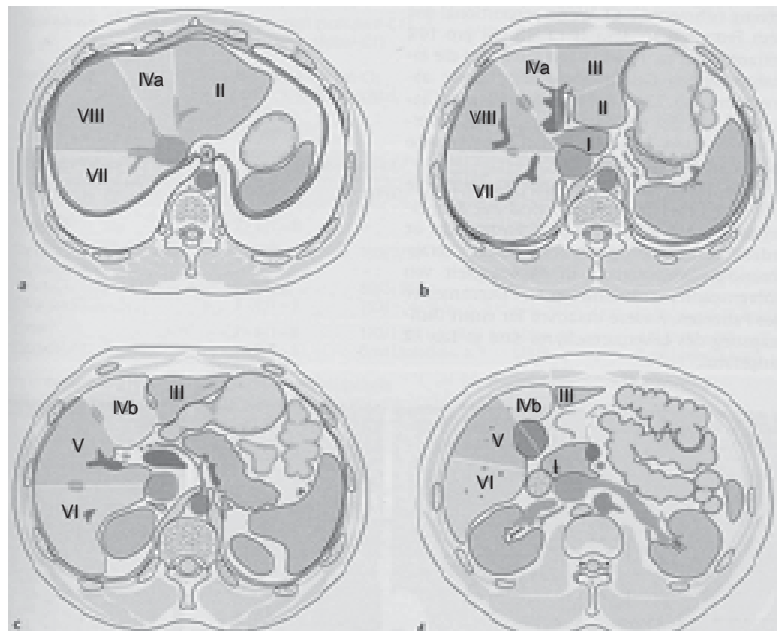
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

13f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

14. Tumor (Record tumor number per diagram)

14a. Number of ablations this session within this tumor

14b. Number of prior RFA sessions for this tumor

14c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

14d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

14e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

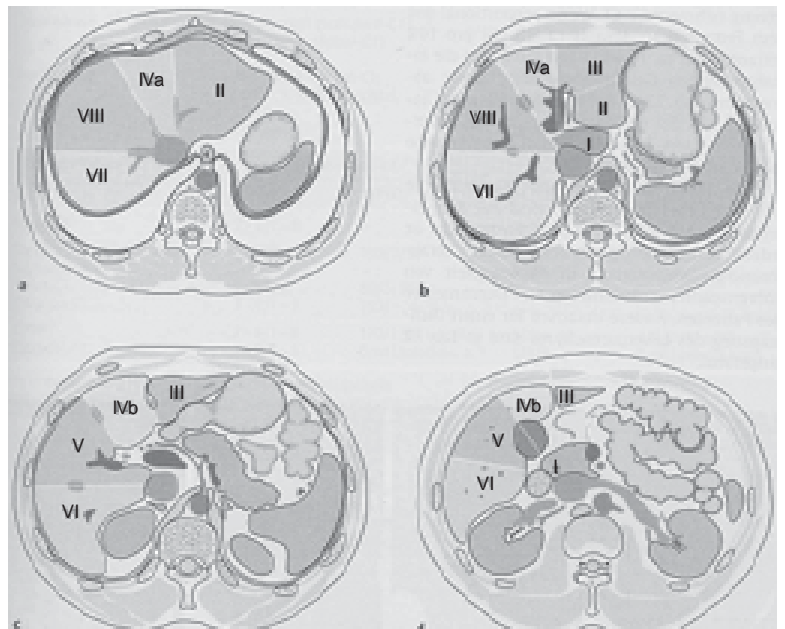
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

14f. Mark location cauterizations on diagram with a "c".



Ablation Treatment Form

[IF NOT APPLICABLE SKIP AND COMPLETE LAST PAGE]

15. Tumor (Record tumor number per diagram)

15a. Number of ablations this session within this tumor

15b. Number of prior RFA sessions for this tumor

15c. Number of cauterizations for this tumor:
 1 2 3 4 5 6

15d. Indicate Valley Lab Cooled Tip

Rf Ablation needles utilized:

- 1 single, 2 cm tip
- 2 single, 3 cm tip
- 3 cluster, 3 prong, 2.5 cm tip

15e. Were any complications encountered?

- No Yes

If yes, check all that apply:

- abscess pneumothorax
- hemorrhage tumor seeding
- other, specify: _____

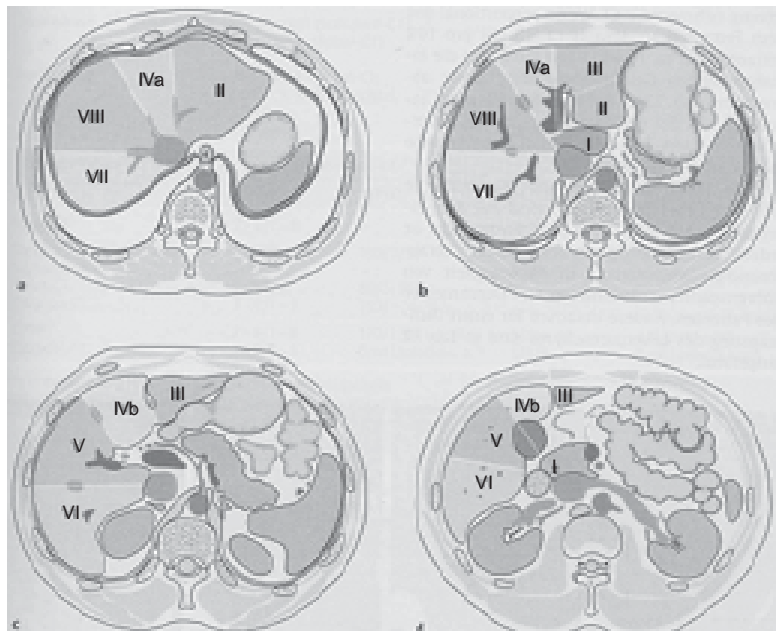
Ablation Number	Baseline Impedance (R)	Treatment Duration (minutes)	One Minute Post Treatment Temperature(°C)	Number of Needle Insertions
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diagram of the Liver

***Couinaud Segments**

- 1 Segment I
- 2 Segment II
- 3 Segment III
- 4 Segment IVA
- 5 Segment IVB
- 6 Segment V
- 7 Segment VI
- 8 Segment VII
- 9 Segment VIII

15f. Mark location cauterizations on diagram with a "c".





Study 6673

Case # _____

Revision

Comments: _____

Signature of person responsible for the data ¹

Date form completed ³ ____-____-____
(mm-dd-yyyy)

Signature of person entering data onto the web ²



**ACRIN 6673
RFA-HCC
Follow-up Form**

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The F2 form is completed at 6, 9, 12, 15 and 18 months post initial RFA procedure by the Research Associate, and submitted via the ACRIN website.

1. Did the participant return for the scheduled follow-up? [1]

- No (Answer 1a, and 1b)
- Yes (Answer 1c)

1a. If no, specify reason: [2]

- Participant refusal
- Participant unable to be contacted
- Unable to be performed and rescheduled
- Other, specify: _____ [3]

1b. Date of last contact:

____-____-____ (mm-dd-yyyy) [4]

1c. Describe follow-up: [5]

- Completed
- Incomplete,
Will return on: ____-____-____ (mm-dd-yyyy) [6]
- Incomplete, return date unknown

2. Date of follow-up contact or attempt:

____-____-____ (mm-dd-yyyy) [7]

3. RFA Follow-up Time Period: [8]

- 6 months
- 9 months
- 12 months
- 15 months
- 18 months
- Other, specify: _____ [9]

3a. Last RFA session date:

____-____-____ (mm-dd-yyyy) [10]

3b. Date of most recent Post-ablation CT scan:

____-____-____ (mm-dd-yyyy) [11]

3c. Are there any reportable complications / adverse events per Sec. 15.7.1 of the protocol? [12]

- No
- Yes (If yes, an AE form must be completed)

4. Participant status: [13]

- Alive (Complete 4a)
- Dead (Complete 4a, 4c, and 4d)
- Unknown/unable to contact (Complete 4a)

4a. Was the liver: [14]

- Transplanted (Complete 4b)
- Resected (Complete 4b)
- Neither
- Unknown

4b. Date of transplant / resection:

____-____-____ (mm-dd-yyyy) [15]

Check if date of transplant/resection unknown:

Date of transplant/resection unknown [16]

4c. Date of death:

____-____-____ (mm-dd-yyyy) [17]

Check if date of death unknown:

Date of death unknown [18]

4d. Cause of death: [19]

- Progressive/persistent cancer
- Complications of protocol treatment
- Progressive cirrhosis
- Other, specify: _____ [20]
- Unknown

5. Performance status (Zubrod Scale) [21]

- Fully active
- Ambulatory, capable of light work
- In bed less than 50% of the time, capable of self-care, but not of work activities
- In bed greater than 50% of the time, capable of only limited self care
- Bedridden
- Not evaluated
- Unknown



If this is a revised or corrected form, please box.

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

6. Any non-protocol treatment started during this follow-up time period: [22]

- No (proceed to Q7)
- Yes (If yes, complete Q6a)
- Unknown (proceed to Q7)

6a. Treatment **Date started**
(check all that apply) (mm-dd-yyyy)

- Chemotherapy [23] _____ - _____ - _____ [24]
 - Start date of Chemotherapy unknown [25]
- Radiation to Non-Study [26] _____ - _____ - _____ [27] Site,
 - Start date of Radiation to Non-Study Site unknown [28]
 Specify Non-Liver site: _____ [29]
- Other treatment, [30] _____ - _____ - _____ [31]
 - Other treatment start date unknown [32]
 Specify treatment: _____ [33]

7. Were there any tumor biopsies performed during this time period? [34]

- No (proceed to Q8)
- Yes (Answer Q7a and Q7b, submit per Sec 11.3 of the protocol)
- Yes, previously submitted (Answer Q7a and Q7b)
- Unknown

7a. Date of biopsy: _____ - _____ - _____ (mm-dd-yyyy) [35]

Date of biopsy unknown [36]

7b. Type of procedure [37]

- FNA
- Core needle

8. Is there evidence of local intrahepatic tumor on the corresponding CT exam for this visit? [38]

- No
- Yes
- Indeterminate

9. Is there evidence of remote intrahepatic tumor on the corresponding CT exam for this visit? [39]

- No
- Yes

10. Will/has this participant been scheduled for reablation? [40]

- No
- Yes

10a. If no to re-ablation, provide reason:

(Check all that apply)

- Size of tumor exceeds 5 cm [41]
- Recurrence adjacent to vital structures [42]
- Evidence of extrahepatic tumor [43]
- Not technically feasible / not clinically indicated [44]
- No local or remote intrahepatic tumor visible [45]

11. AFP drawn within one week of CT Scan? [46]

- No, specify reason _____ [47]
- Yes (answer Q8a and Q8b)

11a. Date drawn: _____ - _____ - _____ (mm-dd-yyyy) [48]

11b. AFP lab value: _____ ng/ml [49]

11c. Has the AFP lab value increased or decreased since the previous follow-up visit? [50]

- No
- Yes, lab value increased
- Yes, lab value decreased

Comments: _____

_____ [51]

_____ [52]
Name of person responsible for the data

_____ [53]
Date Form Completed (mm-dd-yyyy)

_____ [54]
Name of person entering data on web



**RFA-HCC
Follow-up Form**

If this is a revised or corrected form, indicate by checking box.

ACRIN Study 6673

PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

Instructions: The F1 form is completed at day 1, 1 week, 1 month, 3, 6, 9, 12, 15 and 18 months post initial RFA procedure by the Research Associate.

1. RFA Follow-up Time Period:

- 1 1 day
- 2 1 week
- 3 1 month
- 4 0-3 months
- 5 3-6 months
- 6 6-9 months
- 7 4-12 months
- 8 12-15 months
- 9 15-18 months
- 10 Other, specify: _____

1a. Reason for follow-up:

- 1 Telephone contact
- 2 Every 3 month visits
- 3 RFA treatment
- 4 Post-ablation CT scan

1b. RFA treatment date:

____ - ____ - _____ (mm-dd-yyyy)

1c. Date of Post-ablation CT scan:

____ - ____ - _____ (mm-dd-yyyy)

1d. Were any adverse events reported during this time period:

- 1 Yes
- 2 No

If yes, specify date:

____ - ____ - _____ (mm-dd-yyyy)

2. Date of evaluation: ____ - ____ - _____
(mm-dd-yyyy)

3. Patient status:

- 1 Alive
- 2 Transplanted
- 3 Dead
- 4 Lost to follow-up (unable to contact)

3a. Status Date: ____ - ____ - _____
(mm-dd-yyyy)

(Date of death if dead, date of transplant if transplanted, or last date known alive if alive or lost.)

4. Cause of death:

- 0 Alive
- 1 Progressive/persistent cancer
- 2 Complications of protocol treatment
- 3 Both cancer and protocol treatment
- 4 Progressive cirrhosis
- 5 Other, specify _____
- 99 Unknown

5. Tumor number:

- 1 3 5 7
- 2 4 6 8

6. Performance status (Zubrod Scale)

- 0 Fully active
- 1 Ambulatory, capable of light work
- 2 In bed less than 50% of the time, capable of self-care, but not of work activities
- 3 In bed greater than 50% of the time, capable of only limited self care
- 4 Bedridden
- 98 Not evaluated
- 99 Unknown

7. Did the participant return for the scheduled follow-up?

- 1 No (specify reason, STOP and sign form)
 - Participant refusal
 - Participant unable to be contacted
 - Unable to be performed and rescheduled
- 2 Yes
 - Completed
 - Incomplete, will return on: _____

(mm-dd-yyyy)

Incomplete, return date unknown

if No - specify reason:

9. Pre-RFA Treatment Laboratory Evaluations:

[Performed within 14 days prior to RFA]

- 1 done, within normal limits
- 2 done, abnormal elevated
- 3 done, abnormal depressed
- 98 not done
- 99 unknown

<u>Labs Evaluation</u>	<u>Lab Value</u>	<u>Date of test (mm-dd-yyyy)</u> <i>(date is required for all labs)</i>	<u>Normal Range</u> LOW <i>(required for all abnormal results)</i>	<u>Normal Range</u> HIGH <i>(required for all abnormal results)</i>
<input type="checkbox"/> Platelets	<input type="checkbox"/> ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> PT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> PTT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> INR	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Serum Creatinine	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> GGT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> LDH	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> AFP	<input type="checkbox"/> ng/ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGOT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGPT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total bilirubin	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Sodium	<input type="checkbox"/> meq/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Potassium	<input type="checkbox"/> . <input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Chloride	<input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Glucose	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> BUN	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Calcium	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Phosphorus	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total Protein	<input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Albumin	<input type="checkbox"/> . <input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Ammonia	<input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hgb	<input type="checkbox"/> . <input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hct	<input type="checkbox"/> ml/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Wbc	<input type="checkbox"/> . <input type="checkbox"/> k/mm ³	____ - ____ - ____	_____	_____
<input type="checkbox"/> Beta hCg	<input type="checkbox"/> . <input type="checkbox"/> k/mm ³	____ - ____ - ____	_____	_____

9. Post RFA Treatment Laboratory Evaluations:

[Performed within 14 days prior to RFA]

- 1 done, within normal limits
- 2 done, abnormal elevated
- 3 done, abnormal depressed
- 98 not done
- 99 unknown

<u>Labs Evaluation</u>	<u>Lab Value</u>	<u>Date of test (mm-dd-yyyy)</u> <i>(date is required for all labs)</i>	<u>Normal Range</u> LOW <i>(required for all abnormal results)</i>	<u>Normal Range</u> HIGH <i>(required for all abnormal results)</i>
<input type="checkbox"/> Platelets	<input type="checkbox"/> ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> PT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> PTT	<input type="checkbox"/> seconds	____ - ____ - ____	_____	_____
<input type="checkbox"/> INR	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Serum Creatinine	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> GGT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> LDH	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> AFP	<input type="checkbox"/> ng/ml	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGOT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> SGPT	<input type="checkbox"/> u/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total bilirubin	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Sodium	<input type="checkbox"/> meq/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Potassium	<input type="checkbox"/> . <input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Chloride	<input type="checkbox"/> meq/l	____ - ____ - ____	_____	_____
<input type="checkbox"/> Glucose	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> BUN	<input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Calcium	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Phosphorus	<input type="checkbox"/> . <input type="checkbox"/> mg/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Total Protein	<input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Albumin	<input type="checkbox"/> . <input type="checkbox"/> gm/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Ammonia	<input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hgb	<input type="checkbox"/> . <input type="checkbox"/> g/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Hct	<input type="checkbox"/> ml/dl	____ - ____ - ____	_____	_____
<input type="checkbox"/> Wbc	<input type="checkbox"/> . <input type="checkbox"/> k/mm ³	____ - ____ - ____	_____	_____

10. Any non-protocol treatment started during this follow-up periods:

- 1 No
- 2 Yes (if yes, complete 11a)
- Unknown

10a. Treatment Date started (mm-dd-yyyy)

Hormones _____ - _____ - _____

Chemotherapy _____ - _____ - _____

Radiation to _____ - _____ - _____

Non-Study Site,

Specify:

Other treatment, _____ - _____ - _____

Specify:

Comments: _____

Signature of person responsible for the data ¹

Date form completed ³ _____ - _____ - _____
(mm-dd-yyyy)

Signature of person entering data onto the web ²



**ACRIN 6673
Central Reader
Interpretation Form**

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The central reader is to review the abdominal scans for each case and complete one CX form at each imaging timepoint to document tumors and tumor descriptors. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted. This form will be completed and data entered at ACRIN headquarters.

The ACRIN Case Number and Follow-Up Time Period must be recorded on all pages of this form.

Section I.

- 1. RFA Follow-up Time Period** ^[1]
- 1 Pre-enrollment
 - 2 Baseline (initial post-ablation)
 - 3 3 Month
 - 4 6 Month
 - 5 9 Month
 - 6 12 Month
 - 7 15 Month
 - 8 18 Month
 - 88 Other, specify _____ ^[2]

2. Date of Scan: ____-____-____ (mm-dd-yyyy) ^[3]

3. Reader ID ^[4]

Image Quality:

- 3. Interpretable?** ^[5]
- 1 No (complete 3a, then initial and date form)
 - 2 Yes (skip to Q4)

3a. Reason

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Motion ^[6]
- Artifacts ^[7]
- Contrast media ^[8]
- DICOM header ^[9]
- Lost images ^[10]
- Poor S/N ^[11]
- Incomplete anatomic coverage ^[12]
- Other, ^[13] specify _____ ^[14]

Section II.

- 4. Is there evidence of new Extrahepatic Tumor(s)?** ^[15]
- 1 No (skip Q4a)
 - 2 Yes (complete Q4a and Section III)

4a. Specify location(s):

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Adrenal gland ^[16]
- Kidney ^[17]
- Lung ^[18]
- Lymph node ^[19]
- Musculoskeletal ^[20]
- Pancreas ^[21]
- Peritoneum ^[22]
- Spleen ^[23]
- Abdominal wall ^[24]
- Other, ^[25] specify _____ ^[26]



Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Section III.

TUMOR REPORT

* Tumor numbering and location(s) must be the same on every central reader form across all follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
[27]	[28]	[29] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [30] <input type="checkbox"/> Segment V [35] <input type="checkbox"/> Segment II [31] <input type="checkbox"/> Segment VI [36] <input type="checkbox"/> Segment III [32] <input type="checkbox"/> Segment VII [37] <input type="checkbox"/> Segment IVA [33] <input type="checkbox"/> Segment VIII [38] <input type="checkbox"/> Segment IVB [34]	[39] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[40] O 1 No O 2 Yes	[41]
		O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	O 1 No O 2 Yes	
		O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	O 1 No O 2 Yes	
		O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	O 1 No O 2 Yes	
		O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	O 1 No O 2 Yes	



Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please box.

TUMOR REPORT

* Tumor numbering and location(s) must be the same on every central reader form across all follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	



Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

TUMOR REPORT

* Tumor numbering and location(s) must be the same on every central reader form across all follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	
	_____ . _____	<input type="radio"/> 1 Ablated <input type="radio"/> 2 Not ablated	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment V <input type="checkbox"/> Segment II <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment III <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment VIII <input type="checkbox"/> Segment IVB	<input type="radio"/> 1 Tumor absent <input type="radio"/> 2 Tumor present <input type="radio"/> 3 Indeterminate	<input type="radio"/> 1 No <input type="radio"/> 2 Yes	

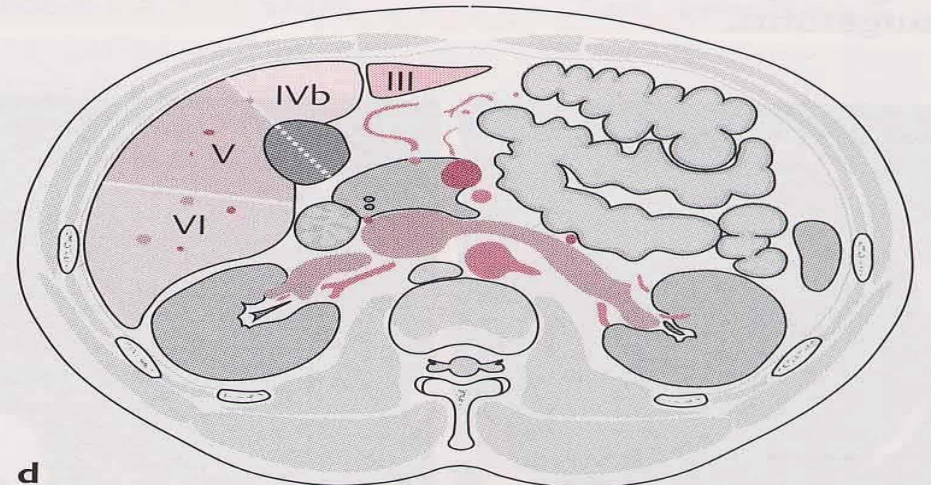
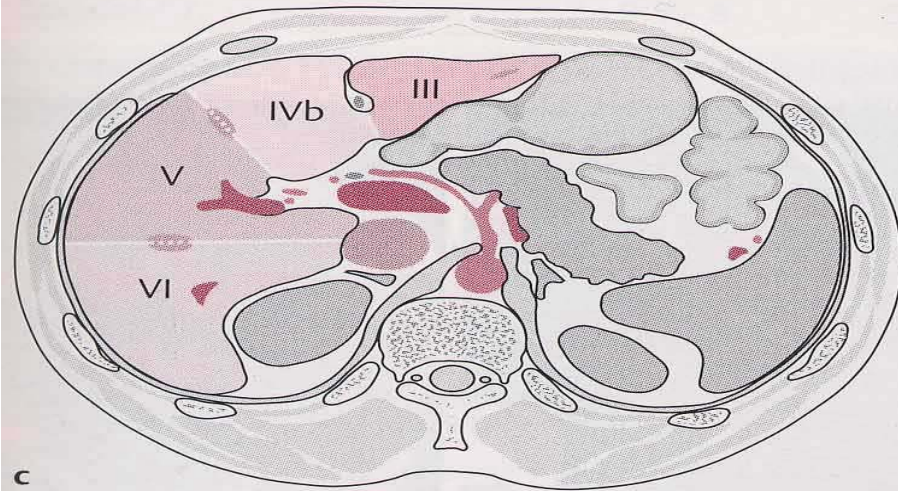
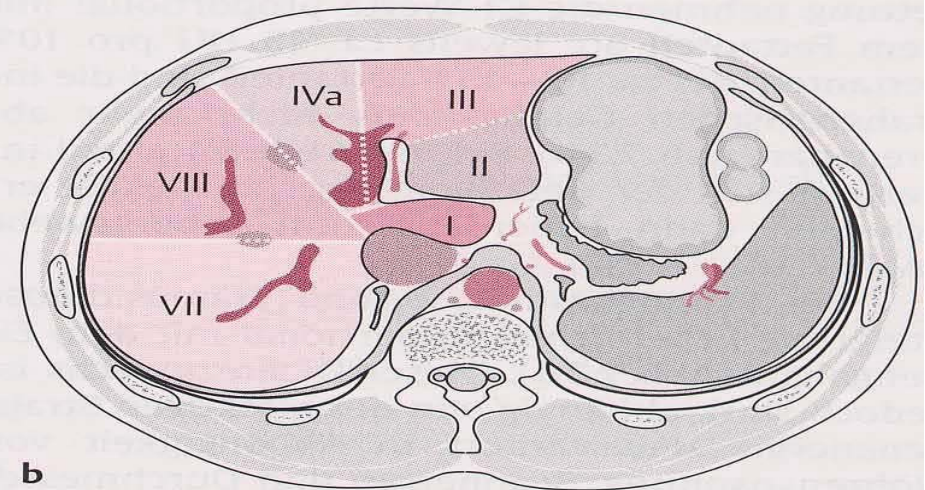
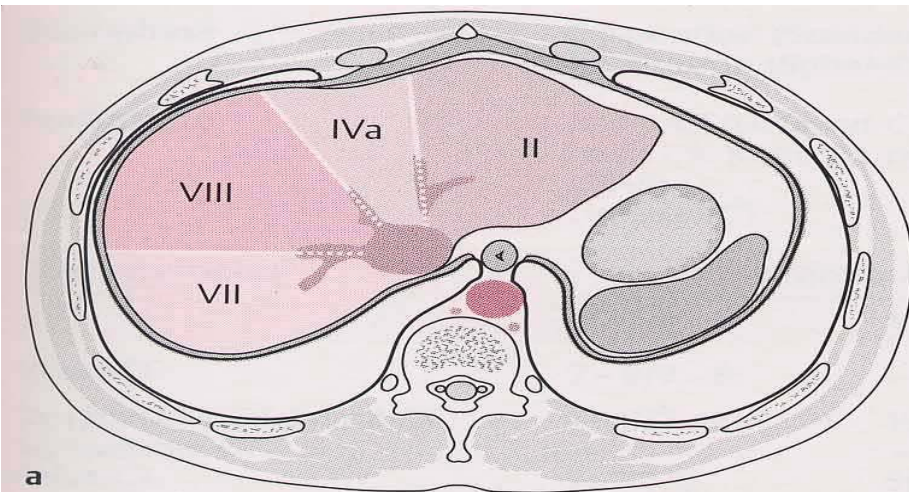
CX**ACRIN 6673
Central Reader
Interpretation Form**If this is a revised or corrected form, please box. **ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions:

- 1) Mark tumor location(s) on the diagram by encircling the tumor number. Example for Tumor #1 **①**
- 2) Mark cauterization location(s) on the diagram with a "c" encircled. Example **Ⓒ**
- 3) Tumor numbering and locations must be consistent throughout central reader interpretation across all follow-up time periods.





Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please box.

Section IV.

Comments: _____

 _____ [42]

 Reader Initials [43]

____ - ____ - ____ [44]
 Date form completed (mm-dd-yyyy)

 Initials of person completing form [45]

Section V: *(ACRIN personnel only)*

This section is completed after tumor matching, by the ACRIN RA.

Adjudicator review required if Central reader and Local reader disagree about:

1. the presence of disease.
2. the size of tumors (tumor size must be within 50% of the size recorded, i.e: if the local measure was 2 cm and the central was >3cm or <1cm then it would require adjudication).
3. the number of tumors.
4. the couinaud segment location of tumors (tumors must be in the same or adjacent segment, i.e: if the local was in segment II and the Central was in segment V then it would require adjudication)
5. the Central reader found a tumor missed by the Local reader.
6. the Local reader found a tumor missed by the Central reader.

- 1. Is adjudicator review required?** [46]
- No
 - Yes

 Initials of person responsible for the data [47]

____ - ____ - ____ [48]
 Date form completed (mm-dd-yyyy)



**ACRIN 6673
Chest CT Imaging Form**

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The CD form is completed by the Site Radiologist to document findings on the Chest CT scan performed at the 18 month visit. This form is submitted via the ACRIN website.

1. Was a chest CT scan performed at 18 months? [1]

- No (Answer Q2)
- Yes (Skip to Q3)

2. If no, give reason (then sign and date form) [2]

- Scheduling problems
- Equipment failure
- Participant refusal
- Medical reasons
- Injection site complications
- Claustrophobia
- Participant withdrew consent
- Progressive disease
- Participant death
- Other, specify _____ [3]
- Unknown

3. Date of Chest CT scan _____ - _____ - _____ [4]
(mm-dd-yyyy)

4. Date of Chest CT interpretation
(Date CT scan reviewed by Study Radiologist)

_____ - _____ - _____ [5]
(mm-dd-yyyy)

5. Reader ID

--	--	--	--	--	--	--	--	--	--

 [6]

6. Was a Helical Chest CT scan performed with slice thickness of 5 – 8 mm? [7]

- No (If no, please submit a PR describing the deviation)
- Yes
- Other, specify _____ [8]

7. Chest CT scan performed [9]

- With intravenous contrast
- Without intravenous contrast

8. Indicate the results of this scan

- Negative (Complete Q8a) [10]
- 8a. If negative, indicate clinical significance** [11]

- No significant abnormalities
- Minor abnormalities not suspicious for pulmonary metastases
- Significant abnormalities not suspicious for pulmonary metastases

- Positive (Complete Q8b) [12]

8b. If positive, indicate overall suspicion for pulmonary metastases [13]

- Low suspicion
- Intermediate suspicion
- Moderately high suspicion
- High suspicion

- Inadequate/suboptimal (Complete Q8c) [14]

8c. If inadequate/suboptimal, indicate reason [15]

- Not enough of body imaged
- Noisy images
- Patient motion
- Metal artifact
- Other, specify _____ [16]



**ACRIN 6673
Chest CT Imaging Form**

If this is a revised or corrected form, please box.

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Comments: _____

_____ [17]

Signature of Site Radiologist [18]

_____-_____-_____
Date Form Completed (mm-dd-yyyy) [19]

C2**ACRIN 6673
Initial Imaging Form**ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box. **Initial Imaging Form**

After enrollment, the Initial Imaging form (C2) is to be completed by the Study Radiologist (the radiologist performing the RFA). A C2 form is completed for **each tumor** and is based on an abdominal scan using either CT or MRI. The tumor is marked within the diagrams (page 2, question 8) with a "t" within the appropriate segment. Once the form data has been entered into the ACRIN website www.acrin.org a copy of page 2 of the C2 form must be mailed to the Data Management Center. A case specific label should be affixed to the form in the designated area.

1. Reader ID#:

2. Type of abdominal scan

- CT
 MRI

2a. Date of abdominal scan:

____ - ____ - ____
(mm-dd-yyyy)

3. Date of Chest CT Scan: ____ - ____ - ____
(mm-dd-yyyy)

4. Is there evidence of metastatic disease on Chest CT?

- No
 Yes

5. Pre-RFA targeted Hepatic Sonogram performed per Section 8.2 of the protocol?

- No (Ultrasound not being used as guidance technique for ablation)
 Yes

6. Imaging findings of cirrhosis present?

- No (skip to Q7)
 Yes (complete Q6a)

6a. Check all that apply:

- Nodular Liver
 Hepatic atrophy/hypertrophy
 Portal varices
 Splenomegaly
 Ascites

7. Number of per protocol tumors for ablation present:

- 1
 2
 3

8. Are there hypervascular lesions (non-protocol lesions) present < 1 cm?

- No
 Yes

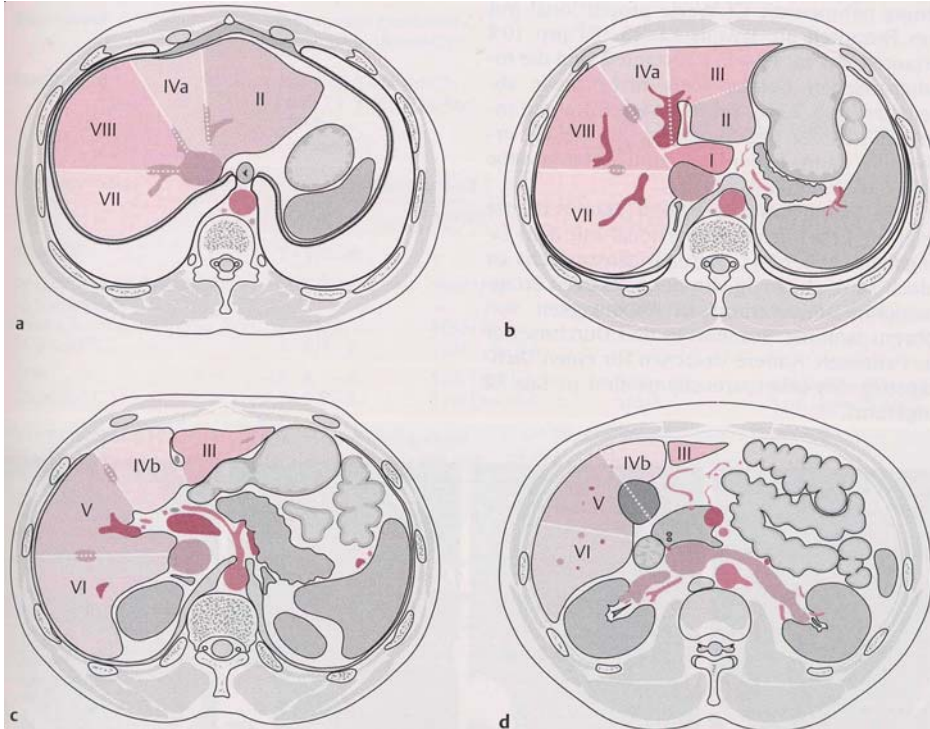
A copy of page 2 (with case specific label) is mailed to the Data Management center.

**American College of Radiology
ACRIN 6673/Data Management
1818 Market Street/Suite 1600
Philadelphia, PA 19103**

Complete description of each tumor

9. This form represents: Tumor Number
(Numbering and location must be consistent throughout the study.)

Diagram of the Liver (Appendix VI)



***Couinaud Segments:**

- Segment I
- Segment II
- Segment III
- Segment IVA
- Segment IVB
- Segment V
- Segment VI
- Segment VII
- Segment VIII

9a. Mark location of this tumor on the diagram with a "t".

Date of Abdominal Scan	Couinaud Liver Segment* (Check all that apply for this tumor)	Size (cm) Largest Size in Diameter	Subcapsular	Contiguous to Major Vessels? (vessels > 5mm)	Does the tumor meet the criteria for RFA treatment as outlined in the protocol?
____ - ____ - 20 (mm/dd/yyyy)	<input type="checkbox"/> Segment I <input type="checkbox"/> Segment II <input type="checkbox"/> Segment III <input type="checkbox"/> Segment IVA <input type="checkbox"/> Segment IVB <input type="checkbox"/> Segment V <input type="checkbox"/> Segment VI <input type="checkbox"/> Segment VII <input type="checkbox"/> Segment VIII	<input type="text"/> . <input type="text"/>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes

Comments: _____

Signature of person responsible for the data ¹ _____

Signature of person entering data onto the web ² _____

Date form completed ³ ____ - ____ - **20**
(mm-dd-yyyy)



**ACRIN 6673
Assessment of
Tumor Resectability**

If this is a revised or corrected form, indicate by checking box.

ACRIN Study 6673

PLACE LABEL HERE

Institution _____ Institution No. _____

Patient's Initials _____ Patient's I.D. No. _____

Instructions: This form must be completed by the Surgical Oncologist.

1. Is the participant a candidate for liver resection?

- No (complete 1a)
- Yes

1a. Reason:

(Select all that apply)

- Tumors in unresectable location.
- Co-morbid disease making the patient a poor surgical candidate.
- Insufficient hepatic reserve.

Comments: _____

 Signature of Surgical Oncologist ¹

Date form completed ³ ____ - ____ - **20**____
 (mm-dd-yyyy)

 Signature of person entering data onto the web ²



ACRIN 6673
Adjudicator Interpretation Form
[Abdominal Scan]

ACRIN Study 6673
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: The adjudicator is to review the abdominal scans for each case and complete one **AS** form at each imaging timepoint to document tumors and tumor descriptors. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted. This form will be completed and data entered at ACRIN headquarters.

The ACRIN Case Number and Follow-Up Time Period must be recorded on all pages of this form.

Section I.

- 1. RFA Follow-up Time Period** ^[1]
- 1 Pre-enrollment
 - 2 Baseline (initial post-ablation)
 - 3 3 Month
 - 4 6 Month
 - 5 9 Month
 - 6 12 Month
 - 7 15 Month
 - 8 18 Month
 - 88 Other, specify _____ ^[2]

2. Date of Scan: ____-____-____ (mm-dd-yyyy) ^[3]

3. Reader ID ^[4]

Image Quality:

- 3. Interpretable?** ^[5]
- 1 No (complete 3a, then initial and date form)
 - 2 Yes (skip to Q4)

3a. Reason

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Motion ^[6]
- Artifacts ^[7]
- Contrast media ^[8]
- DICOM header ^[9]
- Lost images ^[10]
- Poor S/N ^[11]
- Incomplete anatomic coverage ^[12]
- Other, ^[13] specify _____ ^[14]

Section II.

4. Is there evidence of new Extrahepatic Tumor(s)? ^[15]

- 1 No (skip Q4a)
- 2 Yes (complete Q4a and Section III)

4a. Specify location(s):

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Adrenal gland ^[16]
- Kidney ^[17]
- Lung ^[18]
- Lymph node ^[19]
- Musculoskeletal ^[20]
- Pancreas ^[21]
- Peritoneum ^[22]
- Spleen ^[23]
- Abdominal wall ^[24]
- Other, ^[25] specify _____ ^[26]



Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Section III.

TUMOR REPORT

* Tumor numbering and location(s) must be consistent throughout the adjudicator reader interpretation - per follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
[27]	[28] ____ . ____	[29] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [30] <input type="checkbox"/> Segment V [35] <input type="checkbox"/> Segment II [31] <input type="checkbox"/> Segment VI [36] <input type="checkbox"/> Segment III [32] <input type="checkbox"/> Segment VII [37] <input type="checkbox"/> Segment IVA [33] <input type="checkbox"/> Segment VIII [38] <input type="checkbox"/> Segment IVB [34]	[39] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[40] O 1 No O 2 Yes	[41]
[42]	[43] ____ . ____	[44] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [45] <input type="checkbox"/> Segment V [50] <input type="checkbox"/> Segment II [46] <input type="checkbox"/> Segment VI [51] <input type="checkbox"/> Segment III [47] <input type="checkbox"/> Segment VII [52] <input type="checkbox"/> Segment IVA [48] <input type="checkbox"/> Segment VIII [53] <input type="checkbox"/> Segment IVB [49]	[54] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[55] O 1 No O 2 Yes	[56]
[57]	[58] ____ . ____	[59] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [60] <input type="checkbox"/> Segment V [65] <input type="checkbox"/> Segment II [61] <input type="checkbox"/> Segment VI [66] <input type="checkbox"/> Segment III [62] <input type="checkbox"/> Segment VII [67] <input type="checkbox"/> Segment IVA [63] <input type="checkbox"/> Segment VIII [68] <input type="checkbox"/> Segment IVB [64]	[69] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[70] O 1 No O 2 Yes	[71]
[72]	[73] ____ . ____	[74] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [75] <input type="checkbox"/> Segment V [80] <input type="checkbox"/> Segment II [76] <input type="checkbox"/> Segment VI [81] <input type="checkbox"/> Segment III [77] <input type="checkbox"/> Segment VII [82] <input type="checkbox"/> Segment IVA [78] <input type="checkbox"/> Segment VIII [83] <input type="checkbox"/> Segment IVB [79]	[84] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[85] O 1 No O 2 Yes	[86]
[87]	[88] ____ . ____	[89] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I [90] <input type="checkbox"/> Segment V [95] <input type="checkbox"/> Segment II [91] <input type="checkbox"/> Segment VI [96] <input type="checkbox"/> Segment III [92] <input type="checkbox"/> Segment VII [97] <input type="checkbox"/> Segment IVA [93] <input type="checkbox"/> Segment VIII [98] <input type="checkbox"/> Segment IVB [94]	[99] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[100] O 1 No O 2 Yes	[101]



**ACRIN 6673
Adjudicator Interpretation Form
[Abdominal Scan]**

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

TUMOR REPORT

* Tumor numbering and location(s) must be the same on every central reader form across all follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
[102]	[103] ____ . ____	[104] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[105] <input type="checkbox"/> Segment V _[110] <input type="checkbox"/> Segment II _[106] <input type="checkbox"/> Segment VI _[111] <input type="checkbox"/> Segment III _[107] <input type="checkbox"/> Segment VII _[112] <input type="checkbox"/> Segment IVA _[108] <input type="checkbox"/> Segment VIII _[113] <input type="checkbox"/> Segment IVB _[109]	[114] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[115] O 1 No O 2 Yes	[116]
[117]	[118] ____ . ____	[119] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[120] <input type="checkbox"/> Segment V _[125] <input type="checkbox"/> Segment II _[121] <input type="checkbox"/> Segment VI _[126] <input type="checkbox"/> Segment III _[122] <input type="checkbox"/> Segment VII _[127] <input type="checkbox"/> Segment IVA _[123] <input type="checkbox"/> Segment VIII _[128] <input type="checkbox"/> Segment IVB _[124]	[129] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[130] O 1 No O 2 Yes	[131]
[132]	[133] ____ . ____	[134] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[135] <input type="checkbox"/> Segment V _[140] <input type="checkbox"/> Segment II _[136] <input type="checkbox"/> Segment VI _[141] <input type="checkbox"/> Segment III _[137] <input type="checkbox"/> Segment VII _[142] <input type="checkbox"/> Segment IVA _[138] <input type="checkbox"/> Segment VIII _[143] <input type="checkbox"/> Segment IVB _[139]	[144] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[145] O 1 No O 2 Yes	[146]
[147]	[148] ____ . ____	[149] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[150] <input type="checkbox"/> Segment V _[155] <input type="checkbox"/> Segment II _[151] <input type="checkbox"/> Segment VI _[156] <input type="checkbox"/> Segment III _[152] <input type="checkbox"/> Segment VII _[157] <input type="checkbox"/> Segment IVA _[153] <input type="checkbox"/> Segment VIII _[158] <input type="checkbox"/> Segment IVB _[154]	[159] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[160] O 1 No O 2 Yes	[161]
[162]	[163] ____ . ____	[164] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[165] <input type="checkbox"/> Segment V _[170] <input type="checkbox"/> Segment II _[166] <input type="checkbox"/> Segment VI _[171] <input type="checkbox"/> Segment III _[167] <input type="checkbox"/> Segment VII _[172] <input type="checkbox"/> Segment IVA _[168] <input type="checkbox"/> Segment VIII _[173] <input type="checkbox"/> Segment IVB _[169]	[174] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[175] O 1 No O 2 Yes	[176]



**ACRIN 6673
Adjudicator Interpretation Form
[Abdominal Scan]**

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

TUMOR REPORT

* Tumor numbering and location(s) must be the same on every central reader form across all follow-up time periods.

** Local read tumor match number is to be completed after the last follow-up form is completed. Enter "88" if no local tumor matches the tumor found by the central reader.

*Tumor Number	Tumor Size (cm)	Ablation Status Per Follow-Up Time Period	*Tumor Location Couinaud Liver Segment <small>[mark all that apply: <input type="checkbox"/> = 1 Not Marked, <input checked="" type="checkbox"/> = 2 Marked]</small>	Tumor Status	Are there additional tumors to report?	**Local read Tumor match Number
[177]	[178] _____ . _____	[179] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[180] <input type="checkbox"/> Segment V _[185] <input type="checkbox"/> Segment II _[181] <input type="checkbox"/> Segment VI _[186] <input type="checkbox"/> Segment III _[182] <input type="checkbox"/> Segment VII _[187] <input type="checkbox"/> Segment IVA _[183] <input type="checkbox"/> Segment VIII _[188] <input type="checkbox"/> Segment IVB _[184]	[189] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[190] O 1 No O 2 Yes	[191]
[192]	[193] _____ . _____	[194] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[195] <input type="checkbox"/> Segment V _[200] <input type="checkbox"/> Segment II _[196] <input type="checkbox"/> Segment VI _[201] <input type="checkbox"/> Segment III _[197] <input type="checkbox"/> Segment VII _[202] <input type="checkbox"/> Segment IVA _[198] <input type="checkbox"/> Segment VIII _[203] <input type="checkbox"/> Segment IVB _[199]	[204] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[205] O 1 No O 2 Yes	[206]
[207]	[208] _____ . _____	[209] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[210] <input type="checkbox"/> Segment V _[215] <input type="checkbox"/> Segment II _[211] <input type="checkbox"/> Segment VI _[216] <input type="checkbox"/> Segment III _[212] <input type="checkbox"/> Segment VII _[217] <input type="checkbox"/> Segment IVA _[213] <input type="checkbox"/> Segment VIII _[218] <input type="checkbox"/> Segment IVB _[214]	[219] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[220] O 1 No O 2 Yes	[221]
[222]	[223] _____ . _____	[224] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[225] <input type="checkbox"/> Segment V _[230] <input type="checkbox"/> Segment II _[226] <input type="checkbox"/> Segment VI _[231] <input type="checkbox"/> Segment III _[227] <input type="checkbox"/> Segment VII _[232] <input type="checkbox"/> Segment IVA _[228] <input type="checkbox"/> Segment VIII _[233] <input type="checkbox"/> Segment IVB _[229]	[234] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[235] O 1 No O 2 Yes	[236]
[237]	[238] _____ . _____	[239] O 1 Ablated O 2 Not ablated	<input type="checkbox"/> Segment I _[240] <input type="checkbox"/> Segment V _[245] <input type="checkbox"/> Segment II _[241] <input type="checkbox"/> Segment VI _[246] <input type="checkbox"/> Segment III _[242] <input type="checkbox"/> Segment VII _[247] <input type="checkbox"/> Segment IVA _[243] <input type="checkbox"/> Segment VIII _[248] <input type="checkbox"/> Segment IVB _[244]	[249] O 1 Tumor absent O 2 Tumor present O 3 Indeterminate	[250] O 1 No O 2 Yes	[251]



**ACRIN 6673
 Adjudicator Interpretation Form
 [Abdominal Scan]**

**ACRIN Study 6673
 PLACE LABEL HERE**

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please box.

Section IV.

Comments: _____

 _____ [252]

 Reader Initials [253]

____ - ____ - ____ [254]
 Date form completed (mm-dd-yyyy)

 Initials of person completing form [255]



**ACRIN 6673
Adjudicator Interpretation Form
[Chest CT]**

**ACRIN Study 6673
PLACE LABEL HERE**

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

If this is a revised or corrected form, please box.

Instructions: This data is assessed by the adjudicator at ACRIN Headquarters. The ACRIN case number must be recorded on this form. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted.

1. Protocol timepoint [1]

- 1 Baseline
- 2 18 month
- 88 Other, specify _____ [2]

1a. Date of scan _____ - _____ - _____ (mm-dd-yyyy) [3]

2. Reader ID | | | | | | | | | | [4]

Image Quality:

3. Interpretable? [5]

- 1 No (complete 3a, then initial and date form)
- 2 Yes (skip to Q4)

3a. Reason

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Motion [6]
- Artifacts [7]
- Contrast media [8]
- DICOM header [9]
- Lost images [10]
- Poor S/N [11]
- Incomplete anatomic coverage [12]
- Other [13] specify _____ [14]

4. Is tumor present? [15]

- 1 No (Initial and date form)
- 2 Yes (complete Q4a)
- 3 Indeterminate (complete Q4a)

4a. Location of tumor (excluding extra-thoracic)

[mark all that apply: = 1 Not Marked, = 2 Marked]

- Pulmonary [16]
- Mediastinum [17]
- Bone [18]
- Other [19] specify _____ [20]

Comments: _____

Reader Initials [22]

_____ - _____ - _____
Date form completed (mm-dd-yyyy) [23]

Initials of person completing form [24]

APPENDIX II

REGISTRATION/ELIGIBILITY CHECK

(Page 1 of 3)

ACRIN 6673

ACRIN Institution # _____

ACRIN Case # _____

Eligibility Requirements: Inclusion Criteria - a response coded other than what is prompted renders a participant ineligible for enrollment.

- _____ (Y) 1. Biopsy proven cirrhosis, or typical findings of cirrhosis by CT scan.
- (Y) 2. Hepatocellular carcinoma (HCC) proven by: (Check all that apply)
- (1 = No, 2 = Yes)
- Biopsy
- Barcelona imaging criteria [see Appendix VIII, #3]
- Barcelona combined criteria [see Appendix VIII, #3]
- Tumor growth criteria [see Appendix VIII, #4]
3. Hepatic tumor burden meeting the Milan Criteria.
- 3 or fewer tumors \leq 3.0 cm
or
- a single tumor $>$ 3.0 cm but \leq 5 cm in diameter
- _____ (Y) 4. All identified tumors are treatable by percutaneous RFA: all tumors are \geq 1 cm from the main, right and left portal veins and all tumors are \geq 1cm from hollow viscera.
- _____ (0-2) 5. Record performance scale as defined by the Zubrod Performance Scale. [see Appendix V and 5.3.6]
- _____ (Y) 6. Serum creatinine \leq 2.0 mg/dl.
- _____ (Y) 7. Chest and abdominal CT scan within 60 days of initial RFA treatment.
- _____ (Y) 8. Aspirin and nonsteroidal anti-inflammatory medications, anti-platelet medications, or warfarin has been discontinued for a time period that is appropriate given the drug half-life or its known anti-platelet activity (e.g., aspirin for 7 days and ibuprofen 24 hours) prior to the scheduled RFA.
- _____ (Y) 9. All laboratory requirements as described in section 5.3.3 of the protocol have been met.

Eligibility Requirements: Exclusion Criteria - a response coded other than that prompted renders a participant ineligible for enrollment.

- _____ (N) 10. Participant has had prior treatment for HCC by any method. [see Section 5.1.12]
- _____ (N) 11. Surgical candidate. [see Appendix IX]
- _____ (N) 12. Hepatic or portal vein tumor invasion.
- _____ (N) 13. Extrahepatic tumor.

ACRIN 6673

ACRIN Case # _____

_____(N) 14. Active infection. [see Section 5.2.12]

_____(N) 15. History of cholendochoenteric anastomosis and or spincterotomy of duodenal papilla.

_____(N) 16. Absolute contraindication to intravenous iodinated contrast. [see Section 5.2.15]

The following questions will be asked at Study Registration:

_____ 1. Name of institutional person registering this case.

_____(Y)2. Has the Eligibility Checklist (Inclusion/Exclusion Q1-16) been completed?

_____(Y)3. Is the participant eligible for this study?

_____/_____/_____ 4. Date the study-specific Consent Form was signed (mm/dd/yyyy)
(must be prior to study entry)

_____ 5. Participant Initials (last, first): Numeric number may be coded other than the assigned case number, #####.

_____ 6. Verifying Physician (Site PI)

_____ 7. Participant's ID Number (optional: this is an institution's method of tracking participant to a case number; code 99999)

_____/_____/_____ 8. Date of Birth (mm-dd-yyyy)

_____ 9. Ethnic category
1 Hispanic or Latino
2 Not Hispanic or Latino
9 Unknown

10. Race (Check all that apply. 1 = No, 2 = Yes)
 American Indian or Alaskan Native
 Asian
 Black or African American
 Native Hawaiian or other Pacific Islander
 White
 Unknown

_____ 11. Gender
1. Male
2. Female (Complete question 20, negative pregnancy test...)

ACRIN 6673

ACRIN Case # _____

_____ 12. Participant's country of residence (if country of residence is other, proceed to Question 13 for completion)

- 1 United States (Complete question 14, Zip code)
- 2 Canada
- 3 Other (Complete question 13, Other country, specify)
- 9 Unknown

_____ 13. Other Country, specify (completed if Q12 is coded 'Other')

_____ 14. Zip code (5 digit code, completed if Q12 is coded 'United States')

_____ 15. Participant's Insurance Status

- 0 Other
- 1 Private Insurance
- 2 Medicare
- 3 Medicare and Private Insurance
- 4 Medicaid
- 5 Medicaid and Medicare
- 6 Military or Veterans Administration
- 7 Self pay
- 8 No means of payment
- 9 Unknown/Decline to answer

_____ 16. Will any component of the participant's care be given at a military or VA facility?

- 1 No
- 2 Yes
- 9 Unknown

_____/_____/_____ 17. Initial RFA Treatment Date (mm/dd/yyyy)

_____/_____/_____ 18. Registration Date (mm/dd/yyyy)

19. MELD Score:

- Score > 25
- Score 15 – 25
- Score < 15

_____ (Y/N) 20. If female, negative pregnancy test within 24-hours of RFA treatment? ^

_____ (Y/N) 21. Does the participant have a pacemaker?

Study Participant Signature: _____ Date: ____/____/_____

Completed by: _____ Date form completed: ____/____/_____
 (Research Associate, Investigator Designee, or Principal Investigator)

Signature of person entering data onto the Web _____